3 The Uncertainty of Risk but the Reality of Cost

Security is mostly a superstition. It does not exist in nature, nor do the children of men as a whole experience it. Avoidance of danger is no safer in the long run than exposure. Life is either a daring adventure or nothing.
—Helen Keller

Uncertainty, in the presence of vivid hopes and fears, is painful, but must be endured if we wish to live without the support of comforting fairy tales.
—Bertrand Russell

The concept of the mythical man was introduced in the debates on the Clean Air Act—stand by a plant's fence for 70 years, breathe the chemical 24 hours a day, and have a one in one million chance of getting cancer. If that is the case, then shut down the plant. These theories are lost on my colleagues and myself.
—Senate Minority Leader Robert Dole

Toxic Trouble in the Plastics Industry: Vinyl Chloride

"How do you explain the behavior of those geriatric rats?" asked the EPA Administrator. He wanted his medical advisers to explain why three laboratory rats which developed cancerous tumors after being dosed with the toxic chemical vinyl chloride (commonly called VC) had outlived 47 dosed rats which had not developed tumors and 50 rats in a control group which were not exposed to the chemical at all. The life expectancy of rats is 104 weeks, and 97 rats died on schedule. But

the three which were the center of attention had survived until they were 110 to 120 weeks old. "Didn't the three tumor-laden rats simply die of old age?" queried the Administrator.

The experts surmised that the tumors probably developed very slowly and therefore afflicted only the oldest rats. They vigorously argued that despite the uncertainty as to how the tumors evolved, the tumors were real. They were of a unique type known as angiosarcoma of the liver, noted the experts. Therefore, they could be unequivocably linked to the exposure of the rats to VC. Since several workers had died from exposure to VC, no one doubted this linkage. What was on the table for discussion was the *level* of exposure to VC that could cause cancer, and the experts were presenting this laboratory experiment as an important development in determining a hazardous level of exposure.

The Administrator was not belittling the importance of research findings. He simply was trying to understand the relationships between the impact of toxic agents on laboratory animals and their effects on human beings. The Administrator, like his predecessors and successors, was facing the dilemma of weighing limited scientific information in an effort to balance human lives against the expenditures of large national resources required to maintain the viability of probably the most important segment of the American plastics industry. The issue was not *whether* regulation was needed. Rather, the question was *how much* regulation was appropriate. This will continue to be the common problem in controlling toxic chemicals.

An unexpected event led to the May 1974 gathering of the EPA Administrator and his advisers which turned out to be one of the most significant meetings of environmental officials during the mid-1970s. For the first time the toxicity of a chemical threatened the future of an entire industry with annual sales in the billions of dollars.

In January of that year, the B.F. Goodrich Company, the largest American producer of the plastic polyvinyl chloride (known as PVC) which is widely used in consumer and industrial products, notified several government agencies including the EPA that four workers from its PVC manufacturing plant in Louisville, Kentucky, had died from angiosarcoma of the liver. The Department of Labor required such notification of job-related injuries or deaths. The Goodrich officials reported that these four employees had worked for many years in areas of the plant where significant amounts of VC pervaded the air. Good-

rich therefore concluded that exposure to VC had caused the cancers. The EPA Administrator thereupon asked me, as Director of the Agency's Office of Toxic Substances, to lead the EPA's effort in responding to this rather frightening development.

This plastics plant and about 35 other manufacturing plants throughout the country used VC as their initial raw material in the production of PVC. Engineers injected the VC gas into large sealed kettles where a series of chemical reactions at high temperatures and pressures polymerized, or transformed, the gaseous VC into PVC which is a solid material. At that time, the workers in many plants handled the VC raw material in a very sloppy manner despite a general awareness throughout the industry that it had toxic characteristics. Leakages of VC at loading docks and through old valves and fittings within the plants were commonplace. In addition, the reaction processes in the kettles were not well controlled, and large amounts of the VC were not converted to PVC. Residual VC remained either as a waste gas in the kettles or as gas entrapped within the PVC plastic. Subsequently, during cleaning of the kettles or processing of the plastic, VC would leak into the workplace or into the general environment.

The rarity of that particular cancer—angiosarcoma of the liver—and the clustering of four deaths at the Goodrich plant raised immediate flags within the chemical industry and the government that a very serious occupational hazard had been uncovered. Soon government investigators traced ten more deaths of former workers at other plants to VC exposure, and the press reported two cases of the liver disease among nonworkers who had lived near a PVC plant.

The EPA's most immediate task was to determine whether the several million Americans living within a few miles of PVC manufacturing plants were at risk from VC discharges and, if so, to take steps to reduce any such risks. Thus, the first priority was to investigate the extent of the escape of VC from the 35 PVC plants. However, my EPA colleagues and I also suspected problems at some of the 15 other plants throughout the country which produced the VC raw material. In addition, 7500 plants made products from PVC which might be impregnated with residual VC that could leak out as the plastic was molded into different forms. As another concern, plastic pipes made from PVC had become very popular within the home building industry for bringing drinking water into residential areas, and in theory VC temporarily

trapped in new pipes might end up in tap water. Finally, industry used VC to improve the spray properties of several aerosol propellants and also to enhance the homogeneity of a few specialty coatings used to help preserve industrial and consumer products.

In order to address each of these concerns, EPA specialists needed to develop correlations between the levels of exposure of humans to VC and the likelihood of harmful effects. From laboratory studies, they knew that VC caused liver cancer. However, they did not know what level of exposure would trigger the onset of cancer, and they did not know what other adverse health effects could be linked to VC. Operating on a very short time schedule, they had to make do with available scientific data which were far from satisfactory. The commissioning of additional studies with laboratory animals would have been extremely useful. But such studies would have taken six months to three years to carry out, and the pressure was on for immediate decisions.

The EPA Administrator obviously wanted a regulatory approach for dealing with the VC problem very promptly—an approach which in the first instance responded to the public health threat but which also took into account the economic importance of the PVC industry to the nation. One of the choices available for the EPA was to shut down the worst offending plants immediately. Or the Agency could start the process of establishing a national standard to limit air emissions of VC, a procedure which might drag on for two to three years to permit all interested parties to voice their concerns. Of course, the EPA needed to consult with the Occupational Safety and Health Administration of the Department of Labor concerning steps that agency might take to protect workers—steps that would also reduce VC emissions into the general environment. Finally, the EPA needed to coordinate efforts with the Food and Drug Administration and other agencies in addressing plastic pipes in drinking water systems since at that time the EPA's legal responsibility for regulating pipes was uncertain.

The economic stakes were very large. PVC was a widely used plastic and was a backbone of many branches of industrial and commercial activity in the apparel, building, construction, home packaging, recreation, and transportation sectors. The annual wholesale value of PVC products in the United States was billions of dollars. Involved in VC production were 1500 workers; 5000 more were engaged in PVC production, and 350,000 in molding finished plastic products from PVC.

The industry was growing at a rate of 14% annually. Some American companies had effectively penetrated foreign markets, and the industry had established a clear leadership role internationally. Still, firms in other countries were attempting to challenge this leadership. If PVC production costs increased in the United States as a result of environmental controls, imports of plastic from Europe would become far more attractive to American wholesalers at a time when balance of trade was an important political issue in Washington.

During the next four months the EPA mobilized its offices and laboratories nationwide in an aggressive effort to clarify the harmful effects. "What steps could industry take immediately to help correct the problem with a minimum of financial loss?" we repeatedly asked.

