Developing Guidance for Regulatory Analysis: Challenges and Opportunities

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"You will find that you cannot conduct a good regulatory analysis according to a formula. Conducting high-quality analysis requires competent professional judgment."

- U.S. Office of Management and Budget (2003)

Benefit-cost analysis is mandated for major Federal regulations and often conducted to support the development of other regulations and policies. However, few agencies provide comprehensive official guidance on its implementation. In this paper, we review the guidance available and discuss the advantages as well as the barriers associated with its creation.[2] Drafting guidance appears worthwhile, given its potential to promote higher-quality and more wide-spread analysis and encourage evidence-based decision-making, assuming it is carefully developed and periodically updated to reflect the best available research. Regulatory analysis often entails exercising good judgment to address data gaps and inconsistencies; guidance can aid analysts in making such judgments by identifying appropriate methods and criteria for evaluating relevant research.

1.0 Current Guidance

Under Executive Order 12866 (Clinton 1993), as supplemented by Executive Order 13563 (Obama 2011), U.S. Federal agencies must assess the costs, benefits, and other impacts of significant regulations before they are promulgated, and must also assess alternatives if annual economic impacts are expected to be $100 million or more. The U.S. Office of Management and Budget (OMB) in the Executive Office of the President is responsible for reviewing the regulations and the accompanying analyses before they are finalized.

Despite these requirements, such analyses are completed for only a subset of all major regulations. In a recent Report to Congress (OMB 2014), OMB lists nine agencies that issued one or more rules over the previous 10 years that both exceeded the $100 million threshold and were accompanied by an analysis that quantified a substantial portion of their benefits and costs.[3] The list includes 116 rules, of which 34 were issued by the U.S. Environmental Protection

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[2] This paper is based on our personal experiences with conducting these analyses, developing methods and guidance documents, and teaching related courses. Our goal is not to critique the available guidance; rather we focus on issues related to its development. The views we express are our own and do not reflect the views or endorsement of any Federal agency.

[3] Independent regulatory agencies, such as the Consumer Product Safety Commission, the Nuclear Regulatory Commission, and the Securities and Exchange Commission, are not subject to OMB oversight and hence are not included in these counts nor in the discussion that follows. However, these agencies generally follow analytic practices similar to those discussed in this paper and some have developed related guidance.

Agency (EPA), 28 by the U.S. Department of Transportation (DOT), 18 by the U.S. Department of Health and Human Services (HHS), and 14 by the U.S. Department of Energy. Over the same time period, OMB reports that 569 major rules were submitted for review, which suggests that the vast majority (453) were not accompanied by a reasonably complete benefit-cost analysis. (Several may be transfer rules for which such analysis is not necessarily required.[4]) Reviews of the available analyses (e.g., Hahn and Dudley 2007, Harrington et al. 2009, Fraas and Lutter 2011, Ellig et al. 2013) also suggest many ways in which they could be expanded and improved.

These data raise questions about why more comprehensive benefit-cost analyses are not developed for more of these regulations. One contributing factor may be the difficulties inherent in conducting such analysis, which relate both to the technical challenges and to the time and resource constraints under which Federal agencies generally operate. Analytic guidance can help ameliorate these concerns by describing the methods that should be applied, the criteria that should be considered in evaluating the available data and research, and the assumptions and values that should be used for key parameters. However, relatively little such guidance is available. Historically, only OMB, EPA, and DOT have issued formal, publicly-available guidance; HHS is now developing guidance for its rulemakings.[5]

The existing guidance varies substantially in both depth and breadth. The 48-page 2003 OMB guidance (contained in Circular A-4) is relatively general. It is now becoming outdated, given the evolution both in the methods used to estimate various types of impacts and in the available empirical research. At 300 pages, EPA's guidance is more detailed and comprehensive, which seems unsurprising given that its regulations are a substantial fraction of those subject to the analytic requirements in terms of both the number of rules and the magnitude of their impacts. EPA finalized its most recent guidelines in 2010, adding a new chapter in 2014. DOT's guidance is much narrower, targeting two benefit categories. The most recent (2014) updates include a 12-page discussion of the values to be used for fatal and nonfatal injuries and a 29-page discussion of the valuation of travel time. DOT-wide guidance on other analytic components is not available.[6]

Benefits valuation is a major focus of all three agencies' guidance, presumably because of the difficulties inherent in valuing outcomes (such as health risk reductions and environmental improvements) for which market prices are typically unavailable. The approaches in each guidance document differ somewhat, however. OMB focuses on the principles analysts should consider when selecting among methods and studies, providing agencies with flexibility rather

[4] Benefit-cost analysis is not necessarily required for transfer rules under the assumption that moving money from one organization or individual to another does not impose significant resource costs. However, agencies are expected to consider whether transfer rules lead to behavioral changes that are significant enough that benefit-cost analysis is warranted.

[5] We focus on guidance targeted specifically on the benefit-cost analyses required under Executive Orders 12866 and 13563, rather than solely addressing other regulatory impacts (such as information collection burdens or effects on small businesses).

