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RISK ANALYSIS AND THE RETURN TO COMMON SENSE

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I. Introduction

Today, I would like to speak to you about a subject which has in recent years assumed center stage in the debate over how government regulators ought to regulate; namely, the extent to which regulatory decisions should be based on a particular mode of regulatory decision-making called risk analysis. My talk is intended to respond to the complaint, voiced by many, that too often regulations make no sense and actually inhibit the goals they are designed to achieve. For reasons which I hope will become clear, I view risk analysis as an extremely valuable tool which, used appropriately, can restore common sense to regulation and thereby hopefully re-engage the confidence of the American public in their government.

II. The Death of Common Sense

First, though, we need to understand the problem. It is clear that a broad segment of the public believes that we are over-regulated, a sentiment most often expressed in the phrase "get-the-Government-off-our-backs," and that the way to cure this is through extensive de-regulation. It also seems clear that many believe that even where regulation may be warranted such as in the fields of health and safety and environmental regulation, our priorities are skewed. Resources are misdirected to minor problems in such a way that the costs of regulation do not justify the benefits to be derived. At the moment, this anti-regulatory movement may be focused on Federal Government bureaucracies in Washington, but in actuality it extends to State and local regulators as well.

Two authors have recently provided excellent capsule summaries of the regulatory climate which

has ushered in the present anti-regulatory mood. Philip Howard, in his 1994 book entitled The Death of Common Sense: How Law is Suffocating America,¹ gives a variety of examples of how red tape at all levels of government puts a stranglehold on the actions of individuals and companies, including no less a personage than Mother Theresa herself. It seems, according to Mr. Howard, that her order of sisters wanted to convert two fire-gutted buildings in the South Bronx into a homeless shelter. Although the sisters spent more than a year navigating the New York City bureaucracy and eventually obtained the necessary permissions, their plans were ultimately sunk by a requirement that a renovated four-story building have an elevator even though the sisters, for religious reasons, would never have used it and did not think it an appropriate expense. The bottom line--the homeless were deprived of a shelter altogether. Mr. Howard's general thesis is that regulatory requirements have become so detailed and inflexible that regulators cannot make use of common sense to devise regulatory solutions to real-life needs and problems.

The second author, Stephen Breyer, now Justice Breyer on the Supreme Court, focuses particularly on the problem of skewed priorities. His 1993 book Breaking the Vicious Circle: Toward Effective Risk Regulation² asks whether it makes sense to spend enormous sums of money to reduce environmental dangers which pose minimal risk. This problem arises when regulations that are originally sought to reduce risks that most people would consider unacceptable are ultimately made so unnecessarily stringent that large amounts of time and money must be expended to remedy the last little bit of environmental harm even though no significant safety benefit will result. He refers to this as the problem of "the last 10%" and gives, as an example, a lawsuit involving hypothetical dirt-eating children in New Hampshire. The case involved a private party trying to avoid the expenditure of \$9.3 million dollars to clean up the last remnants of a toxic waste dump. The property had already been cleaned up to the point that the waste dump was clean enough for children playing on the site to eat small amounts of dirt daily for 70 days each year without significant harm. The additional cleanup which was being required would enable the children to get their daily dose of dirt for 245 days. Ironically, the actual site was a swamp so there were no dirt-eating children around in any event. His example illustrates a common regulatory problem: at what point does it make sense to say that a given level of risk is acceptable because it does not make sense to expend further resources on the problem. Judge Breyer's broad concern is that there is a "vicious circle" of "public perceptions, Congressional actions and reactions and technical regulatory methods [which] reinforce each other ... diminishing public trust in regulatory institutions and thereby inhibiting more rational regulation."³

In sum, these two books bespeak a public plea to all regulators to return to common sense as a basis for regulation. While one can argue about what the anecdotal evidence employed by these authors proves, I think it is fair to say that much of the public shares their perception that greater

¹Philip K. Howard, The Death of Common Sense, New York: Random House, 1994.

²Stephen Breyer, Breaking the Vicious Circle, Cambridge: Harvard University Press, 1993.

³Id. at 33.

common sense in government regulation is needed.

III. What is Risk Analysis, or Risk-Based Decision-Making?

As I have indicated, I view risk analysis, or risk-based decision-making, as a way to reincorporate common sense into the regulatory process. This mode of decision-making can be divided into at least three distinct components: risk assessment, selection of an acceptable risk level, and risk management. Each of these is important and I want to briefly describe each step. It is also important to note at the outset one other aspect of risk analysis: each of these steps involves an intermix of science and value judgments. It is in the value judgments part of the mix that the "reality check" of common sense ought to be given considerable weight.