Most manufacturers of PVC were quick to acknowledge that while they had not violated any laws or regulations in producing the plastic, they had been lax in not exercising greater care to contain VC. Also, industry itself had taken the initiative several years earlier to sponsor laboratory studies which pointed to the carcinogenic properties of VC in rats. But the sponsoring companies had delayed for many months reporting the results of these studies to the broader scientific community or to the government until Goodrich revealed the deaths of its workers. Industrial representatives reluctantly admitted that this sheltering of scientific data had been a serious mistake even though at that time there was no legal requirement to release the results of animal studies that were voluntarily sponsored. When the issue of corrective action to reduce VC emissions was raised, industry spokesmen pleaded for patience. They argued that they could not make radical engineering adjustments without incurring enormous costs that would result in the closing of some plants.

Returning to the decision meeting with the EPA Administrator, the EPA staff entered the conference room armed with large notebooks of facts and allegations. Their voluminous documents included pollutant measurements around facilities throughout the country, assessments of manufacturing processes within the plants, reviews of epidemiological and laboratory studies of the health effects of VC, and reports of consultations with hundreds of scientists and engineers.

About 20 of the EPA's best specialists characterized the problem for the Administrator and recommended solutions. They tried to reconstruct the levels of exposure which led to the deaths of some workers as

well as the levels which apparently had no effect on thousands of other workers. These studies indicated that the harmful levels were in the range of several hundred parts per million (ppm). Analyses of the toxicological studies depended on extrapolating the effects on humans from animal experiments. These studies suggested much lower levels of concern in the range of 1 to 50 ppm.

Why was there such a large disparity? The toxicologists were very conservative in extrapolating effects on animals to effects on humans on the one hand, while other health experts were quite pragmatic in simply relating observations of the presence or absence of tumors in humans to their estimate, albeit very uncertain, of the levels of exposure. In any event, all of us were concerned by the measurements on the front porch of a home adjacent to the Goodrich plant in Louisville of 40 ppm and by many other household measurements above 1 ppm near several plants.

As to the economic costs of regulatory action, the EPA experts contended that by tightening valves and fittings and by simply improving waste handling procedures within the plants, plant managers could easily reduce the levels of VC emissions. They also concluded that by paying greater attention to operating temperatures and pressures, shift supervisors could reduce the quantities of residual VC gas that remained in the kettles. But the representatives of some companies whom the EPA staff had queried disagreed, particularly those from companies with older plants. They had argued that significant reductions of VC emissions depended on installing entirely new production lines—an undertaking which they could not accomplish overnight.

Having listened intently to the presentations, the EPA Administrator reported briefly on his discussions with White House staff members, senior officials of the Department of Labor, and the head of the Food and Drug Administration. He noted that they were as anxious as the EPA staff to learn his decision, but they had provided little additional information which would influence that decision. They simply stated that the responsibility rested with the EPA and that they would try to ensure that their future steps complemented the EPA's actions. He was particularly disappointed that the Department of Labor had not moved more aggressively to take corrective action and reduce worker exposures. That Department was well equipped to prevent accidents in the workplace, but it simply did not have the scientific or engineering

capability to deal with the complexities of worker exposures to low levels of chemicals.

The Administrator then decided on several courses of action. First, he would summon to the EPA headquarters in Washington the chief executive officers of the 25 companies operating VC and PVC plants and inform them that they had 30 days to reduce the VC emissions in each of the plants. This corrective action was to be "voluntary" on their part, but with the clear implication that the EPA would take legal action to close some plants immediately thereafter if the levels were not reduced significantly. The Administrator correctly surmised that when confronted with this edict, industrial managers would find underutilized technical means to help correct the problem. Second, the EPA would begin the process of establishing an air emission standard for VC: discharges from plants could not result in a concentration exceeding 1 ppm at the fence lines of the plants, according to the proposed standard. Next the EPA would urge the Department of Labor to reach out to the scientific community for assistance in developing the technical justification for immediate steps requiring industry to reduce levels of VC exposures of workers. These steps would also curtail emissions of VC into the general environment. Finally, the EPA would continue its research and would investigate actions to further clarify all aspects of the VC problem.

Within a few days 25 company limousines encircled EPA headquarters as top industrial officials from across the country assembled to learn of these decisions. Managers of both old and new plants unanimously agreed that they could indeed reduce emissions significantly through engineering adjustments, and they did. The levels of VC came down, and no plants closed for environmental reasons.

Meanwhile, the EPA's studies of drinking water pipe and of the molding of plastic products indicated that very minute quantities of VC occasionally leaked from the plastic material, but the levels were of little concern. Also, as the manufacturing processes for converting VC to PVC were tightened to reduce losses of VC which should have been converted to PVC, the problem of residual VC impregnating the plastic would disappear almost entirely.

Compared to many other environmental rulings, the Administrator's decision concerning the production of VC and PVC was relatively easy. No one doubted the seriousness or the cause of the problem.

Indeed, VC is almost unique among environmental chemicals in triggering a disease that can only be attributed to a single chemical. Also, the potential economic consequences were sufficiently large that American engineering ingenuity would be extended to its limits. Finally, the scientific data base, including the data about the geriatric rats, was better than usual.

The decision clearly illustrated many facets of assessing chemical risks and taking immediate steps to reduce risks. First, all available information on health effects must be considered, including both data from carefully designed toxicological studies and information about people who have been exposed to the chemicals of concern. Inevitably wide bands of uncertainty surround such studies and information, but decisions must be made in spite of this uncertainty. Second, programs for the monitoring of concentrations of toxic chemicals in the air, water, food, and other materials during the times of environmental crises and also as a normal course of everyday business are especially critical in determining the extent of risks. There simply is no substitute for authoritative sampling measurements of chemicals suspected of threatening the health of humans.

Also, in responding to chemical risks, government agencies should recognize that industry can usually offer better technical solutions to solve specific problems than can the government. Frequently a push from the government is necessary. But once energized, industrial ingenuity is usually much more effective than technical solutions developed by government experts.[1]

A Threat to the Health of Newborn Infants: PCBs

One year later, I became involved in another aspect of balancing risks and costs. A different toxic chemical posed a risk, and this time a different type of cost was at stake. Exposure to this chemical might cause learning disabilities in children, a loss to families and indeed to society at large.

In mid-1975 the EPA discovered that nearly all nursing mothers in the United States were feeding breast milk contaminated with PCBs to their newborn infants. For a number of years the EPA had routinely collected milk samples from about 1500 mothers at hospitals in different

parts of the country and analyzed these samples for the presence of trace levels of pesticides. In the early 1970s, as the EPA's laboratory analysis methods became increasingly sensitive in detecting low levels of contaminants, government chemists began discovering the presence of trace levels of PCBs in the milk samples in addition to several pesticides. Thus, the revelations in 1975 were not completely unexpected.

However, the 1975 results suggested that the problem was more serious than previously recognized. The alarming aspect of the new reports of PCBs in mother's milk was the high levels found—levels of 1.0 to 5.0 ppm. The EPA's Office of Toxic Substances again became the focal point within the Agency for dealing with an emotionally charged problem.

At that time, a research scientist at the University of Wisconsin had been investigating the effect of PCBs on young monkeys. He fed PCBs to female parent monkeys who then passed the chemical on to their infants through breast feeding. He tested the breast milk and watched the behavior of the newborn monkeys for several years. He reported to the scientific community that the levels of PCBs in the breast milk were in the range of several parts per million. According to him, observations showed learning disabilities among the offspring.

