Risk-Based Regulatory Reform and Public Participation

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AND
PUBLIC PARTICIPATION

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Abstract -- Meaningful public participation has been perceived as difficult to accommodate in regulatory proceedings requiring technical scientific judgments, especially those involving quantitative risk assessments. Quantitative risk assessment, however, is not a purely technical exercise, but instead involves the application of policy preferences in the form of assumptions, extrapolation from animal data to humans and high to low doses, management of incomplete data sets, and resolution of scientific uncertainties. Such junctures at which policy preferences are applied are opportunities to reflect social value choices that are not wholly "scientific." Those opportunities should be explicitly identified as such by the regulator. These considerations argue for a "soft" form of risk assessment that expressly takes societal values into account. Non-adversarial, consensus-based mechanisms of public participation that encourage greater dialogue and interaction among interested parties and with the regulator may enhance the potential for non-scientific social values effectively to be accommodated in regulatory proceedings with a heavy technical component.

I. INTRODUCTION

An underappreciated "sleeper" issue in the regulatory reform debate has been the role of public participation. While the issue of meaningful public input into highly technical regulatory decisions has been recognized for some time, the heavy emphasis on risk assessment in recent regulatory reform proposals [1-4] sharpens this debate far more acutely than in the past. Accordingly, this paper first discusses the utility of quantitative risk assessment methodologies from a scientific point of view. The application in quantitative risk assessment of policy preferences is then identified in such areas as dealing with scientific uncertainty, managing incomplete data sets, extrapolating from animal data to human beings, and extrapolating from high to low doses. After observing that the implicit inclusion of policy preferences in quantitative risk assessments is consequently inevitable, the paper then examines the implications of that conclusion for public participation in regulatory proceedings involving complex scientific judgments.

II. LIMITATIONS IN RISK ASSESSMENT METHODOLOGIES

One of the touchstones of the regulatory reform debate has been an emphasis on "sound science." As applied, this stress on scientifically-based decision-making has translated into a heavy reliance on quantitative risk assessment [5]. In particular, proposals for legislative action that have recently been considered have utilized quantitative risk assessment and comparative risk assessment as screening tools, or preconditions to regulation -- a "gatekeeping" function. This intense focus on quantitative risk assessment as a rigorous condition precedent to regulation invites an inquiry into the extent to which quantitative risk assessment is strictly value-neutral and objectively "scientific."

The quantification of risks as a regulatory policy tool received significant impetus from the National Academy of Sciences's "Red Book" [6], published in 1983. The Red Book endorsed a bifurcation of the regulatory process into two phases: "risk assessment," which in principle establishes the strictly scientific basis for regulatory action; and "risk management," which is the multidisciplinary process of choosing regulatory measures. As described by the Administrator of the Environmental Protection Agency (EPA) at the time,

[1]risk assessment is an exercise that combines available data on a substance's potency in causing adverse health effects with information about likely human exposure, and through the use of plausible assumptions, it generates
an estimate of human health risk. Risk management is the process by which a protective agency decides what action to take in the face of such estimates. Ideally the action is based on such factors as the goals of public health and environmental protection, relevant legislation, legal precedent, and application of social, economic, and political values [7].

In this two stage methodology, scientific questions can supposedly be isolated and addressed in an objective matter through risk assessment methodologies at the beginning of the regulatory process. Pure policy choices are supposedly confined to the second place, risk management. At this stage, science may be relevant for such tasks as evaluating technical options. Risk management decisions, however, also engage other considerations, most notably social values.

Risk assessment is a tool for analyzing empirical data in a manner useful for crafting regulatory policy. Those data may be produced by epidemiological studies that survey exposed human populations. However, in most cases toxicological tests on laboratory animals are the only source of relevant data. This empirical information, whatever its source, must then be extrapolated to actual environmental settings, which may be very different from those under which the data were collected. For instance, animal tests are ordinarily conducted at high doses and over a short period by comparison with the levels to which human beings typically experience long-term exposure to environmental toxins. These inferences, while necessary because of limitations on data gathering in both humans and animals, inevitably introduce uncertainty into any risk assessment. Additionally, this extrapolation necessarily requires inferences, choices, and assumptions that themselves reflect policy preferences, an area sometimes known as "science policy" [6, 8].

