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To: Lorraine D. Hunt OIRA ECON GUIDE/OMB/EOP@EOP

cc:
Subject: Comments on OIRA Draft Economic Guidelines for Regulatory Impact Analyses

Dear Ms. Hunt:

Please find attached my comments on the Draft Economic Guidelines.

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- OIRA Guidelines.doc

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The following are my comments on the OMB Draft Guidelines for the Conduct of Regulatory Analysis and the Format of Accounting Statements (Appendix C to Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations):

General Comments:

This document lays out a comprehensive, clear, and valuable framework for presenting information about the anticipated health and economic consequences of proposed Federal regulations. The framework embodies several key features that foster more informed and transparent decision making.

One key feature of the framework is its emphasis on "meticulous accounting" of health, environmental, and economic impacts in a disaggregated accounting format. This format permits decision makers and the general public to examine the consequences and costs in a form that does not impose any particular set of weights or values. This requirement for disaggregated presentation of costs and consequences over time is valuable because, despite much progress towards consensus among economists and public health professionals regarding appropriate forms of economic evaluation, there remain significant controversies, for example surrounding the use of cost-effectiveness analysis and cost-benefit analysis, and the appropriate rate of discounting.

Another key feature is the requirement that for regulations that affect public health and safety, both cost-effectiveness analysis, using life years or quality-adjusted life years as the effectiveness measure, and benefit-cost analysis, using willingness-to-pay values of health improvements, be performed. Cost-effectiveness analysis is the preferred method for evaluation of health care programs, and a set of "reference case" methods and assumptions have been formulated for the U.S. Public Health Service by the Panel on Cost-Effectiveness in Health and Medicine. Cost-effectiveness ratios calculated using the reference case approach can be compared to one another and thereby reveal how programs compare in terms of their efficiency in the use of resources to produce health improvements. Comparisons of health-improving efficiency across domains of regulation and public health are important elements of information in decision making, although – as the Guide emphasizes – cost-effectiveness should not be used as the sole criterion for regulatory priority or resource allocation. Benefit-cost analysis using willingness to pay can also provide useful information by assigning economic value to health outcomes and thereby permitting a calculation of net economic benefit. However, measures of willingness to pay have serious measurement problems, whether they are based on revealed preference or on stated preferences in surveys. Moreover, willingness to pay is influenced by citizens' ability to pay for their own health risk reduction, which may result in more weight being given to lifesaving or health improvements later in

life when wealth is greatest. In practice the WTP method tends to ignore or understate the relative value people attach to risk reductions for family members or others in the community, relative to their own risk reductions, and this may tend to distort the relative values placed on different age groups or health conditions. Because of its theoretical strength, and its widespread acceptance among environmental economists, benefit-cost analysis using willingness to pay deserves to be placed at center stage *along with cost-effectiveness analysis using life years or quality-adjusted life years* in summarizing the economic evaluation of proposed regulations.

A third key feature of the Guide is its requirements for sensitivity analysis in a number of areas. Different estimates of the consequences of regulations, and different estimates of value parameters such as the weights attached to various nonfatal health states (in QALYs), the discount rate, and the value of statistical lifesaving or statistical life extension, all should be incorporated into the presentation of findings of a regulatory impact analysis.

Finally, the Guide calls for explicit analysis of the probabilities of different sets of health consequences and costs, and formal probabilistic analysis is mandatory for regulations having an economic impact exceeding $1 billion. Probabilistic analysis can be a useful tool for decision makers, because it can reveal whether investment in more information to resolve or inform a key area of uncertainty is worth the cost, and whether a delay in action may be justified. This is an important principle of decision analysis: decisions between alternative actions may best be delayed if the expected value of additional information exceeds the cost of obtaining the information plus the expected cost of delay. Often a decision whether or not to delay a program or regulatory action is viewed contentiously by advocates and opponents of regulation, when in fact a good analysis, informed by explicit assessments of key probabilities, can be used to articulate the rationale for or against delay. By exposing the explicit assumptions that underlie such a decision, parties can debate the evidence surrounding the probabilities of consequences, the quality of the information obtained, and the values attached to the consequences and costs.