Risk Assessment. The first component of risk analysis, risk assessment, attempts to measure and describe the risk or hazard associated with the use of a substance or technology. It is basically a scientific endeavor which becomes more accurate as scientific knowledge grows, as methodologies are perfected and as measuring instruments become more refined. It must be acknowledged, however, that there are considerable gaps and uncertainties in the scientific knowledge which underlies most risk assessments. One must make certain assumptions to bridge these gaps and overcome these uncertainties which, in scientific parlance, are referred to as "default assumptions." These assumptions are essentially policy decisions which rest on value judgments, especially and usually the value judgment that when it comes to unknown hazards "it is better to be safe than sorry."

Selection of an Acceptable Risk Level. The second component of risk-based decision-making is the selection of an acceptable risk level. This stage, while based on the first step, is not strictly a scientific endeavor. Rather, the benefits to society in using the substance or technology, and the costs to society of reducing the risks must be considered. In the process, the risk at issue may be compared with other similar risks confronting society.

This step may be the most contentious because selecting an acceptable risk level clearly calls for value judgments and, therefore, for input from society as a whole. Getting this input represents a real challenge and also involves the important element of risk communication. This is why regulatory agencies should be "up-front" about whatever default assumptions may have been used in a given risk assessment. To make intelligent judgments about what level of risk is acceptable, one needs to have a sense of what certainty there is that there is a risk and what the real nature of this risk may be.

Risk Management. The third component of risk analysis is risk management. This consists of devising a regulatory process designed to keep the risk below the level determined to be acceptable. This has traditionally been the primary task assigned to regulatory agencies by the President and the Congress. The political bodies have sometimes given agencies broad mandates that leave the agency with a good deal of discretion and sometimes have given very detailed instructions as to how risk management is to be accomplished.

IV. The Role of Risk Analysis in the Regulatory Process

Now that we are familiar with the main ingredients of risk analysis, or risk-based decision-making--risk assessment, selection of an acceptable risk level and risk management--we come to the hard question: What role should risk analysis play in the regulatory process?

The Administration, the Congress and probably most of the public familiar with this issue appear to want an increased role for risk analysis in regulatory decision-making. In 1993, President Clinton issued Executive Order 12866 calling for increased use of risk analysis by Federal agencies. He also established in the White House Office of Science and Technology Policy a Regulatory Working Group that includes a Subgroup on Risk Analysis. I am pleased to have served on the Subgroup which has produced risk assessment principles and is currently assessing various Congressional proposals regarding use of risk analysis. The House of Representatives has passed H.R. 9 which includes risk analysis provisions and a number of bills on this subject are pending in the Senate. In short, there seems to be agreement across the political spectrum that Government decision-makers should make increased use of risk analysis.

That having been said, however, it is also true that being in favor of an increased role for risk analysis in the regulatory process is somewhat akin to being in favor of a balanced budget. Just as many agree that having a balanced budget would be desirable so long as my favorite programs are untouched, many agree that risk analysis should be part of the regulatory process but only so long as my favorite regulations are unaffected. There are some who see risk analysis as a poison pill which, once it is dropped into the regulatory process, will destroy the very goals the process is designed to achieve. However, I would like to suggest that risk analysis can be seen as an underused and much needed tool for decision-making, a tool that can restore common sense to the decision-making process. Risk analysis can fill this function if it incorporates common sense at those points of the process where value judgments rather than strict scientific conclusions are needed. To illustrate my point, I would like to look a little more closely at a few of the places in the risk analysis process where value judgments must play a role.

A. The Problem of Cumulative Default Assumptions

The first place to look is at that part of the process where default assumptions are made. You will recall that default assumptions must be employed at the risk assessment stage to bridge the gaps created by scientific uncertainty. Often, the default assumption chosen is the most conservative option based on the judgment that "it is better to be safe than sorry" when it comes to unknown risks. At first sight, that value judgment may seem to be just common sense. However, there is a problem which may not be readily apparent: a single risk assessment will most likely need to incorporate many such assumptions, thereby building conservatism upon conservatism and producing an ultimate picture of the risk which may well be extremely disproportionate to its true nature. Indeed, the National Research Council, in its 1983 report on risk assessment, the Red Book,⁴ identified more than 50 such assumptions that arise in the course of a risk assessment. Unless one takes the position that every conceivable risk must be avoided--a position which I think would make it difficult to get out of bed in the morning--some common-sense approach to bridging scientific gaps and

⁴National Research Council, Committee on the Institutional Means for Assessment of Risks to Public Health, Risk Assessment in the Federal Government: Managing the Process, Washington, D.C.: National Academy Press, 1983.

uncertainties needs to be considered.