By 1975, PCBs had become ubiquitous throughout the environment. The EPA had found the chemical in fish, in sediments, and in soil in many regions of the country. Very low levels were even showing up in drinking water. Of course, from the EPA's program of sampling mother's milk, Agency specialists had known that PCBs were accumulating in people. Also, the EPA had a special program for testing tissues from human corpses nationwide. These tests identified the presence of PCBs, also at levels of several parts per million.

EPA specialists knew of no way to control such widespread contamination in the short run. The manufacturers of PCBs had stopped production. PCBs still in use were being contained in a more responsible manner than in the past. Leakages of PCBs into the environment from waste piles and from contaminated products were gradually being cleaned up or contained. But the impact of these actions on the environmental presence of PCBs would not be seen for some years.

In addition to immediate concerns over the health of newborn infants, we knew that we in Washington would have a massive public relations problem on our hands once the press learned about PCB

contamination of mother's milk. What advice should the government give to nursing mothers? The EPA turned to the Department of Health, Education, and Welfare (now reconstituted as the Department of Health and Human Services) and to its Public Health Service to provide the answer to that question.

The senior officials of the Department were not eager to take on this issue. The Department was still reeling from the aftermath of the advice they had given to the American public the previous year to undergo inoculations for warding off swine flu. This advice had resulted in a barrage of reports of adverse side effects from the inoculations. Thus, the Department's specialists were hesitant to take a stand concerning PCB contamination. Still, they too recognized that it was only a matter of time until the press would have the story, and they would be expected to say something.

The immediate issue was whether the Public Health Service should develop a nationwide Health Advisory bulletin concerning contamination of mother's milk. Should they advise the medical community not to encourage breast feeding or alternatively should they alert doctors of the need to consider the pros and cons of breast feeding in the light of this new information? Even if a health advisory were not issued, what position would be taken in response to the inevitable press inquiries? The EPA operated in a glasshouse environment and simply could not prevent the data from reaching the public domain very quickly.

Meanwhile, EPA scientists were raising questions concerning the validity of the monkey studies. One report reaching the government indicated that the monkeys were not treated properly and had become sick during the experiments. Therefore, attributing their behavior to PCBs was questionable. Other reports suggested that the methods for administering and measuring the dose levels of PCBs were faulty.

In any event, after a few days of handwringing the EPA agreed with the Department's plan to deal with the problem. The Department would convene a *public* meeting at the National Institutes of Health on the edge of Washington where a panel of eminent medical experts would discuss the problem. Under the watchful eye of press representatives, they would recommend actions that should be taken by the Department. The experts would include both health practitioners and research toxicologists.

My role at the meeting was to lead the presentation of the EPA's

findings of PCBs in mother's milk and to orchestrate the discussion of EPA's assessment of the extent of PCB contamination in air, water, fish, and soil throughout the country. Then I was to take a back seat and let the Department's representative direct the rest of the meeting devoted to the health implications.

The medical experts at the meeting included six obstetricians, several general practitioners from the mid-West who had delivered and cared for literally thousands of babies, and three toxicologists. Two prominent observers were a representative of the La Leche League, an organization dedicated to the promotion of breast feeding, and a representative of the canned milk industry. A handful of journalists sat in the back row.

The general practitioners vigorously defended the many health benefits of breast feeding. They stressed over and over both the direct physiological benefits and the more subtle psychological benefits of nursing. The obstetricians supported these views. The toxicologists described the monkey experiments. They were hesitant to comment on the validity of the studies and added little concerning the significance of these experiments for the breast feeding of humans. They offered few insights as to the seriousness of this type of contamination which was being addressed for the first time. The La Leche League representative was quite effective in her summary of testimonials supporting breast feeding by many mothers. In contrast, the industry representative correctly decided that silence was his best course of action since the enormity of the health considerations clearly dwarfed business factors which would have been ascribed to his viewpoint.

The summary of the meeting by the Department's chairman stressed the virtues of breast feeding and the need to conduct more research on the effects of contaminants in mother's milk. He emphasized the recommendations for intensive follow-up studies of the learning capabilities of a sample of children known to have been fed contaminated milk.

The idea of a health advisory was smothered before it was even proposed. The general practitioners from the mid-West persuasively argued that the government should keep quiet. They contended that any statement from Washington would simply confuse doctors and mothers throughout the country who should not be deterred from breast feeding.

The next day I received a telephone call from a colleague in the

Public Health Service who had played a major role in organizing the meeting. He opined that the meeting had been a great success. He pointed to the consensus for a continuation of breast feeding that developed around the table. He added that the Department was especially relieved that the *Washington Post* had not reported the meeting on the front page and had not called for a health advisory.

This problem again pointed out the wide range of uncertainties in dealing with the health effects of toxic chemicals, uncertainties which were compounded by the questions raised over the validity of the principal scientific study being considered. Also, it highlighted some of the types of trade-offs that are encountered in weighing the merits of actions to limit specific risks. However, placing the responsibility for decision making in the hands of an ad hoc panel of scientific experts, even though the experts were carefully chosen by the government to consider both sides of the issue, was a little unusual.

Finally, as is often the case, the press was a major factor in forcing the government to reach a prompt decision on how to respond to a chemical problem regardless of uncertainties in the assessments of risk.[2]

Quantifying the Risks from Toxic Chemicals

During the 1970s, the EPA and other regulatory agencies directed much of their attention to the immediate problems posed by VC, PCBs, and a few other highly publicized toxic chemicals, and particularly to the uncertainties in dealing with their risks to public health. As a consequence of the difficulty in coping with these uncertainties on a crash basis, the need for scientifically credible methodologies for assessing health risks dominated many interagency discussions. Within the EPA, in particular, several offices strengthened their scientific capabilities to assess risks soon after the VC episode.

Meanwhile, economists at the White House Office of Management and Budget and elsewhere within the government pressed for detailed studies of the costs to the economy—both direct and indirect—when regulating chemicals. They insisted that the EPA attempt to balance these costs against health risks in reaching regulatory decisions. In order to carry out such a balance, argued the economists, the

risks and costs needed to be quantified. Soon the "art" of quantitative risk assessment began to emerge.

The EPA thereupon devoted considerable manpower to quantifying the risks from chemical exposures to carcinogens since the concern over cancer was a driving force in seeking new regulatory authorities. Typically, toxicologists administered the suspected carcinogen to laboratory rats or mice at different dose levels, including the highest possible level which would not cause immediate death from poisoning. The number of animals that eventually developed tumors at each dose level could be determined during autopsies, and the probability of a single animal developing tumors was calculated. The biostatisticians then plotted on a graph in the form of a continuous curve the probabilities that the different dosages would cause cancer. Thus, the scientists quantified the carcinogenic risk of a chemical—at least the risk to laboratory animals at high dose levels.

The next step was to relate these findings from the studies of animals subjected to high doses of chemicals in the laboratory to the effects on humans at the much lower pollutant concentrations commonly encountered in the environment. The statisticians extended the curve downward into the lower ranges of exposure. They relied on the scientific judgments of toxicologists as to the biological activity of the chemical at these lower levels since experimental data to guide the extension of the curve were not available. Interminable debates continue to this day, however, over the shape of these curves as the chemical concentrations decline down to the trace levels of contamination in the environment.

