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This is a response to comments requested by OMB on the Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulation (Federal Register, Vol. 68, No. 22, February 3, 2003). My comments are limited to Appendix C: OMB Draft Guidelines for the Conduct of Regulatory Analysis and the Format of Accounting Statements.

I am an economist with Stratus Consulting Inc. I am a frequent contractor with the U.S. EPA on economic benefits assessment and have extensive research experience on the monetary valuation of pollution-related effects to human health and welfare. I also serve on the U.S. EPA Science Advisory Board Advisory Council on Clean Air Compliance. These comments represent my own opinions, not the views of the U.S. EPA or any agency.

Comments on Section III.C: The effectiveness metric for public health and safety rulemakings

OMB recommends more extensive use of cost-effectiveness analysis to supplement cost-benefit analysis for assessment of regulations expected to effect human health. Related to this is the recommendation that various mortality change metrics be considered. These include life-years saved and/or quality adjusted life-years (QALYs) saved as well as counts of lives saved, which is the metric currently used by many federal agencies. With regard to human mortality, the key difference in these metrics is between counting life-<u>years</u> saved or counting <u>lives</u> saved and my comments focus on the implications of this difference.

Measuring lives saved means counting the number of people who experience a reduction in mortality risk and multiplying the number of people times the average change in the probability of death, in some time period. This is a head count approach that makes no differentiation for the age or health status of the people affected. Thus, the very old or very feeble are given the same weight as young and healthy individuals. It has been noted that this metric fails to account for the fact that in some cases the people experiencing a risk reduction may have had only a short time left to live anyway.

An alternative metric that takes into account remaining life expectancy is to calculate life-years saved by using the age of the people affected by the risk change. Age is used to determine the remaining life expectancy, which, when combined with the mortality risk reduction, yields life-years saved. Using this metric to calculate the health benefits of a program means, in effect, that each person's mortality risk change is weighted by their remaining life expectancy. Thus, for example, a 37 year old with a remaining life expectancy of 40 years is given four times as much weight as a 73 year old with a remaining life expectancy of 10 years. Even if future years are discounted, as is often done, the result is similar: mortality risk reductions for individuals are weighted in proportion to the individual's remaining life expectancy (or discounted remaining life expectancy).

These two metrics (lives versus life-years) can lead to different policy conclusions in circumstances where the age distribution of those affected by a policy is different from the age distribution of the general population. So, is there any basis to evaluate which metric is better for use in measuring health outcomes of policy alternatives?

A common argument in favor of using life-years saved, rather than lives saved, is that no one's death is ever permanently prevented, but rather life expectancies are changed. This is true, but it does not automatically mean, as is implicit when a life-years saved metric is used, that the value of a year added to a person's life expectancy is always the same regardless of the person's current life expectancy. The question of how lives saved or life-years saved are valued is rooted in the precepts of cost-benefit analysis, if that is the analytical context in which the metric is to be used. Cost-benefit analysis is rooted in the concepts of welfare economics in which benefits are defined as gains to individuals' utilities. Measures of change in utility associated with a change in mortality risk are based on an affected person's own assessment of the tradeoffs they are willing to make (as revealed by actual behavior or by responses to hypothetical questions in a survey context). The monetary metric for this change in utility is willingness to pay (WTP).

It is an empirical question whether changes to individuals' utilities are better characterized by lives saved or by life-years saved. If life-years saved were a better metric, we would expect to see WTP values for mortality risk reduction declining proportionately with remaining life expectancy, or equivalently, declining proportionately with increasing age. The empirical data on this question are limited, but available evidence suggests that the relationship between WTP and age is statistically weak and does not decline proportionately with age. If, in fact, WTP for mortality risk reduction is relatively invariant with respect to age, this means that the value per life-year saved is not a constant, but rather is an increasing function of age. This also suggests that counting people affected, rather than years of life expectancy gained, may be a better indicator of gains in utility.

Life-years, either quality adjusted or not, is a commonly used metric in public health and health care analysis. The analytical framework used in this arena is not typically cost-benefit analysis and the focus is often on gains to the individual patient. Quality adjusted life-years, for example, is a very useful metric for gauging tradeoffs between extensions to life expectancy and quality of life, as might occur with certain medical interventions that cause some temporary or permanent impairment, but extend life expectancy. An extreme example may be an amputation to stop a life threatening infection.