The inherent limitations in the utility of the quantitative risk assessment methodology are multiplied when applied to "comparative risk assessment," in which multiple risk assessments are compared. Risk estimates reduced to a single number, even one modulated by a quantified range of uncertainty, often cannot be compared. For one, the metrics for comparison may diverge on such issues as whether risks are summed over a lifetime of exposure. For example, the frequently quoted risk of one in nine of developing breast cancer refers to the likelihood that a woman will contract the illness at some time over her entire lifespan. Second, synergistic effects may not be reflected in a risk assessment for a single substance. The nature of the risks from various substances themselves often cannot be equated. For instance, the likelihood of non-cancer neurological effects in children from low-level lead exposure are relatively certain, nondichotomous, and directly correlated to the level of exposure. By contrast, risk estimates of carcinogenicity embody much more of a probabilistic concept, addressed to the likelihood of effects in the relatively distant future and not to the severity of the illness.

Serious data gaps for even the most highly suspect bad actors can seriously affect the confidence level of individual risks assessments and undermine their "comparability." Reducing an incomplete data set to a single number does not necessarily generate any additional insight into the effects of the substance involved. Indeed, such an approach may well mask significant underlying uncertainties. For precisely this reason, policy-makers have been discouraged from precisely defining "point estimates" of risk, and instead encouraged to offer a range of risks commensurate with the integrity of the underlying data set. As an influential publication of the National Academy of Sciences recently observed, "risk ranking under uncertainty is a complicated and error-prone process, regardless of whether conservative, average, or other point estimates are used to summarize each risk" [9].

Although at first blush comparative risk assessment may be appealing in a somewhat milder form for establishing regulatory priorities, as has often been proposed, such an approach if anything raises even more profound questions. Establishing regulatory priorities inevitably and necessarily engages issues that in a single regulatory proceeding might be considered within the domain of "risk management:" the involuntary or voluntary character of exposure to the risk; the extent to which the risk is concentrated in particular populations; the potential for catastrophic harm even if the long-term, chronic risk is low; the availability of technological options to reduce or eliminate the risk; the necessity for collective or governmental action as opposed to individual responses; the kind and degree of collective action required — e.g., labelling as opposed to an outright ban; the extent to which the costs of regulation may be unevenly distributed; the administrative resources likely to be required to reduce or eliminate risks; and the political acceptability of likely public policy responses.

III. SCIENCE AND VALUES IN RISK ASSESSMENT

Much of the public debate over comparative risk assessment has been driven by allegations of the incoherence of existing regulation. Many of these accounts are anecdotal in nature, are questionably motivated, and do not necessarily withstand close scrutiny [10, 11]. Consequently, the scope of the "problem" is far from clear.

Nonetheless, there is a widespread perception of the need for alternative, scientifically-based decision-making tools, and especially those that can be used to establish a hierarchy of
priorities. The apparent power of the comparative risk assessment methodology from this perspective is undeniable. Against this background, many of the admonitions about the scientific limitations of comparative risk assessment have been ignored rather than heeded by enthusiastic supporters of the approach. Quantitative risk assessment and comparative risk assessment are increasingly utilized by regulatory agencies even as the methodologies are being elaborated. While methodological limitations need to be kept firmly in mind, suggestions for incremental improvement, as opposed to wholesale abandonment, are also needed.

A. Quantitative Risk Assessment

As discussed above, the utility of quantitative risk assessment from a scientific perspective -- as "sound science" -- is limited by uncertainty, incomplete data sets, the need for assumptions, extrapolation from animal data to human beings, extrapolation from high to low doses, and the like. Addressing these challenges is not a strictly scientific or technical issue, but instead reflects often unstated embedded policy preferences. As reinforced by the title of a recent influential publication [9], crafting a risk assessment involves not only science, but also the exercise of judgment at numerous decision-making points. If quantitative risk assessment is therefore less than completely value-neutral and objective, then there is a role for societal values even in this compartmentalized, scientific aspect of regulatory decision-making.

Many, if not all, of the junctures at which scientific judgment is required also necessarily engage social value choices, which not only can, but of necessity must, intrude into the supposedly purely scientific exercise of risk assessment. For example, the protracted debate over the use of "conservative" assumptions in risk assessments is, at least in part, an extended dialogue over social values. Similarly, the "precautionary principle," which counsels governmental authorities to err as a matter of public policy on the side of environmental protection in formulating public policy in contexts characterized by conditions of scientific uncertainty, may very well find application not only in risk management decisions but also in quantitative risk assessment. Indeed, in Europe there is a lively debate over whether precautionary approaches are, or should be, firmly grounded in science or should transcend scientific considerations.

