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Science, Risk, and Public Policy

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We are now in a troubled and emotional period for pollution control; many communities are gripped by something approaching panic and the public discussion is dominated by personalities rather than substance. It is not important to assign blame for this. I appreciate that

confidence. The polls show that scientists have more credibility than lawyers or businessmen or politicians, and I am all three of those. I need the help of scientists.

This is not a naïve plea for science to save us from ourselves. Somehow, our

ner laid down by its statutes. That manner is to set standards and enforce them, and our enforcement powers are strong and pervasive. But the standards we set, whether technology- or health-related, must have a sound scientific base.

Science and the law are thus partners at EPA, but uneasy partners. The main reason for the uneasiness lies, I think, in the conflict between the way science really works and the public's thirst for certitude that is written into EPA's laws. Science thrives on uncertainty. The best young scientists flock into fields where great questions have been asked but nothing is known. The greatest triumph of a scientist is the crucial experiment that shatters the certainties of the past and opens up rich new pastures of ignorance.

But EPA's laws often assume, indeed demand, a certainty of protection greater than science can provide with the current state of knowledge. The laws do no more than reflect what the public believes and what it often hears from people with scientific credentials on the 6 o'clock news. The public thinks we know what all the bad pollutants are, precisely what adverse health or environmental effects they cause, how to measure them exactly and control them absolutely. Of course, the public and sometimes the law are wrong, but not all wrong. We do know a great deal about some pollutants and we have controlled them effectively by using the tools of the Clean Air Act and the Clean Water Act. These are the pollutants for which the scientific community can set safe levels and margins of safety for sensitive populations. If this were the case for all pollutants, we could breathe more easily (in both senses of the phrase); but it is not so.

Summary. A climate of fear now dominates the discussion of environmental issues. The scientific community can help alleviate this fear by making a greater effort to explain to the public the uncertainties involved in estimates of risk. Current statutory mandates designed to protect public health both demand levels of protection that technology cannot achieve and are uncoordinated across government agencies. A common statutory framework for dealing with environmental risks is needed. In addition, care must be taken to separate the scientific process of assessing risk from the use of such assessments, together with economic and policy considerations, in the management of risks through regulatory action.

people are worried about public health and about economic survival, and legitimately so, but we must all reject the emotionalism that surrounds the current discourse and rescue ourselves from the paralysis of honest public policy that it breeds.

I believe that part of the solution to our distress lies with the idea that disciplined minds can grapple with ignorance and sometimes win: the idea of science. We will not recover our equilibrium without a concerted effort to more effectively engage the scientific community. Frankly, we are not going to be able to emerge from our current troubles without a much improved level of public

democratic technological society must resolve the dissonance between science and the creation of public policy. Nowhere is this more troublesome than in the formal assessment of risk—the estimation of the association between exposure to a substance and the incidence of some disease, based on scientific data.

Science and the Law at EPA

Here is how the problem emerges at the Environmental Protection Agency. EPA is an instrument of public policy, whose mission is to protect the public health and the environment in the man-

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More than 10 years ago, EPA had the Clean Air Act, the Clean Water Act, a solid waste law, a pesticide law, and laws to control radiation and noise. Yet to come were the myriad of laws to control toxic substances from their manufacture to their disposal—but that they would be passed was obvious even then.

When I departed EPA a decade ago, the struggle over whether the federal government was to have a major role in protecting our health, safety, and environment was ended. The American people had spoken. The laws had been passed; the regulations were being written. The only remaining question was whether the statutory framework we had created made sense or whether, over time, we would adjust it.

Scientific Realities

Ten years ago I thought I knew the answer to that question as well. I believed it would become apparent to all that we could virtually eliminate the risks we call pollution if we wanted to spend enough money. When it also became apparent that enough money for all the pollutants was a lot of money, I came to believe that we would begin examining the risks very carefully and structure a system that would force us to balance our desire to eliminate pollution against the costs of its control. This would entail some adjustment of the laws, but not all that much, and it would happen by about 1976. I was wrong.

