Exploring the Role of Cost-Benefit Analysis in Government Regulations
Acknowledgments

The authors would like to thank several anonymous reviewers for their thoughtful comments and suggestions about previous versions of the paper.
Foreword

In 2003, a controversy arose around the role Cost-Benefit Analysis, also known as Benefit-Cost Analysis (BCA), plays in government regulations and, in particular, the role age plays in this type of analysis. In a BCA published by the Environmental Protection Agency (EPA), EPA assumed that the value of a life saved for people over age 70 was only 63 percent of the value of life saved for those under age 70, an assumption that critics branded as the “senior death discount.”

EPA’s use of a lower value for older lives saved attracted considerable public attention, including that of AARP. The Office of Management and Budget later prohibited federal agencies from using this approach1 and Congress adopted a one-year ban on the use of differential valuation for lives saved based on age.2 However, federal agencies continue to estimate the value of benefits based on the value of life years saved which implicitly adjusts the value of life saved for life expectancy (i.e., age).

Due to the widespread and expanding use of BCA and Cost-Effectiveness Analysis (CEA), a sub-category of BCA, for government regulatory impact analysis, the information presented in this paper, and the issues discussed, are as relevant today as they were when the controversy erupted around the use of a senior death discount. Understanding how BCA and CEA are performed and their roles in the overall regulatory impact analysis process is essential for those who are concerned about the integrity of the process, and for those who care about and want to influence the substantive regulations the process produces. This understanding can be crucial for evaluating the economic and political implications of environmental, health, and safety regulations and in developing policy positions for lobbying the administration and Congress on substantive issues of concern to older Americans.

This issue paper describes the context and application of these techniques in a clear and balanced presentation. The views described do not represent formal AARP policies and are not intended to imply that AARP endorses the use of these techniques or of any quantitative technique in the process of regulatory impact analysis. Nor does AARP endorse the use of age-based criteria in applying these techniques.

We hope this paper will help readers understand the basics of BCA and CEA and their role in government regulations. In addition, we hope the issues we raise in this paper will raise the level of awareness about some of the more controversial aspects of BCA and CEA as these techniques are applied to important federal regulations.

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EXPLORING THE ROLE OF COST-BENEFIT ANALYSIS IN GOVERNMENT REGULATIONS

Executive Summary

PURPOSE

The primary purpose of this paper is to educate policy makers, researchers and advocates so they are better prepared to discuss issues surrounding techniques commonly referred to as Cost-Benefit Analysis (BCA), and Cost-Effectiveness analysis (CEA). The expanded use of BCA and CEA to analyze federal health, safety, and environmental regulations has heightened concerns regarding the appropriate role of these techniques in the regulatory decision-making process. In addition, wide variations in theoretical and practical application of these techniques, along with the wide discretion afforded to analysts performing any particular analysis, has raised questions about the implications of these techniques. Some of these questions were highlighted in the controversy around the Environmental Protection Agency's (EPA) use of the “senior death discount” (see Section 6.1, Age as a Factor).

METHODOLOGY

This paper describes the role of BCA and CEA in government regulations and provides background information on the current and historical use of these analytic techniques. It identifies strengths and weaknesses of each technique, individually and comparatively. It also highlights key factors, including age, among others, that can have a substantial influence on the results of an analysis. Finally, this paper brings BCA and CEA more sharply into focus through two cases studies (see Appendices A and B) that describe the practical application of these techniques as performed by different federal agencies (EPA and the Food and Drug Administration [FDA]) in regulatory impact analyses on two different regulations. For its sources, the paper relies on a combination of the professional literature guided by the expert opinion of the authors with frequent references to relevant federal government guidance documents.

The paper addresses a series of questions designed to inform the reader of the role of BCA and CEA and their broader role in the context of federal regulatory impact analysis.

- Who uses BCA and why?
- Why is BCA a critical part of regulatory impact analysis?
- Why are only selected regulations subjected to BCA?
- How are BCA and CEA performed?
- How are BCA and CEA related?
- What are the implications of using age in the calculation of BCA and CEA?
- How are these tools actually applied?

Finally, the paper attempts to place the tools of regulatory impact analysis (i.e., BCA, CEA and others) in the context of the federal rule-making process by describing underlying assumptions and framework for analysis used by policy makers: Why do we regulate? What are the overall goals of regulation?

RESULTS IN BRIEF

Federal agencies are required to perform a regulatory impact analysis for major regulations (i.e., impact over $100 million), including BCA and CEA. These techniques estimate social costs and social benefits to assess the economic efficiency of regulations for the United States. Since the 1960s, BCA has been required for well-defined federal projects, such as hydro-electric power projects. Since 1981, federal agencies have been required to perform such analyses of all new major regulations.

As an analytical tool in the regulatory context, BCA is designed to measure the net contribution of any public policy to the economic well-being of the members of society. BCA seeks to determine if the aggregate gains that accrue to those who are made better off are greater than the aggregate losses of those made worse off by the policy choice. Both the gains and losses are measured in monetary terms and are defined as the sum of each individual’s willingness to pay to receive the...
gain or to prevent the losses the policy imposed. If the gains exceed the losses, the policy improves economic efficiency. BCA informs decision making by providing an objective format for enumerating the positives and negatives of the policy options.

The Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) oversees the development and review of federal regulations. While all major federal regulations are subject to review by OMB, “social regulations” are subject to BCA. Social regulations impose compliance costs on the private sector, and generate social benefits, and include air and water quality standards, average fuel economy rules, auto safety requirements, minimum wage requirements, worker safety rules and public health regulations, such as food safety requirements. In 2002, only six of the 31 significant regulations reviewed by OMB fell into this category.

Using BCA to assess the economic efficiency of health and safety regulations requires valuing their economic costs and benefits. Economists typically measure benefits in terms of peoples’ “willingness to pay” (WTP) to obtain the benefit or avoid the loss of the benefit. While alternative measures of benefit may also be used, WTP is the most widely accepted and commonly used for BCA. WTP can be derived either directly through survey techniques or indirectly through inferences from people’s economic choices. One can obtain WTP estimates by performing studies for the specific purpose of the BCA in question. However, such studies can be expensive and time consuming. As a result, estimated benefits are often transferred from the results of previous studies. To facilitate the process of benefits transfer, many values have been assembled and made publicly available in tables, such as Environment Canada’s Environmental Valuation Reference Inventory.

As an alternative approach to WTP, a “cost of illness” approach seeks to estimate the resource costs associated with illness, including both direct costs, such as medical care, and indirect costs, such as economic costs of disability and lost wages. While the cost of illness can often be estimated more easily and reliably than can WTP, this cost fails to capture intangible costs associated with pain, suffering, and death. As a result, economists prefer to rely on WTP, rather than cost of illness.

Value of Statistical Life or Life Years

The cost of avoiding a death due to the effect of regulations is often characterized as the value of saving a statistical life (VSL). This can also be characterized as the sum of the value of statistical life years saved (VSLY). Economic studies typically take the average of all individuals’ WTP for risk reduction to arrive at a single value of statistical life (VSL). For instance, in 2001, EPA adopted a VSL of $6.5 million based on 26 published studies that used both revealed preference and stated preference methods to estimate VSL. FDA has adopted a VSL of $5 million. While adopting a single VSL is standard economic practice, a number of factors may affect WTP.

Age as a factor can have a substantial influence on the results of analysis. Economic theory makes no prediction about the relationship between age and WTP, and empirical studies that have examined the relationship between VSL and age have produced mixed results. Labor market studies based on wage differentials have found that VSL varies with age in an inverted-U-shape relationship. However, other studies that specifically address older workers’ labor market behavior have found that VSL for U.S. seniors remains constant until at least age 70 or increases with age. Estimates of VSL may also be affected by population characteristics other than age. Approaches that estimate the cost of avoiding death based on the sum of life years (VSLY) include an implicit age adjustment, since the number of life years saved will be fewer for an older person than for a younger person. An implication of the use of VSLY or QALYs, described below, as an outcome measure is that they will tend to value saving the life of a younger person more highly than it will that of an older person, though this is not always the case as shown by the FDA case study below.

Discount Rates over Time

To compare benefits and costs that arise at different times and to allow for more consistent comparison among alternatives, the process of discounting offers a standard adjustment for timing differences in costs and benefits. The concept of discounting, which reflects the time
value of money due to waiting or deferred consumption, is applied independently from adjustments that may be necessary to account for inflation and conditions of risk and uncertainty.

Most economists and OMB have settled on a discount rate of 7 percent as the appropriate discount rate for private investment capital (i.e., the average pretax rate of return on investments net of inflation) while a discount rate of 3 percent is used for private consumption (i.e., the average personal preference for consumption rather than savings). The discounted value of a stream of future costs and benefits is referred to as the “net present value.” The effect of discounting is to reduce the value of future benefits. For instance, a benefit of $100 received 30 years in the future has a present value of $41 when discounted at 3 percent but only $13 when discounted at 7 percent.

Experts also agree that discounting should be applied to health benefits, as well as to non-health benefits, whether or not the health benefits are monetized. The basis for this approach is that people prefer an immediate health gain to an identical health gain in the future. Not discounting also has some troubling implications whether or not the benefits are monetized. Whatever the wisdom of discounting the value of future health benefits, this approach has the effect of reducing the weight given to the avoidance of future disease and injury.

Risk Aversion and Risk Neutrality

Despite individual tendencies to avoid risk, economists typically assume that society, as a whole, is risk-neutral because, on average, winners and losers will balance out. The effect of this discrepancy between individual and social risk preferences is that, while policy analysts are often able to take into account various levels of risk, the results of analysis often imply a degree of social paternalism because policies that appear best for society as a whole, may not be those that, if left to their own devices, individuals prefer.

Sensitivity Analysis

The reliability of BCA estimates may be tested by systematically varying the underlying assumptions and values used to derive the best estimate in the primary analysis. This process, referred to as “sensitivity analysis,” describes how different each assumption and data point would have to be to change the results of the primary analysis. Sensitivity analysis may also be used to reflect differences of opinion about the probability of expected outcomes by re-running the analysis with adjusted values. The results of various sensitivity analyses are compared to other sensitivity cases or to the effect of specified changes rather than to the primary analysis. Sensitivity analysis is a standard procedure performed as a supplementary analysis to BCA for all major federal regulations and is the appropriate context in which to address questions about the effect of age as a factor in the analysis. Other techniques are available for testing the magnitude and effects of uncertainties in BCA, such as meta-analysis and Monte Carlo computer simulation.

Distributional Effects

Distributional effects of policy changes can be assessed by using modified approaches to BCA, such as Economic Impact Analysis. By assigning different weights to the benefits and costs that are expected to fall on different groups, these techniques can also examine the impact of non-economic, as well as economic, costs that fall on particular populations, such as children and those with chronic conditions. Congress has required formal assessments of the impact of regulations on a number of specific areas, including small businesses; state, local, and tribal governments; children; minorities; and low-income populations. OMB guidance makes it clear that any distributional effects should be discussed for specially affected sub-populations by income, race, gender, time (i.e., intergenerational effects), physical sensitivity (i.e., allergy, immunodeficiency), and geography.

Cost Effectiveness Analysis

In limited circumstances, one can perform an analysis using a sub-category of BCA, known as CEA. When either the costs or the benefits are fixed and only other factors will vary, CEA compares the cost of various approaches using a single, non-monetary measure of effectiveness. CEA’s primary advantage is that it avoids difficulties associated with converting benefits into dollars and, in the case of health effects, avoids monetizing the value of life. CEA does not evaluate health effects using individual WTP. By
treated gains in health and longevity equally regardless of differences in individual wealth and income, CEA also appears to avoid potential inequities associated with ability to pay based on WTP that arise in BCA. On the other hand, CEA does not allow comparison among various regulatory options with different outcomes and does not help decide how much regulation will produce the most efficient outcome.

While CEA avoids the controversial step of attributing dollar values to goods, it is a more limited method than BCA for assessing alternative regulatory policies. CEA provides additional information that can be used to complement BCA in the context of regulatory impact analysis (RIA) but is not regarded as a substitute for BCA. Health insurers sometimes use CEA to inform coverage and payment decisions. CEA is also used to establish public health guidelines, such as immunization and screening recommendations. While the economic and accounting concepts of CEA in these contexts are essentially the same, application of these concepts differs substantially in the context of RIA.

**Quality-Adjusted Life Years**

For CEA, measures of effectiveness can combine multiple outcomes into a single, integrated measure, such as a quality-adjusted life year (QALY). Effectiveness measures based on QALYs combine several factors, such as non-fatal illness, injury, disability and quality of life, as well as premature death, into a single numerical health status index. QALYs are commonly used in CEA when health effects are the primary outcomes of concern. QALYs are scores that describe various states of health, illness and disability that are ranked according to personal preferences in an index from zero to one with one being perfect health and zero being death. One may design and construct a health status index used to measure QALYs for use with a particular intervention or may use a generic index found in the professional literature. For instance, the Harvard Center for Risk Analysis has compiled a data base of QALY weights for several thousand health conditions or statuses as reported in more than 500 articles in clinical journals.

While integrated measures of effectiveness, such as QALYs, offer many advantages, they also carry underlying assumptions that can limit their usefulness for regulatory impact analysis. For instance, by assigning a uniform value or weight to each state of health, a QALY implies that people of all ages attach the same value to extending their own life for one year. Similarly, QALYs imply that although people may currently have different levels of health or illness, they all attach the same value to incremental improvements or declines in health. In other words, through the use of its ordinal scale, QALYs imply that health status changes of equal magnitude are of equal value.

**Summary of Case Studies**

Appendices A and B are case studies of regulatory impact analysis that provide real-world illustrations of how federal agencies actually perform BCA. (See Section 7 for case summaries and Appendices A and B for case descriptions.) These cases highlight the difficulties analysts face and how they address them. The first case study of EPA’s off-road diesel emission rule includes the controversial assumption in a secondary sensitivity analysis that the VSL for people over age 70 was only 63 percent of the VSL for non-seniors, which later became known as the “senior death discount.” In an unexpected twist, this assumption still produced a higher value of a statistical life year (VSLY) for seniors than for non-seniors. The paradoxical result was that equivalent life extensions would yield greater value for older persons than they would for younger persons.

The second case study covers FDA’s bar code rule requiring manufacturers to include bar codes on all drug labels in an effort to reduce medication errors and adverse drug events. FDA assumed that requiring manufacturers to include bar codes on drug labels would accelerate hospitals and nursing homes’ adoption of bar code. This case study highlights FDA’s approach to valuing health effects for different age groups of patients served by these providers. FDA reported results of both its cost of illness analysis and its BCA of avoiding adverse drug events. FDA monetized the number of QALYs saved using a standard VSLY. FDA sidestepped the age issue by assigning the same monetized values for avoiding adverse drug events for both hospital and nursing home patients. In its primary analysis, FDA found that adopting the bar code rule would result in substantially
greater savings from avoiding adverse drug events than the cost of compliance that would be imposed on industry. However, in a significant omission, FDA did not discuss potential sources of payment for bar code systems that hospitals and nursing homes were expected to adopt, even though Medicare and Medicaid are the largest sources of payment to these providers and were not expected to reimburse these costs.

Conclusion

BCA and CEA have become standard components of the impact analysis for most major federal health, safety, and environmental regulations. These analytic tools help to identify and quantify the impact of regulations on various aspects of society. Efforts are under way to further standardize the methodology used for these RIAs, reduce sources of potential bias, and make the results more transparent to independent experts and the public. Although the use of BCA and CEA have been mandated by Congress and OMB as part of the regulatory impact analysis process, these tools are not the only quantitative or non-quantitative techniques that can be used for this purpose. Even when taken together, BCA and CEA do not necessarily provide complete information about the likely impact of regulations and the results of these analyses should be viewed in the context of the underlying data and assumptions.

Age plays an important, though not always explicit, role in assessing the impact of regulations based on BCA and CEA. Age is implicated in estimates of the value of statistical life and life years. In many cases, the impact of regulations on different age groups, such as children, is taken into account explicitly through an Economic Impact Analysis. The two case studies offer real-world examples of how federal agencies have performed regulatory impact analyses using BCA and CEA and taking age into account. In the EPA case, the agency adopted a 38 percent discount for seniors over age 70, which was later rescinded. In the FDA case, the agency avoided the issue, to a large extent, by assigning the same value of life to both hospital and nursing home patients, despite widely differing average ages for these groups.

While age plays an important role in BCA and CEA, it should be clear from this paper that there is no straightforward way to remove age as a factor from these analytic techniques. The results of these analyses depend heavily on the specific regulations under consideration along with the data and assumptions used in the analysis. As a result, it would be quite difficult to anticipate what effect removing, limiting or significantly changing the role of age would have on the results of these analyses. To the extent that BCA and CEA are made part of regulatory impact analysis, transparency in the methods and opportunity for public scrutiny and comment are essential features of the process.
1. Introduction

There is an on-going debate among policy makers about how economic and non-economic effects should be taken into consideration when the federal government promulgates regulations, particularly those that affect health and safety. Some advocate that economic considerations have a dominant role in analyzing regulatory impacts through the application of formal analytic tools, such as a technique commonly referred to as Cost-Benefit Analysis, also referred to by economists as Benefit-Cost Analysis (BCA), the term used throughout this paper, and a second technique which is a sub-category of BCA referred to as Cost-Effectiveness Analysis (CEA). Others see BCA and CEA as devices that systematically under-value health and safety and are used as a means to avoid costly regulations that would have large but unquantifiable social benefits.

While this debate is not new, it most recently flared up enough to gain public attention in 2003 when, in connection with its analysis of a proposed regulation, the Environmental Protection Agency (EPA) assumed that the value of a statistical life saved for people over age 70 would be lower than that of a person under age 70. Critics immediately labeled this adjustment the “senior death discount.”\(^3\) In an effort to place this debate in context and to summarize and simplify the detailed and sometimes arcane practice of these analytic techniques, this paper provides background information regarding BCA and CEA, describes current and historical practices of federal regulatory impact analysis (RIA), the role of BCA and CEA in this process, and implications of these techniques for public policy purposes. More specifically, the paper addresses the following questions:

- Who uses BCA and why?
- Why is BCA a critical part of RIA?
- Why are only selected regulations subjected to BCA?
- How are BCA and CEA performed?
- How are BCA and CEA related?
- What are the implications of using age in the calculation of BCA and CEA?
- How are these tools actually applied?

This paper also attempts to place these analytic techniques in a broader context necessary to understand the regulatory decision-making process. In doing so, it asks, why do we regulate? What motivates regulators in their choice of regulations? What alternative approaches to regulation are available? Under what overarching assumptions are regulators typically operating? What is the framework for regulatory impact analysis? With these underpinnings in place, the role of BCA and CEA and their impact on the process become clearer.

1.1. BACKGROUND

When Congress enacts laws, it often leaves the details of statutory implementation to administrative agency discretion. For instance, the federal Clean Water Act\(^4\) does not indicate exactly how clean the water should be or the exact process by which pollution is to be reduced. Similarly, many safety laws, such as those related to auto safety and food safety, do not always indicate exactly how safety is to be achieved or how much safer things should be made.

In an effort to increase economic efficiency of regulatory options, as discussed further below, years ago, federal agencies began to weigh the costs and benefits of various regulatory alternatives to achieve statutory objectives. Eventually, federal agencies were directed to subject proposed rules to formal BCA in response to public criticism that the federal regulatory process was arbitrary and inefficient.

Since 1936, some form of BCA has been required for federal water projects. As methods have

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4 33 USC § 1314(b)(2)(B).
improved, there has been a growing reliance on BCA for government regulatory analysis. Since the mid-1970s, EPA has been conducting benefit-cost analyses of major regulations. The requirement to conduct such analyses for all new major regulations was extended to all federal agencies in 1981 by President Ronald Reagan. Presidents George W. Bush and Bill Clinton continued this requirement with executive orders of their own. In the Office of Management and Budget (OMB), the Office of Information and Regulatory Affairs (OIRA) oversees the administrative process of regulation development, regulatory impact analysis, and implementation of the relevant executive orders requiring BCA and CEA.

BCA is primarily a means to organize thinking about the positive and negative aspects of economic decisions by making quantitative estimates of the changes in social well-being caused by a particular action. BCA provides a set of analytical tools designed to measure the net contribution of any public policy to the economic well-being of the members of society. Actions affecting any aspect of the economic well-being of the members of society are reduced to the common measure of dollars. For any policy, BCA produces a comparison of dollars of benefits generated and dollars of costs.