[6] DOT has issued benefit-cost analysis guidance for its Transportation Investment Generating Economic Recovery (TIGER) grant program, but this guidance was not designed to apply to its regulations.

than mandating specific values.[7] EPA provides a more detailed review of the advantages and limitations of various benefit valuation approaches, recommending a specific estimate solely for the value per statistical life (VSL) as discussed below. The DOT guidance is more prescriptive, mandating the use of specific values and describing their derivation. Only EPA provides detailed guidance on assessing costs, focusing on the types of costs likely to be associated with its regulations.

Analytic guidance is needed in part because the textbooks used in academic courses are not sufficient to guide agency analyses, although they provide substantial useful information. For example, Boardman et al. (2011) is one of the most widely-used and well-regarded benefit-cost analysis texts. At 541 pages, its coverage of both theory and practice is substantially broader than even the EPA guidance. However, the amount of time that elapses between when a textbook is developed and when it is published and used means that the research it presents is often outdated. In addition, such texts generally address analyses conducted in numerous contexts and are not necessarily able to delve in detail into the issues of concern to a particular regulatory agency. While such textbooks may offer recommendations, they reflect the judgement of the authors, which may incorporate differing considerations than would an agency decision.

The valuation of mortality risk reductions, conventionally expressed as the VSL, provides an important example, in part because such risk reductions often account for a major share of the quantified benefits of regulations subject to the analytic requirements. OMB allows agency discretion to apply the VSL estimates that are most appropriate for their regulations. The two agencies that have issued formal VSL guidance, EPA and DOT, rely on entirely different sets of studies. If updated to 2013 dollars, the central values are practically identical, however: $9.4 million and $9.2 million for EPA and DOT respectively. The variation in the studies considered, and in the estimates, reflects differing decisions about which methods to emphasize, what studies to include, and when to update the guidance (see Robinson and Hammitt 2015a, 2015b for more discussion). The EPA value is based on a literature review published in the early 1990s, while the DOT value is based on a review completed in 2013. EPA has developed several proposals to revise its estimates and better tailor them to address environmental risks, consulting with numerous expert panels, but has not yet issued an update.[8]

In contrast, the Boardman et al. (2011) text recommends a value of $5.0 million, with a range of $2.4 million to $7.2 million (2008 dollars), based on four meta-analyses published between 2000 and 2006. If inflated to 2013 values, the central estimate becomes $5.4 million, much lower than the values now recommended by Federal agencies. These meta-analyses were criticized by two EPA expert panels (EPA 2006, Cropper et al. 2007), who indicated that they were not of sufficient quality to be used as the basis of estimates applied in regulatory analyses.

[7] One exception is discounting; OMB recommends that the results be presented using a 3 percent and a 7 percent rate as well as undiscounted, but allows analysts to also present the results using other rates if justified. OMB has also issued separate guidance on the social cost of carbon (https://www.whitehouse.gov/omb/oira/social-cost-of-carbon).

[8] Because these values are likely to vary depending on the characteristics of the risks and of those affected, ideally each agency would use values tailored to the risks it regulates. However, the existing research is not sufficient to fully support such tailoring.

DOT concurred with this judgement when drafting its current guidance, and relies on individual studies rather than the available meta-analyses. Thus the methodological judgments made by the textbook authors differ from those made by the experts advising the agencies, perhaps in part because of the timing of the development of the recommendations as well as the agency-specific context in which the estimates would be applied.

In addition to illustrating the effects of differing judgments about the quality of the available studies and their applicability, this example is significant because the VSL is relatively well-studied, unlike many analytic inputs. Where more substantial gaps and inconsistencies in the research base exist, these types of judgements may be of even greater importance, requiring careful review and evaluation of the options and clear communication of associated uncertainties. Guidance on what factors to consider in conducting such reviews and in applying the results in various regulatory contexts is likely to be very useful.

2.0 The Costs and Benefits of Guidance Development

The costs of creating guidance seem largely self-evident. Like any effort, diverting staff and other resources to guidance development imposes opportunity costs. These resources will not be available for alternative productive uses, such as supporting other aspects of the agency's mission. EPA's and DOT's guidance development process, as well as the HHS process now underway, spanned several years. These processes generally involve substantial effort to identify the topics to be addressed, review the relevant theoretical and empirical literature, develop draft guidance, subject it to review by internal and independent experts, resolve areas of disagreement, and ultimately finalize the document. We are not aware of an all-inclusive estimate of these costs, but expect it would be in the hundreds of thousands of dollars if the guidance is to be reasonably comprehensive.[9]

The benefits are even more difficult to quantity, but may be significant – given that these analyses help agencies make better choices for regulations that each typically involve national impacts exceeding $100 million annually. For example, if an analytic improvement attributable to the guidance alters one regulatory decision so that net benefits increase by $1 million (less than one percent of the quantified impacts), the impact of that decision alone could be viewed as justifying the guidance development costs. More specifically, the benefits of developing guidance relate to increasing the amount of information available as well as its consistency and quality, as discussed below.