Controversy abounds over the way different chemicals behave in the bodies of both laboratory animals and human beings at high and low dose levels. Do they trigger formation of other chemicals? How do they promote tumors? Do some chemicals inhibit the development of tumors? Why do some chemicals cause tumors in one animal species and not in another? Despite these and many other uncertainties, scientists are required by the regulatory agencies to provide their best estimates of the likelihood that cancer will develop from low levels of exposure to chemicals which are identified as carcinogens, and they render judgments.[3]

The substantial differences between the physiological charac-

teristics of humans and those of rodents undoubtedly influence the onset of cancer. When providing risk estimates for regulatory agencies, toxicologists assume that humans are much more vulnerable than are experimental animals to cancer induction from exposures to chemicals. Therefore, they incorporate safety factors into the process of extrapolating from animals to humans to take account of this increased sensitivity of humans. The toxicologists then present the data about risks to humans in quantified probabilities.

In 1973 the EPA published in the *Federal Register* its first formal quantitative estimate of the risk of cancer posed by human exposure to a toxic substance. The chemical was benzidine—a chemical which was widely used at that time in dyes.[4] Since then, the Agency and many other governmental and nongovernmental bodies have carried out hundreds of quantitative risk assessments which have been used as the basis for regulating carcinogens.

In responding to the economic concerns of the Office of Management and Budget, the EPA also strengthened its economic assessment capabilities. Soon the dialogues over risk within the Agency took new tacks. For example, the advocates of cost–benefit analyses argued about the likelihood of cancer developing in a specific individual as the result of exposure to a specified level of a carcinogen. Was it one chance in a thousand, one in a million, or one in ten million? Knowing the answer, the decision maker could then balance costs and risks and attempt to determine the price of life that would be associated with specific regulatory actions, continued the logic of the argument.

One type of analysis proceeded as follows. If the public health risk of not taking a regulatory action to control a carcinogen could be quantified as the likelihood of 100 cancer deaths nationwide and if the cost to the economy of regulation could be estimated at $10,000,000, the responsible regulatory official could decide whether life should be valued at more or less than $100,000 per person. His or her value judgment would then drive the decision to regulate or not regulate.

The remnants of this type of simplistic analysis now reside largely in think tanks and academic settings. Few decision officials are prepared to consider the evidence in such narrow terms. Few members of the public will agree to put a price tag on the lives of loved ones. Nevertheless, the price of life remains a lively issue in the courtroom

hearings on toxic litigation directed to compensation for alleged injuries from environmental contaminants.

Another type of analysis estimates the costs to society in caring for the victims of pollution. For example, one high estimate by a health advocacy group is that the adverse health effects of air pollution from automobile exhausts currently cost the nation about $50 billion annually. This estimate includes both lost productivity due to absences from work and the costs of providing health care for those persons who are particularly sensitive to such pollution. Such estimates buttress the case for stronger controls. The industries which must abide with air pollution laws point out the costs to the nation of compliance with new controls—in this case the industry presents its high estimate of about $40 billion per year. This would seem like a reasonable trade-off, but political complications arise since those who most bear the cost are not necessarily those who are suffering the adverse impacts.[5]

Clearly, quantitative risk assessments can be helpful, and in many cases essential, in clarifying the toxicity traits of chemicals and the severity of problems they can cause. Similarly, quantitative estimates of economic impact are important to provide a perspective for responsible decision making. But making direct quantitative trade-offs between public health and economic impacts as the sole basis for reaching decisions on regulating chemicals is unrealistic. Too many scientific and economic uncertainties and too many nonquantifiable political and social factors are involved in such decisions. In the words of a report of the National Academy of Sciences: "Benefit–cost analysis should be thought of as a set of information-gathering and organizing tools that can be used to support decision-making rather than as a decision-making mechanism itself."[6]

During the past decade, quantitative risk assessments of chemicals believed to be carcinogens have continued to be a major activity for many regulatory agencies in Washington and throughout the country. Highly sophisticated computer models predict the relative carcinogenic potency of many chemicals, and other models provide the basis for estimating the likely exposures of populations to chemicals. Extensive guidelines for carrying out quantitative risk assessments have been developed and endorsed by the nation's leading scientists, within and outside government, and even the courts have demonstrated a remark-

able degree of familiarity with and dependence on assessments based on these guidelines.[7]

In taking steps to codify their approaches to quantifying carcinogenic risks, the federal regulatory agencies point out that "three types of evidence can be used to identify substances that may pose a carcinogenic hazard. . . (1) epidemiologic evidence derived from studies of exposed human populations, (2) experimental evidence derived from long-term laboratory studies of animals, and (3) supportive or suggestive evidence derived from studies of chemical structure or from short-term or other tests that are known to correlate with carcinogenic activity."[8]

The most persuasive evidence that a chemical induces cancer is an epidemiological study which shows a high correlation between groups of individuals exposed to the chemical, such as industrial workers, and unusual numbers of cancers within the groups as was the case with VC. The number of chemicals which now can be clearly labeled as "human" carcinogens based on such studies is about two dozen. However, epidemiologists have hesitated to develop techniques for providing quantitative estimates of risk from these chemicals, usually arguing that *any* exposure to a known human carcinogen is unacceptable.

Laboratory studies which show that chemicals will induce cancer in experimental animals are much more common and are the principal determinants in classifying chemicals as carcinogens. As discussed, they also provide the data for quantitative risk assessments. The government has indicted about 200 chemicals as carcinogens based on evidence from long-term animal studies. Many more chemicals have shown carcinogenic tendencies in less comprehensive animal studies or in other types of laboratory investigations.

The regulatory agencies repeatedly acknowledge the difficulties in extrapolating from high doses in the laboratory to low doses in the environment and from experimental animals to humans. In some cases the estimate of potency can vary by more than 10,000 times depending on the extrapolation model which is chosen.

Central to risk estimation within the regulatory agencies is the following philosophy: ". . . current methodologies which permit only crude estimates of human risk are designed to avoid understatement of the risk."[8] In short, the agencies are conservative and err on the side of safety. In this regard, scientists are not able to prove that carcinogens

will have no health impact at even the very lowest conceivable level of exposure. In the words of the regulatory agencies, ". . . exposure to any amount of a single carcinogen, however small, is regarded as capable of adding to the total carcinogenic risk."[8] Such statements are repeatedly used by environmental extremists in advocating bans on all carcinogens regardless of economic considerations.

In addition to the toxicity of a chemical, the extent of exposure of individuals to the chemical is a critical factor in determining risks. At one end of the spectrum, if the chemical is produced exclusively in an industrial process and survives only for a millisecond inside a sealed reaction vessel until it is changed into another form, then the chemical is of no risk to society regardless of its toxicity. At the other extreme, workers who breathed asbestos on the job in shipyards for many years obviously were at very high risk.

Determining the extent of human exposure to chemicals is even more difficult than estimating the potency of the chemicals. Many forms of cancer and other chronic diseases develop slowly during a period of 20 years or more. Thus, histories of human exposure patterns over a long period of time are important. But relating the life-style of a single individual, let alone a group of individuals, to the presence of a chemical over a period of years is fraught with uncertainty. Then relating human exposures to exposure of laboratory animals can be even more speculative. For example, humans may be exposed to a chemical for a few seconds or minutes or intermittently over a period of many years whereas laboratory animals are often continuously exposed to the chemical for their entire lifetimes.