In 1994, the Department of Energy published an interesting study of the interplay between science and policy judgments with respect to default assumptions titled Choices in Risk Assessment: The Role of Science Policy in the Environmental Risk Management Process.⁵ This book cites an example of two risk assessments done for exposure to tetrachloroethylene or "PCE." The risk assessments were done in the same manner except for the default assumptions used to bridge uncertainties in the scientific evidence with respect to three questions: (1) whether the dose-response relationship is linear at low doses where no scientific data exists when data indicate a dose-response relationship at high doses; (2) whether the scaling factor applied in extrapolation from animals to humans should be based upon surface area or body weight equivalence; and (3) whether experiments involving mice or rats ought to be used for the extrapolation. The assessment which used conservative default assumptions to answer each question produced a risk estimate for exposure to PCE that was 35,000 times greater than the estimate reached when alternative default assumptions were used.

This example suggests that it may be more reasonable to produce risk assessments that will result in a range of risk estimates rather than in a single number or perhaps that the wisest course would be, in appropriate cases, to forego quantitative risk assessments altogether and instead provide a qualitative description of the risk. DOE's study on Choices in Risk Assessment describes a variety of alternatives to conservative default assumptions which are scientifically respectable and reasonable in given circumstances. My point here is not that conservative default assumptions must be abandoned altogether in favor of more realistic alternatives. Rather, my point is that the goal of the risk assessment stage of the risk analysis process should be to produce a credible picture of the nature of the risk. To the extent that multiple conservative default assumptions render a given risk assessment incredible, surely it is reasonable to search for and make use of alternatives. Doing so is simply common sense.

There are, I know, contrary views. Some contend that conservative default assumptions should be used wherever there are scientific uncertainties that must be overcome because this assures the greatest conceivable amount of public protection. In this view, the inherent biases of conservative assumptions are best dealt with by rendering them explicit; i.e., as long as the public is aware of where "guesstimates" have been made, they will know how to regard the risk estimate. However, I happen to think this is unsatisfactory, especially when the risk is ultimately expressed as a number, because it is too easy to lose sight of the gaps in the evidence on which that number rests. Moreover, simply recognizing that there is a built-in bias doesn't reveal the extent of the bias and leaves both decision-makers and the public uncertain as to how the risk assessment should be used. It is the function of risk managers, based on input from both the scientific community and the general public, to determine the desired degree of public protection; risk assessment, on the other hand, should be oriented toward giving the decision-maker the most credible picture of the problem possible.

B. The Problem of Determining an Acceptable Level of Risk

⁵Regulatory Impact Analysis Project, Inc., Choices in Risk Assessment, U.S. Department of Energy: Washington, D.C., 1994.

This brings me to a second area in the risk analysis process where value judgments are particularly important. Once the nature of the risk is characterized, an acceptable level of risk must be determined. This is, perhaps, the most difficult value judgment to be made in the course of doing a risk analysis. It is difficult because the answer cannot be reached on the basis of scientific data alone but must take into account both expert and popular views on what type of risks are socially acceptable and the views of these two groups can be quite divergent. The matter becomes even more complex when the risk in question stems from exposure to a non-threshold substance; that is, a substance which is known to cause harm when humans are exposed to it at high dose levels but where the risk from exposure at low dose levels is unknown and possibly non-existent but is assumed to exist down to zero.

I would like to focus on a particular case where a regulatory agency struggled to determine an acceptable level of risk so that we can see the interplay of science and value judgments and also so that we can ask what role common sense might play in this determination. The regulatory agency is the Environmental Protection Agency and the particular case was EPA's effort to establish an air emission standard for vinyl chloride, a non-threshold carcinogen. This is one of the emission standards, called a NESHAP or National Emission Standard for Hazardous Air Pollutant, mandated by the Clean Air Act. Under the regulatory scheme set up by the Clean Air Act, EPA must first identify suspect "hazardous air pollutants"--meaning pollutants which might cause or contribute to death or serious illness--and then promulgate emission standards for such pollutants unless the Administrator of the EPA finds that the suspect air pollutant is not in fact hazardous. Congress also provided EPA with the standard it must use in promulgating a NESHAP: any standard must be at a level which will provide an ample margin of safety to protect the public health from the hazardous air pollutant.