There is no accepted quantitative methodology that prescribes those scientific inferences or regulatory outcomes that are appropriate under the conditions of incomplete or unavailable information that characterize many quantitative risk assessments. Indeed, it is very likely impossible to imagine a numerical calculus for anticipating the wholly unexpected or predicting the unpredictable, which could range from a minor deviation in expected outcome to a catastrophic event. Instead, the realm of scientific uncertainty requires the exercise of judgment and discretion from the perspectives of both science and public policy.

Attempting to deal with questions of scientific uncertainty through the exercise of judgment that is portrayed as purely "scientific" compounds perceived problems of accountability. By contrast, reconciling scientific uncertainties through approaches that take into account not only scientific considerations, but also social value choices, can be expected to enhance perceptions of legitimacy. Precautionary approaches, which do precisely that, have been criticized on occasion as a vehicle for rejecting science. Properly understood, however, an appropriate precautionary principle articulates a social preference against which uncertain science should be interpreted in a policy setting.

B. Comparative Risk Assessment

The role of social value choices in the ostensibly "scientific" process of risk assessment is particularly pronounced in the application of comparative risk assessment methodologies. As discussed in section II above, the endpoint of such exercises is a decision to consider risk-reduction measures in one area and not others, or a risk-based ranking that anticipates such a choice as part of a larger regulatory agenda.

An example chosen by Justice Stephen Breyer in his recent, influential book *Breaking the Vicious Circle* [12] demonstrates why this sort of sorting or ordering cannot be purely scientific, or even strictly risk-based no matter how broadly that term is construed. Breyer invites his reader, presumably an American citizen, to compare how governmental resources devoted to an overly zealous toxic waste cleanup in New Hampshire might be redirected to combat deforestation in Madagascar. Although Breyer suggests that the loss of forest cover on another continent is a compelling problem by comparison, there is no guarantee that the U.S. government's resources will have the slightest impact there. U.S. government officials may have little influence with those of a foreign state, which may, in turn, have its own priorities that do not include saving trees. Or, despite its best intentions, a foreign government may have little capacity to influence the behavior of those within its territory that are responsible for forest destruction. Under these circumstances, the United States as a society might devote significant governmental resources to a problem judged by experts or the public or both as immensely important with little or nothing to show for the effort.
More generally, public health and environmental objectives must be coherent with other social policies in order to be efficacious. If not, those aims will not be perceived as legitimate and the policy goals will remain unrealized. Public health and environmental protection initiatives consequently must mesh with the public's notions of the appropriate role of governmental action, or lack thereof, in fostering greater equity, economic advancement, and social justice. For example, the health costs of smoking or firearms accidents could be substantially reduced through outright prohibition on the manufacture and sale of cigarettes or handguns. Similarly, exposures to lead could be further reduced by banning most remaining uses of the metal, but a relatively explicit public policy compromise to protect the manufacture and sale of cigarettes or handguns.

The reason that such proposals are controversial, at least among the American public today, is that the other costs of those actions are perceived as highly detrimental to widely-held notions of public order and the appropriate role of governmental action. At least since Prohibition, outright bans of this sort have not frequently been advocated by even the most zealous public health champions. Prohibition itself is widely regarded as a failed effort to reduce the risks from alcohol consumption not because a ban on alcohol production and consumption was ineffective in achieving the public health goal, but because the public policy strategy employed diverged from underlying expectations and values in American society.

By contrast, genuine and meaningful public participation in bureaucratic decision-making, particularly those that are carried out by unelected officials in settings like administrative rulemakings, facilitates accountability to the public and the regulated community, informed choices by public authorities, and governmental efficiency [13-19]. In a highly technical setting, public participation is hence a strategic vehicle for enhancing the credibility of the regulator and the efficacy of its actions.

IV. PUBLIC PARTICIPATION IN RISK-BASED DECISION-MAKING

Much of the debate over risk-based regulatory reform has focussed on substantive regulatory outcomes. Considerably less attention has been devoted to the potential for the use of risk assessment as a screening or "gatekeeping" function to attenuate the legitimacy of regulatory actions. The emphasis on risk assessment and "sound science" in much of the current debate over regulatory reform increases the stakes dramatically from the point of view of bureaucratic accountability to a technically inexpert public.

A. Articulating Values in a Scientific Setting

Many critiques lament the lack of access by a technically inexpert public to decision-making processes with a high scientific component. The usual conclusion is a need for greater public education to assist a lay citizenry in providing more meaningful input. But to the extent that public debates can and should incorporate societal policy preferences, such as "solution" is only partially helpful. In particular, such a perspective inappropriately suggests that technical expertise is a necessary precondition to meaningful participation. If the art of risk assessment implicitly relies on hidden policy choices, as it does, then even technically "inexpert" or putatively "uninformed" inputs from the public can and should be accommodated through the process of public participation.

