VALUING HEALTH: AN OMB PERSPECTIVE

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Remarks Prepared for Conference on
Valuing Health Outcomes: An Assessment of Approaches

RESOURCES FOR THE FUTURE
1616 P Street, NW
Washington, DC

February 13, 2003

Thank you for the opportunity to offer these remarks. The questions you are addressing in this conference are central to the quest for more efficiency and fairness in the health and safety policies of the federal government. On behalf of President Bush, I want to thank each of you for your efforts to offer knowledge and insight about how federal agencies can improve their regulatory analysis and their decisions.

As I was preparing these remarks last week, it occurred to me that there is no organization better equipped to organize this conference than Resources for the Future. I would be remiss if I did not thank in particular Michael Taylor and Alan Krupnick and their planning committee for the hard work in making this conference happen. Serious problems deserve the attention of talented and serious thinkers – this is exactly what RFF has provided, and I praise you for that accomplishment.

OMB RECENT REPORT TO CONGRESS

Last week OMB published its draft Report to Congress on the Costs and Benefits of Federal Regulation. This annual Report is required by the Regulatory Right-to-Know Act and it is now available for public comment, expert peer review, and interagency review. We expect the Final Report to be released later this year.

This Report assembles information on the costs and benefits of all major rules issued by executive agencies over the past 10 years. Overall, the Report estimates annual regulatory benefits of $135 to $218 billion and annual costs of $38 to $44 billion.

For the first time, we released this report at the same time as the federal budget. This will permit appropriators in Congress to consider cost-benefit information as they do their work .

Another first in this Report is information about programs within agencies as well as agencies as a whole. We have learned that one particular unit, the clean air program at EPA, accounts for the majority of the national regulatory benefits accomplished over the past ten years. Although there is significant uncertainty in these estimates, the Administration believes that the clean-air program at EPA has an excellent track record. In fact, the President has recently asked Congress for expanded authority for this program to further reduce air pollution from electric powerplants. I am referring to the Clear Skies Initiative that will reduce powerplant emissions by 70% over the next 15 years through an expanded market-based trading program.

OMB'S DRAFT REGULATORY GUIDANCE DOCUMENT

OMB has also released a draft revision to our government-wide guidance on how to do high-quality regulatory analysis. This draft was prepared by my staff in collaboration with the President's Council of Economic Advisors. I would like to recognize my task force co-chair, Dr. Randy Kroszner of CEA, and one of his key associates, Dr. John List. OMB and CEA have had our share of spirited

exchanges in preparing this document and we have also learned from each other. We would like your comments on how we can improve this guidance document.

As you consider commenting, please recall how the guidance is used. Each year federal agencies issue about 4,500 rulemaking notices. About 500 of these rules will be judged significant enough to justify OMB review. However, even these rules are not required to have a formal regulatory analysis. Only those rules with an economic effect of $100 million per year or more (benefits or costs) must have a supporting analysis. Thus, the guidance document is directed primarily at the 50 to 100 rulemakings each year that have the biggest overall impact on our country.

To do this job, I supervise a staff of 57 career civil servants with training in economics, statistics, policy analysis, and information policy. We have recently added expertise in the fields of engineering, toxicology, epidemiology, decision science and health policy. At OMB we do not typically perform original analysis; our role is to evaluate the information prepared by agencies. If we find that an agency's analysis and decisions are sensible, we clear the rule. If the analysis or decision making are inadequate, we return the rule to the agency for further consideration under Executive Order 12866, which has been in effect for almost a decade.

HOW OMB GUIDANCE IS CHANGING

The OMB guidance document serves as an important reference in discussions between my staff and analysts in the agencies.

Our proposed guidance is best understood as a refinement rather than a revolution. Perhaps the most important changes for health and safety rulemakings are the following.

First, our guidance calls for agencies to present a cost-effectiveness analysis (CEA) as well as a benefit-cost analysis (BCA) in support of major rules. CEA is useful because it provides information about which regulatory alternatives will produce the most health gains per unit of resource investment. It is a "bang for the buck"exercise, where the payoff is measured in health units rather than dollars. My experience as both a professor and government administrator is that some people who are skeptical of traditional benefit-cost analysis gain insight from the cost-effectiveness perspective. I think it is instructive that the peer-reviewed medical and public health literature is far more dominated by CEA than BCA (see attachment). Since the CEA only provides relative comparisons, we need BCA to determine whether the benefits of any particular alternative justify the costs.