Should risk estimates be oriented toward exposures of specific individuals to chemicals or to exposures of large groups of people? Obviously both are important. However, it is often easier to present risk estimates in terms of risks to population groups than to specific individuals. An illustrative statement might be: If 10,000 people are exposed to an air pollutant for five years at a specified concentration, eight additional cases of cancer will develop. A much different type of statement is the following: If my sister who is in her early thirties and is a heavy smoker lives among that population group, her chances of having lung cancer by age 50 are increased by 1%. Most risk assessment methods are oriented toward the first example of considering aggregated populations.

Despite the difficulties in estimating the potency of toxic chemicals and the still greater difficulties in reconstructing or predicting exposures over a long period of time, decisions must be based on both of these considerations. If ever there were areas of science crying for more intensive research, chemical toxicity and exposure assessment are the areas. While science will never provide definitive answers, research can certainly provide better tools for improving the basis for judgments, and particularly research aimed at evaluating laboratory experiments with animals in light of epidemiological investigations of human populations.

Finally, we as a society need to accept the concept of *de minimis* risk of toxic chemicals—a level of risk that is so low that it should be of only minimal concern to regulatory agencies. This concept has been used for many years in the field of nuclear radiation. Normal exposure to sunlight and x rays, for example, is commonly accepted, and costly regulations to limit exposure to still lower levels of other types of radiation should be accorded very low priority.

Similarly, there is risk from exposure to naturally occurring toxics in general and carcinogens in particular which we must tolerate in our daily lives. As in the case of radiation, society should accept minimal levels of man-made chemical exposures as the price for living in an industrial society and should concentrate on preventing the higher levels which are much more harmful.

The most commonly suggested *de minimis* risk level for carcinogens is a level of exposure that will induce cancer in one person in a population of 1 million persons who are exposed to the chemical. This is a small risk indeed in comparison with the overall rate of 230,000 of every 1 million deaths in the United States being attributable to cancer from all causes. Of course, the government should encourage steps to minimize exposures to all types of chemicals but should press for regulation of those that make a significant difference. Government officials should not fuel the notion that zero risk of cancer from man-made chemicals is an achievable goal, either technically or economically.

The foregoing discussion highlights the enormous effort which environmental specialists throughout the country have devoted during the past 15 years to understanding and quantifying the risks posed by carcinogens. Their research efforts have helped clarify the magnitude of

risks and have repeatedly pointed out the uncertainties in developing risk estimates. This valuable research should continue apace.

At the same time, there has been an undesirable consequence of quantitative risk assessments. They have been targeted almost exclusively on carcinogens, inadvertently diverting attention from many other types of risks of comparable importance. Some chemicals can induce heart disease, birth defects, genetic changes, and nervous disorders, for example. Since such impacts of chemical exposures are not easy to detect (i.e., they do not have signatures such as tumors which can be easily recognized), scientists have great difficulty persuading the public of their importance and their possible linkages to chemical exposures. Also, scientists are at a loss as to how to quantify these adverse effects. Thus, the public now has an exaggerated view of the *relative* threat posed by man-made chemicals which have carcinogenic tendencies.

More than a decade ago, a leading American scientist foresaw this distortion in the public's perception of the carcinogenic hazards of man-made chemicals and pointed out: "Much of the cancer occurring today, in addition to that caused by cigarette smoke and radiation (such as ultraviolet light which induces skin cancer), appears likely to be due to the ingestion of natural carcinogens in our diet. For example, fat intake has been correlated with breast and colon cancer, and many plants used in the human diet have developed a wide assortment of toxic chemicals (probably to discourage insects and other pests from eating them) that may be mutagens and carcinogens. In addition, powerful nitrosamines and nitrosamide carcinogens are formed from certain normal dietary biochemicals containing nitrogen, by reaction with nitrite. Nitrite is produced by bacteria in the body from nitrates that are present in ingested plant material and water. A number of molds produce powerful carcinogens such as aflatoxin and sterigmatocystin; these molds can be present in small amounts in foods such as peanut butter and corn."[9]

The important point is that the cancer risk from man-made chemicals should be kept in perspective. We are frequently exposed to higher levels of natural carcinogens than man-made carcinogens. Plants produce carcinogens for their own protection against insects, and thus some vegetables and grains contain carcinogens. Also, the overall cancer rate for the United States has remained essentially constant for the

past 50 years even though the production of chemicals has increased dramatically. Of course this does not mean that we should not try to limit exposures to man-made carcinogens, for we should; and quantitative risk assessments are critical in determining strategies for limiting exposures and reducing risks.

On Being Exposed to Mixtures of Chemicals

For the past two decades, most of the national effort in Washington, in state capitals, and in scientific laboratories to improve the scientific basis for regulating toxic chemicals has been based on studies of individual chemicals. Yet, as we have seen, some of the most pressing toxic problems result from exposures of people or ecological resources to many chemicals at the same time.

I have joined teams of EPA specialists investigating fishkills in polluted streams in Montana, Texas, and New York. These streams were threatened not by single pollutants but by multiple contaminants. In Montana, several toxic metals were draining from mining areas. In Texas, factories refurbishing aircraft were flushing both metals and organic solvents into the stream. In upstate New York, many toxic organic chemicals from a poorly operated sewage treatment plant had destroyed all aquatic activity.

We have all stood in the wake of heavy-duty trucks spewing diesel exhausts. When we drink heavily chlorinated water, we hope that the strange taste is a signal that good chemicals override both bacteria and bad chemicals. And when we see those barrels of toxic wastes, we urge that they be taken far away lest they corrode and begin to leak near our homes.

Further, our scientists must now expand their limited efforts of the past to assess the likely problems associated with mixtures of chemicals. While toxicologists may be able to ensure that their experiments expose laboratory animals to chemicals one at a time, real-life experiences are surrounded by chemical mixtures in our industrial cities. Mixtures of chemicals lurk in living rooms bedecked with plastic and subjected to a variety of household cleaning agents, and in restaurants mixtures of artificial food ingredients are often considered a key to elegant dining. Some doctors are increasingly asking, "Can we attribute many allergic

reactions—sneezing, hives, and rashes—to our constant exposure to seemingly insignificant levels of many man-made chemicals?"

In a few cases, industry and government laboratories routinely carry out studies on mixtures. One example is the testing of pesticides. Pesticide chemicals are seldom sprayed in the field in pure form. The materials applied to crop areas, for example, usually contain small amounts of chemicals which help in the spreading of the pesticide. Also, very small amounts of waste by-products from the processes of manufacturing pesticides may be present. Consequently, regulations for approval of pesticides require testing of the "technical-grade" materials—the materials used in the field which are actually mixtures of chemicals.

Often, scientists attempt to assess the properties of newly encountered mixtures based on tests that have been conducted on similar but not identical mixtures. The new mixtures may contain the same individual chemicals in different ratios or may include most but not all of the chemicals. For example, studies of the impact of a wide variety of diesel exhausts on laboratory animals have been conducted for years. Even though diesel exhausts may vary from vehicle to vehicle, generalized inferences concerning the health effects of new mixtures of diesel fuel are made from the extensive data base already developed.

More commonly, however, specialists attempt to assess the risks associated with mixtures using studies of the individual chemicals which make up the mixture. If two or three chemicals dominate the mixture, the task is simpler than if there are a dozen chemicals present in significant amounts.