For purposes of estimating the impact of proposed regulations, federal agencies seek to compare the economic costs of regulation with the improvements in social health and welfare. Through BCA, federal agencies compare the economic value of expected reductions in morbidity, mortality, and other benefits with the costs necessary to achieve them. Some people refer to this process as valuing life, but it can be referred to more accurately as estimating the opportunity costs of reducing the risk of death. Unlike clinical decisions that require physicians to weigh treatment alternatives and often have life and death implications for individual patients, regulatory options typically do not involve direct risk of life or death for specific individuals but reduce the risk of death or ill-health in a population.

BCA uses social costs and social benefits to identify potential economic efficiency gains—that is, areas in which performance can be improved at relatively low cost. The basic premises underlying BCA are that the purpose of economic activity is to increase the well-being of individuals who make up the society and that each individual is the best judge of how well off he or she is in a given situation. To make the most of scarce resources, economists compare what is received in the form of increased well-being from policies or activities with what is given up by taking resources from other uses. BCA measures the value of what is gained (the benefits) and what is lost (the costs) in terms of the preferences of those who experience these gains and losses. According to economic theory, actions should be undertaken only if the results are worth more, in terms of individuals’ values, than what is given up by diverting resources from other uses. Economists assume that one resource can be substituted for another to achieve a given level of well-being and that increasing individual well-being is one of the central objectives of government policy.
EXPLORING THE ROLE OF COST-BENEFIT ANALYSIS IN GOVERNMENT REGULATIONS

2. The Context of Regulatory Decision Making

2.1. IMPLEMENTING LEGISLATED POLICY

Federal regulations are based on Constitutional authority and laws passed by Congress and signed by the President. Laws define the scope of issues to be addressed, the agency to address them, and, in general, the manner in which the agency is to address the issue. The federal system delegates a great deal of discretionary authority to federal agencies to implement laws. For example, The Clean Water Act directed the EPA to issue water pollution guidelines that require discharging facilities to use the “best available technology that is economically feasible.” Congress left discretion to EPA to answer many questions, such as which industries to regulate first, what technologies are economically feasible, and how to measure them. Congress defined the goals (i.e., stop factories discharging waste to waterways) and selected the means to address them (i.e., technology-based treatment standards), but Congress left to the agency the task of defining how the law would be implemented through regulation.

Regulatory agencies often have great latitude in identifying issues to address and the tools with which to address them within the legal framework established by statute. While few laws require that regulations pass a strict cost-benefit test, often, the use of BCA or some other economic efficiency criterion is implied. For example, the Clean Water Act directs EPA to establish effluent limitation guidelines for plants that discharge directly to waterways based on the “best available technology” that is economically achievable.

2.2. REGULATORY MOTIVES AND APPROACHES

Academics have developed several theories to describe how regulators wield their power. Each theory implies different decision criteria and, therefore, different analytic approaches to support regulatory choices. In deciding whether to support, reject, or propose modifications to the current model of regulation, it is important to understand alternative models that might be available. The following section highlights alternative theories of regulation that have been suggested for federal agencies in the absence of a formal requirement that RIA include BCA.

Economic and Social Planner/Regulation of Market Failure

The dominant model of regulation is that the government serves the public interest as a “social planner” when competitive markets fail. While the classical economic model holds that a competitive economy will find the most efficient allocation of resources to maximize the total social welfare, in some cases, competitive markets will fail to arise or will operate inefficiently. In the social planner model, the government’s role is to improve economic efficiency and social welfare while interfering as little as possible with the normal operation of competitive markets and imposing as few excess costs as possible through appropriate regulations.

In this model, the economic rationale for government intervention must be either that the market is somehow failing to achieve the classical economic model, or that it uses an inappropriate method to allocate resources. Some of the reasons for market failure include (1) public goods, (2) externalities, (3) imperfect flow of information, (4) transaction costs, (5) absence of markets for some goods, and (6) monopoly market power (see Exhibit 1). This model also allows alternative, non-efficiency, social rationales for government intervention in the form of, for example, welfare redistribution programs, such as Social Security and Medicare. Such redistribution programs may be adopted to improve social equity. While some may disagree, many economists view such social...
EXHIBIT 1

Reasons for Market Failure

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Public Goods</strong></td>
<td>A classic example of the need for government intervention is public goods, such as roads, sidewalks and lighthouses, as well as national defense, flood control, weather forecasts, public parks, and wilderness areas. These goods or services will not be produced or maintained if the task is left to markets alone. Even though they are to everyone’s benefit, there is no efficient mechanism for individuals to pay for or acquire them, nor is there any way to exclude individuals who don’t pay from receiving their benefits.</td>
</tr>
<tr>
<td><strong>Externality</strong></td>
<td>These are situations in which the actions of one person affect another outside of the market system, particularly by imposing costs. A well-recognized example of an environmental externality is that those who pollute the air or water impose both monetary and non-monetary costs on non-polluters. An example of a positive externality is health insurance which allows those seeking health care services to impose costs on healthy subscribers, while at the same time producing benefits to society through the reduced spread of disease and increased productivity. In both cases, private markets do not require the individuals, themselves, to bear the full costs they incur. Without government intervention, people will engage in activities that produce externalities but the divergence between private and social costs causes uncoordinated individual actions to produce inefficient results.</td>
</tr>
<tr>
<td><strong>Imperfect Information</strong></td>
<td>Efficient operation of competitive markets requires the free flow of accurate information. Markets become less competitive as information about price and quality of alternative goods and services becomes less available. Improving the flow of information levels the playing field between buyers and sellers. The government often intervenes to improve the flow of accurate information through such measures as financial disclosure requirements, bans on insider trading, truth-in-advertising, truth-in-lending, food and drug labeling laws and professional licensure laws.</td>
</tr>
<tr>
<td><strong>Transaction Costs</strong></td>
<td>When the costs of conducting business become significant, markets become inefficient. Transaction costs include the costs of bargaining, legal fees, and finding a buyer or seller. The government facilitates business transactions by establishing mechanisms to reduce transaction costs, such as contract laws and dispute resolution laws (i.e., labor laws, arbitration, and courts).</td>
</tr>
<tr>
<td><strong>Absence of Markets</strong></td>
<td>In some cases, private markets entirely fail to arise and operate. If transaction costs are too high or insufficient information is available, a market may fail to arise or may operate inefficiently. For instance, private markets have arisen for insurance against losses associated with life, health, fire, and auto accidents, but in the absence of government intervention, these markets tend to operate inefficiently. In other cases, such as unemployment insurance and retirement insurance (i.e., Social Security) and health insurance for the elderly (i.e., Medicare), government intervention was required. In some cases, the government has intervened to suppress private markets that would otherwise arise, such as slavery, prostitution, and recreational drugs.</td>
</tr>
<tr>
<td><strong>Monopoly Market Power</strong></td>
<td>When only one or a few buyers or sellers control a large portion of sales and have the power to raise prices without losing market share, private markets become inefficient. Market power may develop for several reasons, such as cost advantages due to economies of scale or legal barriers to entering the market for government-sanctioned monopolies. In some cases, the government intervenes to discourage the abuse of market power, in cases of both government-sanctioned and privately acquired monopolies (i.e., AT&amp;T, public utilities, labor unions, Microsoft, Standard Oil), while in other cases, to foster innovations that benefit society, government creates monopolists and allows them to exercise market power (i.e., patents and copyrights).</td>
</tr>
</tbody>
</table>

rationales as a legitimate legislative response to political pressures.

BCA and CEA are regarded as effective tools for achieving the goals of economic and social planning. In the context of RIA, these techniques limit the discretion of regulators to adopt alternative, more or less arbitrary models of regulation.

Minimizing the Worst Outcomes

Another regulatory model selects the option that minimizes the likelihood of the worst possible outcome. Rather than comparing benefits and costs, such a strategy considers only the costs of possible outcomes. This approach tends to select the least costly or least risky option, without regard to benefits that may be available from other alternatives. Frequently, the least bad outcome appears to arise from delaying regulation until additional information becomes available.

Choosing to delay regulations may have either positive or negative effects depending on future developments. Delay may allow further study and/or technological developments to improve approaches to achieve the same ends. For instance, renewed smallpox vaccinations to protect against bioterrorism were delayed to allow further study of the potential health risks. On the other hand, delay may result in a missed opportunity or force harsher corrective measures in the future. For instance, years of delay in regulating “greenhouse gases” may have worsened global warming with potentially catastrophic consequences that could require even more drastic measures to stop or reverse its impact.

Rights-Based Regulation

In some cases, regulations are based on rights, such as constitutional rights or civil rights. These regulations are not subject to economic regulatory impact analysis requirements. Congress has specifically exempted some regulations from economic regulatory impact analysis, such as endangered species regulations, which are based on the right of other species to exist. Some environmental groups reject the idea that environmental regulations should be subject to economic analysis asserting that some things, like clean air and water, should not be traded off against money or other alternatives. These groups often advocate application of rights-based regulations in place of economic regulatory analysis.

Affected parties have always been able to challenge federal regulations in the courts. Frequently, regulated entities have felt that the federal agency has overstepped its authority or failed to follow proper administrative procedures. The remedy for errors is usually an injunction preventing implementation of the new regulation, and remand to the agency to reassess the rule or comply with appropriate procedures. In most cases, it is not feasible or appropriate for a court or plaintiff to draft new regulations since the law grants the agency the rule-making authority. However, courts and plaintiffs often apply an injunction against agency action as leverage to insist on inclusion of certain regulatory provisions they prefer.

A recent trend has been for advocacy groups to sue agencies to force them to issue rules. The Natural Resources Defense Council (NRDC) and Public Citizen, for example, reached a settlement with EPA in 1992 regarding effluent guidelines under the Clean Water Act. This consent decree drove EPA's effluent guideline agenda for 12 years. Forcing the agency to consider regulation does not force adoption or implementation of any specific regulation. Thus, EPA's final action may well be to issue “no-rule” for any particular pollution category that it examined.

Similarly, the Center for Biological Diversity has successfully enforced the Endangered Species Act through litigation. Several courts have ordered the Fish and Wildlife Service to declare certain areas as “critical habitat” under the Endangered Species Act.

While rights-based criteria can be used to set a regulatory agenda, they are less helpful in selecting among alternative options that

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6 67 FR 55012, August 27, 2002.
7 Center for Biological Diversity, 2003. “Critical habitat” declarations may affect the way property within the critical habitat can be used and thereby reduce its value. The right of the species to exist conflicts with the property rights of the landowner. Rights-based decision-making offers no guidance for choosing which rights are more important when conflicts arise.
accomplish similar ends. As discussed further below, BCA or CEA offer more meaningful information for selecting the best option from among an array of alternatives than does a rights-based approach.

**Personal Interest Regulation**

Over the years, critics have imputed a variety of motives, some nefarious, to regulators. One less benevolent models, often assumed by critics of regulation to be the most likely, is that regulators act in their own personal interest. They may seek power and status by trying to increase the size of the budget they control, the number of employees within their agency, and the scope of activity it controls. With this goal in mind, regulatory actions that expand the agency’s spheres of influence or set new precedents will be preferred.

Another personal interest theory suggests that some regulators are closely allied with, or “captured” by, special interest groups. The administrator of a captured agency is assumed to establish the regulatory agenda to curry favor with these outside interest groups in gratitude for past help or in anticipation of future personal rewards. In a captured agency, regulatory assessments identify winners and losers and regulatory decisions favor the interests of previously identified special groups.

**Which Theory Is Right?**

While the objective of BCA is to increase economic efficiency and improve social welfare, the other motivations that have been imputed to federal agencies could easily serve as the basis for implementation of federal regulations. Each of these models of regulation has been used to characterize government decisions at different times and continues to influence the regulatory process to varying degrees. While reasonable minds may differ about the appropriate basis for regulation, a broad swath of congressional and executive branch efforts, including OMB guidance, has endorsed a limited social planner/market failure model of regulation.

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3. The Current Regulatory Framework

3.1. FEDERAL REGULATORY IMPACT ANALYSIS

Efforts to rationalize and limit the federal regulatory process based on the social planner model have produced a vast and complex framework for federal RIA. All federal agencies are required to conduct regulatory analyses of proposed new major regulations and major revisions to existing regulations. These regulatory analyses are governed by multiple public laws, executive orders, OMB guidelines, and court decisions. The level of controversy these rules generate typically depend on the stringency and rigor with which they are applied, which tends to fluctuate with each successive administration.

During the 1970s, Presidents Nixon and Ford created a formal mechanism for regulatory review in OMB. Their executive orders called for inflation and economic impact analyses of all proposed regulation. President Carter’s 1978 Executive Order 12044 required regulatory impact analysis for all “significant” rules (i.e., those with an annual effect on the economy of $100 million or more). In 1981, President Reagan’s Executive Order 12291 specifically required BCA as part of the RIA for all “major rules” and mandated selecting the regulatory option that minimizes net costs and maximizes net benefits, unless otherwise precluded from doing so by applicable law. Since then, BCA has been required for every major social regulation promulgated by agencies of the federal government.

In 1993, President Clinton replaced President Reagan’s Executive Order with Executive Order 12866, which defines the principal elements of the regulatory analysis for all regulatory agencies and gives direct regulatory oversight authority to the Office of Information and Regulatory Affairs (OIRA) in OMB. In 2002, President Bush amended Executive Order 12866 with Executive Order 13258, primarily eliminating the role of the Vice President in managing the regulatory process. In 2007, President Bush expanded the application of regulatory analysis to significant guideline documents in Executive Order 13422. President Clinton’s Executive Order 12866 remains essentially intact. OIRA continues to oversee all final rules promulgated by a federal executive branch agency that meet criteria defined as economically significant or major rules.

Federal Rule-Making Process

Executive Order 12866 sets forth economic criteria for rule evaluation and establishes rigorous compliance procedures for significant regulatory actions. President Clinton expanded the definition of “significant” regulations that are subject to RIA to include, in addition to any rule with an annual effect on the economy of $100 million or more, any rule that raises new legal or policy issues. Notably, certain categories of agency action are excluded from the definition of major or significant regulations or rules for purposes of RIA, as discussed below.

For each “significant” regulation with an expected annual impact of $100 million or more, an agency is required to submit a regulatory impact assessment that includes an explicit analysis of anticipated costs and benefits of the proposed regulation to the U.S. economy, as a whole; private markets, including productivity, employment, and competitiveness; state and local governments; health and safety; and the natural environment.

9 Executive Order 12044.
10 Executive Order 12291; Congressional Budget Office (CBO), 1997.
11 Executive Order 13258.
12 Executive Order 13422.
13 OMB, 2003a.
14 Executive Order 12866, sec 2.
For significant rules, the agency is also required to submit additional information to OIRA/OMB that includes an assessment of costs and benefits of potentially effective and reasonably feasible alternative rules. To allow OMB to make an independent assessment of the viability of alternative approaches, this additional information must also clearly present the underlying analysis that aided the agency’s decision-making process.

As amended by President Clinton, the Executive Order permits an agency to adopt a regulation “only upon a reasoned determination that the benefits of the intended regulation justify its costs” but recognizes that quantifiable benefits may not exceed quantifiable costs. President Clinton also added a provision that stresses the importance of distributional issues. These changes substantially relaxed the threshold for promulgating new regulations.

Subsequent legislation codified many of the requirements of President Clinton’s Executive Order 12866 in a way that was intended to protect states and small businesses from costs imposed by federal regulations and made it more difficult to promulgate federal regulations by reinforcing the directive that agencies must select the “least costly, most cost effective, and least burdensome alternative that achieves the objectives of the rule.”

Regulatory actions are also subject to analysis and review of their impacts on children, small businesses, and state, local, and tribal governments. (See Equity and Distributional Issues, below, and Appendices for further details.) To a large extent, information developed to comply with RIAs for “significant” rules either satisfies the requirements of other more specific RIAs (i.e., impact on small business, etc.) or provides substantial background information necessary to satisfy these requirements. Thus, although multiple RIAs are often required in connection with a proposed regulation, a single body of information is usually sufficient to describe the likely impact of the rule on many affected populations. As a result of numerous mandates and constraints imposed by these and other statutes, regulations and executive orders, the federal rule-making process is complex and requires OMB review at several stages, as shown in Exhibit 2 below.

Under President Clinton’s Executive Order and the Administrative Procedure Act, with some minor

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**EXHIBIT 2**

**Federal Rule Making Process**

<table>
<thead>
<tr>
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<td>Final Regulatory Flexibility Analysis (FRFA)</td>
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<td>Development Document</td>
<td>Public Hearings</td>
<td>Final Economic Analysis</td>
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<td>Docket Filing</td>
<td>Intra- and Inter-Agency Review</td>
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<td>Response to Comments</td>
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<td>Intra- and Inter-Agency Review</td>
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<td>Small Business Advocacy Review Panel/Small Entity Representatives (SER)</td>
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</tbody>
</table>

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15 Executive Order 12866, sec (1)(b)(6).
16 The Unfunded Mandates Reform Act of 1995 (UMRA) and Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA).
17 CBO, 1997.
18 5 USC §§ 551 to 559.
exceptions, federal agencies are required to submit their rules through OIRA/OMB at several stages of the process (i.e., Advanced Notice of Proposed Rulemaking [ANPRM], Notice of Proposed Rulemaking [NPRM], and Final Regulation). The scope of the regulatory review requirement is quite broad and includes both proposed and final rules, in effect giving OMB broader latitude and multiple opportunities to decide which regulations to subject to more intense scrutiny. In 2007, the scope of regulatory review was expanded to include agency "guidance documents." Through such sub-regulatory guidance, agencies provide their interpretation of existing law and regulation without the force of law.

Ultimately, Congress has the authority to veto or repeal any regulation either directly or by enacting superseding laws. Of course, such legislative action may be vetoed by the President. In an effort to streamline congressional review and circumvent the need for presidential action, Congress granted itself the right to veto any rule it finds too burdensome, inappropriate, or duplicative, without Presidential approval. As of June 2007, this disapproval mechanism has been used only once, to block implementation of the Occupational Safety and Health Administration’s (OSHA) Ergonomics Rule.

3.2. OMB/OIRA

The Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) oversees the administrative process of regulation development and implementation of the relevant executive orders. While all major federal regulations are subject to OMB review, not all regulations are subject to BCA. OMB categorizes rules as “Social Regulations” or “Transfer Regulations.”

Social Regulations

Social regulations impose compliance costs on the private sector and generate social benefits. Social regulations include air and water quality standards, average fuel economy rules, auto safety requirements, minimum wage requirements, worker safety rules, and public health regulations, such as food safety requirements, mandatory vaccination, and quarantines. BCA is useful for addressing economic efficiency issues in social regulations. In 2002, only six of the 31 significant regulations OMB reviewed fell into the category of social regulations.

Transfer Regulations

Transfer regulations implement federal budgetary programs to redistribute federal funds among various interest groups. They transfer funds from the Treasury (and ultimately from present or future taxpayers) to target beneficiaries. Transfer regulations implement congressional efforts to redistribute wealth contemporaneously or between generations and to address issues of equity, rather than efficiency, with such programs as Medicare, Medicaid, and Social Security.

While transfer regulations undergo extensive economic review, RIA for these rules focuses on fairness, adequacy, compliance, incentives they create, and federal budget impact. Since the goals of transfer programs are well defined and are likely to have measurable outcomes for comparison, BCA is largely irrelevant for transfer regulations. For these regulations, more limited measures of effectiveness, such as CEA discussed further below, may be used since the most cost-effective alternative will typically achieve the program goal at the lowest cost. In 2002, 25 of 31 economically significant OMB rules reviewed were transfer regulations.

Other Regulations

Although federal subsidy programs, such as agriculture, education, and housing subsidies; disaster assistance; food stamps; and victim compensation funds, are also examples of transfer programs, OMB only reviews regulations under these programs when they are initially promulgated or amended or are exempt from RIA as appropriations. Annual appropriations that provide funding for these subsidy programs and others, such as military and federal agency

21 Office of Management and Budget (OMB), 2003a.
appropriations, are not categorized as “rules” for purposes of OMB review.

**Comparative Regulatory Effectiveness – League Tables**

OMB and others have argued that government should first address those problems where its intervention will do the most good for the least cost. In an effort to focus public attention on the relative cost of different regulations, OMB has issued “league tables,” which rank regulations by their cost-effectiveness at saving statistical lives (see Exhibit 3, below). For instance, safety rules are often more cost effective than health or environmental rules. Other authors have used BCA and CEA as common yardsticks to make comparisons across myriad types of regulations.23 However, even most supporters of the league table concept recognize that government has many roles, and comparisons across roles may not be particularly useful.