In assessing the risk posed by human exposure to vinyl chloride, EPA had little difficulty in concluding that a NESHAP was needed. The problem came in determining what level of risk was acceptable, given the impossibility of establishing any definite threshold level below which no adverse health effects would occur. As EPA saw the matter, it had two alternatives. First, it could determine that the statutory mandate to establish a standard that would provide an ample margin of safety meant that a complete prohibition was necessary because only a zero emission limitation would assure complete safety. Or, as a second alternative, it could set the limitation at the lowest level achievable by use of the best available control technology if it found that the cost of achieving a zero emission standard would be grossly disproportionate to the benefits of removing the risk. EPA selected the latter course upon finding that a zero emission standard could require closure of an entire industry, a cost it found extremely high for elimination of a risk to health that is of unknown dimensions.

EPA's choice did not prove satisfactory to all segments of society and the struggle to determine an acceptable level of risk moved to the judicial branch of the Government. The lawyers among you will likely be familiar with the case that decided this controversy: National Resources Defense Council v. Environmental Protection Agency, a 1987 en banc decision of the United States Court of Appeals for the District of Columbia Circuit which is usually referred to as the "Vinyl Chloride

decision."⁶ The court was willing to give EPA broad discretion in determining the meaning of the term "ample margin of safety" but concluded that the agency had ducked the issue. EPA was not faulted for rejecting a "zero release" standard. As the court put it, "safe" does not mean "risk-free" or that the matter is free from uncertainty. But the court did insist that EPA decide, as a predicate to formulating an "ample margin of safety" standard, what was "an acceptable level of risk" and not avoid the issue by simply basing the standard on whatever the best available technology could produce.

The court even suggested a method for accomplishing this task. This method is a two-step process. The first step focuses solely on the risk to health. The agency would consider not only scientific information but also "what risks are acceptable in the world in which we live." And the court gave as examples of such socially acceptable risks daily activities like driving a car or breathing city air. Only after completion of the first step would the agency, in a second step, consider other factors like cost and technological feasibility to come to a conclusion as to what standard represented "an ample margin of safety."

At the risk of some oversimplification, what it seems to me the court was saying here was: Use your common sense! Being safe from possible harms does not mean living in suspended animation; it means accepting reasonable risks. As the court put it, "safety" does not mean "risk-free." When you must answer a difficult question like "what level of risk is acceptable" from the possible harms of a carcinogen, take a look at other risks people accept in daily life, risks like driving a car or breathing city air. Both of those activities entail risk but millions of people every day decide to "chance it," to take the risk. Of course, carried too far this mode of thinking could freeze the status quo and defeat the goal of producing a healthier and safer environment. But I don't think the court was suggesting a trap; I think the court was suggesting that some common-sense judgment needed to be made as to what risks are acceptable and then attention can be focused on what costs society might be willing to pay to further reduce the risks.

There is one further point I would like to make before leaving the Vinyl Chloride decision. The court provided EPA with considerable flexibility in devising its NESHAPS. Recall that EPA had originally seen only two options for its standard-setting: "zero release" and "best available technology." But the court said: find out what is an acceptable risk, not what is the minimal risk technology might achieve. Of course, after determining the acceptable risk, EPA was free to decide that an ample margin of safety would only exist if the standard was based on the best available technology. But EPA was equally free, at this second step, to consider the full range of the costs of further reducing the risk from what was found to be acceptable. The effect of the court's decision, oddly enough, was to permit EPA to take a good deal more stock of the costs and benefits of a proposed standard once it had made its "acceptable level of risk" decision.

C. The Problem of Comparing Risks

I do not mean to downplay the difficulties involved in actually determining an acceptable level of risk, whether for vinyl chloride or for any other hazardous substance or technology. In fact, a

⁶National Resources Defense Council v. EPA, 824 F.2d 1146 (en banc) (D.C. Cir. 1987).

third area of the risk analysis process in which value judgments play an important role is in the comparison of risks. A number of studies have shown that many factors influence a person's willingness to accept a given risk, factors such as the certainty and severity of the risk, the reversibility of the health effect, the knowledge or familiarity of the risk, whether the risk is voluntarily accepted or involuntarily imposed, the benefit to be derived from accepting the risk and who the responsible party may be. There are also difficulties in comparing actuarial risks where available statistics give a very accurate picture of the risk, such as the risk of death in an auto accident, with risks that are substantially hypothetical. Finally, one of the most vexatious problems in comparing risks is the problem of how to reconcile the views of the "experts" and the views of the lay public which are often quite disparate. Since we are dealing primarily with value judgments, the scientists cannot assume that science alone must dictate the solution.