As we have seen, both PCBs and dioxin are mixtures of closely related chemical molecules. In recent years, determining the toxicity of the different molecules composing these mixtures as well as the toxicity of commonly encountered combinations of these molecules has commanded high governmental priority. Still the risk estimates of the different possible mixtures remain uncertain. The focus on these two chemicals has given impetus to the development of broad data bases concerning many other chemicals that could help in clarifying risks from various mixtures that have differing ratios of the same ingredients.

In addressing mixtures, policy officials usually assume the harmful effects of one ingredient must be added to the harmful effects of other ingredients to understand the overall hazard of the mixture al-

though the methods of addition are not clear. For example, the presence of 10 ppm of one toxic chemical and 10 ppm of another will induce a harmful effect which is more severe than the adverse effects induced by either of the chemicals acting independently, according to expert advisers.

The concept of addition seems reasonable in the absence of better information. However, when the purpose of risk assessment is to support regulatory actions in numerical terms, crude estimates based on simple addition are hardly adequate. If the economic stakes are sufficiently high that proposed regulations are challenged by the affected parties, the advocates of simple addition will be hard pressed to defend their risk estimates. The methodology for estimating risks to humans and to ecological resources from exposures to mixtures is clearly a neglected area of the environmental sciences.

Chemical Threats to Ecological Resources

Another poorly understood, but critical, aspect of risk assessment is the hazard to ecological resources posed by some man-made chemicals. In the laboratory, some of the effects of one or a few chemicals on several types of plants, fish, or vertebrates can be studied under highly controlled conditions. Numerous studies of the ecological toxicity of individual chemicals have been carried out in artificial streams, aquariums, and greenhouses for many years. But in nature, many chemicals of both natural and human origin are constantly disrupting a wide variety of flora and fauna, and more extensive field studies are essential to extend the laboratory investigations into real-life situations.[10]

Some of the more obvious ecological effects of man-made chemicals can be easily observed, such as the dieback of forests attributable to air pollution and the disappearance of fish in polluted streams located near industrial complexes. However, many subtle but significant chemical interactions within highly integrated ecological systems remain cloaked in mystery, particularly in areas where pollution has not simply overwhelmed every form of biological life. For example, the effects of pollutants on the reproduction of species, on the competition among aquatic organisms for nutrients, and on the susceptibility of plants to

predators and disease cannot be adequately tested in the laboratory and cannot be readily observed in the field.

In some areas of the country the ecological impacts of toxic chemicals are very important for the future survival of individual species or of entire ecosystems. In other situations, their significance is lessened by much worse woes: bulldozers leveling the land, careless campers igniting forest fires, and developers draining marshlands.

The changing character of Lake Mead, the recreational area behind Boulder Dam on the Colorado River, illustrates the difficulty in determining whether ecological changes are for better or for worse. While the changes were not induced by toxic chemicals, this case study vividly illustrates the trade-offs involved in tampering with nature.

In 1987 and again in 1988 local scientists organized a fleet of more than 300 small motorboats to fertilize the lake. Each year they dumped more than 130 tons of ammonium polyphosphate fertilizer into one of the arms of the lake. The scientists wanted the fertilizer to serve as a nutrient for the lake and to increase the amount of algae in the lake. They claimed success. Why did they want algae which had been the scourge of Lake Erie 15 years earlier and had clogged many other inland aquatic reserves?

In the early 1980s, the city of Las Vegas had installed a tertiary sewage treatment system at the insistence of the EPA to reduce the flow of nutrients into the lake. Previously these flows of wastewater had carried biologically active materials which contributed to the nutrient loading of Lake Mead. Meanwhile, nutrient levels in the lake had already been declining due to the trapping of naturally occurring sediments behind the new Glenn Canyon Dam upstream on the Colorado River. Thus, two sources of nutrients for the lake were being cut off. But nutrients lead to algae, and reducing the levels of algae in the nation's lakes had become a major environmental objective. Weren't these approaches contributing to this objective?

However, with the disappearance of the algae, the lake had become too clean. While water-skiers enjoyed sparkling aquatic clarity, the more important sport fishing industry was in serious trouble. The striped bass and rainbow trout which depended on an abundance of nutrients were fast disappearing. Thus, out went the cry for the scientists to help restore the biological productivity of the lake. Today the fish seem to be

returning, and the water-skiers are still out in force every weekend. Nevadans are learning how clean is "clean enough."[11]

One of the most difficult aspects of ecological risk assessment is the identification of "end points"—those types of observable effects from pollution which indicate the onset of irreversible damage. Such damage may be occurring within individual cells; it may be affecting the composition of an entire community of a species; or it may be disrupting an ecosystem. More likely, destruction is occurring at several levels at the same time. With regard to animal species, some scientists have suggested that the destruction of habitats where reproduction takes place, such as nesting areas, may be the key to identifying serious ecological damage. As to broader ecosystem concerns, scientists have proposed that changes in the quantities and types of organic matter which are naturally regenerated, for example in a forest, are a salient indicator of serious ecological impacts which may be attributable to pollution.

Ecology has been called the science of resiliency. If given a chance following the destructive practices of man, streams will recover, forests will regenerate, and wildlife will come back. However, at some point, pollution stretches nature beyond its limit. Like a rubber band, biological resiliency has a breaking point. When does chemical pollution push biological systems to that breaking point? This is a major challenge for ecological risk assessment.

As to the "value" of nature, a few years ago the Congress began to require assessments of damage to natural resources that resulted from hazardous wastes. Such assessments can play an important role in financial settlements at Superfund sites. Determining reasonable financial losses due to ecological damage is not easy. The lost incomes associated with fish that are destroyed, trees that are damaged, and recreational visitors who stay away from polluted areas are very important to a local economy in the short term. However, a more comprehensive measure of loss that has been used in court actions is the decline in the sale value of properties in the affected areas—current values in comparison to values of similar property in nearby unaffected areas. This approach, while far from perfect, attempts to integrate many indirect costs associated with ecological damage.

During the past two decades our nation has not given adequate

attention to ecological risk. The experts often don't even have a good starting point. They don't know the state of ecological resources, and trends in the conditions of our forests, our vegetation, and our animal populations have not been adequately established. Too frequently, scientists must rely on anecdotal evidence and on a never-ending series of complaints by interested parties as resources continue to be destroyed.

Recently the EPA launched a major nationwide monitoring program to begin to improve appreciation of the condition of the nation's land and water on a scientific basis. The program is targeted specifically on near-coastal waters, forests, freshwater wetlands, surface waters, agroecosystems, and arid land. In each type of environment a number of questions will be addressed. What are the key resources that deserve immediate attention, and what type of damage have these resources already endured? Are the extent, magnitude, and location of the damage changing? Is the damage related to pollution or to other disturbances? What level of uncertainty is associated with the estimates? What can be done to reverse undesirable trends, and what are the costs? A monitoring program will not fully answer any of these questions but will certainly help improve the basis for managing natural resources that cannot be easily replaced.[12]

Since the mid-1970s, the EPA's priorities have been tilted toward reducing threats to public health from man-made chemicals while paying far less attention to ecological concerns. However, health and ecological aspects are intertwined, particularly for future generations of Americans who will increasingly disperse into the most isolated corners of the nation. Techniques for assessing ecological damage of the past and predicting future impacts of uncontrolled chemical activities will be desperately needed in the years and decades ahead. No longer should they be considered only of secondary importance because of the urgency of public health problems.