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**EXHIBIT 3**

League Table - Opportunity Costs per Statistical Life Saved (OCSLS)

<table>
<thead>
<tr>
<th>Regulation</th>
<th>Year Issued</th>
<th>Agency</th>
<th>OCSLS (millions of 2002 $)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Childproof lighters</td>
<td>1993</td>
<td>CPSC</td>
<td>0.1</td>
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<tr>
<td>Respiratory protection</td>
<td>1998</td>
<td>OSHA-H</td>
<td>0.1</td>
</tr>
<tr>
<td>Logging operations</td>
<td>1994</td>
<td>OSHA-S</td>
<td>0.1</td>
</tr>
<tr>
<td>Electrical safety</td>
<td>1990</td>
<td>OSHA-S</td>
<td>0.1</td>
</tr>
<tr>
<td>Steering column protection</td>
<td>1967</td>
<td>NHTSA</td>
<td>0.2</td>
</tr>
<tr>
<td>Unvented space heaters</td>
<td>1980</td>
<td>CPSC</td>
<td>0.2</td>
</tr>
<tr>
<td>Safety standards for scaffolds</td>
<td>1996</td>
<td>OSHA-S</td>
<td>0.2</td>
</tr>
<tr>
<td>Cabin fire protection</td>
<td>1985</td>
<td>FAA</td>
<td>0.3</td>
</tr>
<tr>
<td>Trihalomethanes</td>
<td>1979</td>
<td>EPA</td>
<td>0.3</td>
</tr>
<tr>
<td>Organ procurement regulations</td>
<td>1998</td>
<td>HHS</td>
<td>0.3</td>
</tr>
<tr>
<td>AED on large planes</td>
<td>2001</td>
<td>FAA</td>
<td>0.3</td>
</tr>
<tr>
<td>Mammography standards</td>
<td>1997</td>
<td>HHS</td>
<td>0.4</td>
</tr>
<tr>
<td>Food labeling regulation</td>
<td>1993</td>
<td>FDA</td>
<td>0.4</td>
</tr>
<tr>
<td>Stability &amp; control during braking/trucks</td>
<td>1995</td>
<td>NHTSA</td>
<td>0.4</td>
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<tr>
<td>Electrical power generation</td>
<td>1994</td>
<td>OSHA-S</td>
<td>0.4</td>
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<tr>
<td>Passive restraints/belts</td>
<td>1984</td>
<td>NHTSA</td>
<td>0.5</td>
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<tr>
<td>Fuel system integrity</td>
<td>1975</td>
<td>NHTSA</td>
<td>0.5</td>
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<tr>
<td>Underground construction</td>
<td>1983</td>
<td>OSHA-S</td>
<td>0.5</td>
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<tr>
<td>Head impact protection</td>
<td>1995</td>
<td>NHTSA</td>
<td>0.7</td>
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<tr>
<td>Alcohol &amp; drug control</td>
<td>1985</td>
<td>FRA</td>
<td>0.9</td>
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<tr>
<td>Servicing wheel rims</td>
<td>1984</td>
<td>OSHA-S</td>
<td>0.9</td>
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<tr>
<td>Reflective devices for heavy trucks</td>
<td>1999</td>
<td>NHTSA</td>
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<tr>
<td>Seat cushion flammability</td>
<td>1984</td>
<td>FAA</td>
<td>1.0</td>
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<tr>
<td>Side impact &amp; autos</td>
<td>1990</td>
<td>NHTSA</td>
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<td>Medical devices</td>
<td>1996</td>
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<td>1.1</td>
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<td>Floor emergency lighting</td>
<td>1984</td>
<td>FAA</td>
<td>1.2</td>
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<td>Crane suspended personnel platform</td>
<td>1984</td>
<td>OSHA-S</td>
<td>1.5</td>
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<td>Low-altitude wind shear</td>
<td>1988</td>
<td>FAA</td>
<td>1.8</td>
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<td>Electrical equipment standards</td>
<td>1970</td>
<td>MSHA</td>
<td>1.9</td>
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<tr>
<td>Trenching and excavation</td>
<td>1989</td>
<td>OSHA-S</td>
<td>2.1</td>
</tr>
<tr>
<td>Traffic alert &amp; collision avoidance</td>
<td>1988</td>
<td>FAA</td>
<td>2.1</td>
</tr>
</tbody>
</table>

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23 For examples, see: Hahn and Layburn, 2003; Tengs, et al., 1995.
### League Table - Opportunity Costs per Statistical Life Saved (OCSLS)

<table>
<thead>
<tr>
<th>Regulation</th>
<th>Year Issued</th>
<th>Agency</th>
<th>OCSLS (millions of 2002 $)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children's sleepwear flammability</td>
<td>1973</td>
<td>CPSC</td>
<td>2.2</td>
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<tr>
<td>Side doors</td>
<td>1970</td>
<td>NHTSA</td>
<td>2.2</td>
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<tr>
<td>Concrete &amp; masonry construction</td>
<td>1985</td>
<td>OSHA-S</td>
<td>2.4</td>
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<tr>
<td>Confined spaces</td>
<td>1993</td>
<td>OSHA-S</td>
<td>2.5</td>
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<td>Hazard communication</td>
<td>1983</td>
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<td>Child restraints</td>
<td>1999</td>
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<td>3.3</td>
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<td>Benzene/Fugitive emissions</td>
<td>1984</td>
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<td>3.7</td>
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<td>Rear/Up/Shoulder belts/Autos</td>
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<td>Asbestos</td>
<td>1972</td>
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<td>ED8W drinking water standards</td>
<td>1991</td>
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<td>EPA</td>
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<td>Radionuclides/Uranium mines</td>
<td>1984</td>
<td>EPA</td>
<td>6.9</td>
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<td>Roadway worker protection</td>
<td>1997</td>
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<td>Grain dust</td>
<td>1988</td>
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<td>Electrical Equipment Stds./Coal mines</td>
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<td>MSHA</td>
<td>13.0</td>
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<td>1997</td>
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<td>13.0</td>
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<td>66.0</td>
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<td>1994</td>
<td>OSHA</td>
<td>71.0</td>
</tr>
<tr>
<td>Arsenic</td>
<td>1978</td>
<td>OSHA-H</td>
<td>77.0</td>
</tr>
<tr>
<td>Asbestos ban</td>
<td>1989</td>
<td>EPA</td>
<td>78.0</td>
</tr>
<tr>
<td>Ethylene oxide</td>
<td>1984</td>
<td>OSHA-H</td>
<td>80.0</td>
</tr>
<tr>
<td>Lockout/tagout</td>
<td>1989</td>
<td>OSHA-S</td>
<td>98.0</td>
</tr>
<tr>
<td>Hazardous waste mgt/Wood products</td>
<td>1990</td>
<td>EPA</td>
<td>140.0</td>
</tr>
<tr>
<td>Diethylstilbestrol (DES) in cattle feed</td>
<td>1979</td>
<td>FDA</td>
<td>170.0</td>
</tr>
<tr>
<td>Benzene/revised: waste operations</td>
<td>1990</td>
<td>EPA</td>
<td>180.0</td>
</tr>
<tr>
<td>Sewage sludge disposal</td>
<td>1993</td>
<td>EPA</td>
<td>530.0</td>
</tr>
<tr>
<td>Land disposal restrictions</td>
<td>1990</td>
<td>EPA</td>
<td>530.0</td>
</tr>
<tr>
<td>Hazardous waste: solids dioxin</td>
<td>1986</td>
<td>EPA</td>
<td>560.0</td>
</tr>
<tr>
<td>Prohibit land disposal</td>
<td>1988</td>
<td>EPA</td>
<td>1,100.0</td>
</tr>
<tr>
<td>Land disposal restrictions/Phase II</td>
<td>1994</td>
<td>EPA</td>
<td>2,600.0</td>
</tr>
<tr>
<td>Drinking water: Phase II</td>
<td>1992</td>
<td>EPA</td>
<td>19,000.0</td>
</tr>
<tr>
<td>Formaldehyde</td>
<td>1987</td>
<td>OSHA-H</td>
<td>78,000.0</td>
</tr>
<tr>
<td>Solid waste disposal facility criteria</td>
<td>1991</td>
<td>EPA</td>
<td>100,000.0</td>
</tr>
</tbody>
</table>

*Source: Morrall, 2003.*
3.3. CURRENT TRENDS

Over the years, the tendency of the federal government to rely on BCA has varied, to a large extent depending on the policy preferences of the presidential administration. The Bush administration took an activist role in regulatory oversight by appointing a strong proponent of BCA, John D. Graham, as chief of OIRA to oversee federal rule-making at OMB. In his previous role as Director of the Center for Risk Analysis at the Harvard School of Public Health, Dr. Graham was an outspoken advocate of quantitative analysis of regulation.24

While the President has always had great influence over the regulatory agenda, regulations were typically initiated by the implementing agency. Dr. Graham instilled a new activism in OMB’s rule-making machinery and made BCA more controversial by involving OMB earlier in the regulatory process. Rather than reviewing a completed regulatory document when it is submitted by the proposing agency, OMB has become involved in suggesting options to be considered and acceptable methods of analysis. Because OMB’s involvement is informal, it is not well documented and may be constrained by provisions of the Administrative Procedures Act and Executive Order 12866.25

As part of its more proactive posture and acknowledging that regulation may be warranted in some cases, Dr. Graham introduced the “prompt” letter in which OMB identifies specific areas that an agency may want to explore for cost-effective opportunities for regulation. For instance, OMB has suggested further regulation may provide a cost-effective opportunity to save lives in the work place by requiring them to have automatic external defibrillators.

24 In April 2007, Susan Dudley became administrator of OIRA.
As part of regulatory impact analysis, BCA provides a framework and set of tools to compare alternative strategies for approaching a particular action. BCA requires systematic description of all of the benefits and costs of a proposed action. It is most useful for evaluating well-defined projects to decide whether to undertake the project in the first place and, if so, to select among options and determine the optimum scale. The rationale for BCA is economic efficiency; its objective is to facilitate the optimal use of resources.

The earliest work on the theory and practice of BCA was done in the context of water resources development. This work resulted in several major treatises on the techniques of BCA and culminated in U.S. Water Resources Council’s “Principles and Standards for Planning Water Resources Development,” first issued in 1973 and revised in 1980.

While government has used BCA to analyze water projects for many years, BCA has been embraced more readily by the private sector where it has been widely adopted and developed to ever higher levels of sophistication.

4.1. PRIVATE SECTOR BENEFIT-COST ANALYSIS

Private firms routinely use BCA for many major financial and business decisions. For private firms, the measure of net benefits is simply the change in net income or stockholder value. Almost every nontrivial corporate decision is subject to at least an informal BCA. Formal, rigorous BCAs are typical in acquisition planning, product development, and capital budgeting decisions. A company often has several alternative projects that demand resources. Such private sector projects typically range from replacing old equipment to building new plants or entering new sectors, but they are unlikely to encompass the magnitude or nature of federal regulations and programs that are subject to RIA. For each alternative, the company estimates the costs of the decision over its expected lifetime. The company must also project the expected price, revenue, and profit from the decision over the lifetime of the investment. As in the policy world, the costs are more predictable than the benefits.

Costs and benefits are discounted through time to describe differing patterns of expenditure and reward in the same terms. If the resources invested in the equipment were invested elsewhere, they would earn the “opportunity cost of capital”, that is, the discounted cost of capital in relation to the alternative use of the resources. This value is expressed as the net present value or the discounted benefits minus the discounted costs of the project. If the net present value is greater than zero, then the project will bring in more money over its lifetime than the alternative use of capital would. If net present value is zero or less, the company is better off putting its resources into an alternative investment where it can earn the opportunity cost of capital.

As in the policy arena, other factors are important in corporate investment decisions. Net present value ignores the relative sizes of projects and their risks. A large project with a small payoff and limited risks may be a better option than a smaller, risky project with potentially large payoffs. In addition, corporate strategy, marketing, and competitive factors must be considered.

4.2. PUBLIC SECTOR BENEFIT-COST ANALYSIS

Historical Background

Some government actions are closely analogous to corporate decisions. Whether to build a dam is much like any corporate capital budgeting issue. Indeed, the Army Corps of Engineers’ (ACE) civil works program has been at the forefront in applying BCA to its decisions. ACE projects are among the few areas of federal activity that are required to meet strict benefit-cost criteria. The first legal requirement to base public policy decisions...
on BCA is found in the Flood Control Act of 1936, which required that flood control projects be undertaken only if “the benefits, to whomsoever they may accrue, are in excess of the estimated costs.” This requirement was later modified into the concept of National Economic Development costs and benefits, which made a crucial distinction between local effects and national effects of water projects. The Army Corps of Engineers uses market-based, monetized costs and benefits to analyze a project and evaluates its options much like a corporate decision maker.

When the government activity moves from producing flood control projects to regulating the public welfare, use of BCA for regulatory analysis moves a step further away from private sector BCA. In an analysis of social regulations, the costs and benefits of policy changes do not accrue to a single entity and, in fact, are typically expected to fall on quite different segments of society. In many cases, neither the costs nor benefits can be estimated from market-based, monetary values. Instead, measurement of costs and benefits, but particularly benefits, is often expressed in terms of the impact on individual well-being or social welfare.

For purposes of evaluating social policies, the concept of societal well-being is more complex than the typical private sector measure of net financial gain. The basic premise of welfare economics is that each individual is the best judge of how well off he or she is, and that the well-being of society is the sum of the well-being of its individuals. With that individualistic premise, the benefit-cost decision rule is very simple: if the benefits of an action are greater than its costs, society will be made better off by doing it. If there is a continuum of action, BCA will also indicate how much of the action to undertake. For example, the benefits of improving water quality in a highly polluted river to the point that fish are safe to eat may outweigh the costs, but improving the water quality to the point that the water is drinkable may not. Finding the optimal level of water quality involves comparing the marginal benefits of each improvement in water quality with the marginal costs of obtaining it. At the optimum level of water quality, marginal benefits are just equal to marginal costs, and the net benefits of water quality improvement are maximized.

Thus, two important differences between private sector use of BCA and public sector use of BCA are that (1) a private firm is concerned only with benefits and costs that accrue to itself, while social BCA is concerned with all of the benefits and costs to society at large, and (2) the costs and benefits can be readily monetized for a private firm, particularly a for-profit business, whereas the impact of social regulations is often quite difficult to quantify in dollars.

**Foundations of BCA: Welfare Economics**

How should the effect of policy choices be weighed in terms of social welfare? This question asks, what should we measure, not how should we measure it or what standards of measurement should we apply? The former question needs to be answered before a decision is made about how to assess the impact of regulations. Welfare economics recognizes three basic approaches to answering this question.

One approach describes social welfare in terms of society’s preferences for the distribution of benefits. A quantitative model that describes society’s trade-off of one individual’s welfare against another person’s welfare is called a social welfare function. By clearly defining society’s preferences, such a model allows efficient and equitable social choices that maximize social welfare. However, this approach requires social judgments regarding the relative deservingness of different individuals. While defining a social welfare function greatly facilitates evaluation of public policies, the main problem with the social welfare function is determining the weights for valuing changes in individual welfare. For instance, some have suggested that a social welfare function that would achieve the highest welfare for the worst-off in society would result in the greatest social welfare. Others have argued that more is always better, even though it may leave those at

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the bottom of society the same or even worse off. Publicly defining a formal national social welfare function would be highly controversial. Consider the furor over affirmative action, which has similar implications. To our knowledge, no effort has been made to apply a social welfare function to government rule-making.

A second approach to valuing changes in social welfare requires that policy changes make at least one person better off and no individual worse off. This approach, known as the Pareto criterion (after its Italian author), deliberately rules out adding up welfare measures for different individuals. Welfare economics is based, in part, on the principle that voluntary exchanges in competitive markets will respect the Pareto criterion because no individual would willingly buy or sell in a manner that hurts his or her own welfare. However, application of the Pareto criterion to regulatory analysis is limited by the requirement that no one be made worse off. This assumption poses an important limitation since, in the case of social regulations, someone must invariably bear the cost of regulation.

The third approach, which might be considered a sub-category of the Pareto criterion, maximizes the net benefits to society if, under any policy, the gainers could, in theory, fully compensate the losers for their welfare loss and still have a net welfare gain. Under this approach, known as the Kaldor-Hicks criterion, the policy is deemed to result in an overall improvement in social welfare, even if the gainers do not, in practice, fully compensate the losers. This “potential compensation test” is deemed efficient since, if the compensation were actually paid, everyone would be better off, thus satisfying the Pareto criterion.

In the interest of economic efficiency, the Pareto and Kaldor-Hicks criteria accept the existing distribution of wealth in society and ignore equity concerns. Under both approaches, a policy that produces a $1 million gain for Bill Gates would be equivalent to a policy that gives $10,000 to 100 homeless families. Under the potential compensation test of the Kaldor-Hicks criterion, a policy that allows a rich patient to buy an organ for transplant from a poor donor would be deemed efficient because the rich gainer is compensating the loser for his or her losses. In fact, under these criteria, such a policy would be deemed efficient even if it required the poor to donate organs to the rich without payment actually changing hands because, in theory, the gainers could compensate the losers for their losses.

The Kaldor-Hicks potential compensation test provides a controversial foundation for standard welfare economics. Its application has been justified on the grounds that, if a large enough number of projects with positive net benefits is undertaken, benefits and costs will be spread broadly across society so that, in the long run, things will average out and on the whole, everyone will be a net gainer. Thus, some view the foundation for BCA as a shaky basis for policy choices. However, this has not deterred successive administrations from using the Kaldor-Hicks criterion as a rationale for many kinds of policy choices, nor economists from advocating greater use of it in a wider range of environmental and resource policy questions.

4.3. PROS AND CONS OF THE BENEFIT-COST ANALYSIS DEBATE

Whether the weaknesses of the Kaldor/Hicks criterion described above matter for decision making depends on what decision is being made. BCA is not well suited to deciding between regulating air emissions from power plants and regulating automobile safety. The political process is better suited to balancing a variety of disparate and sometimes competing interests. However, once the political process has established goals and priorities, BCA can be used to select among alternative approaches to accomplish these specific objectives.

As described below, application of BCA requires certain types of information, much of it quantitative data regarding costs and benefits, that can be converted into dollars or some other comparable measure. To the extent that these data are unreliable or missing, analysts tend to estimate values based on the best available information.

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31 See the discussion in Adler, 1999. Rethinking Cost-Benefit Analysis.
32 For more discussion of the Pareto criterion, see Freeman, 2003.
33 Hicks, 1940; Kaldor, 1939.
In addition, assumptions about the future are an important part of any BCA. The robustness of the data and related assumptions can significantly affect both the results and credibility of BCA.

More fundamentally, there has been a lively debate about whether the results of BCA and economic considerations in general should play any role in public policy and regulatory decision making, especially where human health and safety issues are involved. Some argue that BCA should play the sole, or at least the dominant, role in such decisions, while others see BCA as a fatally flawed basis for policy making. Differences of opinion arise from a variety of factors, including philosophical differences, such as whether decisions should be based on economic efficiency or legal rights, lack of faith that BCA produces reliable results, and political disagreements over the most appropriate regulatory choices.

A few critics, in particular, argue that applying BCA in the context of regulatory decisions is deeply flawed and insist that technology- and market-based regulations have been successful without relying on the problematic method of BCA. Their five main criticisms are:

1. Political decisions are very different from market decisions so reducing life, health, and the natural world to monetary values is misguided.
2. Discounting is a financial construct and cannot reasonably be used to make policy choices about non-economic harms between or within generations.
3. BCA ignores equity issues.
4. BCA is hard for lay people to understand, so it is resistant to public scrutiny. Rather than creating greater objectivity and transparency, BCA rests on a series of value judgments that are obscured by its quantitative veneer.
5. Quantitative results of BCA are inevitably incomplete and draw attention away from important qualitative considerations that are not easily monetized.

While admitting most of these points, most mainstream economists argue that the search for perfection should not pose an insurmountable barrier to improving the public policy decision process. Thus, proponents of BCA have attempted to deal with each criticism with progressive refinements to elements of the technique, such as monetization, equity, discounting, and transparency, all of which are discussed later in this paper. Despite the practical and theoretical difficulties involved, in the real world, governments need to and do, in fact, make decisions. As a result, with increasing frequency over the past three decades, federal policy makers have chosen to follow the advice of mainstream economists, such as Nobel laureate Kenneth Arrow, who has advised that “benefit-cost analysis has a potentially important role to play in helping inform regulatory decision making, although it should not be the sole basis for such decision-making.”

The quantitative results of BCA can attract the focus of much attention from decision makers and the public. As a result, both proponents and critics of BCA often describe its role as if BCA is the sole criterion that is applied to a decision. This is virtually never the case. In the federal regulatory process, BCA is only one component in a highly complex decision making process. Alternative measures and supplementary analyses bolster many of the perceived weaknesses of BCA, as described in the two historical case studies, below. Ultimately, BCA is part of a decision making process but does not mandate the choice of any specific option. Rather, it is a tool to guide and focus decision makers. Selection of the preferred option is always within the control of the decision maker.