D. The Problem of Prioritizing Risks

Finally, I want to mention a problem that transcends the issues involved in doing any particular risk analysis and that is the overarching problem of how society can assure that attention and resources are devoted to the regulation of risks that are truly significant and not have them diverted to further reductions of minimal risks. This is the problem that attracted the attention of Judge Breyer in his book Breaking the Vicious Circle. As he sees it, the results of America's investment in risk reduction have been very uneven but this "hodgepodge of results does not reflect a public that really wants dirty Boston harbors and superclean swamps; rather, such policy priorities more likely reflect the psychological and practical difficulties of making risk decisions one substance at a time."⁷ His solution - creation of an elite corps of civil servants with interagency jurisdiction and authority whose mission would be to build an improved, coherent risk-regulating system with established priorities within and among programs - has proved controversial but he has undeniably raised an issue that needs to be addressed.

There are other ideas out there. For example, the Harvard Group on Risk Management Reform, in its report, Reform of Risk Regulation: Achieving More Protection at Less Cost, makes a number of recommendations including this one: "Congress should authorize the President's science advisor to lead, integrate, and oversee the assessment and ranking of health, safety, and environmental risks in collaboration with federal agencies responsible for risk regulation."⁸ This group urges that a new organization be created within the Office of Science and Technology at the White House to be administered by a Director of Risk Analysis and whose duties would include preparation of risk assessment guidelines and creation of methods for citizen participation in risk-ranking exercises. Finally, I might mention the Committee for the National Institute for the Environment which advocates legislation to create a new Government agency whose mission would be to improve the scientific basis for environmental decision-making policy. Whether any of these ideas will get off the ground remains to be seen but the ongoing ferment on this issue seems likely to produce some results.

⁷Breyer, op cit., p. 55.

⁸ Harvard Group on Risk Management Reform, Reform of Risk Regulation: Achieving More Protection at Less Cost, Boston: Center for Risk Analysis, Harvard School of Public Health, March 1995, p. 3.

V. The Need To Establish a Uniform Methodology for Standard-setting: Federal Radiation Protection Standards as a Case Example

I have suggested that increased use of risk-based decision-making by federal agencies can serve as a vehicle for putting more common sense into federal regulations and thereby enhance the credibility of those regulations with the public. This goal will not be achieved, however, if each federal agency does risk analysis differently. We need to forge agreement among the federal agencies with respect to how risk analysis is properly done and particularly with respect to how common sense needs to be inserted into the process.

An example of this need and of how it is currently being met is provided by federal radiation protection standards. In September 1994, the General Accounting Office issued a report entitled Nuclear Health and Safety: Consensus on Acceptable Radiation Risk to the Public is Lacking.⁹ As the title of the report indicates, the GAO found inconsistencies, gaps and overlaps in the radiation protection standards issued by different federal agencies. The GAO Report prompted Senator Glenn to request the EPA and the NRC to develop a plan for addressing these problems and for achieving greater consistency in these standards. The two agencies are currently developing a joint "White Paper on Risk Harmonization" which is intended to provide a common understanding of the statutory and logical rationale underlying the agencies' risk assessment and management decisions. EPA and NRC are also members of an interagency steering committee which is reviewing the current radiation regulatory framework.

Given that the agencies do risk analysis differently, it really should come as no surprise that they wind up with different standards. However, this is exactly the situation that puzzles and frustrates the public. The current effort to reexamine methodologies and achieve greater consistency in standards is certainly worthwhile. The potential harm to the public from exposure to radiation is, after all, the same whether the harm is regulated by EPA, NRC or any other agency. My hope is that this review will provide an opportunity to assure that all federal radiation protection standards will be grounded both in good science and in good common sense.

VI. Conclusion

I have attempted today to describe a particular method of regulatory decision-making, risk analysis, and to show you some of the points in the process where it may be possible to return to common sense in the course of making necessary value judgments. Risk analysis is neither an insidious device for destroying the environmental gains of the last 25 years nor a scientific "deus ex machina" which will precisely calibrate the right degree of risk with the right degree of benefit without the need for making any "judgment calls." Rather, judgment calls need to be made but they can be made in a common sense and democratic fashion which will result in the right degree of regulation to resolve agreed-upon health and safety and environmental needs. The issue of the near future will be to figure out how to best use the tool of risk analysis to achieve this end--both the environmental and the economic well-being of our society are in peril if we don't.

⁹Nuclear Health and Safety: Consensus on Acceptable Radiation Risk to the Public is Lacking (GAO/RCED-94-190, Sept. 19, 1994).