As discussed in sections II and III above, quantitative risk assessment is not, strictly speaking, objectively "scientific" and value-neutral. Risk assessments reflect policy choices implicitly but inherently embedded in those analyses. Consequently, there is an appropriate role even in the supposedly scientific process of risk assessment for social values as expressed in policy preferences. This suggests a two-fold, considerably stronger conclusion that is much more consistent with accepted notions of democratic government and accountability: First, the public's role in risk management phase. Second, risk assessments and, particularly, comparative risk assessments not only can, but should, acknowledge these social value choices. In other words, it is not just appropriate but necessary that even the most highly technocratic decisions made by government take into account the preferences and priorities of the public.

The accommodation of social value choices in risk assessments requires not only a reevaluation of public participation in regulatory decision-making, but also a redefinition of the purpose of technocratically expert decision-making in the first place. Risk assessment must respond to, and operate within the confines of, public preferences and priorities. Self-consciously and expressly reflecting policy preferences at appropriate junctures in a risk assessment is entirely consistent with the methodology. This suggests that the more appropriate way to view risk assessment is not as a scientifically rigorous endeavor, but instead to adopt what is sometimes called a "soft" approach that proceeds from the premise that risk is multidimensional and represents the confluence of a variety of public values and attitudes. A soft ranking of risks, therefore, would tend to be more
impressionistic than formulaic; it might use the number of fatalities as a rough starting point, but would modify the ranking by folding in various factors, such as the qualities of dread, mistrust, and uncertainty associated with each risk, the equity (or lack thereof) in how each risk is borne by various individuals and subpopulations, and the perceived benefits the risk substance or activity confers. According to the proponents of the soft version, the only way to incorporate such factors, and enhance the legitimacy of the resulting priorities or risk rankings, is to give the public equal stature with the experts from early stages of the analysis [20].

This insight in turn has important ramifications for the nature of regulatory processes involving technically complex considerations. It is unrealistic to view the purpose of such undertakings to be the determination of the "right" answer when there is no single scientifically valid outcome that exists apart from social value preferences. As one commentator has noted:

The job of the public administrator is not merely to make decisions on the public's behalf, but to help the public deliberate over the decisions that need to be made. Rather than view debate and controversy as managerial failures that make policymaking and implementation more difficult, the public administrator should see them as natural and desirable aspects of the formation of public values, contributing to society's self-understanding [14].

B. Consensus Models of Participation in a Scientific Setting

As one observer has documented, "few terms in our contemporary political lexicon have been used with so little semantic precision" as public participation [13]. While the precise content of the concept may not be entirely clear, so-called "notice-and-comment" or "informal" rulemaking is probably the most familiar example. Requirements at the federal level for public notice of proposed regulations, an opportunity for public comment on those proposals, and the necessity for agency response to public comments are intended to assure the responsiveness and efficacy of bureaucratic initiatives. Although ordinarily not required, federal agencies may also hold oral hearings at which citizens may testify. It is also critically important to bear in mind that public participation does not necessarily shift authority and control over the ultimate decision from a public authority:

The goal of public participation . . . is not to transfer the actual decision-making power over the formulation and adoption of rules to the interested public, but only to assure an adequate opportunity for interested persons to communicate their views and information to the appropriate . . . officials [16].

To the extent that risk assessment is less than rigorously scientific and value-neutral, it might appear that there is no reason why existing mechanisms for public participation cannot be used as vehicles to articulate public preferences. That said, there is no denying that regulatory issues that require scientific expertise are different. The particular inadequacies of existing avenues for providing input from a lay public in situations involving highly scientific or technocratic issues has been extensively documented [13, 14]. Despite the appellation "informal," notice-and-comment rulemakings even under the best of circumstances are frequently very rigidly structured often afford members of the public little real opportunity to influence the outcome of administrative decision-making processes. Those deficiencies may be magnified many times over in situations requiring extensive scientific expertise. As highly technocratic decision-making processes require more technical capabilities, there is a need for technically-skilled intermediaries, such as so-called "public interest groups," to represent broader public concerns. Rather than altering the fundamental dynamics of interest group interactions, "the increasing involvement of technical experts in policy disputes has politicized expertise" [13]. The simple fact is that the outcome of a risk assessment is of critical importance because that result inevitably tends to drive the remainder of the policy process.