Documenting Uncertainty Leads to Informed Decisions

The previous sections have considered human health risks from exposure to carcinogens, risks posed by mixtures of chemicals, and risks to ecosystems from chemical releases into the environment. While

scientists use very different approaches to estimate these types of risks, almost all risk assessments are surrounded by high levels of uncertainty.[13]

One senior government scientist has noted that the difference between risk assessment and five-year weather forecasting is that at least with the weather forecast, if you wait five years, you find out if you were right.[14] Or in the words of former EPA Administrator William Ruckleshaus, risk analysis ". . . is a kind of pretense; to avoid paralysis of protective action that would result from waiting for 'definitive' data, we assume that we have greater knowledge than scientists actually possess and make decisions based on these assumptions."[15] At the same time, he was a vigorous supporter of detailed risk assessments based on available information, no matter how sparse, and of efforts to improve the methodologies for carrying out such assessments.

Regulators and litigators need numerical limits that reflect risk judgments—numbers which can be used as the basis for setting tolerable limits of exposure, for determining when polluters are posing a threat to society, and for demonstrating before the courts that cease and desist orders are needed. In response to this demand for clear estimates of risk, scientists continually stretch the limits of their knowledge, interpolating and extrapolating at every turn. They have no alternative.

Scientists must be prepared to defend their scientific judgments not only before their peers but also before government officials, hostile opponents, the media, and the public. Why was a safety factor of 1000 and not 100 used in extrapolating the effects of chemicals on mice to those on humans? Why were laboratory experiments showing a chemical affecting mice at very high dose levels considered more important than studies of workers exposed to the same chemical who had no adverse reactions? Why are outdoor air pollution levels given so much weight when most people spend 22 hours each day indoors? How can scientists talk about the impact of acid rain on 200,000 American lakes when they have made measurements in only 2000 and every lake is unique?

The list of questions concerning the soundness of risk assessments seems endless. Thus, many judgments must be made en route to a recommended numerical limit. These judgments should be clearly documented and explained in language understandable to both scientists and nonscientists. In some cases, debates will ensue as to whether

judgments are scientific or are laden with policy viewpoints. In any event, placing the full rationale for risk estimates in public view should lead to decisions that best serve societal interests.

The Times Beach incident of dioxin contamination mentioned earlier illustrates that judgments can be important in developing a risk assessment. Many uncertainties persisted concerning the health effects of dioxin on laboratory animals, let alone humans, and only guesses were available as to the frequency and intensity that children would play in contaminated soil and absorb dioxin through the skin or by licking their fingers. Different scientists could easily have concluded that an appropriate action level should have been 100 parts per trillion (ppt) or 100 parts per billion (ppb) rather than 1.0 ppb. Then a responsible policy official should decide how numerical limits are to be used in the best interests of society—interests that transcend science.

Yet the recommended action level was presented by the toxicologists as a single number. Little effort was made to document the uncertainties surrounding the number in a manner that permitted the choice of any level other than 1.0 ppb. The scientists decided themselves that the correct number was 1.0 ppb. They did not provide a framework which would have allowed the officials responsible for setting the limit an opportunity to examine the implications of alternative numerical limits, in terms of health effects and economic and social consequences.

In short, analysts can seldom hope realistically to determine the precise risk associated with a chemical or a mixture of chemicals. Rather, the analyst can articulate the extent of knowledge about the hazard of the chemical and the uncertainties associated with this knowledge. This information should be presented in terms of a range of numerical limits within which the true hazard is likely to fall. If the scientific information about the chemical is quite complete and of high quality, the range will be narrow. If the data are sparse, the range will be broad.

Science, Values, and Environmental Priorities

During the past few years, the EPA and other environmental regulatory bodies at the federal and state levels have become sensitive to

the fuzzy dividing line between science and policy as was illustrated in the case of dioxin. They have tried to separate the process of assessing risks from the decisions of whether and how to reduce risks. Proponents of such separation argue that risk assessments should be based only on science whereas regulatory decisions, while drawing on the assessments, must employ a different type of analysis—a balancing of political, economic, and social factors within legal constraints.[16]

This second type of analysis must ask, for example: How much can society afford to spend to curtail this risk? How quickly should and can the risk be reduced? Should all polluters be required to take the same actions, or should some, such as small business, be exempted? What precedents will be set by this regulatory action, and what are the future implications?

The vigorous advocacy of separating science from social policy to make regulatory decisions has helped clarify the boundaries between scientific facts, scientific judgments, and value judgments. However, this concept of separation should not be pushed too far since the dividing lines are seldom completely clear. Value judgments which transcend science are inevitably encompassed in assessing risk, with the choice of safety factors being a case in point. Furthermore, articulating the uncertainties surrounding risk assessments in a manner which can be understood by policy officials is seldom easy. Invariably, decision officials want to know how uncertain is "uncertain." In response, scientists frequently develop statistical measures of uncertainty, only to be told that they should be more precise in the future.

Sometimes, important inhibitions to separating science and values arise as a risk assessment moves into the political arena. Many policy officials are most comfortable when making decisions based on "objective" analyses which can be set forth on computer graphs and printouts. They are not eager to open up debates on the assumptions which could undermine the objectivity of "scientific" risk assessments. Very simply, they may look at a risk assessment as a crutch to justify a political decision rather than as an aid in reaching the decision.

Clearly, separating facts from judgments should be encouraged to the fullest extent possible. Since complete separations are seldom possible, policy officials should participate directly in scientific assessments as necessary to understand the process and the assumptions. Also, scientists should play a continuing role as these officials reach

their regulatory decisions which often rest, or are said to rest, on an appreciation of scientific assessments and uncertainty.

Regardless of the imperfections in the risk assessment process, I have repeatedly stressed that quantitative assessments have enormous value. In addition to providing a springboard for reaching regulatory decisions, they help government agencies and other institutions set their priorities. Funds are never available to address every risk situation immediately. If one analysis indicates that perhaps one dozen people may be at risk from an environmental problem and a second assessment of another situation suggests that as many as 1000 lives are in jeopardy, officials have a basis for deciding how to divide their resources in addressing the two situations.

At the same time, we must be wary of those who argue that until "major" risk problems are resolved, the government shouldn't divert its attention to correcting related "minor" problems. For example, they may ask, "If there are multiple polluters along a stream, is forcing one of the minor polluters to limit discharges before the major polluters take corrective action fair?" Or, "Should the public be concerned with chemicals entering into surface waters from the discharge pipes of industry when in the same region 80% of the contamination of the same water bodies is coming from agricultural runoff?"

Obviously, the largest polluters should be the major targets for enforcement offices. But even small amounts of some very toxic chemicals can be harmful. The regulatory process has become so complicated that the only sensible approach is to address simultaneously as many environmental hazards as possible with priorities tilted toward the greatest risks as necessary. Waiting to address all risks seriatim on the basis of "worst polluter first" may delay important corrective actions for decades. Indeed, resolving minor problems often places greater pressure on the major polluters to clean up their acts.