34 Ackerman and Heinzerling (2004); Ackerman and Heinzerling (2002); Kelman (1981).
35 Ackerman and Heinzerling (2002); Ackerman and Heinzerling (2004).
36 Arrow, et al.,1996.
37 Ibid.
38 Hahn and Layburn, 2003.
39 Ackerman and Heinzerling, 2002.
5. The Practice of Government Benefit-Cost and Cost-Effectiveness Analysis

An analytical tool in the regulatory context, BCA measures the net contribution of any public policy to the well-being of members of society. BCA is rooted in neo-classical welfare economics and can be described in terms of supply and demand for goods both in markets and outside of them (externalities). Regulation changes the status quo by shifting the balance among the markets. Often a regulation internalizes an externality, for example, requiring a polluter to clean up his waste water. In this example, regulation requires the producer to reallocate resources to pay the cost of a formerly free good (i.e., waste water). The new cost to the producer reflects the loss of productivity from this reallocation. On the other hand, downstream users gain as the cost of the externality that they had been bearing (i.e., pollution) is relieved. Regulation reverberates through the economy as producers and consumers change their resource use. BCA attempts to quantify these changes.

In practice, BCA usually describes a narrowly defined, technical economic calculation that attempts to reduce all benefits and costs to a common quantitative metric (i.e., dollars). BCA seeks to determine if the aggregate gains that accrue to those who are made better off are greater than the aggregate losses to those made worse off by the policy choice. Both the gains and losses are measured in monetary terms and are defined as the sum of each individual’s willingness to pay to receive the gain or to prevent the losses imposed by the policy. If the gains exceed the losses, the policy improves economic efficiency.40

BCA for federal rulemaking considers only flows of real resources at the national level. Costs must be measured as opportunity costs, not market cost (see section 4.1, Private Sector Benefit-Cost Analysis). Thus, the cost of water diverted to help an endangered species is measured as the productivity lost by reallocating the water from its next best use, such as for irrigation, rather than as the cost of building the canals or the retail price for drinking water. This opportunity cost may not bear any relation to the price farmers pay for water, although price may sometimes be used as a proxy for opportunity cost.

While CEA avoids the controversial step of attributing dollar values to goods, CEA is a more limited method than is BCA for assessing alternative regulatory policies (see Section 5.3, for discussion of CEA).

5.1. SOME PRINCIPLES OF BENEFIT-COST ANALYSIS

BCA involves comparing two different states of the world: one in the absence of the project or policy, referred to as the baseline scenario (i.e., status quo without policy implementation), and the other with the project or policy in place, referred to as the alternative scenario (i.e., with policy implementation). As part of this process, analysts must first develop a comprehensive model of the relevant parts of the economic system affected by the project and define the expected evolution of this model under alternative policies. Within this descriptive model, the type and extent of the impact on affected individuals and organizations must be identified, measured or estimated, and valued. Analysts must decide

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40 Historically, many analysts attempted to standardize the results of BCA by expressing them as a ratio (i.e., a favorable benefit-cost ratio exceeds one). However, to maximize total returns, the results should be evaluated in terms of net benefits rather than as a benefit-cost ratio because a project that has a higher benefit-cost ratio may produce fewer net benefits than an alternative project with a lower ratio. The following example illustrates this point:

<table>
<thead>
<tr>
<th>Project</th>
<th>Benefits</th>
<th>Costs</th>
<th>B/C Ratio</th>
<th>Net Benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>$3</td>
<td>$1</td>
<td>3</td>
<td>$2</td>
</tr>
<tr>
<td>B</td>
<td>$15</td>
<td>$10</td>
<td>1.5</td>
<td>$5</td>
</tr>
</tbody>
</table>
who and what needs to be counted and define and measure benefits and costs. When data are unavailable or insufficient to allow accurate measurements or estimates, analysts must decide whether to make assumptions or exclude missing values from the analysis. Finally, analysts must produce an estimate of net effects from the policy and test the sensitivity of this primary estimate to potential variations in their data and assumptions from the appropriate perspective.

While OMB mandates a comprehensive societal perspective to analyze health and environmental regulations, it may adopt other perspectives to analyze different policies. For instance, although Medicare regulations are not subject to formal BCA or CEA under OMB rules, Medicare regulations are often analyzed for other reasons. In this case, the analysis can be performed from the perspective of the government simply as a payor or from the government's broader societal perspective, which would influence which costs and benefits are included in the analysis, such as changes in the health of non-Medicare patients, changes in productivity and tax implications. This section describes the process involved in BCA.

**Baseline and Alternative Scenarios**

To construct the baseline and alternative scenarios, a model is needed that is capable of predicting the magnitudes of all of those things that will affect individuals' well-being under the two scenarios. For example, if the proposal is a regulation requiring drivers and passengers in automobiles to wear seatbelts, the baseline must describe the numbers of drivers and passengers potentially affected, the numbers and types of accidents, and the resulting injuries and fatalities that are anticipated in the absence of the regulation. The alternative scenario must predict not only how wearing a seatbelt reduces the number of fatalities and severity of injuries but also how the regulation affects the behavior of drivers and passengers. For example, what will be the compliance rate? Will drivers compensate for the reduction in risk of injuries by driving at higher speeds, thus having more accidents?

**What Needs to Be Counted?**

While the rules for determining what is counted in an analysis may not be immediately obvious to all observers, once the scope and perspective for the analysis has been determined, independent analysts generally agree on what items to include or exclude on the whole, although they may disagree about the disposition of items in gray areas. Defining the scope and perspective of an analysis is often the key to whether it is performed at all. OMB requires that federal agencies performing formal BCA and CEA take into account all relevant societal costs and benefits, both public and private. Of course, other perspectives are often taken as well, depending on the circumstances.

In principle, comparing baseline and alternative scenarios in a BCA requires that the changes in well-being (either positive or negative) of every person affected by a regulation be measured and added up. If the regulation will require actual payment of appropriate compensation so that there are no losers (as required to satisfy the Pareto criterion), then the winners and losers must be identified. Typically no effort is made to compensate the losers.

While policies may have international impact, for purposes of federal regulatory analysis and BCA, policy makers usually attempt to measure the impact of policy changes within the political boundaries of the United States.

**5.2. DEFINING AND MEASURING BENEFITS AND COSTS**

Defining and measuring the expected benefits and costs of regulations are essential functions of BCA. Over the past 30 years, economists have struggled to measure the value of non-market services, such as environmental quality and health. This section describes basic measures of economic benefits and costs, methods for estimating these measures, and valuation of the benefits of human health and safety regulations.

**Benefits and Costs**

The concept of net benefit or consumer surplus is used to aggregate the impact of regulations on
many goods. Consumer surplus arises because most consumers are willing to pay more than they are required to pay for a good. In the case of public goods, they are not required to pay anything directly. Economics assumes that an increase in the quantity of one good can compensate or substitute for a decrease in another good. The concept of “substitutability” is at the core of the economist’s concept of value because it establishes the possibility of trading off any good for another. Even when market prices are not available, trade-off ratios can be used to impute economic values. Thus, the price of a market good can be used to establish a value for non-market goods. For this reason, how people value substitute goods based on empirically observed choices is referred to as “revealed preference.”

Measures for the value of substitute goods can be expressed in terms of dollars as either willingness to pay (WTP) or willingness to accept compensation (WTA). WTP and WTA measures can be defined in terms of any good that an individual is willing to substitute for the good being valued. In the following discussion, dollars are used to express trade-off ratios, but WTP and WTA can also be measured in terms of other goods that matter to the individual. For example, some values are more easily expressed in terms of time: a person might be willing to drive 15 minutes out of his or her way to save a dollar on gas.

WTP is the maximum sum of money an individual is willing to pay rather than do without an increase in some good or benefit, such as an environmental amenity (i.e., ocean view) or a medical treatment option (i.e., surgery). This amount of money makes the individual indifferent about paying for a benefit or forgoing the benefit while keeping the money to spend on other things.

By contrast, WTA is the minimum sum of money an individual is willing to accept to voluntarily forgo a benefit that he or she would otherwise have. It is the amount that would make the person indifferent about having the benefit or forgoing the benefit while getting the money, instead.

While both WTP and WTA are based on the assumption of substitutability in preferences, they adopt different reference points. As a starting point, WTP assumes the absence of the improvement, while WTA assumes the presence of the improvement as the baseline for estimating changes in welfare. In principle, WTP and WTA need not be exactly equal since WTP is constrained by the individual’s income and assets (i.e., ability to pay), whereas there is no upper limit on what that person could demand as compensation for forgoing the improvement. These differences have important implications for valuing benefits.

Revealed Preference Methods

One method of determining WTP or WTA is to base these values on empirically observed choices of people acting in real-world settings, where they must live with the consequences of their actions. This approach, referred to as the “revealed preference” method, uses price differentials to infer the relationship between market-based goods and services and non-market items. Revealed preference methods involve a kind of detective work in which clues about the values individuals place on non-market goods and services are pieced together from the evidence that people leave behind as they respond to prices and other economic signals. When an individual chooses one action from among a set of possibilities, he or she is indicating a preference for that set of characteristics over others.

Revealed preference methods are often used to estimate the value people place on non-market health and environmental services in the absence of market prices. For instance, a person with cancer who chooses to undergo chemotherapy, rather than radiation or watchful waiting, indicates a preference for chemotherapy over the alternatives. By observing hundreds of such choices and comparing the characteristics of each therapy (efficacy, cost, side effects, duration, etc.), economists can infer patients’ WTP for cancer treatments with specific attributes.

Similarly, revealed preference models can be used to estimate WTP to reduce job risk based on wage differentials for occupational hazards and WTP for environmental amenities, such as a house with a pleasant view, based on housing prices. Other examples of revealed preference models include the “household production model,” which estimates the value people place on reducing pollution based on household spending to clean and repair damage caused by air pollution, and
the “travel cost demand model,” which estimates the value of environmental amenities based on the cost people incur to travel to different quality recreation sites.

**Stated Preference Methods**

A second approach to determining WTP or WTA is to gather data from people's subjective responses to hypothetical questions rather than from observations of real-world choices. This approach, referred to as the “stated preference method,” asks people directly about the values they place on non-market items, in effect, creating a hypothetical market. For example, people might be asked what value they place on a specified change in environmental or health services, or how much of a service they would “purchase” at a given price. One approach, the contingent valuation method (CVM), simply asks people what value they would place on a specified hypothetical change in an environmental amenity or the maximum amount they would be willing to pay to have a specified event occur. Their responses, if truthful, represent direct expressions of WTP or WTA.

While a variety of question formats is possible, the most common is the referendum format, which asks for a yes or no answer to a question, such as, “Would you be willing to pay $X for Y item?” Named for their similarity to voting referenda on public policy and tax issues, basic referendum questions reveal only an individual’s upper bound (for a no) or lower bound (for a yes) on the relevant welfare measure. Statisticians can estimate the population’s WTP from many individual responses to higher and lower dollar amounts.

Stated preference methods suffer from a number of concerns regarding the validity and reliability of the responses. Skeptics ask whether the hypothetical nature of the questions inevitably leads to systematic bias in the results or produces responses that are too unreliable to be useful for drawing inferences. Other issues arising from stated preference methods are specific to the particular form of the question asked. For example, when people are asked how much they are willing to pay for something, they might say “zero” because they reject the idea of having to pay for something they consider by right to be theirs.

In addition to methodological issues, conducting a study of revealed preferences or stated preferences can be costly and time consuming. In most cases, government agencies rely on previous studies to derive estimates of WTP or WTA using a practice referred to as “benefits transfer.”

**Benefits Transfer**

Benefits transfer refers to the practice of generalizing or extrapolating the results of a previous study to a new and different situation. Analysts commonly refer to the policy being evaluated as the “policy site” and the source of the values being used as the “study site.” Benefits transfer involves applying non-market values obtained from the study site to evaluation of a proposed or observed change at the policy site that is of interest to the analyst.

The use of benefits transfer is illustrated by EPA’s estimation of benefits from a regulation that was expected to reduce harmful health effects from disinfectants. When EPA was unable to find values in the literature for WTP to avoid the non-fatal bladder cancer associated with disinfectants, EPA transferred a value from a study of WTP to avoid chronic bronchitis. These conditions were different in some clinical respects. Bladder cancer causes more severe acute health effects, whereas chronic bronchitis has more lingering effects. However, for purposes of BCA, EPA decided that, in terms of their economic implications for long-term health and lifestyle effects (e.g., the need for life-long dependence on medical equipment and limitations on recreational and job activities), the impact of these two conditions was sufficiently similar to warrant using benefits transfer in this case. As a result, EPA analysts inflated the dollar value of WTP from the earlier study to the correct year using the Consumer Price Index. To allow subsequent reviewers, such as OMB and the public, to compare similarities and

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43 Other types of stated preference questions include contingent ranking, contingent activity, and conjoint analysis.

44 Benefits transfer is not related to transfer regulations, discussed earlier.

45 Stage 1 Disinfectants/Disinfection Byproducts Rule, U.S. Environmental Protection Agency (EPA), 1998.
differences between the two cases, EPA estimated the distribution of results and reported both the median and range of benefit values, rather than reporting a single value for WTP. While EPA’s estimate of the value transferred might have been improved by considering differences between the sample of chronic bronchitis patients and the population likely to suffer bladder cancer, such as age, income, and other demographic characteristics, peer reviewers and OMB approved the results of this benefits transfer.

Other examples of benefits transfer include:

- using a value for recreational fishing derived from a travel cost study at one lake to estimate the value of increased fishing at another lake;
- using WTP to avoid an asthma attack derived from a study of avoidance behavior to estimate the value of preventing other respiratory symptoms; and
- using WTP to preserve a tropical rainforest derived from a stated preference study in one country to estimate the value of preserving a rainforest in another country.

The primary advantage of benefits transfer is that it avoids the cost and time required to perform new studies to determine WTP or WTA. Because BCA often requires estimated values for numerous parameters, without the option of transferring benefit estimates across studies, in most cases, performing BCA would be prohibitively expensive and time consuming. As a result, many health-related values have been assembled and made publicly available in tables, such as EPA’s Cost of Illness Handbook.46 To provide environmental values for benefit transfer, other databases have been established, such as the Canadian Environmental Ministry’s Environmental Valuation Reference Inventory.47

The practice of benefits transfer became common in the economic analysis of environmental regulations in the United States in the mid-1980s. Since then, accepted conventions have been established for terminology, procedures, and protocols. In addition, the validity of the practice of benefits transfer is beginning to be tested. While application of benefits transfer methods became more rigorous in the early 1990s48, the validity of the application of any particular benefits transfer needs careful assessment. This technique deserves special scrutiny when applied to populations with different characteristics from the original study population. For example, academic researchers sometimes base WTP on preferences of conveniently located college students. In other cases, researchers may not include race and gender variables in BCA studies because data were insufficient in the original studies or cross-national benefit transfers may have been confounded by socioeconomic factors and cultural differences. In some cases, it may simply be inappropriate to apply benefits transfer methods, such as transferring WTP for environmental protections in Sweden in the context of Darfur, Sudan.

**Measuring the Benefits of Improved Health and Safety**

Performing BCA of federal health and safety regulations requires application of the principles described above (i.e., baseline and alternative scenarios; defining and measuring benefits and costs) to quantify the effects in terms of reductions in the risk of premature mortality, diseases, and adverse health events, such as injuries. The standard economic approach is to estimate the amount individuals would be willing to pay to reduce their own risk of disease and death.

**Avoiding Premature Mortality**

In response to those who argue that human lives are too valuable to place a monetary value on them, economists say, in fact, individuals and society make trade-offs between changes in the probability of death and other goods that have monetary values all the time. These trade-offs make it possible to infer the implicit prices that people and society attach to changes in the probabilities of death. Assuming that individual preferences provide a valid basis for making judgments about changes in economic welfare,

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48 See Brookshire and Neil, 1992, for an introduction and overview of papers on benefits transfer.
reductions in the probability of death due to accident or illness can be valued according to an individual’s WTP to achieve the reductions or WTA compensation to forgo the reductions. In this situation, using WTP and WTA presupposes that individuals treat longevity more or less like any other good, rather than valuing life differently from other goods.

Although surprising to some, the assumption that life is a fungible commodity has been shown to be reasonable, at least for small changes in mortality risk. In their daily lives, people make many choices that trade off changes in the risk of death in exchange for other economic goods. For example, some people prefer the convenience and shorter time involved in traveling to work by car, rather than by bus or walking, even though driving increases their risk of death. People knowingly accept jobs that carry a higher risk of accidental death in exchange for higher wages. In such cases, people perceive themselves as better off. An individual’s WTP or WTA is revealed by these choices and can be measured in dollars. These choices are the basis of measures of the economic value of reductions in the risk of death. Empirically, however, isolating WTP to avoid the risk of accidental death can be confounded by other motives, such as convenience, as in the case of driving rather than flying, and altruism, as in the case of firefighters and military enlistees.

Most regulations to which BCA is applied involve relatively small changes in individual mortality risk. For example, a pollution control policy that would reduce the probability of premature death for one year by one in 10,000 (say, from .0004 to .0003, a change of .0001) means that there would be, on average, one less death during the year in a community of 10,000. If each person in the community were willing to pay $500 for this risk reduction, the total WTP would be $5 million. For purposes of BCA, WTP for reductions in the probability of death is often expressed as the value of a statistical death avoided or the value of a statistical life (VSL). In this example, the VSL is $5 million.

However, thinking of WTP or WTA as a measurement of the “value of life” does not reflect the nature of the economic analysis. The economic question is not about certain death since, in most cases, people would be willing to pay their entire wealth, including future earnings, to avoid certain death. Also, probably no finite sum of money could compensate an individual for the certain loss of his or her own life. Rather, the economic question is about how much the individual would be willing to pay to achieve a small reduction in the probability of death during a given period or how much compensation that individual would require to accept a small increase in that probability.

The standard practice in economic studies has been simply to take the average of all individuals’ WTP for risk reduction to arrive at a single VSL. While this practice has come under increasing criticism for failing to adequately reflect a variety of factors thought to influence individuals’ WTP, including differences in income, health status, cause of death, the nature of the risk, and baseline level of risk, OMB has directed all federal agencies to follow this standard approach of selecting a single, average VSL. For instance, in 2001, EPA adopted a VSL of $6.5 million based on 26 published studies, which used both revealed preference and stated preference methods to estimate VSL. Before 2001, EPA used a VSL of $5 million. FDA has also used a VSL of $5 million for some analysis but has not published an explanation of the basis for this value.

Reducing Morbidity

Morbidity refers to illness, injury, disability, or being in less than “good” health. Morbidity can be described in a variety of ways, such as duration of the condition (chronic or acute), degree of activity impairment, or type of symptoms. Morbidity might be characterized as either an episode of acute illness lasting only a matter of days with a well-defined beginning and end or as a chronic episode of a longer-term or indefinite duration. The degree of impairment could be defined in terms such as “restricted-activity days” (i.e., days

49 Freeman, 2003.
50 OMB, 2003a.
51 For further discussion, see Section 6.1 or Alberini, 2003.
52 Hammitt, 2000.
during which a person is able to undertake some, but not all, normal activities), “bed disability days” (i.e., days during which a person is confined to bed, either at home or in an institution, for all or most of a day), or “work loss days” (i.e., days during which a person is unable to engage in ordinary gainful employment).

Broadly speaking, valuation of reduced morbidity may take either of two forms: those based on individual preferences (WTP or WTA), or those based on resource and opportunity costs associated with illness, also referred to as a “cost-of-illness” or “damage cost” measure.

WTP for reduced morbidity can be derived either from survey interviews (i.e., stated preferences) or observed behavior (i.e., revealed preferences). Revealed preference values for WTP can be inferred either from activities that reduce exposure to risk factors for illness, such as running an air purifier or staying indoors to reduce exposure to air pollution, or activities that mitigate the severity or duration of illness, such as taking medication or visiting a doctor. However, deriving reliable estimates of WTP typically requires substantial data and resources and may ultimately be unobtainable. Relationships among the health outcome of interest, mitigating and averting behaviors, and their economic value or cost must be measured or estimated. In addition, the actual or perceived effectiveness of these risk-averting behaviors must be measured or estimated, which can be quite time consuming and expensive.

A cost of illness approach seeks to estimate both direct costs for medical care and indirect costs, such as the economic cost of disability (i.e., family burden and lost wages). These costs, stated in terms of cost per case or cost per day of illness, are multiplied by the number of cases or days to arrive at an aggregate estimate of the costs associated with illness.

In theory, WTP estimates are expected to capture both the direct and indirect costs of illness, as well as intangible costs, such as pain, suffering and other quality of life effects. In practice, in addition to being limited by ability to pay, WTP may underrepresent the full cost of illness for insured individuals who share only part of these costs as copayments. While economists prefer to rely on WTP as the measure of the value of reduced morbidity, as a result of the difficulty and cost of obtaining the necessary information, WTP for morbidity risk reduction is often omitted in favor of cost of illness measures. However, when relevant information on which to base WTP estimates is unavailable, OMB has encouraged agencies to consider commissioning a stated-preference study.