Executive Orders 12866 and 13563 indicate that the goal of these analyses is to explore whether regulatory costs are justified by the benefits (both quantified and unquantified) and to ensure that the selected option maximizes net benefits to the extent allowable under statute. However, the summary measure (net benefits) is only one of many types of data these analyses provide. The analytic process often unearths substantial useful information related to effectively implementing the regulation as well as to understanding its impacts. Research conducted to

[9] We discuss less tangible costs at the end of this section.

support the analysis may lead, for example, to better understanding the availability and effectiveness of relevant technologies, the characteristics of the individuals or entities likely to bear the costs, and the extent to which individuals with different characteristics are likely to be exposed to a hazard and may experience adverse health effects. The analysis may aid decision-makers in anticipating policy impacts that would otherwise be unexpected, including potential sources of support and opposition.

Guidance can increase the extent to which these types of information are available by making it easier to conduct the analysis and clarifying related requirements, which in turn may encourage agency staff to assess a larger fraction of agency regulations as well as to develop more complete analyses. Such guidance can provide an analytic template as well as information on methods, assumptions, and values.

Perhaps a more obvious benefit of developing guidance is that it increases analytic consistency and comparability. Generally, a regulatory analysis considers options for addressing a single, narrowly-defined policy goal (reduce emissions of pollutant "X," decrease foodborne illnesses from consumption of "Y"). In the absence of guidance, each analysis may rely on different methods and assumptions and report inconsistent summary measures. In addition to creating more consensus on the most appropriate methods, the guidance may be used to provide a standard set of assumptions and values for key parameters that becomes a reference case for comparison across regulations, as is the case with the current guidance on cost-effectiveness analysis in health and medicine (Gold et al. 1996). Ideally, the guidance would also allow analysts to present the results using alternative sets of assumptions, if well-justified given the characteristics of the particular regulation. Policymakers can then review the findings across policies without the distortion caused by the use of differing methods and assumptions, while also considering how alternative analytic approaches affect the conclusions.

Other benefits relate to the quality of the analysis. Responsible agency staff often have undergraduate or graduate degrees in economics, yet our (informal) searches suggest that most benefit-cost analysis courses are taught in public policy programs rather than economics departments. Full-term courses in benefit-cost analysis seem relatively rare; frequently such analysis is introduced in a few sessions within a broader course (e.g., in micro-economics or environmental policy) rather than explored in-depth. In addition, real world analysis is usually messier than the textbook approach, involving difficult decisions under the stress of time pressures and resource constraints as well as problems related to data availability. Thus many analysts arrive at the agency with little directly-relevant training. Engaging in the guidance development process and participating in whatever formal training is subsequently offered aids in expanding their knowledge and abilities, supplementing the significant educational role of the guidance document itself. Such training is particularly important given the role of professional judgment in conducting these analyses.

Another factor that affects analytic quality is the substantial effort that typically goes into developing best practice recommendations for inclusion in the guidance. Drafting guidance generally involves a deliberative process that includes careful review of theory, methods, and the

empirical literature, involvement of analysts from throughout the agency as well as outside experts, and independent peer review. The results ultimately increase the validity and reliability of the analysis itself as well as the likelihood that the results will be accepted by stakeholders and others. By developing consensus on how cross-cutting concerns should be assessed, this process also frees-up resources to address other issues of importance within the context of a particular analysis. For example, the availability of agency-wide VSL guidance means that analysts can concentrate on valuing other (regulation-specific) impacts, rather than devoting time to determining what VSL estimate to use. Criteria for selecting among methods and among studies also enable analysts to concentrate on which specific models and estimates to apply, rather than needing to first address broader methodological issues.

This process also focuses attention on those areas where more work is needed, identifying inputs that may significantly affect the analytic conclusions but for which the available research is dated, of low quality, or inconsistent. The agency can then highlight these areas for future work, both as part of its own research programs and independently. For example, our work has indicated the need for more primary research on the value of time (including its use for market and nonmarket production as well as leisure), of nonfatal illness and injury risk reductions, of ecological risk reductions, and of how costs initially imposed on industry are distributed across income groups. Given the large number of transfer rules, more work on the extent to which associated behavioral changes are likely to affect resource use and social welfare more generally also seems desirable.

If our assessment of the net benefits of developing guidance is accurate, why hasn't more guidance been created? Our guess is that the lack of guidance in part reflects the limited extent to which agencies follow the analytic requirements in Executive Orders 12866 and 13563, as suggested by the statistics provided earlier. This limited implementation may in turn reflect the significant resource constraints under which Federal agencies operate, and their desire to focus on program delivery and other activities with more direct and immediate impacts. In addition, the guidance development process is difficult, requiring that those involved set-aside time from other pressing tasks and engage in discussion of numerous difficult issues. The development of guidance inevitably means that the preferences of some analysts will be overridden, and places limits on the extent to which individual analysts can exercise discretion.

In sum, the opportunity costs of guidance development appear to be outweighed by the potential benefits, which include encouraging the provision of useful information, increasing the consistency and comparability of the analyses, and improving their quality. These factors in turn aid in communicating the data, assumptions, and analyses considered in the decision-making process, and help decision-makers and stakeholders clarify areas of agreement and disagreement. However, overcoming the barriers to development of such guidance may require significant effort.

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