This time around as administrator of EPA, I am determined to improve our country's ability to cope with the risk of pollutants over where I left it 10 years ago. It will not be easy, because we must now deal with a class of pollutants for which it is difficult, if not impossible, to establish a safe level. These pollutants interfere with genetic processes and are associated with the diseases we fear most: cancer and reproductive disorders, including birth defects. The scientific consensus is that any exposure, however small, to a genetically active substance embodies some risk of an effect. Since these substances are widespread in the environment, and since we can detect them down to very low levels, we must assume that life now takes place in a minefield of risks from hundreds, perhaps thousands, of substances. We can no longer tell the public that they have an adequate margin of safety.

This worries all of us, and it should. But when we examine the premises on which such estimates of risk are based,

we find a confusing picture. In assessing a suspected carcinogen, for example, there are uncertainties at every point where an assumption must be made: in calculating exposure; in extrapolating from high doses where we have seen an effect to the low doses typical of environmental pollution; in what we may expect when humans are subjected to much lower doses of a substance that, when given in high doses, caused tumors in laboratory animals; and finally, in the very mechanisms by which we suppose the disease to work.

One thing we clearly need to do is ensure that our laws reflect these scientific realities. The administrator of EPA should not be forced to represent that a margin of safety exists for a specific substance at a specific level of exposure where none can be scientifically established. This is particularly true where the inability to so represent forces the cessation of all use of a substance without any further evaluation.

Functions of Regulatory Agencies

It is my strong belief that where EPA, OSHA (the Occupational Safety and Health Administration), or any other social regulatory agency is charged with protecting public health, safety, or the environment, we should be given, to the extent possible, a common statutory formula for accomplishing our tasks. This statutory formula may well weigh public health very heavily, as the American people certainly do.

The formula should be as precise as possible and should include a responsibility for assessing the risk and weighing it, not only against the benefits of continued use of the substance under examination, but against the risks associated with substitute substances and the risks associated with the transfer of the substance from one environmental medium to another through pollution control practices. I recognize that legislative change in the current climate is difficult. It is up to those of us who seek change to make the case for its advisability.

But my purpose here is not to plead for statutory change; it is to speak of risk assessment and risk management and the role of science in both. It is important to distinguish these two essential functions, and I rely here on a recent National Academy of Sciences report on the management of risk in the federal government. Scientists assess a risk to find out what the problems are. The process of deciding what to do about the problems

is risk management. The second procedure involves a much broader array of disciplines and is aimed toward a decision about control.

In risk management it is assumed that we have assessed the health risks of a suspect chemical. We must then factor in its benefits, the costs of the various methods available for its control, and the statutory framework for decision. The NAS report recommends that these two functions—risk assessment and risk management—be separated as much as possible within a regulatory agency. This is what we now do at EPA and it makes sense.

Risk Assessment

We also need to strengthen our risk assessment capabilities. We need more research on the health effects of the substances we regulate. I intend to do everything in my power to make clear the importance of this scientific analysis at EPA. Given the necessity of acting in the face of enormous scientific uncertainties, it is more important than ever that our scientific analysis be rigorous and the quality of our data be high. We must take great pains not to mislead people about the risks to their health. We can help to avoid confusion by ensuring both the quality of our science and the clarity of our language in explaining hazards.

I intend to allocate some of EPA's increased resources to pursuing these ends. Our 1984 request contains significant increases for risk assessment and associated work. We have requested \$31 million in supplemental appropriations for research and development, and I expect that risk assessment will be more strongly supported as a result of this increase as well.

I would also like to revitalize our long-term research program to develop a base for more adequately protecting the public health from toxic pollutants. I will be asking the outside scientific community for advice on how best to focus those research efforts.

In the future, this being an imperfect world, the rigor and thoroughness of our risk analyses will undoubtedly be affected by many factors, including the toxicity of the substances examined, the populations exposed, the pressure of the regulatory timetable, and the resources available. Despite these often conflicting pressures, risk assessment at EPA must be based only on scientific evidence and scientific consensus. Nothing will erode

public confidence faster than the suspicion that policy considerations have been allowed to influence the assessment of risk.

Risk Management

Although there is an objective way to assess risk, there is, of course, no purely objective way to manage it, nor can we ignore the subjective perception of risk in the ultimate management of a particular substance. To do so would be to place too much credence in our objective data and ignore the possibility that occasionally one's intuition is right. No amount of data is a substitute for judgment.