5.3. COST-EFFECTIVENESS ANALYSIS

In limited circumstances, when either the costs or the benefits are fixed and only other factors vary, a comparison can be performed using a sub-category of BCA, known as cost-effectiveness analysis (CEA). For instance, when the budget is fixed in advance, the most cost-effective project may be characterized as that which produces the greatest benefit where benefit may be specified in either monetary or non-monetary measures. Conversely, when the amount of benefit that must be produced is specified in advance, the most cost-effective project is the one that produces the required benefit for the lowest cost.

CEA identifies the regulatory alternative that achieves a given objective or measure of policy outcome at the lowest possible total cost. CEA is used to compare a group of alternative approaches that have the same primary outcome or multiple outcomes that can be integrated into a single numerical index. The primary advantage of CEA is that it avoids difficulties associated with converting benefits into dollars and, in the case of health effects, avoids monetizing the value of life. CEA does not evaluate health effects using individual WTP. By treating gains in health and longevity equally regardless of differences in individual wealth and income, CEA also appears to avoid potential inequities associated with ability-to-pay based on WTP that arise in BCA. In practice, income differences in WTP are not an issue since the population average WTP is usually used.

The most common form of CEA compares the costs of various approaches in terms of a single,
non-monetary measure of effectiveness, such as tons of toxins removed from waterways in dollars per ton. For purposes of CEA, health effects may be assessed using a variety of measures of effectiveness. These measures may be related to mortality (i.e., lives saved or life years saved), morbidity (i.e., cases or years of illness, injury, or disability), quality of life, or a combination of effects (i.e., quality adjusted life years (QALYs) or disability adjusted life years).55

OMB does not currently require federal agencies to adopt any specific measure of effectiveness. In fact, OMB encourages agencies to report results for multiple measures of effectiveness that offer different insights and perspectives and to explain why OMB selected different measures. OMB also encourages agencies to publicly disclose these explanations along with the underlying data, including morbidity and mortality data, the age distribution of affected populations, and the severity and duration of disease conditions and trauma, so that the public can construct apples-to-apples comparisons between rulemakings that use different measures.56 At OMB’s request, the Institute of Medicine (IOM) has completed an evaluation of the technical and ethical issues associated with various effectiveness measures and provided guidance in how to improve the measurement of effectiveness of public health and safety regulations.57

A modified form of CEA, known as “risk-benefit analysis,” is commonly used for clinical decision making to facilitate diagnostic and therapeutic choices by patients and physicians when the primary benefits are expected to be changes in longevity and/or quality of life. This approach is a useful tool for assisting a patient to select among treatment options, such as radiation, chemotherapy, or surgery for cancer. In such cases, specific health effects are weighed in terms of the probability of their outcomes so there is no need to convert the benefits to dollars. In addition, an individual patient (along with his or her physician) is the sole decision maker so there are no distributional effects that could affect the fairness of the treatment choice.

CEA is often applied to proposed public health and safety policies, such as disease screening tests, automobile seat belts, and pollution control, when the primary benefits are also expected to be specific health effects.58 Of course, such policies may be subject to BCA as well. Insurers also sometimes use CEA to inform coverage and payment decisions. While the economic and accounting concepts of CEA in these contexts are essentially the same, application of these concepts differs substantially in the context of RIA.

While CEA allows ranking of alternative approaches along a single measure of effectiveness, CEA carries important limitations. CEA is less informative than BCA for a variety of reasons:

1. CEA cannot tell whether society will be better off by achieving the most cost-effective end because
   - CEA does not allow direct assessment of whether total benefits justify total costs because benefits and costs are measured in different units.
   - CEA does not allow comparison among various regulatory options with different outcomes.
   - CEA does not allow identification of the most efficient outcome in the manner permitted by BCA through application of the Pareto criterion (i.e., no one made worse off) or the Kaldor-Hicks criterion (i.e., winners compensate losers).
   - CEA does not indicate the optimal level of budget expenditure for an intervention.

2. Comparison of alternative interventions may be complicated or impossible for multiple

55 Most of what is said in this paper about QALYs also applies, with minor modification, to the related concept of Disability Adjusted Life Years.
56 OMB, 2003a, p. 131.
57 In May 2004, IOM convened the Committee to Evaluate Measures of Health Benefits for Environmental, Health and Safety Regulations and asked this panel to assess the scientific validity, ethical implications, and practical utility of effectiveness measures for health and safety regulations currently in use by federal agencies. The panel issued its report in January 2006 (Miller, Robinson, and Lawrence, 2006).
58 Gold, 1996.
outcomes, such as health and non-health effects, which require separate measures of effectiveness.

3. The results of CEA may differ from the results of BCA due to differences in assumptions about individual preference functions.

Due to limitations associated with both CEA and BCA, OMB has requested that agencies perform regulatory impact analysis of major rules using both BCA and CEA and use at least one integrated measures of effectiveness, such as QALYs, when a rule creates a significant impact on both mortality and morbidity.\(^\text{59}\)

Quality-Adjusted Life Years

While single non-monetary measures of effectiveness, such as lives saved and cases of illness avoided, are relatively straightforward, they are of limited usefulness when researchers are interested in more than one type of benefit. To address this problem, integrated measures of effectiveness that reflect both life expectancy and health-related quality of life are often used in CEA. QALYs are the most extensively developed and widely used of these integrated non-monetary health measures. A QALY is a relatively simple building block that can be applied at both the individual and population level.

Effectiveness measures based on QALYs combine several factors, such as nonfatal illness, injury, disability, and quality of life, as well as premature death, into a single numerical health status index between zero and one, where zero represents death and one represents perfect health. An intervention that produces one year of life in perfect health is said to yield one QALY. By the same token, interventions that improve health status from 0.25 to 0.75 for two years or that extend life by five years at a quality level of 0.2 also yield one QALY.\(^\text{60}\)

A health status index used to measure QALYs may be a generic index found in the professional literature or an index that has been designed and constructed for a particular intervention. Some health status indices are derived using survey interview techniques, such as the stated preference method of contingent valuation described above, in which healthy individuals are asked to rate descriptions of various states of health, illness, or disability on a scale. As shown in Exhibit 4, many indices are determined by clinicians’ or authors’ judgment. Each state of health includes varying degrees of illness, disability or pain, etc. While other techniques may be used, each approach results in average numerical values or weights between zero and one that are assigned to each health status description to produce a quality of life index (see Exhibit 4, below).\(^\text{61}\)

Integrated measures of effectiveness, such as QALYs, carry underlying assumptions about people’s preferences that can limit their usefulness for regulatory impact analysis.\(^\text{62}\) For QALYs to represent an individual’s preferences regarding risks of changes in health and longevity, the individual’s preferences must satisfy three conditions. First, his preferences must be risk neutral. For example, the individual must be indifferent between (1) living 25 more years for certain and (2) a gamble offering (A) a 50 percent chance of living 50 more years for certain and (B) a 50 percent chance of dying immediately. Second, the individual’s preferences must exhibit a constant proportional trade-off of longevity for health. This implies that this individual is equally willing to give up 10 years of life from 50 remaining years and one year of life from five remaining for a given health improvement. Finally, for QALYs to be an accurate representation, an individual’s preferences for health and longevity must be independent of his wealth and future income. Other valuation

\(^{59}\) OMB, 2003a, p. 130.

\(^{60}\) For further discussion of QALYs and references, see Gold, 1996; Hammitt, 2000; Freeman, 2002; Freeman, 2003.

\(^{61}\) The Harvard Center for Risk Analysis has compiled a data base of QALY weights for several thousand health conditions or statuses as reported in more than 500 articles in clinical journals; available at http://www.hsph.harvard.edu/hcra/.

\(^{62}\) See Harvard Center for Risk Analysis, Catalog of Preference Scores, Exhibit 4. Sample health status index with preference scores for selected conditions.

\(^{63}\) Freeman, 2002.
## Catalog of Preference Scores

<table>
<thead>
<tr>
<th>ICD-9</th>
<th>Reference</th>
<th>Health State</th>
<th>Preference</th>
<th>Range</th>
<th>Preferences</th>
<th>Measurement</th>
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<td>(listed below)</td>
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<td></td>
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<tr>
<td>7</td>
<td>11</td>
<td>Patients with congestive heart failure before heart transplant</td>
<td>0.20</td>
<td>0.15–0.3</td>
<td>Patients</td>
<td>Standard Gamble, Rating Scale</td>
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<td>11</td>
<td>Patients with congestive heart failure after heart transplant</td>
<td>0.70</td>
<td>0.55–0.85</td>
<td>Patients</td>
<td>Standard Gamble, Rating Scale</td>
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<td>158</td>
<td>Congestive heart failure epoprostenol treatment</td>
<td>0.50</td>
<td></td>
<td>Community, Patients</td>
<td>EuroQoL</td>
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<td>108</td>
<td>Living after hospitalization for pulmonary edema</td>
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<td>Community, Clinicians, Patients</td>
<td>Rosser index</td>
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### Hypertension

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<tr>
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<td>2</td>
<td>Side effects of hypertension treatment</td>
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<td>Authors</td>
<td>Authors/Clinical Judgment</td>
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<td>39</td>
<td>Side effects of antihypertensive medication</td>
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<td>0.98–0.995</td>
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<td>Fanshel &amp; Bush, Oper Res 18:1021-66</td>
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<td>7</td>
<td>83</td>
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<td>Patients</td>
<td>Time Trade Off</td>
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<tr>
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<td>Antihypertensive treatment with propanolol</td>
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<td>0.98–0.995</td>
<td>Authors</td>
<td>Authors/Clinical Judgment</td>
</tr>
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<td>0.98</td>
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<td>Authors/Clinical Judgment</td>
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<td>206</td>
<td>Hypertension treatment</td>
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<td>Clinicians, Authors</td>
<td>Authors/Clinical Judgment</td>
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### General Cardiac

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<th>Reference</th>
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<td>Authors/Clinical Judgment</td>
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<td>Asymptomatic, with or without history of myocardial infarction (MI)</td>
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### Stroke

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<th>Preference</th>
<th>Range</th>
<th>Preferences</th>
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<tbody>
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<td>155</td>
<td>Stroke free</td>
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<td>187</td>
<td>Transient cerebral events (transient ischemic attacks (TIA’s) or reversible strokes)</td>
<td>0.80</td>
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<td>Authors</td>
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<tr>
<td>7</td>
<td>20</td>
<td>Neurologic impairment following embolus (stroke)</td>
<td>0.50</td>
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</tbody>
</table>

techniques that do not carry these restrictive assumptions may rank alternative regulatory options differently from a QALY-based technique. To the extent the population’s preferences diverge from these three assumptions, the QALY technique will misrepresent the regulation’s effect on the population’s well-being.  

5.4. GUIDANCE FOR GOOD PRACTICE

Since Congress and OMB have mandated use of these techniques, and OMB assumed responsibility for overseeing RIAs conducted by other federal agencies, OMB issued “best practice” guidelines for BCA and CEA in 1996 and revised them in 2003. EPA has issued its own more detailed instructions for preparing economic analyses for environmental regulations. While OMB’s best practice guidelines are designed to standardize the methodology and presentation of BCA and CEA, the quality and depth of public scrutiny is often limited by the extent to which underlying data and assumptions are disclosed. While the Administrative Procedures Act provides opportunities for public comment on RIAs, independent experts and OMB agree that BCA and CEA should follow standard procedures for valuing costs and benefits, and that their effects should be summarized essentially as described above. In addition, these authorities agree that BCA and CEA deserve special oversight when used in the context of RIAs, as discussed below.

Transparency

According to experts, regulatory BCAs should be transparent, peer-reviewed, and take into account prior BCAs. The analysis should provide sufficient detail for a reader to reproduce the results and conclusions. All aspects of the analysis should be described clearly, especially the sources of data, the assumptions used, and the methods of computation.

Peer Review

Important regulatory analyses should undergo a scientifically rigorous review and critique of methods and results by outside experts not associated with the agency sponsoring the analysis (i.e., peer reviewed). OMB has established government-wide standards for peer review and public participation in peer review activities. These standards allow agencies to scale the intensity of peer review activities to the importance of the regulatory action and set strict procedures for external review of significant information for major rules. OMB recognizes the authoritative weight of articles published in peer-reviewed journals and does not require agencies to re-review such published materials; it does, however, require disclosure of the peer review panel’s comments and the agency’s response.

Ex Post Review

To check the validity of the initial prospective analysis of proposed regulations, agency RIAs, including BCA and CEA, are subjected to retrospective review and analysis to determine the actual impact of regulations as implemented, referred to as “ex post review.” As an example of such an ex post review of BCA, in 1997, EPA performed a retrospective analysis of the benefits and costs of the Clean Air Act from 1970 to 1990.

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64 For further discussion of implications of QALYs for age, see Section 6.1.
65 OMB, 2003a.
68 Miller, Robinson, and Lawrence, 2006.
69 70 FR 2664, January 14, 2005, final bulletin.
70 EPA, 1997.
6. Related Issues

A number of factors can influence the results of BCA and CEA in important ways. Some of the most important of these factors are age, racial diversity, the period over which costs and benefits are measured, whether the results are discounted to account for differences in time, how risk and uncertainty are taken into account, and how equity issues and distributional impact are addressed. The following section discusses these important issues.

6.1. AGE AS A FACTOR

Age and BCA

For both analytic and political reasons, age as a factor can have a substantial impact on the results of BCA. The importance of the role of age and its impact on the analysis is illustrated by the controversy that arose in late 2002 when EPA published its economic analyses of President Bush’s Clear Skies Initiative and Off-Road Vehicle Emissions Standards under the Clean Air Act (see Appendix A, EPA case study, below). As part of its sensitivity analysis, EPA used a VSL for those affected people over age 70 that was only about 63 percent of the VSL for the population under age 70. This differential was apparently used at OMB’s insistence, and became known as the “senior death discount” when seniors began appearing at EPA field hearings wearing price tags saying, “Seniors On Sale – 37% Off.” But the controversy abated, at least for the time-being, when OMB issued a memorandum advising federal agencies against using this practice and directing agencies to use the same VSL for all age groups. Congress affirmed that the concept of a senior citizen discount should be rejected by adopting an amendment to an appropriations bill that prohibited federal agencies from applying “monetary values for adult premature mortality that differ based on the age of the adult” in an estimate of the benefits of an agency action under Executive Order 12866.

Economic theory makes no prediction about the relationship between age and WTP. As a threshold matter, choosing any measure based on years of life saved (i.e., as measured by VSLYs) rather than on the number of lives saved (i.e., as measured by VSLs) immediately implies an adjustment for life expectancy. In some cases, such as the EPA case study described below, even VSL may be adjusted for age.

Although it seems plausible that older people may be willing to pay less to reduce their risk of premature mortality because they expect fewer years of remaining life, results of empirical studies examining the relationship between VSL and age have been mixed.

Labor market studies typically rely on wage rates and accident rates by industry sector to derive different VSLs related to risk and income. Most labor market studies that use revealed preference methods to derive VSL include only people of working age and exclude children and retirees who are not in the labor force. A recent survey of 47 labor market studies found the average age of the sample populations ranged from 32 to 44 years old. If the population affected by a regulatory policy is mostly older workers or retirees, and if WTP depends on age or expected years of life remaining, then a VSL based on these studies may not represent the affected population’s WTP.

75 U.S. Congress, 2003; as an amendment to an appropriations bill, this provision was effective only through the end of FY 2004.
77 Mrozek and Taylor, 2002.
Some of these labor market studies imply implausibly low, even negative, values for VSL among older age groups. Labor market studies based on wage differentials have found that VSL varies with age in an inverted-U shaped relationship—that is, through their job choices, younger and older workers tend to indicate a lower VSL than do workers in their middle years. One early study that found an inverted-U shaped distribution of VSL across age groups, also found income and social class had a significant effect on VSL but, surprisingly, found no significant difference between the values drivers and non-drivers place on transportation risks.\textsuperscript{78}

Economic models have shown that VSL declines steadily with age if there are perfect annuity and insurance markets, but forms an inverted-U shape peaking at age 40 in an economy with no borrowing and no insurance.\textsuperscript{79} In this simplified utility model, increased consumption implies a greater VSL. The availability of annuities allows the individual to maintain higher consumption into later life because he does not need to hoard money in case of an unexpectedly long life. The inverted-U shape reflects the inability of the individual to transfer wealth from one period of life to another. To some extent, the findings of these studies depend on the structural assumptions of their model\textsuperscript{80} and the data sets they use.\textsuperscript{81} One recent study noted that the shape of the age-VSL relationship may be driven by a disproportionate share of middle aged groups in the sample.\textsuperscript{82}

Two recent studies have challenged the notion of a lower VSL for seniors. One of these studies used the Health and Retirement Survey (HRS) specifically to address older workers’ labor market behavior.\textsuperscript{83} The HRS follows a panel of respondents through time, thus giving a detailed picture of their employment choices. When near-elderly employment behavior was considered, individual VSL increased with age. This study found no reason to conclude that VSL estimates used for adults up to age 65 should be reduced from consensus estimates in the literature. Recent contingent valuation surveys in Canada and the United States have found that WTP for risk reductions are constant until at least age 70 in both countries.\textsuperscript{84} While WTP declined with age after age 70 for Canadian respondents, it did not decline for U.S. respondents.

**Age and CEA**

In the context of CEA, QALYs have several important age-related implications. First, QALY techniques place more weight on regulatory alternatives that enhance the health of people with longer expected life spans. Simply put, the young have more years over which their quality of life can be improved. Second, QALYs imply that, although people may currently have different levels of health or illness, they all attach the same value to incremental improvements or declines in health. In other words, through use of its ordinal scale, QALYs imply that health status changes of equal magnitude are of equal value. For instance, a change of 0.1 QALY has the same value whether this represents a decline from 0.1 to 0.0 (death) or a decline from 1.0 (perfect health) to 0.9 QALYs. These limitations have caused some experts to call for continued reliance on BCA, rather than a wholesale shift to CEA, for purposes of regulatory impact analysis, at least until research and published studies regarding CEA and QALYs are expanded and refined.\textsuperscript{85}

### 6.2. AGGREGATING DIVERSE POPULATIONS

Population characteristics other than age may significantly affect estimates of VSL. A recent study of the effect of racial differences on VSL found that employment choices of African American men indicated a VSL one-half to

\textsuperscript{78} Jones-Lee, Hammerton, and Philips, 1985.

\textsuperscript{79} Shepard and Zeckhauser, 1984.

\textsuperscript{80} Aldy and Viscusi, 2003; Johansson, 2002.

\textsuperscript{81} Mrozek and Taylor, 2002.

\textsuperscript{82} Aldy and Viscusi, 2003.

\textsuperscript{83} Smith, Evans, Kim and Taylor, 2003.

\textsuperscript{84} Alberini et al., 2003.

\textsuperscript{85} Johnson, 2003.
two-thirds lower than that for white men.\textsuperscript{86} This finding was only partially attributable to differences in individual preferences and seemed to relate more to differing employment opportunities for whites and African Americans. These findings have implications for other VSL estimates where individual characteristics may affect employment and earning potential. The findings also confirm the need to examine the comparability of populations in source studies to the population of interest in the analysis for which VSL and WTP estimates are transferred in BCA.

6.3. TIME AND DISCOUNTING

In theory, the benefits and costs of a project that occur simultaneously can be compared directly; however, this is rarely the case. A typical regulatory policy entails large front-end costs, such as investments in pollution control equipment, while the stream of benefits begins at a later time, only after these costs have been incurred. Whenever streams of benefits and costs arise at different times, it is necessary to convert all of these payments to a common time of reference to allow comparison and to derive net benefits.

Experts agree that benefits and costs that occur sooner are generally more valuable than those that occur later.\textsuperscript{87} As implied by the old adage, “a bird in the hand is worth two in the bush,” the concept of discounting reflects people’s positive time preference. In welfare economic terms, this adage simply means that consumers attribute greater value to immediate ownership and consumption than to a promise of future ownership and deferred consumption. Economists infer support for these observations from consumer spending and allocation decisions (i.e., people prefer to spend most of their money and save only a small portion of it) and interest rates (i.e., positive interest rates imply that money will be worth less in the future). The concept of discounting, which reflects the time value of money due to waiting or deferred consumption, is applied independently from adjustments that may be necessary to account for inflation and for conditions of risk and uncertainty.\textsuperscript{88}

In order to compare effects that occur at different times, to avoid \textit{ad hoc} comparisons on a case-by-case basis and to allow more consistent comparison among alternatives, the process of discounting offers a standard adjustment for timing differences in costs and benefits. The effect of discounting is to reduce the value of future benefits. The discounted value of a stream of future costs and benefits is referred to as the “net present value.” The choice of discount rate has a significant impact on the present value of costs and benefits. For instance, a benefit of $100 received 30 years in the future has a present value of $41 when discounted at 3 percent but only $13 when discounted at 7 percent.