Specific Comments:

Introduction:

1. The emphasis on transparency in detailing assumptions and values in a "regulatory accounting statement" is excellent.

2. "Where all significant benefits and costs can be quantified and expressed in monetary units, benefit-cost analysis provides decision makers with a clear indication of the most efficient alternative…" At some level, this statement is true. The question is what is the standard for determining whether significant benefits and costs *can be* expressed in monetary units. There is considerable controversy as to whether this can be done reliably for environmental and health outcomes. In theory, willingness to pay provides the answer, but there are problems that may limit any empirical assessment. For example, have the values people attach to the lives or health of others been measured? Have the option values for future generations been measured adequately? Can we believe surveys of stated willingness to pay? Do revealed preference studies rely too much on the assumption of full information and rationality, and are there problems extrapolating from groups of workers in high-risk

occupations? These are just some examples of the practical problems with implementing benefit-cost analysis. The point is that there is a necessary judgment of whether monetary values of significant outcomes are measurable; that this judgment is often controversial should be acknowledged here. Implicitly, it is acknowledged throughout the Guide, and reflected in the requirement for cost-effectiveness analysis and for meticulous accounting.

I.A.3.

Another reason that consumers may not be sufficiently informed to make optimal decisions in the private market is that technical information may be involved, as in medical care. Where the required information is technical and complex, consumers making their own decisions may not be optimally informed. If consumers entrust their decisions to informed agents such as physicians or insurers, incentives to these agents may not align with those that would lead to optimal decisions for consumers.

III. Introduction

1. The recommendation for both CEA and BCA is appropriate in situations where the primary benefit is health improvement. The implication that CEA is not required when health change (either improvement or diminution) is a minor consequence is also appropriate.

2. There is a problem with the statement that "if *some* [emphasis added] of the primary benefit categories cannot be expressed in monetary units, you should also conduct a CEA." What if there are two or more such benefit categories (e.g., health and environmental preservation)? Which one would be the effectiveness measure in a CEA? CEA is best suited to situations where there is a single effectiveness measure, or where multiple effectiveness measures can be combined (for example, different dimensions of health combined into quality-adjusted life years). Approaches in such circumstances might be (1) to report the accounting framework only, or (2) to monetize one of the major benefit categories, leaving the other as the effectiveness measure in a CEA.

III.B.

1. More guidance is needed on how to perform incremental cost-effectiveness analysis correctly. This is one of the most widely misapplied concepts in economic evaluation, and needs careful explanation. For example, explain that it is never correct to calculate costs and effects relative a "null" alternative of zero cost and zero effect. Explain concepts of strong and weak dominance, and give guidance on how to report results of incremental CEA (Gold et al., 1996 offers some suggestions.)

2. More guidance is needed on the importance of avoiding double counting of effects in both the numerator and denominator of a cost-effectiveness ratio. For example, it is incorrect to assign monetary value to life extension if life years are used as the effectiveness measure in the denominator. Handling of productivity gains and losses is more difficult and controversial, but for the time being the recommendation of the Panel on Cost-Effectiveness in Health and Medicine is to not monetize productivity gains if the

QALY weights reflect the value of income lost, and if the lost income is judged to be a (nearly) complete measure of the economic cost of the lost productivity.

3. A statement should be made that, in CEA, effectiveness measures that are valued outcomes are preferred to intermediate outputs such as tons of pollution, crashes avoided, or cases of disease averted. These intermediate endpoints (or waystations) have many valued aspects, with economic, environmental, and health values attached to them. These different dimensions of value should be sorted out and valued in their appropriate units, including dollars for economically valued consequences. In order to facilitate comparisons of cost-effectiveness findings across programs, common denominators should be encouraged, and QALYs represents the best available health preference measure for that purpose.