OMB recognizes that the quality-adjusted life year (QALY) is a widely used measure of effectiveness in the medical literature (see attachment). We also understand that refinements and alternatives to QALYs are also under development.

Rather than require any specific effectiveness measure, OMB believes that multiple effectiveness measures based on different value assumptions and research designs should be encouraged. Of course, we then face a consistency problem. In order to promote more consistency, OMB will be sponsoring interagency discussions about the most promising and practical effectiveness measures. We will also request that agencies supply OMB their original data on mortality and morbidity. OMB will then be in a position to compare rulemakings across agencies using similar methods and assumptions. The Administration is moving with determination toward more performance-based budgeting, and a greater focus on cost-effectiveness and net benefits should be helpful in budgeting.

Second, our guidance takes a modified position on how future benefits and costs should be presented by analysts. Historically, we have recommended a uniform 7% rate of discount. For reasons discussed in the guidance, we are now asking analysts to present results using several discount rates. For rules with impacts primarily in this generation, results are to be computed at 3% and at 7%. For rules with intergenerational impacts, sensitivity analyses are to be conducted with rates as low as 1%. For rules that displace corporate investment, agencies should conduct sensitivity analyses with rates higher than 7%, as appropriate for the particular sector of the economy.

It is easy to forget the mathematical power of the discount rate, but I will provide one vivid example. What is the present value of 1000 lives saved 50 years from now? It is 608 when evaluated at 1%, 228 when evaluated at 3% and 34 when evaluated at 7%. The same mathematics – by looking forward at annual rates of return – can illustrate why we should be hesitant about adopting new regulations that might discourage promising investments in the future growth of our economy.

Finally, our proposed guidance adds a new analytic requirement for the handful of rules each year that have an economic impact of more than $1 billion per year. Unless the benefits and costs of these rules are known with a high degree of certainty, OMB requests that agencies supply formal probability analysis of benefits and costs rather than a single number.

Why do we suggest imposing this added burden on agencies? The information on probabilities is critical when regulators must decide whether to act now, based on imperfect science, or whether to collect additional information prior to regulating. OMB believes that this "option-value" approach to regulatory analysis needs to become integrated into how federal agencies exercise precaution in their most important rulemakings. We need to begin using these more advanced tools when regulators face complex and uncertain science about low-probability, high-consequence events such as the events of September 11th.

In the report just released, we specifically seek comment on how regulators address the need for precaution in risk management and how, in the case of homeland security, we can improve the quality of benefit-cost analysis of anti-terrorism measures.

RESEARCH NEEDS

Since I have a group of talented and creative researchers before me, I cannot resist offering reflections on several research needs, gaps in knowledge that OMB and agencies struggle with on a day-to-day basis.

In BCA, the monetary valuation of lifesaving is as important as it is controversial. While we have made major progress compared to the simple human-capital estimates of 30 years ago, we need to learn more. Most of our willingness-to-pay studies of lifesaving address people in the middle of their lifespan. Yet the rules we review may also offer lifesaving benefits for our nation's children and our senior citizens. Analysts at agencies need valid information to compute benefits for these groups.

The few studies that have been done in this area – valuable as they are – raise as many questions as answers. For example, some researchers have reported that reducing daily risks of life at age 40 is valued no more strongly by consumers than reducing similar risks of life at age 60. Yet actuaries tell us that the typical 40-year old stands to lose twice as many expected years of life as the 60-year old . Do these studies teach us that the number of life years saved is not important to consumers? Is it possible that life years are important but seniors value highly the precious few life years they have remaining? Could it be that people at age 60 are often wealthier than people at age 40, when both assets and income are properly counted, and their superior ability to pay is influencing these results? Are people at age 40 undervaluing safety in their market behavior because they perceive they cannot borrow against their future income stream? Could it be that life years saved would be valued by informed consumers but they do not have experience with this construct, and thus do not adjust their preferences accordingly? In order to perform high-quality BCAs, we need answers to these questions.