Different federal agencies are dealing with many different kinds of decisions. For example, the Environmental Protection Agency's regulatory actions are often designed to address market failures with respect to the emissions of pollutants to air, water, and land. Benefit measures need to reflect the many outcomes expected as a result of such regulations including benefits to human health, human welfare and the natural environment. Human health is one of many important factors, which complicates the selection of effectiveness metrics.

One of the concerns expressed regarding WTP measures is that they are a function of ability to pay. There is an operating assumption in the public health area that ability to pay should not determine provision of health care decisions for individuals. However, with environmental regulations the benefits are often accrued via public goods, such as air and water quality, the use of which is not determined based on an individual's ability to pay because no one is excluded from the use of public goods. Provision decisions are influenced by the population's total willingness to pay (when cost-benefit analysis enters into the regulatory process). This will be a function of the level of income in the population from which the WTP values are drawn, but the availability of public goods to an individual is not restricted by the individual's ability to pay.

Comments on section IV.B.5: Contingent valuation

The statement that in-person and telephone survey modes are preferred is too restrictive. Most modern survey textbooks recognize each survey mode (in-person, telephone, mail, internet and mixed mode) has advantages and disadvantages for different types of applications based on sampling, information presentation, clarity, cost and other criteria. OMB's preference for in-person or telephone survey modes for contingent valuation is too broad and unfounded. Which survey mode is best for a given application should be decided on a case-by-case basis. A judgment must always be made about how to obtain information adequate to support regulatory decision making given limited research resources. In-person surveys are very expensive, and that expense may not be justified in many cases, as illustrated by the primary use of mail for the U.S. Census – the single most important national survey. Sampling issues are not the only factors that need to be considered in the survey mode decision and there are sampling issues with each mode (e.g., lack of access for in-person interviews, no answer on telephone surveys). Moreover, the potential significance of sampling issues with each mode can be reduced by careful planning and quantitatively assessed if the survey process is designed appropriately. Needs of the survey instrument design are also key issues in selecting a survey mode. For example, if detailed information needs to be presented and visual aids are needed to support respondent comprehension, telephone surveys may be a poor choice. Other instrument design issues include customization needs for respondent circumstances and question branching.

Stressing that contingent valuation studies must meet rigorous sampling and response rate protocols ignores the reality that imperfect sampling exists in nearly all the sources of information used in the regulatory analysis process. For example, many wage-risk studies from which some VSL estimates are obtained are based primarily on blue collar labor markets. Epidemiology and toxicology data are often extrapolated from less than random national samples. Similarly, weights used to adjust for quality differences when calculating QALYs are also often based on nonrandom samples of respondents. Very few studies in any field are based on national probability samples. Quantitative information to support regulatory impact assessments is a scarce commodity; analysts need to have the flexibility to make reasonable use of available information while recognizing the limitations of that information. I see no reason why contingent valuation studies should be held to a higher standard than other studies used in the assessment process or why contingent valuation studies are being singled out in this document.

Comments on Section IV.B.8.b. Premature mortality risks

This discussion makes reference to associated monetary values for statistical lives saved and statistical life-years saved. The available economics studies provide WTP/WTA values for changes in mortality risk. This literature provides estimates of utility-based value of statistical life (VSL). This literature does not provide utility-based value of a statistical life-year (VSLY). Simply dividing the VSL by the average number of expected life-years (or discounted life-years) remaining for the sample from which the VSL was drawn is only valid if it has been demonstrated empirically that VSL varies in proportion to remaining life expectancy. If this is not the case then there is no reason to expect that the value per life-year remaining is constant throughout a person's life cycle. Empirical data on this are limited, but new studies (e.g. Krupnick, Alberini, Cropper, Simon, O'Brien, Goeree, and Heintzelman, "Age, health and the willingness to pay for mortality risk reductions: a contingent valuation survey of Ontario residents," *Journal of Risk and Uncertainty* 24:161-186, 2002) support previously available evidence (e.g., Jones-Lee, Hammerton, and Philips, "The value of safety: results of a national sample survey," *The Economic Journal* 95:49-72, 1985) that this assumption is not correct. Results from these studies suggest such a calculation of average VSLY for the whole study sample would tend to undervalue the remaining life expectancy for those older than the average age, and overvalue remaining life expectancy for those younger than the average. Thus, a VSLY obtained in this way should not be considered a WTP value for a life-year for anyone other than the average age person in the population for which the original VSL estimate was obtained. Scaling VSL according to remaining life-years (or discounted life-years) implies assumptions that are contradicted by available evidence and should not be done.

Sincerely,

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