IV.A

This is a very important section. The emphasis on incremental analysis, and the selection of a sufficiently wide range of comparator options, is vital. But see comment #1 under III.B.1. Inexperienced practitioners of CEA will need more guidance on how to avoid some of the common pitfalls in incremental CEA.

IV.B.1

1. More guidance is needed concerning the sources of the probability distributions. Probability distributions may be derived from sampling errors in empirical investigations, parameter uncertainty in models used to extrapolate from one setting to another (for example, animal toxicity to humans), and judgmental uncertainty about unverifiable events such as future climate change or bioterrorist attacks, or about the validity of unverifiable causal models. It should be stated that all such sources of uncertainty should be reflected in an overall probability distribution for an input to a CEA or BCA. Analysts should be cautioned against making the uncertainty range too narrow, for example by assuming that sampling error is the only source of uncertainty. At the same time, the legitimacy of expert judgment, ideally elicited through validated structured opinion elicitation methods such as the Delphi method, should be reinforced.

2. In constructing probability distributions for several parameters, care should be taken to reflect dependencies between parameters. For example, the amount of global warming under two regulatory options may be modeled as separate distributions of mean temperature change, but these are not independent distributions, since they depend on many common factors. It is often possible to transform the parameters so that they are independent; for example, one distribution might be attached to the temperature change under the status quo scenario, and an independent distribution could then be assigned to the increment or decrement (either additive or multiplicative) from this baseline.

3. As a way of presenting results of formal probabilistic analyses of CEAs, the methods of acceptability curves and net health benefits should be suggested. Both are described in: Briggs, Andrew H., “Handling Uncertainty in Economic Evaluation and Presenting the

Results", in (Drummond, Michael F, and Alistair McGuire, Eds.) *Economic Evaluation in Health Care: Merging Theory with Practice*. Oxford, UK: Oxford University Press, 2001. Distributions of C/E ratios are problematic and should not be used, because of ambiguities of sign and problems near zero net benefit or zero net cost. For BCAs, presentation is more straightforward, as a distribution of net benefit.

IV.B.2

Although WTP and WTA are approximately equal in theory, they are often dramatically different in practical elicitation experiments. The implication is often stated that the choice of which one to use should depend on the property rights context. But this is not a satisfactory answer, since these widely diverging compensating variations are plainly inconsistent, provided that the change in the underlying risk is relatively small. Differences between WTP and WTA could be regarded as evidence of a framing effect, thus suggesting caution in their use.

IV.B.8.a

1. There is quite a lot of information in the Guide on how to derive a value of statistical life for BCA, but only one very sketchy paragraph on health utility measures of CEA. Perhaps there could be more guidance on the following:

    a. available preference-weighted utility scales, such as the Health Utilities Index (HUI-3), the EQ-5D, the SF-6D, the QWB, and the FCI;

    b. methods for eliciting health-state weights (embedded in the above utility scales) – the limits and advantages of rating scales, time-tradeoff, standard gamble, and person tradeoff.

2. There should be some discussion of the importance of using life years, rather than lives saved in CEA. Lives are never "saved"; they are only extended.

IV.C

1. A real discount rate of 7 percent seems high, even as an upper bound. The argument in favor of this rate is that it may correspond to some estimates of long-term, pre-tax, returns on investment in the private sector. It can be questioned whether it is plausible as a long-term, real return on investment either in the long-term past or looking into the long-term future. Even accepting 7 percent for this purpose, the economic literature favors a shadow price of capital approach, in which the rate of discounting is derived from the implications of foregone investment opportunities for future consumption. Even if investments could earn 7 percent, the returns would translate to consumption opportunities, which should then be discounted at the social rate of time preference, i.e., 2-3 percent.

2. A real discount rate of 3% is actually at the high end of recent estimates of the long-term, riskless, real rate of return on debt instruments. Current thinking supports discount rates of 2.5-3% (see Gold et al.).

3. Some practitioners may need guidance in how to calculate annualized values correctly.

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