Further, we must search for ways to describe risk in terms that the average citizen can comprehend. Telling a family that lives close to a manufacturing facility that no further controls on the plant's emissions are needed because, according to our linear model, their risk is only 10^{-6} , is not very reassuring. We need to describe the suspect substances as clearly as possible, tell people what the known or suspected health problems are, and help them compare that risk to those with which they are more familiar.

To effectively manage the risk, we must seek new ways to involve the public in the decision-making process. Whether we believe in participatory democracy or not, it is a part of our social regulatory fabric. Rather than praise or lament it, we should seek more imaginative ways to involve the various segments of the public affected by the substance at issue. They need to become involved early, and they need to be informed if their participation is to be meaningful. We will be searching for ways to make our participatory process work better.

For this to happen, scientists must be willing to take a larger role in explaining the risks to the public—including the uncertainties inherent in any risk assessment. Shouldering this burden is the responsibility of all scientists, not just those with a particular policy end in mind. In fact, all scientists should make clear when they are speaking as scientists, *ex cathedra*, and when they are recommending policy they believe should flow from scientific information.

What we need to hear more of from scientists is science. I am going to try to provide avenues at EPA for scientists to become more involved in the public dialog in which scientific problems are described.

Lest anyone misunderstand, I am not suggesting that all the elements of managing risk can be reduced to a neat mathematical formula. Going through a disciplined approach can help to organize our thoughts so that we include all the elements that should be weighed. We will build up a set of precedents that will be useful for later decision-making and will provide more predictable outcomes for any social regulatory programs we adopt.

In a society in which democratic principles dominate, the perceptions of the public must be weighed. Instead of objective and subjective risks, the experts sometimes refer to "real" and "imaginary" risks. There is a certain arrogance in this—an elitism that has ill served us in the past. Rather than decry the ignorance of the public and seek to ignore their concerns, our governmental processes must accommodate the will of the people and recognize its occasional wisdom. As Thomas Jefferson observed, "If we think [the people] not enlightened enough to exercise their control with a wholesome discretion, the remedy is not to take it from them, but to inform their discretion."

Interagency and International Coordination

Up to this point I have been suggesting how risks should be assessed and managed in EPA. Much needs to be done to coordinate the various EPA programs to ensure a consistent approach. I have established a task force with that character.

I further believe we should make uniform the way in which we manage risk across the federal regulatory agencies. The public interest is not served by two federal agencies taking diametrically opposed positions on the health risks of a toxic substance and then arguing about it in the press. We should be able to coordinate our risk assessment procedures across all federal agencies. The risk man-

agement strategies that flow from that assessment may indeed differ, depending on each agency's statutory mandate or the judgment of the ultimate decision-maker.

But even at the management stage there is no reason why the approaches cannot be coordinated to achieve the goal of risk avoidance or minimization with the least societal disruption possible. I have been exploring with the White House and the Office of Management and Budget the possibility of effecting better intragovernmental coordination of the way in which we assess and manage risk.

To push this one step further, I believe it is in our nation's best interest to share our knowledge of risks and our approach to managing them with the other developed nations of the world. The environmental movement has taught us the interdependence of the world's ecosystems. In coping with the legitimate concerns raised by environmentalists, we must not forget that we cope in a world with interdependent economies. If our approach to the management of risk is not sufficiently in harmony with those of the other developed nations, we could save our health and risk our economy. I do not believe we need to abandon either, but to ensure that it does not happen, we need to work hard to share scientific data and understand how to harmonize our management techniques with those of our sister nations.

In sum, my goal is a government-wide process for assessing and managing environmental risks. Achieving this will take cooperation and goodwill within EPA, among Executive Branch agencies, and between Congress and the Administration, a state of affairs that may partake of the miraculous. Still, it is worth trying, and the effort is worth the wholehearted support of the scientific community. I believe such an effort touches on the maintenance of our current society, in which a democratic polity is grounded in a high-technology industrial civilization. Without a much more successful way of handling the risks associated with the creations of science, I fear we will have set up for ourselves a grim and unnecessary choice between the fruits of advanced technology and the blessings of democracy.