For estimating the financial value of future private investments, economists and financial analysts typically select a discount rate that reflects the historical rate of return on investments made by the private business or investor in question. Economists estimate that the average annual before-tax rate of return for private capital in the U.S. economy is about 7 percent, net of inflation. OMB has directed federal agencies to adopt this discount rate (7 percent) as the opportunity cost of capital for the cost of regulations that are expected to affect the private sector primarily by displacing or altering the use of capital.\textsuperscript{89}

The pre-tax opportunity cost of capital is not considered an appropriate reflection of the after-tax rate at which society discounts future consumption or would be willing to pay for regulations that affect primarily private consumption through higher prices (i.e., the social rate of time preference). Economists infer a lower discount rate for US consumers, both through their choice of consumption, rather than savings, and the persistent divergence between the rate of return individual consumers earn on savings and the rate of return on commercial investments. Economists have estimated the social rate of time preference at about 3 percent per year.\textsuperscript{90}

\textsuperscript{86} Viscusi, 2003.
\textsuperscript{87} Lind, 1982.
\textsuperscript{88} Economists refer to risk as a situation where the probabilities of alternative outcomes are finite and knowable; uncertainty refers to a situation in which the outcome probabilities are simply unknowable.
\textsuperscript{89} OMB, 2003a.
\textsuperscript{90} OMB, 2003a.
Intergenerational Equity and Discounting

While using the same discount rate across generations would avoid potential inconsistencies, it does raise ethical questions. When the effects of regulation fall on those who are currently living, gainers compensating losers is at least theoretically possible, but this assumption is more difficult to maintain if a policy imposes costs on a future generation. More important, future generations have no voice in present decisions, and it is difficult to impute preferences to future generations in a meaningful manner.

Rather than apply a fixed discount rate to intergenerational effects, some have suggested enhancing the relative importance of costs and benefits to future generations by applying a lower discount rate for them. However, this approach creates inconsistencies such that, simply waiting would increase the relative benefits or costs of a regulation.

Incongruities also arise if costs and benefits are not discounted, at all, which is equivalent to adopting a discount rate of zero. Because lowering the discount rate increases the value of savings the current generation undertakes, the logical implication of zero discounting is the impoverishment of the current generation due to reduced current consumption to increase savings. Applied to every generation, each successive generation finds itself impoverished for the well-being of the next generation. The question of intergenerational equity and discounting raises challenging issues, and economists have not yet reached a consensus on the appropriate answers.

Discounting Non-monetary Effects

To the extent that non-monetized benefits and costs arise at different times, experts agree that they should be discounted in the same manner and at the same discount rate as monetized values. The conceptual basis for this approach is that society applies the same principles of discounting to benefits and costs, whether or not they are monetized.

Experts also agree that discounting should be applied to health benefits, as well as non-health benefits, whether or not the health benefits are monetized. The basis for this approach is that people prefer an immediate health gain to an identical health gain in the future. Similarly, people prefer to delay any deterioration in health rather than suffer the same health loss immediately. In addition, if costs are discounted but health benefits are not, then a policy that produces immediate health benefits will produce even greater benefits if delayed. This discrepancy grows even larger when the effect of a policy is to reduce chronic diseases that may take years to become evident.

Alternatively, if the benefits are expected to continue at a constant level, they may be reported on an undiscounted annual basis, such as QALYs per year or units of pollutant per year, and compared to undiscounted annual costs.

6.4. RISK

Risk assessment is a fundamental aspect of BCA and CEA in terms of estimating both the costs and the benefits because neither is known with certainty before a particular policy or regulation is adopted. A variety of factors may influence the valuation of risk and risk reduction. These factors may, in turn, influence the value of costs and benefits included in the analysis, particularly when these estimates are based on WTP.

Researchers have found that individual perception of risk often differs from empirical evidence of the probability an event will occur. For instance, many people probably underestimate the risk of death or injury associated with driving. In addition, people have difficulty distinguishing between small changes in risk. Researchers have found that people are willing to pay the same amount to eliminate a risk of one in 1,000 as a risk of one in 100,000 of the same adverse event.

Individuals also perceive and react differently to risks depending on the type of risk. Even when the probability of occurrence is the same, people seem to react differently to a risk of sudden
death, cancer, and risks that are entered into by choice. For example, many people prefer to invest public health resources in avoiding outbreaks of Ebola virus, rather than food poisoning due to salmonella bacteria. These people perceive Ebola as the more dangerous of the two illnesses due to its sudden occurrence and catastrophic consequences (i.e., higher mortality rate), whereas salmonella is perceived as occurring only sporadically, avoidable through proper food handling, and less likely to be catastrophic (i.e., lower mortality rate). In fact, salmonella causes more total cases of illness and death.

Researchers have found that eight dimensions of risk seem to influence how people perceive different types of risk and how they expect government to react to them (See Exhibit 5).

While researchers have been able to roughly identify these aspects of risk perception, they have been unable to establish the magnitude of the effect of these factors. Most experts agree that attempts to adjust values of WTP or WTA measured for one type of risk to apply them to another are inadequate.

Another factor affecting the valuation of risk reduction is that most individuals are “risk-averse”—that is, they prefer a sure thing to a gamble, even if the expected value of the two outcomes is equivalent. For instance, due to the high probability of losing a dollar, a risk-averse individual would choose not to buy an actuarially fair lottery ticket for one dollar where there was a one in 1,000 chance of winning $1,000. Similarly, a patient’s desire to avoid serious illness and life-

EXHIBIT 5
Dimensions of Perceived Risk

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Controllable/Uncontrollable</td>
<td>The sense of control often enters into risk assessments. People who worry about dying in a plane crash will drive long distances to feel “in control,” even though the risk of a fatal automobile accident is much greater than dying in a plane crash.</td>
</tr>
<tr>
<td>Voluntary/Involuntary</td>
<td>Similarly, risks entered into by individual choice are preferable to risks thrust upon one. People go bungee jumping but still react strongly to the hazardous waste dump next door, which presents a smaller risk.</td>
</tr>
<tr>
<td>Natural/Man-made</td>
<td>Risks created by human actions are considered more threatening.</td>
</tr>
<tr>
<td>Old/New</td>
<td>People become inured to old risks while new ones raise new fears. Traffic accidents kill and maim thousands of people each year but it is such new threats as West Nile virus that people think are more dangerous.</td>
</tr>
<tr>
<td>Necessary/Unnecessary</td>
<td>One might also argue that traffic accidents are a necessary evil in this car dependent society, so they present an acceptable risk.</td>
</tr>
<tr>
<td>Occasional/Continuous</td>
<td>People perceive ongoing risks such as exposure to environmental carcinogens as a greater threat than occasional exposure.</td>
</tr>
<tr>
<td>Ordinary/Catastrophic</td>
<td>This is one of the aspects of risk that sets work place deaths apart from those deaths usually associated with health and safety regulations. Workplace injuries are a daily part of many workers’ jobs, while a terrorist attack is catastrophic. Given equal probabilities of individual injury, people are more likely to see the terrorist attack as a greater threat.</td>
</tr>
<tr>
<td>Delayed/Immediate</td>
<td>This aspect also sets work place injuries apart from risks addressed by regulation. The effects of reducing a carcinogen in the environment, for example, will take many years to decrease the incidence of cancer. Work place accidents, on the other hand, take an immediate toll.</td>
</tr>
</tbody>
</table>

Source: Slovic, 2000; Miller, 2006.
threatening outcomes plays an important part in individual risk aversion.\textsuperscript{94}

While individuals may be risk averse, economists typically assume that society as a whole is risk-neutral because, on average, winners and losers balance out. For example, in the case of federal regulations that generate both favorable and adverse effects (i.e., costs and benefits), analysts assume these effects will be spread across the nation (see section 4.2 Public Sector Benefit-Cost Analysis, Foundations of BCA: Welfare Economics, above). As a result, OMB recommends caution in adjusting VSL or other benefit measures for the type of risk or characteristics of the population affected.\textsuperscript{95} The effect of this discrepancy between individual and social risk preferences is that, while policy analysts are often able to take into account various levels of risk, the results of analysis often imply a degree of social paternalism. This occurs because policies that appear best for society as a whole may not be those preferred by individuals, if left to their own devices.

\textbf{6.5. COPING WITH UNCERTAINTY}

Unlike “risks” for which all outcomes can be determined and taken into account by ascribing a statistical probability to each outcome, “uncertainty” arises from unknown and, in some cases, unknowable, outcomes and probabilities. For instance, the odds that one of 12 numbers will come up when a pair of dice is rolled is a risk that one can determine with relative precision, either mathematically or experimentally. By contrast, while scientists may suspect that a particular industrial pollutant causes a specific disease, they may be unable to quantify the extent of this causal relationship or the dose response relationship of the pollutant to the disease. In the latter example, uncertainty arises from incomplete scientific knowledge, but there are many other sources of uncertainty.

Policy makers are faced with various levels of uncertainty all the time but still manage to make decisions. Some uncertainties may be resolved in time simply by waiting. However, the cost of waiting may be significant. For example, by the time evidence of global warming becomes irrefutable, there may be limited options to address it. Similarly, an opportunity may be lost to avert a smallpox epidemic due to a bioterrorist attack if a vaccination program is delayed for further study to reduce uncertainty regarding risks associated with the program.

Policy analysts are often unable to account fully for the effects of uncertainty based on scientific data. The most common approach to uncertainty is to base calculations of benefits and costs on the best available data for uncertain parameters. As part of this process, analysts may have to supply estimates based on inferences, assumptions, and professional judgment. The choice of the best estimate or range of estimates and related assumptions is within the discretion of those performing the analysis. As discussed above, where there is uncertainty in the analysis, the analyst is expected to supply supporting documentation to identify and explain the basis for selecting values and related assumptions. In addition, risk and uncertainty can be addressed through other approaches discussed below.

\textbf{Sensitivity Analysis}

While the primary analysis of BCA or CEA may produce a single “best estimate” of net benefits or net costs, analysts can improve the decision-making process by testing the sensitivity of this estimate to changes in the underlying data and assumptions. This process, referred to as “sensitivity analysis,” describes how key assumptions would have to change the results of the primary analysis. Sensitivity analyses are used to reflect differences of opinion about the probability of expected outcomes by re-running the analysis with adjusted values.

The results of various sensitivity analyses are compared to assess how robust the primary analysis is to changes in assumptions. For instance, if a small change in VSL changes the sign of the overall result of a BCA from plus to minus (i.e., from a net benefit to a net cost), then the policy is relatively sensitive to changes in the estimate of VSL. Such a sensitive parameter may be considered a “critical” variable for the

\textsuperscript{94} Redelmeier, and Tversky, 1990.

\textsuperscript{95} OMB, 2003a.
analysis. On the other hand, if even large changes in VSL do not produce changes in the sign of the overall result (i.e., the policy continues to show net benefits or net costs), the policy is said to be relatively insensitive to changes in VSL. Even when sensitivity analysis does not produce changes in the sign (+ or –) of the primary analysis, critical variables may be deemed sensitive to change if such changes produce relatively large swings in the results of the primary analysis.

Sensitivity analysis must be performed as a supplementary analysis to BCA and CEA for all major federal regulations, as described in the case studies below. In practice, fewer than half of all social impact regulations unambiguously pass a benefit-cost test based exclusively on the best estimate of their quantified benefits and costs. On the other hand, only a small proportion of regulations unambiguously fail a benefit-cost test. Most regulations fall into a gray area where other factors must inform the uncertainty associated with quantified benefits and costs.

If age has not been addressed as part of the primary analysis, sensitivity analysis is the appropriate context in which to address questions about the effect of age as a factor in the analysis. For instance, in the case study on off-road diesel engines, EPA performed a sensitivity analysis exploring the effect of age on WTP for reductions in fatality risk, among other things. As discussed in the case study, this aspect of EPA's analysis later attracted public attention and became controversial. In the case study of the bar code rule, FDA addressed the effect of age differences among hospital and nursing home patients in its primary analysis and then performed sensitivity analyses using alternative estimates of the relative frequency of fatalities that might be avoided.

Other Techniques for Addressing Uncertainty

In the event that decision makers need more information about the magnitude and effects of uncertainties in estimates of benefits and costs, they can use several approaches to provide additional information, including:

- **Scenario analysis** — estimating a range of possible outcomes, such as worst-case and best-case scenarios, in addition to the most likely outcome;
- **Delphi methods** — using expert advice to characterize the potential likelihood of possible outcomes;
- **Meta-analysis** — synthesizing data and results from a number of different studies to arrive at more precise estimates and to characterize the range and distribution of key variables; and
- **Monte Carlo simulation** — using computer-generated outcomes based on models that take into account complex interactions of multiple variables.

Delphi methods, meta-analysis, and Monte Carlo simulation all require substantial time and resources, so federal regulatory impact analyses use them selectively. OMB only requires Monte Carlo simulation of key parameters for rules with expected benefits and/or costs of more than $1 billion per year. Most regulatory impact analyses, however, include either a scenario analysis or sensitivity analysis to characterize the impact of alternative values on key parameters. Experts recommend that regulatory impact analyses should, at a minimum, identify key assumptions and qualitatively assess the potential impact of each assumption on the results of the analysis.

6.6. EQUITY AND DISTRIBUTIONAL ISSUES

BCA assesses the aggregate impact of policy changes on real resource allocations and on the welfare of society as a whole without regard for how the benefits and costs are distributed across society. Yet policy makers are often concerned with how these distributional impacts affect different groups in society, such as rich versus poor, young versus old, sick versus healthy, male versus female etc.

Such a distributional analysis is addressed in the Economic Impact Analysis section of an RIA which is designed to identify “winners and losers” from a policy change. While standard BCA estimates the cost of regulation to society as a whole, an Economic Impact Analysis uses the same, or similar, economic models as BCA but
its purpose is to estimate changes in production, industry financial distress, business closures, employment losses, and similar private sector economic effects. Economic Impact Analysis focuses on after-tax regulatory compliance costs that fall on private sector industries and markets most affected by a policy as they comply with regulatory requirements. An Economic Impact Analysis may also examine the impact of costs that fall on particular populations, such as children and those with chronic conditions. Unlike BCA, Economic Impact Analysis includes transfer payments that cancel out in the BCA calculation of net social benefits.

Despite the potential controversy that would surround public adoption of a national social welfare function described above (see section 4.2 Public Sector Benefit-Cost Analysis, Foundations of BCA: Welfare Economics), in practice, decision makers implicitly construct a social welfare function that reflects their equity concerns and preferred distributional effects. Decision makers can accomplish this easily by assigning different weights to the benefits and costs that are expected to fall on different populations and incorporating these values into an Economic Impact Analysis. For example, the BCA of two alternative regulatory options might show that manufacturers’ retooling costs to comply with either option would be $100 million, while each option generates social benefits of $200 million. The two options are indistinguishable in a benefit-cost test. The decision maker may wish to consider that Option 1 places $75 million of the costs on small manufacturers. The Economic Impact Analysis shows that many of the small manufacturers could not bear these costs and 123 would be forced out of business. Option 2 reduces the costs to small manufacturers to $25 million and only 25 shaky firms fail. The Economic Impact Analysis provides the decision maker with the distributional data to distinguish between the two options. The level of importance he assigns to large versus small manufacturers may determine which option the decision maker chooses.

While policy makers have discretion to request various analyses of equity and distributional impacts of policy changes to inform their decision process, law or executive order requires formal assessments of the impact of regulations on a number of specific areas, including small businesses; state, local, and tribal governments; children; minorities; and low-income populations. Small businesses have been identified separately because they have fewer resources to devote to regulatory compliance and, therefore, may be unduly burdened by regulation-related costs. State, local, and tribal governments have been identified separately to reduce the burden of “unfunded mandates” from the federal government. Children have been singled out because they are still developing, and their size and behavior patterns make them more susceptible to harm. Minority and low-income populations have been identified separately because they may be affected more adversely by regulations than the general population would be. Finally, OMB guidance makes it clear that any distributional effects should be discussed for specially affected sub-populations by income, race, gender, time (i.e., intergenerational effects), physical sensitivity (i.e., allergy, immunodeficiency), and geography.

The point is that federal agencies have the ability to analyze and describe equitable and distributional effects of regulations as well as economic efficiency. Indeed, Congress has required that these regulatory effects be identified separately for a number of groups of special concern. Far from a mechanistic benefit-cost test, federal rulemaking is a nuanced consideration of political, social, and economic expectations.

98 For an example of an Economic Impact Analysis of proposed regulation of storm water at construction sites, see http://www.epa.gov/waterscience/guide/construction/econ.htm.
99 Executive Order 12898.
100 Regulatory Flexibility Act of 1980 (PL 96-354); Small Business Regulatory Enforcement Fairness Act of 1996 (PL 104-121).
102 Executive Order 13045.
103 Executive Order 12898.
104 OMB, 2003a.
7. Summary of Case Studies

The appendices include two case studies on EPA and FDA rules that illustrate the practice of BCA as applied to RIA. These case studies highlight how these federal agencies actually have dealt with some of the thorny issues discussed above (not necessarily using the best or worst way of addressing them), such as estimating VSL and VSLY, benefits transfer, discounting, and age.

The case studies that follow reveal federal agencies’ actual practice of BCA and CEA techniques in the context of regulatory impact analysis. These cases do not necessarily reflect best practices, but they do highlight real-world problems encountered in applying the techniques and various approaches to addressing these problems. We selected these two cases because they offer opportunities to demonstrate application of these techniques to both environmental and health/safety regulations, the areas most commonly subjected to BCA and/or CEA.

7.1. EPA CASE STUDY: OFF-ROAD DIESEL EMISSION RULE

The first case, concerning EPA’s regulation of off-road diesel emissions, includes analysis of several health-related and non-health-related effects (the latter include visibility, crop yields, and ecosystem changes). Key health effects that EPA considered included preventable mortality as well as both acute and chronic illnesses associated with respiratory and cardiovascular diseases. In its primary analysis, EPA assumed $6.0 million for a standard value of statistical life (VSL) for each avoided premature mortality, regardless of life expectancy or age.

This case study describes analysis of the federal rule in which, as part of its sensitivity analysis, EPA made a controversial assumption that the value of a life saved for people over age 70 accounted for only 63 percent of the value of life saved for those under age 70, an assumption that critics characterized as the “senior death discount.” In an unexpected twist, this assumption still produced a higher value of life per year for those over age 70 than it did for those under age 70 because a substantially shorter life expectancy was applied as the denominator to derive the value per year, as we explain further in the case. The paradoxical result was that equivalent life extensions would yield greater value for older persons than they would for younger persons.

In its BCA, EPA used two approaches to valuing the benefits of avoiding illnesses under the rule: (1) WTP estimates and (2) cost-of-illness estimates. EPA’s analysis also included a CEA that focused narrowly on the incremental costs for reengineering diesel engines, reducing emissions, producing and operating compliant diesel engines, and producing diesel fuel. EPA also estimated the broader economic impact under the rule of these costs on various market segments.

Under its primary analysis of the rule, EPA estimated that health benefits would be about $7.9 billion per year in 2030, with the vast majority of this amount attributable to lives saved. Under EPA’s sensitivity analysis, which substantially reduced the value attributed to lives saved, the health benefits of the rule amounted to less than $1 billion per year in 2030; however, even at the reduced value of lives saved, the benefits still substantially outweighed the costs of regulation.

While EPA was unable to monetize all of the positive effects of the rule (i.e., improved visibility, increased crop yields, healthier ecosystems), it did infer that these positive effects should be added qualitatively to the benefits side of the equation. This led EPA to conclude that its quantitative estimate of positive net benefits represented the lower bound of the rule’s likely impact.

This case study also includes an example of apparent market failure because EPA’s analysis found that not only would the rule result in cleaner air, it also would allow consumers to save money by purchasing more fuel-efficient vehicles. Yet, in the absence of the rule, manufacturers had not adopted these emission control technologies.

7.2. FDA CASE STUDY: BAR CODE REGULATION

A second case study illustrates the application of both BCA and CEA in FDA’s effort to reduce...
preventable medical errors by requiring UPC bar codes, like those used in supermarkets, on all prescription drug labels. This rule illustrates the role and effect of age because, in its analysis, FDA had to value the benefits of avoiding adverse drug events for populations in two distinctly different age groups: hospital patients and nursing home patients.