The motivation for bifurcating regulatory processes into distinct and sequential risk assessment and risk management phases appears to have been improving the scientific integrity of such proceedings by insulating scientific determinations from non-technical considerations. But even those questions that appear to be strictly scientific can give rise to significant debate and controversy. Adversarial, quasi-adjudicatory approaches to resolving scientific issues, such as the discredited proposal for "science courts," are now generally thought to be impractical. For example, a review of the activities of a science advisory panel on pesticides convened under EPA auspices concludes that "the science court mode of operation, in short, has severe drawbacks. In practical terms there is little or no chance that a science court could definitively settle the issues in cases of intense controversy, and certainly not in a timely fashion [21]." By contrast, such collegial bodies as EPA's Science Advisory Board, whose activities are more in the nature of peer review than adversarial adjudication, are generally thought to have been more successful vehicles for resolving contentious scientific debates. While administrative rulemaking not have the same adversarial character as a "science court," neither is that activity collegial or consensus-based, with clear "winners" and "losers" often identifiable at the end.
If anything, the challenge of providing meaningful opportunities for a lay public that is not conversant with, or fully informed with respect to, the nuances of scientific issues that arise in highly technical regulatory proceedings is even greater. In extreme cases, only the opinions of technically expert professionals, even those that are purely subjective, may be perceived as credible. Phrased in terms of the excerpt quoted above, "help[ing] the public deliberate over the decisions that need to be made" is doubly difficult when the experts seem to hold all the cards.

Over the past decade or so, models of agency decision-making that involve genuine dialogue rather than adversarial jousting have begun to gain acceptance [22]. Initially, these consensus approaches were employed in settings such as so-called "regulatory negotiations," where interest group dynamics had effectively limited the potential for agency action. Since then, many agencies, industry representatives, and members of the public have become more comfortable with this sort of two-way interaction as an alternative to unidirectional demands made through the ordinary regulatory process. Non-adversarial, consensus-building processes may very well find application in regulatory proceedings that involve scientific judgments concerning public health and the environment [23]. Such approaches can be expected both to educate a technically inexpert public with respect to scientific questions and to provide a vehicle for taking into account policy preferences based on social values. The time now is very likely ripe to extend such approaches more generally to situations involving scientific and technical complexities that otherwise might be inaccessible to members of the lay public.

One of the widely agreed benefits of consensus processes are enhanced efficacy and perceptions of legitimacy, at least in some cases. Indeed, the two are related. Stakeholders that have agreed to a particular regulatory action after weighing all the consequences to their own interests are far less likely to challenge that action in alternative venues such as the courts or the legislature. More subtly, the effectiveness of regulatory action in almost all cases, at least in a democracy such as the United States, depends not only on the state's coercive power but also consensual implementation by private parties. More the regulated community and the public at large have "bought into" a particular regulatory approach, the greater the degree of voluntary compliance that can be expected. On the other side of the ledger, the perceived accountability of consensus-based approaches to the public at large depends to a large extent on the identity of the participants. Although difficult at times, care must be taken in structuring such approaches to assure that broad-gauge public values, and not solely narrow interest-group dynamics, are adequately represented.

V. BIOGRAPHY

David A. Wirth is Associate Professor of Law at Washington and Lee University in Lexington, Virginia, where he teaches environmental, administrative, public international, and foreign relations law, with a particular emphasis on teaching and research in the area of the international environment. During calendar year 1996, while on sabbatical leave from Washington and Lee, Professor Wirth serves as Director of the Trade, Health, and Environment Program of the Community Nutrition Institute in Washington, D.C. Prior to joining the Washington and Lee faculty, Professor Wirth was Senior Attorney and Co-Director of the International Program at the Washington, D.C. office of the Natural Resources Defense Council (NRDC), a nonprofit public interest law firm, where he specialized in international environmental issues. Professor Wirth has also been Attorney-Adviser for Oceans and International Environmental and Scientific Affairs in the Office of the Legal Adviser of the U.S. Department of State in Washington, D.C., where he had principal responsibility for all international environmental issues.

Professor Wirth is a 1981 graduate of the Yale Law School and served as law clerk to Judge William H. Timbers of U.S. Court of Appeals for the Second Circuit in New York for a year thereafter. He holds undergraduate and graduate degrees in chemistry from, respectively, Princeton and Harvard Universities. He is the only North American member of the European Bank for Reconstruction and Development's Environmental Advisory Council. Professor Wirth is the author of more than three dozen articles and reports on environmental law and policy for both legal and popular audiences. Recent publications have appeared in the Yale Law Journal, the Columbia Law Review, Foreign Policy, and the American Journal of International Law.

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VII. REFERENCES