While these issues are crucial in BCA, they may be considered less important for CEA. In the health field, CEA is often defended partly on a social-contract basis rather than on a pure free-market basis. Here is a version of the social-contract argument. In what the late John Rawls called the "original position", where citizens are blinded by a "veil of ignorance" to their own age, health status and wealth, they might rationally prefer a social contract that would maximize the number of healthy life years saved through public policy, given the resources available. Of course, I am not aware of any interest groups in this town who are prepared to wear this veil of ignorance when they visit Congress or OMB, but that is "just" a practical problem!

In the valuation of nonfatal injuries and diseases, the range of severities are bewildering: from the common cold and arthritis to hip fractures and paraplegia. Although the research needs are enormous, I believe the BCA and CEA traditions have much insight to share with each other.

CEA researchers have learned that a condition-by-condition approach to valuation is not very tractable; we need to find valid shortcuts. They have, for example, constructed what are called general health-classification systems – computerized schemes that map clinically-defined conditions into the basic dimensions of health: mobility, social relations, cognitive functioning, emotional functioning,

sensory functioning, pain and so forth. Any clinical condition can then be rated by patients according to its impact on these basic dimensions of health. Health-utility ratings are often derived this way. I believe there is merit in building parallel willingness-to-pay models – general models that produce monetary values for these changes in the basic dimensions of health.

Likewise, the contingent-valuation literature in BCA has much to offer the health-utility researchers. As Dr. Krupnick is fond of reminding me, stated-preference researchers have developed more rigorous tests of validity – such as the external scope test – than is typically applied by health-utility researchers. Before an agency analyst uses a specific quality weight for a health condition, we need to have some confidence that the weight represents real public preference. If this conference accomplishes nothing else, it is my hope that it will begin a constructive dialogue about how to better measure health preferences – building on what has been learned in both BCA and CEA.

For the institutional specialists here today, there is also merit in more comparative studies of how different federal health and safety agencies value health outcomes, both in the this country and abroad. Current analytic practices are quite disparate. Some agencies, such as EPA and FAA, perform only BCA but do so using monetary values of lifesaving that vary by a factor of two or more. NHTSA refrains from doing BCA but performs CEA using a measure called "equivalent lives saved", though they also have a QALY-like system under development. OSHA does not do either CBA or CEA while FDA performs a hybrid of CEA and BCA. FDA's last six food-safety rulemakings have made explicit use of quality-adjusted life years. In addition to comparing analytic practices, there is value in comparing the implicit valuations made by the Congress and federal agencies in the laws and rules that are adopted or rejected. Comparisons of Europe, the USA and developing countries would also be instructive.

In conclusion, let me thank RFF for the opportunity to participate in this important conference. Twenty years from now, I believe we will all look back on this meeting and acknowledge that it was important, perhaps like the RFF meeting on social time preference convened in the early 1990s. I want each of you to know that we at OMB care about the work you do, we consider and use the results that you publish, we are open to new insights and methods, and we urge you to participate in the deliberative process that is now underway. Thank you again and I look forward to comments and questions.

COUNTS OF ECONOMIC EVALUATIONS IN THE MEDICAL/HEALTH LITERATURE

1975 – 2000

	CEAs*	BCAs**
1975	2	0
1976	0	0
1977	0	0
1978	2	0
1979	2	0
1980	2	1
1981	4	1
1982	2	1
1983	2	0
1984	5	1
1985	4	0
1986	10	0
1987	11	1
1988	17	0
1989	15	0
1990	27	1
1991	26	3
1992	53	5
1993	66	5
1994	123	13
1995	222	9
1996	282	6
1997	272	14
1998	334	13
1999	300	8
2000	288***	15

* Cost-effectiveness analyses (CEAs)

** Benefit-cost analyses (BCAs)

*** 62% of the evaluations used "QALYs Saved" or "Life Years Saved" as the metric of effectiveness

Source: Dr. Peter Neumann, Harvard School of Public Health (MEDLINE Search)