FDA had the authority to require drug manufacturers and repackagers to include bar codes on drug labels, but it lacks the authority to require hospitals to use bar code scanners. In its regulatory analysis, FDA assumed that the rule would generate benefits by accelerating hospitals’ and nursing homes’ voluntary adoption of bar code technology. As it turned out, this voluntary aspect of the rule had important federal budget implications under Medicare and Medicaid.

To estimate the number of errors bar code systems could potentially prevent, FDA examined the relative frequency of errors that occur in each stage of the medication administration process, including prescribing, transcribing, dispensing, administering, and monitoring. While the largest percentage of medication errors occur at the prescribing stage, bar coding can do little to reduce errors occurring at the prescribing and transcribing stages since it assumes that orders are correct as entered into the computer by the pharmacist. Conversely, while fewer errors occur at the dispensing and administration stage, bar code systems intercept these types of errors very effectively, so FDA assumed these systems would prevent 50 percent of drug errors that occur at the dispensing and administration stages.

FDA developed two separate measures of the benefit of avoiding adverse drug events. The first measure, a cost-of-illness estimate, was based on the direct cost of avoiding unnecessary medical treatment due to adverse drug events. The second measure was based on patients’ WTP to avoid an adverse drug event. FDA arrived at its WTP estimate by monetizing the estimated loss in QALYs adjusted for the event’s degree of severity. FDA derived the value of a statistical life year (VSLY) by amortizing its standard VSL over the average patient’s remaining expected years of life.

FDA also estimated that the cost of adopting the bar code rule would be about $600 million per year for drug manufacturers, repackagers, hospitals and other affected entities, such as nursing homes, pharmacies, and retail stores.

Ultimately, FDA sidestepped the age issue by assigning the same monetized values to each health impact for both hospital and nursing home patients. FDA found that the average savings of $45,000 from avoiding adverse drug events in nursing homes was considerably less than the $183,000 it found for hospitals. This difference
was due primarily to the much higher number of preventable deaths from medication errors that have been reported in hospitals than in nursing homes. FDA estimated that the net benefits of accelerated adoption of the bar coding system by hospitals would be about $5.4 billion per year, mostly due to patients WTP to avoid adverse events. In a break-even analysis, FDA estimated that if only 0.1 percent of hospitals adopted the technology more rapidly than expected each year, the benefits would about equal the cost of the rule. Ultimately, FDA decided to promulgate the bar code rule based on the high level of expected net benefits attributable to avoiding adverse events at hospitals without claiming any benefits for nursing homes.
8. Conclusion

BCA and CEA are analytic tools designed to increase economic efficiency. As indicated above, these are not the only techniques that one can use for regulatory impact analysis. However, Congress and OMB have mandated using BCA and CEA as part of the regulatory impact analysis process. In most cases, these techniques provide supplementary, rather than substitute, information for policy makers. Even when taken together, BCA and CEA do not provide complete information about the impact of regulations. Rather, they are part of a much larger process of regulatory impact analysis used to assess the effects of federal regulations. While policy analysts typically urge that quantitative results of BCA and CEA should not be overemphasized, decision makers often ignore this advice. Even when the results of these analyses suggest that a regulation will produce substantial net benefits, it is important to understand that, in most cases, the results will produce losers as well as winners, and that the losers rarely, if ever, receive compensation for their losses. Of course, there may be more losers in the absence of a new regulation than there would be if it is adopted.

None of this makes the decision to regulate or the choice of specific regulatory provisions any easier. However, proponents of the process hope that collecting and analyzing information about regulations through regulatory impact analysis, including BCA and CEA, will yield the greatest improvement in public welfare. To the extent that BCA and CEA are made part of this process, essential features should include independence from prejudicial influence, transparency of the analysis to outside reviewers, public access to the information and assumptions used for the analysis, and meaningful opportunity for public discussion and input into the decision-making process.
INTRODUCTION

Under the Clean Air Act, EPA is required to set emissions standards for engines that contribute significantly to ozone and carbon monoxide concentrations in polluted areas. EPA is also authorized to set emissions standards for engines that contribute significantly to air pollution that may reasonably be anticipated to endanger public health or welfare, or that contribute significantly to visibility impairment. EPA used all three rationales to set emissions standards for off-road engines that emit hydrocarbon (HC), carbon monoxide (CO), nitrogen oxide (NO\textsubscript{x}), and particulate matter (PM), including recreational marine diesel engines, large spark-ignition engines (i.e., forklifts, generators, aerial lifts, pumps, balers, and other agricultural and irrigation equipment), and recreational vehicles (i.e., snowmobiles, all-terrain vehicles (ATVs), and off-road motorcycles). In November 2002, as part of the President’s Clear Skies Initiative, EPA published its rule, Control of Emissions from Non-road Large Spark-Ignition Engines and Recreational Engines (Marine and Land-Based). 105

Much of the following discussion is based on the background document, Final Regulatory Support Document: Control of Emissions for Unregulated Non-road Engines.106

For the off-road emission rule, EPA performed both a CEA focused narrowly on engineering costs and emission reduction and a BCA that encompassed broader measures of total economic costs and benefits to society.

COST EFFECTIVENESS

EPA first performed a narrowly focused CEA to estimate the effectiveness of the rule on engineering cost per ton of reduced air pollutant emissions. EPA calculated two cost-effectiveness ratios, cost per ton of reduced emissions, with and without savings from improved efficiency.

Engineering Costs

EPA estimated both variable and fixed engineering costs of the regulation. Fixed costs, including retooling, research and development, and engine certification, were amortized over five years (in some cases longer), then divided by number of vehicles projected to be produced during this time to estimate the average fixed cost per vehicle per year.

EPA estimated variable costs on the basis of the average incremental hardware and assembly costs per vehicle necessary to meet the emissions limitations under the rule. Variable costs were inflated by 29 percent to cover overhead and profit. To account for the improved manufacturing productivity expected over time, EPA assumed that variable costs would decrease by 20 percent after the third year of production and by an additional 20 percent after the sixth year of production.

While EPA estimated these costs on the basis of specific manufacturing technologies that allowed each engine class to meet the rule’s emissions requirements, EPA did not mandate the use of these specific technologies. Rather, EPA inferred that using these technologies would allow manufacturers to meet public health standards imposed by the rule at economically viable costs.

Emissions

EPA estimated exhaust emissions (HC, CO, NO\textsubscript{x}, and PM) from existing engines and engines modified to meet the standards under the rule as a function of utilization for the number of engines in each class (type and power). EPA’s model accounted for deterioration over

105 67 FR 68242, November 8, 2002.
time in existing engines due to wear and tear. Estimating the number of each engine type in use required forecasting both sales of new engines and retirement of existing engines to model the changing percentage of engines that would comply with the rule over time. EPA also estimated HC emissions due to evaporation from the fuel system based on regional models of ambient air temperature and fuel properties.

**Primary Analysis**

EPA’s primary measure of cost-effectiveness was the ratio of engineering cost per ton of emissions (HC + NOx) removed from the air. EPA calculated this by dividing the net present value (NPV) of compliance costs per vehicle by the NPV of lifetime reductions in tons of emissions over the vehicle’s expected life. Researchers performed the analysis on a short- and a long-term basis to account for the projected decrease in manufacturing costs over time and used discount rates of 7 percent and 3 percent. The 7 percent rate permitted comparison with the results of earlier rules, while the 3 percent rate permitted comparisons with future rules.

When compared with the CE ratios of nine other mobile source air pollution reduction programs, CE ratios for this rule were lower than those for six of the nine other rules, and were of similar magnitude to the CE ratios for the remaining three programs. Based on this primary analysis, EPA concluded that the rule was clearly cost effective.

**Secondary Analysis**

As a secondary measure, EPA estimated the CE ratios of the rule including the projected savings attributable to improved fuel economy and lower maintenance costs. However, under the Clean Air Act, EPA may only promulgate rules that are justified by improvements in health and environmental benefits. Thus, in the absence of health and environmental benefits, EPA would not have been permitted to adopt the off-road emission regulation, even though it might have been cost effective and produced net benefits, if these benefits arose solely from improved vehicle efficiency.

EPA’s secondary analysis showed that, for many engine classes, the cost per ton of reduced emissions was negative, that is, it sometimes resulted in substantial net savings. For example, for large spark-ignition engines, the CE ratio (including fuel savings) was about –$1,150 per ton of reduced emissions. The obvious implication was that the United States would not only have cleaner air, but it would save money as well. Thus, the rule appeared to offer a win-win situation for some engine classes: cleaner air and savings for vehicle owners.

EPA’s conclusion begged the question, “Why had market forces not yet driven manufacturers to use these emissions technologies in the absence of the rule?” Assuming EPA’s analysis was correct, analysts assumed that, in the absence of the rule, there must be some inefficiency that led to the market’s failure to incorporate these technologies. As one explanation, EPA suggested that businesses and consumers do not fully value fuel efficiency in their purchase decisions. For industrial engines, such as forklifts, EPA posited that, for budget reasons, managers tend to focus on initial investment costs rather than lifetime operating costs. For recreational vehicles, EPA conjectured that consumers ignore fuel costs which are relatively small in proportion to acquisition costs, since vehicles are often used only a few hundred hours per year.

**BENEFIT-COST ANALYSIS**

To obtain a broader estimate of the full economic effects of the rule, EPA also performed a BCA to estimate potential savings from avoiding adverse health effects of pollution, along with the costs to industry and consumers. Finally, EPA performed a sensitivity analysis to assess the effect of potential variability in key assumptions on the results of its primary BCA.

**Economic Costs**

Conceptually, EPA expected the rule to affect both the demand for each type of vehicle as well as the supply due to changes in fuel economy, maintenance costs, and vehicle attributes (e.g., a snowmobile with a four-cycle engine instead of a two-cycle engine). For example, as the purchase price for these vehicles rises due to the cost of manufacturers’ compliance with the rule, some consumers will no longer purchase them, others will postpone their purchase, and still others will purchase less-preferred vehicles (i.e., used instead of a new ones or those with less power). These
changes will reduce the satisfaction consumers receive from purchasing the vehicle, referred to as “consumer surplus.” Similarly, manufacturers that sell fewer vehicles and/or receive a lower profit per vehicle because of the rule lose “producer surplus.”

To estimate the economic costs of the rule to society, EPA used a market model for each type of affected vehicle to capture a snapshot of the rule’s expected economic effects at one point in time. In successive periods, baseline unit sales in the absence of the rule were expected to grow over time, while compliance costs were expected to vary as fixed costs were amortized and average variable costs decreased due to learning by doing. To model these changes, EPA developed a series of market models to estimate the stream of future losses in consumer surplus and producer surplus. EPA then discounted this stream of social costs over the period 2002–2030 using discount rates of both 3 percent and 7 percent. Over all engine types, in 2030, the rule was projected to cost $216.6 million in lost producer and consumer surplus, while fuel efficiency gains were projected to be $770.1 million.

Estimation of Benefits

EPA estimated the monetary benefits of reducing adverse health and welfare effects through pollution emission reductions. EPA only estimated quantitative benefits attributable to reductions in PM and NOx-related PM from large spark-ignition engines because that was the only category for which a suitable model was available for benefits transfer. EPA decided that the operating characteristics and locations of these off-road engines (e.g., forklifts and other industrial machinery) were sufficiently similar to on-road vehicles in urban areas that benefits transfer from previous studies was appropriate. Other engines covered by this rule are used primarily for recreational purposes, and neither the operating characteristics nor the locations were considered similar enough to use results from the on-road vehicles model. For example, a model of on-road vehicles in urban areas would not be appropriate to estimate the health effects of a reduction in snowmobile emissions on cross-country skiers.

Primary Analysis

EPA estimated and monetized the health benefits of a reduction in particulate matter from large engines using values per case avoided derived from other studies. Adverse health effects of PM include premature mortality, bronchitis, asthma, other respiratory illnesses, restrictions on activities, and loss of work.

EPA estimated the benefit of reduced emissions based on the incidence rate of diseases associated with NOx-related PM and directly emitted PM. The agency calculated the incidence rate per ton of NOx and PM for the following health effects: premature mortality due to long-term exposure, hospital admissions for chronic obstructive pulmonary disease (COPD), pneumonia, asthma, asthma-related emergency room visits, asthma attacks, acute bronchitis, chronic bronchitis, upper- and lower-respiratory symptoms, cardiovascular diseases, work loss days, and minor restricted activity days. The estimated incidence rate of premature mortality due to long-term exposure to PM was based on a study of such exposure’s effects on more than 500,000 individuals in 151 U.S. metropolitan areas over a 10-year period (while controlling for smoking and other risk factors). The study found that one ton of NOx emissions added 0.0016 premature deaths from long-term exposure, based on the 2001 U.S. population of 277 million. One ton of PM emissions was considerably more lethal, causing 0.0221 premature deaths per ton.

EPA applied monetary values to those health effects from studies that used differing methodologies. The monetized benefits of avoided premature mortality were based on EPA’s estimate of $6 million as the value of a statistical life (VSL; see the discussion of avoiding premature mortality in section 5.2). EPA assumed that the total value of VSL was saved for each avoided death, regardless of life expectancy and used a variety of techniques to value morbidity outcomes. Chronic bronchitis was valued at $331,000 using willingness-to-pay (WTP), while hospital admissions for COPD ($12,378), pneumonia ($14,693), asthma ($6,634), cardiovascular diseases ($18,387), and asthma-related emergency room visits ($299) were all valued on a cost-of-illness basis (i.e., average hospital costs). EPA estimated the WTP per day to avoid acute bronchitis ($57) and upper- and lower-respiratory symptoms.
($24 and $15, respectively) as combinations of WTP to avoid individual symptoms associated with those diseases. Work loss days were valued on the basis of forgone wages, and minor restricted activity days were valued using WTP.

EPA projected the cases for each type of health effect from emissions both with and without the rule in place. The difference between these two calculations was the reduction in the incidences of these health results. Analysts then multiplied these reductions by the monetized value of each health effect. The products were then summed over all health effects to estimate the total health benefits of the rule. Based on these calculations, EPA estimated the economic benefit of avoided morbidity per ton of reduced emissions of NO\textsubscript{x} as $10,200, and almost $143,000 for PM. These figures were added to the monetized benefits of avoided premature mortality.

EPA also identified, but did not quantify, a large number of adverse effects of emissions from all engine types, including health effects, such as premature adult mortality, infant mortality, various respiratory illnesses, cardiovascular effects, cancer, and anemia and other diseases of the blood. Non-health effects cited included lower crop yields, poor visibility, nitrogen and sulfate deposition on forests and fisheries, toxic effects on animals, and accumulation in the food chain.

**Sensitivity Analysis Using VSLY and Age Category**

To assess the importance of key assumptions in its primary analysis, EPA performed a sensitivity analysis for which, among other things, it assumed different values for the VSL and explored the effect of age on WTP for reductions in fatality risk.

The standard VSL estimate of $6.0 million, which EPA used for the primary benefits analysis was based on 26 studies using a combination of both revealed preference (i.e., wage premium) methods and stated preference (i.e., contingent valuation) methods. Based on studies that have found that people perceive and react differently to voluntary and involuntary risks (see section 6.4 – Risk, above), EPA excluded wage-risk estimates of the VSL on the grounds that WTP to reduce voluntary risks (e.g., employment choices) derived from wage premium studies might be different from WTP to avoid involuntary risks (e.g., exposure to air pollution) derived from stated preference studies. EPA used only stated preference studies of WTP (i.e., contingent valuation) in this sensitivity analysis, which were expected to better capture WTP to avoid involuntary risks. This change reduced the VSL by about 40 percent, from $6.0 million to $3.7 million.

While the theoretical basis for narrowing the study selection may have been reasonable, when EPA made this change at OMB’s insistence, critics challenged its appropriateness. Apparently adding fuel to the fire, EPA only tested the sensitivity of downward revisions to the VSL estimate but did not test the effect of corresponding upward revisions of VSL as the primary analysis already showed favorable net benefits and cost-effectiveness ratios.

In another important variation of its sensitivity analysis, EPA tested the effect of estimating benefits based on the value of statistical life years (VSLYs) saved, rather than on whole lives saved (VSLs). EPA reasoned that, since everyone dies sometime, the most the regulation could accomplish would be to delay death, rather than avoid it entirely. By this logic, the full VSL would be an inappropriate measure of savings, which should be valued in terms of years saved, rather than lives saved. In general, short-term studies on which EPA based its estimates of premature mortality showed that reductions in air pollutants contemplated by the new rule would extend the life of people with target conditions by about five years. However, these short-term studies also indicated a distinction between premature mortality rates for COPD and other causes. To account for this difference, EPA assumed that premature deaths associated with COPD resulted in six months of life lost (i.e., the individual would have died six months later in the absence of elevated PM levels), while five years of life would have been lost as a result of death from other causes. EPA then estimated the monetary value of avoiding a fatality for six months or five years.

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107 EPA, 2002, Table 10.3-4.
Finally, in an element of its sensitivity analysis that drew public attention and became quite controversial, EPA addressed the relationship between VSL and age. Some studies have indicated that people over age 70 have a lower WTP for mortality risk reductions than do those under age 70 (see discussion in section 6.1 – Related Issues: - Age as a Factor). To show the impact of an age adjustment on the results, EPA adopted an adjustment factor of 63 percent, which reduced the VSL to $2.3 million for those over age 70 rather than $3.7 million for those under age 70.

EPA estimated the VSLY by amortizing the VSL for each age group over the expected life remaining for that age group, arriving at a VSLY of $163,000 for a 40-year-old and $258,000 for a 70-year-old. Although the VSL for a 70-year-old was lower, the VSLY was higher because it was amortized over a shorter (10-year) life expectancy, whereas the VSL for a 40-year-old was amortized over a longer (35-years) life expectancy. Thus, EPA estimated that the monetized value of delaying death by five years was $790,000 for a 40-year-old (the present value of $163,000 per year over five years discounted at 3 percent) and $1.25 million for a 70-year-old (the present value of $258,000 per year over five years discounted at 3 percent). Using similar calculations, EPA estimated the value of delaying a premature fatality by six months as $90,000 for a 40-year-old and $130,000 for 70-year-old.

The methodology EPA used in the sensitivity analysis dramatically reduced estimated benefits of the off-road emission rule. Under EPA’s primary analysis, estimated annual benefits totaled $7.9 billion in 2030, including $7.5 billion due to avoided premature mortality, $280 million for avoided chronic bronchitis, and $90 million for reduction of other health effects due to PM, in addition to many benefits that could not be monetized. Under the sensitivity analysis, the monetized annual benefits amounted to only about $900 million— $810 million due to avoided premature mortality plus $90 million for avoided chronic bronchitis. Annual costs, ignoring fuel efficiency savings, were $216 million. So, even with the sensitivity analysis’s extreme assumptions, the regulation generated substantial net benefits.

NET RESULTS OF THE BENEFIT-COST ANALYSIS

EPA’s analysis found that the net social gain from the off-road emission rule, not counting health and welfare benefits, would be $553.5 million in 2030, due to fuel efficiency gains of $770.1 million, less economic costs of $216.6 million, due to lost producer and consumer surplus. With monetized health benefits projected to be $7.9 billion, the estimated impact of the rule in 2030 would be a net gain to society of $8.4 billion. From 2002 to 2030, EPA estimated that the rule would produce net benefits to society of $82.1 billion (i.e., the net present value of net benefits discounted at 3 percent). The rule was also expected to generate additional benefits that EPA had not been able to quantify for inclusion in its BCA.
Appendix B. FDA Case Study: Bar Code Regulation

INTRODUCTION

A significant percentage of drug related mortality and morbidity results from preventable errors. In addition to this human cost, these iatrogenic events impose significant economic costs on the U.S. health care system. In 1999, the Institute of Medicine (IOM) drew attention to the large number of deaths that may occur in the United States every year from preventable medical errors in hospitals.109

As the federal agency that regulates drugs and biologics, FDA responded to the IOM report by reviewing options for reducing drug-related errors. FDA determined that one means of reducing hospital medication errors is using Universal Product Code (UPC) bar codes on pharmaceutical and blood products. If nurses who administer most drugs in hospitals could use a bar code scanner like those used in supermarkets, to quickly compare a drug product to a specific patient’s drug regimen, the nurse could verify the five “rights of medication administration” (i.e., the right patient is receiving the right drug at the right dose at the right time via the right route). The availability of bar codes on pharmaceuticals and blood products could also facilitate other patient safety initiatives, such as automated drug prescribing and ordering.

In 2004, FDA promulgated its Bar Code Label Requirement for Human Drug Products and Biological Products110, which requires manufacturers to include bar codes on human prescription drug products, including vaccines, blood and blood products, other biologic products, and over-the-counter (OTC) products that are dispensed in hospitals. As part of the RIA for this rule, FDA performed a BCA.111

In assessing the regulatory impact of the bar code rule, FDA faced at least two challenges.

First, while FDA has authority to regulate drug manufacturers and repackagers, it does not have authority to directly regulate users of drug products (i.e., hospitals, nursing homes, physicians and patients). While hospitals are the users most likely to use bar code scanners, FDA could not require them to use the scanners. This meant that the rule could result in costs without yielding benefits if hospitals did not adopt bar code scanners voluntarily. On the other hand, hospitals have been adopting bar code systems on their own initiative. Eventually, all hospitals were expected to adopt the technology. However, hospitals have been discouraged from adopting bar code scanners by the cost of placing bar codes on drugs that are not coded routinely as part of the packaging process. FDA reasoned that requiring manufacturers to apply bar codes would reduce the cost of operating bar code systems to hospitals, so more hospitals would adopt the technology sooner. Thus, the rule could be expected to generate benefits by accelerating the technology’s adoption. As a separate matter, FDA needed to value the benefits of avoiding adverse drug events differently for hospitals and nursing homes to reflect age differences in their respective patient populations.

FDA’s approach was to estimate the costs of the rule separately on the pharmaceutical industry, which would be directly affected, and other sectors of the health care industry, which would be indirectly affected. FDA estimated the benefits of the bar code rule, in terms of both avoided health care costs (i.e., cost of illness) and patients’ willingness-to-pay to avoid medication errors (i.e., WTP). Finally, FDA examined how the rule would affect the rate at which hospitals would adopt the technology over time both with and without the rule.

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110 Final Rule 69 FR 9119 (February 26, 2004); proposed Rule 68 FR 12499, March 14, 2003.
111 Food and Drug Administration (FDA), 2003.
COSTS OF THE RULE

To estimate the direct costs of the rule on the pharmaceutical industry, FDA interviewed drug manufacturers, repackagers, printers, representatives of the Uniform Code Council, and manufacturers of bar coding equipment to determine the likely industry response to the rule and the likely cost of meeting its requirements. Combining this information with trade association survey data, census data, and other information, FDA estimated the costs of the rule to different industry sectors that would be directly affected.

In addition, the rule was expected to affect many other entities indirectly, including pharmacies, convenience stores, and grocery stores as well as hospitals. FDA estimated the indirect costs of the rule to hospitals and retail outlets separately for current users who would have to incur costs to continue using bar code scanners and for new users who had not yet adopted the technology but would be encouraged to do so as a result of the rule.

Drug Manufacturers and Repackagers

In estimating the cost of the bar code rule, FDA examined the cost of requiring all drug packages to contain bar codes in the linear format currently in use based on a unique identifying number, referred to as the National Drug Code (NDC), which FDA assigns to each drug product. FDA also examined the possibility of requiring that bar codes be based on a more compact format, referred to as a reduced space symbology (RSS), instead of the current linear format. FDA thought RSS would be easier to apply to very small packages, such as vials and unit dose packages.

While many drug packages currently carry an NDC in the linear bar code format, few carry the newer RSS bar code. Compared to using a linear bar code, FDA estimated that the cost of requiring RSS bar codes on drug packages would quadruple the initial compliance cost of the rule because almost all drug packages would need to be redesigned. However, adopting the RSS option would not fundamentally affect how companies print labels and package their products, so the rule’s annual operating and maintenance costs would be essentially the same under either regulatory approach.

FDA also considered requiring inclusion of lot number and expiration date as part of the bar code to facilitate tracking and prevent administration of recalled and expired drugs. However, this change would require changing the bar code frequently to imprint unique identifying information for each product lot and date. Requiring incorporation of such variable data on labels was expected to be very expensive to the pharmaceutical industry.

FDA expected that the costs of compliance with the bar code rule would directly affect primarily drug manufacturers and drug repackagers. (Repackagers are companies that purchase drugs in bulk from manufacturers and repackage them for sale to hospitals and other health care facilities for administration on the premises and to retail outlets as store brand and generic products.) For these companies, the process of modifying labels includes not only redesign and printing cost to modify labels, but also modification of packages that are too small to accept label changes. After designing new labels, manufacturers must obtain FDA approval for label changes, thus incurring the cost of meeting these regulatory requirements. Finally, depending on how quickly FDA required them to comply with the rule, companies could incur inventory losses if labels on previously packaged products became outmoded before they could be sold. Although these costs were expected to be modest for each product, they were to be multiplied across as many as 150,000 different packages.

To reduce the cost of compliance, FDA considered delaying implementation of the final rule to allow drug packagers to adopt the mandated modifications during routine label changes. Drug labels must be changed periodically to incorporate new data and for marketing purposes. FDA examined the effects of delaying the rule through a sensitivity analysis of different lead times.

Current Users

FDA estimated the cost for hospitals and retail outlets that were currently using bar code scanners to continue using this technology based on the type of bar code that the rule would require. If FDA mandated adoption of a linear bar code, then the costs to current users were expected to be minimal, if not zero, since current bar code scanners can read linear bar codes. However, if
FDA required labels to use RSS, only a fraction of the millions of scanners currently in use could read the new, more compact bar codes. While many existing scanners can be upgraded, current users would have to incur costs prematurely to replace or upgrade scanners that cannot read RSS. The lead time of an RSS rule would not affect costs incurred by current users because, once even a small fraction of packages began using RSS, all current users would need to adopt compatible technology to handle the RSS-labeled products.

**New Users**

FDA used a combination of publicly available data and expert opinion to estimate the costs of implementing bar code medication administration systems in hospitals. Bar code systems generally work by checking for a three-way match among the medication to be administered, the patient, and the nurse responsible for administering the medication. Using a handheld scanner to read the bar codes on a patient’s wrist band, the system only allows the nurse to administer the medication after the computer has checked the five rights of medication administration (i.e., right drug at the right dose to the right patient at the right time via the right route).

To implement the system, hospitals must purchase computer hardware and software, including scanners and hand held bar code readers, place bar codes on medications, and train nursing staff to use the system. FDA modeled these purchase costs as a function of the number of hospital beds in the hospital, the total number of patient days, and other relevant factors.

Adopting a bar code system can impose potentially significant costs by increasing the amount of nursing time required to administer medications, thereby decreasing productivity. For instance, a one percent decrease in overall nursing productivity could cost the health care industry almost $700 million per year. FDA was unable to find any empirical studies that have quantified the impact of bar code systems on nursing productivity and could have been transferred for this BCA. As a result, FDA had to rely on anecdotal evidence of productivity effects, which ranged from reports of “significant negative impacts” estimated as perhaps a 10 percent reduction, to such characterizations as, “It takes slightly longer” and “It forces them to slow down and do what they should be doing anyways.” Conversely, it was suggested that bar code systems may reduce nursing time spent on record-keeping tasks through the use of computer-generated medication records, which eliminate the need for manual recording. Faced with a complete lack of scientific data or peer-reviewed studies, FDA assumed that advantages associated with electronic record keeping would not completely offset increased time needed to administer medications, so it projected a small negative impact on nursing productivity.

FDA also analyzed the use of bar codes in blood transfusions. Hospitals typically have stringent transfusion procedures, which require two nurses to double-check each unit of blood prior to administration to minimize errors. If the hospital purchases a bar code system for medication administration, the incremental costs of using a bar code system for blood transfusions would be negligible. Most blood products already carry a bar code for inventory purposes, but it is not used at the administration stage. The ability to scan patient identification bracelets and blood bags could reduce the need for double-checking, thus leading to both safety and efficiency gains.

FDA performed a separate BCA for nursing home adoption of bar code systems and found that nursing home costs to install and operate a bar code system are comparable to hospital costs for similar-size facilities.

**BENEFITS OF THE RULE**

FDA assumed that the benefits of the rule would arise from preventing harmful medication errors exclusively in hospitals, and that these benefits would begin to accrue only when hospitals installed bar code scanning equipment for medication administration sooner than they would have without the FDA requirement.

**Avoiding Adverse Drug Events**

To estimate the benefits of hospitals’ using bar code systems, FDA first estimated the number and type of adverse drug events or episodes and the percentage that might be prevented by bar code systems. FDA based its estimates of adverse drug events on four studies published in medical journals that examined the incidence of adverse drug events among hospital patients. These
studies estimated the rate of adverse drug events per hospital admission, and the percentage of those events that could be considered preventable. For example, an adverse event resulting from an allergic reaction of a patient to a drug was not deemed preventable if nobody, including the patient, knew of or reported the allergy. Conversely, if the allergy was known, but the patient received the medication anyway, because someone forgot to write the allergy in the patient’s medical record or failed to read the record before the drug was prescribed and administered, then the resulting reaction was considered preventable.

Combining statistics on patient admissions with the rate of adverse drug events per admission and the percentage of events that were preventable, FDA estimated the number of preventable adverse drug events that occur in U.S. hospitals annually. This estimate represented the total number of events that could have been affected by the bar code rule.

To estimate the number of errors that bar code systems potentially could prevent, FDA examined the relative frequency of errors that occur in each stage of the medication administration process, including prescribing, transcribing, dispensing, administering, and monitoring. For example, the largest percentage of medication errors occurs at the prescribing stage. Although pharmacists and nurses intercept almost half of these errors before they reach the patient, bar coding can do little to reduce errors occurring at the prescribing and transcribing stages since it assumes that orders are correct as entered into the computer by the pharmacist. Conversely, while fewer errors occur at the administration stage, almost none of these errors are intercepted before reaching the patient. Bar code systems intercept these types of errors, as well as dispensing errors, very effectively.

Although published reports of hospital experience with bar code systems indicated significantly higher error prevention rates, FDA assumed that these systems would prevent 50 percent of drug errors that occur at the dispensing and administration stages. FDA adopted this estimate as the basis for its benefits analysis.

### Monetizing the Benefits of Avoided Drug Errors

FDA estimated two elements of benefits from avoided adverse drug events.

#### Direct Health Care Costs

First, FDA estimated direct costs to society resulting from unnecessary treatment and extended hospitalization due to adverse drug events. Several published medical studies estimated the incremental cost due to increased hospital length of stay and related health care expenditures associated with preventable adverse drug events. These studies derived an average value by adjusting the costs of responding to an adverse event for the frequency and severity of the event. FDA multiplied these cost figures by the estimated number of adverse drug events to derive the total value of health care resources used because of avoidable events.

#### Willingness to Pay

FDA derived a second measure of benefits of the rule by estimating patients’ willingness to pay to avoid an adverse drug event. FDA estimated the loss in quality adjusted life years (QALYs) associated with events that could be prevented using bar code systems, and then monetized these lost QALYs as a proxy for WTP. However, as noted in section 4 above, only changes in individual welfare as expressed in WTP are considered valid benefit measures. By contrast, monetized QALYs offer only a vague approximation of actual WTP.

FDA adjusted its estimate of lost QALYs for the frequency of different degrees of severity of adverse events (i.e., clinically significant, serious, life threatening, and fatal), as well as typical symptoms and duration of each condition. Analysts obtained QALY preference scores from the Harvard Center for Risk Analysis (HCRA) CEA Registry. FDA selected different QALY values to represent the severity of several categories of adverse event (e.g., a serious episode was represented by transient cerebral events with a QALY preference score of 0.8, while a life-threatening event was represented by acute renal failure with a QALY preference score of 0.6). The value of lost QALYs was expressed as one minus

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112 While HCRA screened these studies for scientific validity before including them in the database, many QALY preference scores were determined by expert clinical judgment, rather than by stated preference method or other formal survey (see HCRA, foot note above; Exhibit 4).
the QALY preference score, then multiplied by the duration of the condition in years.

The medical literature indicated that most adverse events are temporary and short term, while a few events tend to result in permanent disability or death. To account for this bimodal distribution, FDA assumed that the duration of adverse events was either short term (i.e., two days to nine days) or permanent (i.e., assuming remaining life expectancy of a 35-year-old). Based on these assumptions, serious short-term events, for example, were expected to last five days, with a preference score of 0.80, so an individual would lose 0.0027 QALYs \((1 – 0.8) \times \frac{5}{365}\) years. Persons suffering a permanent disabling event were expected to lose 17.4 QALYs \((1 – 0.6) \times 43.5\) years.

FDA derived the value of a statistical life year (VSLY) by amortizing its standard VSL of $5 million over the expected 43.5 remaining years of life for a 35-year-old at 7 percent, yielding $373,000. FDA monetized the benefit of avoiding an adverse hospital event by multiplying lost QALYs by the VSLY for one of four classes of event—significant, serious, life-threatening, or fatal. For example, a serious event was monetized as $1,022 (0.027 QALYs *$373,000).

For events that were expected to result in permanent disability, FDA discounted the stream of monetized lost QALYs over the remaining years of life, using a 7 percent real discount rate. Fatal adverse drug events were valued at FDA’s standard VSL of $5 million. While EPA started with a higher VSL of $6.0 million in its off-road vehicle RIA, FDA’s method of calculating VSLY was similar to the method used by EPA, except that EPA derived one VSLY of $163,000 for people under age 70 and a different VSLY of $258,000 for people over age 70. Ironically, FDA derived a still higher VSLY of $373,000 for the average hospital patient.

FDA estimated an average benefit of an avoided adverse drug event by weighting each type of event by its relative frequency. Exhibit 6 illustrates the calculation. Serious events, for example, occur 41.7 percent of the time, so the $1,022 value received a weight of 0.417 in the average. After adjusting for frequency of event type, FDA estimated the average value of avoiding an adverse drug event at $183,000. As in the case of EPA’s off-road diesel rule, the value of avoided fatalities dominated the benefits of the bar code rule. Because of the uncertainty associated with the frequency of avoidable events resulting in death, FDA performed sensitivity analyses using alternative estimates of the relative frequency of fatalities.

### Valuing the Timing of Technology Adoption

Due to uncertainty associated with projecting hospital adoption rates for bar code technology, FDA consulted with industry experts to develop a model for hospital industry adoption. Experts estimated that, in the absence of the rule, the hospital industry would adopt bar code systems over about 20 years to improve quality of care and patient safety. As a result, FDA assumed that costs would not be incurred simply because hospitals adopted the technology, but because they would adopt it sooner than they would have in the absence of the rule and thus, would incur implementation costs sooner. If the rule

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<th>Health Impact</th>
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<th>Nursing Home Relative Frequency</th>
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was promulgated, FDA estimated that lower implementation costs would cause hospitals to adopt the technology within about 10 years. Based on these assumptions, FDA projected that, starting from a base year in which only about 2 percent of hospitals used bar code systems, without the rule, 50 percent of hospitals would use bar codes after 10 years, and after 20 years, adoption would be complete. On the other hand, FDA projected that, if the rule was mandated, this process would be accelerated, so that 50 percent of hospitals would have bar code systems within five years, and adoption would be complete after 10 years. Due to uncertainty concerning technology adoption patterns, FDA performed a sensitivity analysis of several scenarios using alternate assumptions concerning adoption rates in addition to its primary analysis.

COST-BENEFIT CALCULATIONS FOR HOSPITALS

FDA generally found that the benefits to society of adopting the bar code rule, expressed primarily as patients’ WTP to avoid adverse events, exceeded the costs to society, including costs to drug manufacturers and repackagers as well as hospitals, under all scenarios analyzed, by as much as 600 percent under some scenarios. Pharmaceutical manufacturers and repackagers would incur costs of $5.9 million per year to implement the simplest bar coding scheme. The net benefits of accelerated adoption of the bar coding system by hospitals were $5.4 billion per year. Only one percent of the total benefits were derived from avoided direct health care costs. The majority of these benefits were attributable to people’s WTP to avoid adverse drug events. Considered from the perspective of a break-even analysis, for the rule to produce positive net benefits, only 0.11 percent more hospitals would need to adopt the technology annually than would have adopted it without the rule. Even if FDA’s assumptions about the rate of hospital adoption were incorrect, there was a wide margin of error in which the rule would still pass a benefit-cost test.

For the nursing home sector, however, FDA found that costs exceeded benefits because FDA could only document a very low rate of avoidable adverse drug events in nursing homes. This difference was probably attributable to data gaps as few studies of drug error rates have been performed in the nursing home sector, and nursing homes tend to keep less complete records than hospitals do. These factors made it difficult for FDA to document the incidence of adverse drug events.

METHODOLOGICAL ISSUES ASSOCIATED WITH THE BAR CODE STUDY

Hospital versus Social Impact

In its analysis of the rule, FDA did not attempt to identify to whom the benefits of bar code systems would accrue. Individual patients accrue the most savings from avoiding medical errors by avoiding injury and death. By contrast, hospitals and other health care providers receive only small direct benefits from avoiding medical errors. For patients whose care is paid for under fixed prospective payments, such as Medicare Diagnostic Related Groups (DRG) payments, hospitals may accrue savings from reduced complications and shorter length of stay by avoiding adverse drug events. However, for patients whose care is reimbursed on a fee-for-service basis, such as per diem payments, preventing adverse events does not save the hospital additional costs of care. In fact, hospital revenue may be lower for these patients, who have a shorter length of stay. Instead, health insurers and HMOs and patients do not have to pay for care related to adverse events, and life insurers may reduce payouts for deaths.

To some extent, malpractice insurers might pay out fewer claims for injuries and deaths related to adverse events, and hospitals may benefit from lower insurance premiums. No insurers currently offer discounts to hospitals with bar code systems, though physician groups already receive discounts of 10 percent to 30 percent on their malpractice insurance premiums for electronic prescribing systems. FDA estimated that only 2.45 percent of malpractice claims could be attributed to preventable adverse drug events. Even if bar coding could eliminate all of these claims, it would have little effect on historical loss rates for many years. While FDA examined the effect that bar code systems might have on hospital

113 Rothschild et al., 2002.
malpractice insurance premiums, it did not incorporate those estimates into its overall BCA.

While FDA estimated that hospitals’ annualized cost to adopt bar code systems early would be $606.3 million, FDA did not discuss potential sources of payment for bar code systems that hospitals were expected to adopt. This is significant because, due to the voluntary effect of the rule on hospital adoption, Medicare, the largest single source of hospital payments, would not be expected to reimburse hospitals directly for these costs.

**Estimating Benefits for Different Age Groups**

In estimating the benefits of bar code systems to nursing homes compared with hospitals, FDA found that the average age of nursing home patients was 83, whereas the average age of hospital patients was 35. FDA considered adjusting its benefit estimates for differences in average patient age. Draft OMB guidance directed agencies to base the estimated number of life years saved for a disabled population on the average life expectancy for the relevant age cohort. FDA based its estimate of life expectancy for nursing home patients on census data that projected the average 83-year-old would live for 7.5 years, 17 percent of the 43.5 years of hospital patients’ life expectancy.

To monetize the benefits of the rule, FDA considered using the same VSLY of $370,000 for both hospital and nursing home patients, but adjusting the number of QALYs based on life expectancy. This approach would have valued avoiding death or permanent disability for a nursing home patient at about 20 percent of that of a hospital patient. The alternative of recalculating VSLY based on distributing a $5 million VSL over 7.5 years of remaining life, as EPA did in its off-road diesel rule, would have yielded a VSLY of $880,000, more than twice the value of a hospital patient’s life. FDA rejected both approaches as unpalatable.

As an alternative, FDA considered assigning different VSLs for hospital and nursing home patients, as EPA did. However, FDA found little evidence on which to base such an assumption, and by that time (i.e., fall 2003), OMB had prohibited this approach, so FDA rejected it. FDA did not perform a sensitivity analysis on the effect of age because changes in benefits associated with nursing home patients were not significant compared with the impact of hospital costs and benefits.

Ultimately, FDA sidestepped the age issue by assigning the same monetized values for each health impact for both hospital and nursing home patients. For instance, FDA assumed that avoiding a serious drug reaction was valued at $1,022 for all patients in all settings, as shown in Appendix B, above. After adjusting these values for severity and frequency, the values for hospitals and nursing homes differed because the relative frequency and severity of adverse events differed in the two settings (see Exhibit 6, above).

FDA found that the average savings from avoiding adverse drug events in nursing homes was $45,000, considerably less than the $183,000 saved in hospitals. The difference in values pales in comparison with the difference in the number of events prevented. Nursing home data about adverse drug events are not as complete as hospital data and have attracted less research interest. Thus FDA had less information to estimate the impact of bar coding system on nursing homes. It is apparent, however, that preventable adverse drug events are far less frequent in nursing homes than they are in hospitals. FDA estimated that bar coding systems in nursing homes would prevent only 5,200 events per year nationwide, including 21 fatalities. In comparison, FDA estimated that hospital bar code systems could prevent 84,000 events, including 2,400 fatalities. FDA decided to promulgate the bar code rule based on the high level of expected net benefits at hospitals and did not claim any benefits from nursing home adoption of bar coding technology.

114 OMB, 2003a, p. 130.
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