As early as 1970 President Nixon presented a then popular and seemingly rational approach for addressing environmental risks in his statement accompanying the reorganization of the federal environmental effort:

> . . . for pollution control purposes the environment must be perceived as a single interrelated system. A single source may pollute the air with smoke and chemicals, the land with solid wastes, and a river or lake with chemical and other wastes. Control of air pollution may

> produce more solid wastes which then would pollute the land or water. . . . A far more effective approach to pollution control would identify pollutants; trace them through the entire ecological chain, observing and recording changes in form as they occur; determine the total exposure of man and his environment; examine interactions among forms of pollution; [and] identify where on the ecological chain interdiction would be most appropriate.[15]

Such sophistication was too difficult to translate into practical terms and quickly gave way to more pragmatic steps of simply turning off the obvious pollution sources which were contaminating streams and clouding the air. This indeed was the approach the government adopted for a number of years following the 1970 statement. However, many toxic chemicals which are far less obvious than chimneys belching smoke eluded almost everyone. Indeed, toxic problems remain largely invisible, and their impacts are often delayed for decades. Thus, returning to a more comprehensive analytical approach to help guide the way in addressing the risks posed by chemicals seems appropriate. Still, care is needed to ensure that shortcomings in mathematical models and scientific data bases do not become excuses for inaction until the totality of the problem is better defined.

During the 1990s the United States will spend tens of billions of dollars each year to prevent and to clean up chemical problems in the environment. While procrastination in controlling toxic chemicals cannot be tolerated, the nation must use its financial resources wisely. Comparable attention must also be directed to other problems that erode the natural environment such as unrestrained development of estuaries and wetlands which often can be far more destructive than chemical pollution. In short, we need well-structured decision frameworks that can help in balancing the multiplicity of environmental, economic, and fairness concerns attendant to environmental regulatory decisions—concerns that reflect societal interests in the broadest sense of the term.

The Judiciary Speaks Out on Risk and Uncertainty

Since the birth of the EPA, the decisions of the Agency to regulate environmental chemicals have been under close scrutiny by the judici-

ary throughout the country. Environmental groups repeatedly petition the courts to force the EPA to strengthen regulatory approaches which they consider too timid. Individuals harmed by toxic chemicals turn to the courts for compensation. Conversely, regulated parties frequently seek redress for proposed regulations which they believe are based on exaggerated estimates of risk and which they contend will have disastrous consequences for them.

The U.S. Court of Appeals for the District of Columbia Circuit, in particular, has been seized with reviewing and ruling on the appropriateness of risk-based decisions of the EPA. In a very perceptive and well-reasoned speech in 1980, former Senior Circuit Judge David L. Bazelon of that court provided incisive commentary on the problems facing both the government and society in addressing environmental risks. He noted, for example:

> . . . the electorate must have an opportunity for the final say about which risks it will assume and which benefits it will seek. Elitists will say that most people are incapable of evaluating risks. Such a claim has no more place in an agency's decision-making than in an individual's choice about health care. Experts who are beyond reach and beyond view must never be allowed to arrogate those decisions to themselves.
>
> But what if an agency lacks the knowledge to state risks with certainty? For some activities, the magnitude of potential harm and the probability of its occurrence may be essentially unknown. . . . Risk estimates may depend on future contingencies of human behavior or other highly complex and unpredictable variables. . . . The best risk estimates are subject to an unknown degree of residual uncertainty and may thus overstate or understate the dangers involved. Many times, however, an agency must act in circumstances that make a crap game look as certain as death and taxes.
>
> . . . Perhaps those who seek to conquer uncertainty do not see eye to eye with those who act in spite of it. A "pure" scientist is usually acutely aware of the tenuousness of his assumptions, the competing interpretations of the data, and the limits of his knowledge. He presses outward upon the line between the known and the unknown. He does not resist disclosure: indeed, his career advances through it. If anything, the scientist is more likely to overemphasize uncertainty than to hide it.
>
> Those who must make practical decisions, on the other hand—regulators, physicians, engineers—cannot always afford science's

> luxury of withholding judgment. Indeed, they may be tempted to disregard or even suppress uncertainty. Uncertainty is messy. It cannot be stated as an objective quantity or factored into a decision as if it were a risk of known probability. Decision makers must consider data from many disciplines. Uncertainty detracts from simplicity of presentation, ease of understanding, and uniformity of application.
>
> To focus on uncertainties is to court paralysis: to disclose them is to risk public misunderstanding, loss of confidence, and opposition. Even though some uncertainty is inevitable, pointing it out will always create pressures for "just one more study." And yet, the decision maker knows too well that delay is also choice, with risks of its own.
>
> I am told that instead of disclosing uncertainty, decision makers may want to compensate for it by intentionally inflating risk factors. Engineers and physicians likewise choose to build in safety margins and err on the side of caution. I do not criticize those "conservative" decision rules; indeed, where health and safety are concerned, they are the only ones that make sense. But such rules cannot erase the uncertainty inherent in many decisions.[17]

Judge Bazelon has left behind a legacy of sophistication in judiciary understanding of the day-to-day problems faced by regulatory agencies in attempting to balance the many factors that comprise societal interests.

Of course the courts have also become a battleground for people who have been injured by environmental chemicals and seek financial compensation. They enter claims against the government, alleging that federal or state authorities have not done their jobs in providing protection from exposure to environmental chemicals. They also sue private companies that are responsible for the manufacture, distribution, or disposal of chemicals. Causation—relating the injury to the action of the defendant—is almost always a central issue in these court hearings. A second issue is the amount of compensation that is appropriate once causation has been established.[18]

During the past decade several courts have devoted considerable attention to allegations of government negligence in handling nuclear materials. While the analogy between nuclear radiation and toxic chemical problems is far from exact, these radiation cases have been instructive in clarifying the concerns of the courts when considering risk issues and in determining compensation levels for victims of hazardous exposures. In one case in the mid-1980s, the judge priced the

life of a person at about $500,000. Using this figure as a baseline, he ordered the government to pay the survivors of individual cancer victims from radiation exposure sums in the hundreds of thousands of dollars depending on the age, earning capabilities, and general value to the community of each victim.[19]

The risks being weighed by the courts in compensation cases relate to past exposures of specific people to specific chemicals. In both radiation and nonradiation cases, a particularly difficult aspect for the claimants is reconstructing and documenting their past personal behavior patterns over periods of up to twenty years. These patterns should persuasively show the degree of contact the claimants had with the chemical of concern. Sometimes, such as in the case of residents of industrial areas subjected to pollutants from many sources, behavioral patterns also reveal exposures to other injurious chemicals as well. In addition, the problems of relating a specific type of exposure to the particular injury—for example, lung cancer, leukemia, heart disease, kidney dysfunction—are formidable since such diseases can result from many causes.

Reflecting frustrations in this area of causation, one popular legal doctrine now holds that each contributing party should be fully liable for injuries that result from a chemical problem. For example, three companies may manufacture a product which is shown to have injured a particular consumer. In this case it is impossible to distinguish which company's product caused harm to the consumer due to his random selection of the brands over a period of many years. Thus, the court would rule that each of the companies can be held liable for the injury. In another type of case, if several companies have disposed of chemical wastes in a particular dump and the wastes become comingled, each company can be held liable for any of the problems caused by the dump.

Two recent dramatic cases show the magnitude of the claims recently filed in the courts by people who had been injured from chemical exposure problems.

In Bhopal, India, often called the chemical industry's Three Mile Island, a toxic gas used in the production of pesticides escaped from a manufacturing plant owned by the Union Carbide Company and blanketed a densely populated urban area. The death toll exceeded 2000, and thousands more were blinded or maimed for life. The source and the

effect of the release of the gas were never in dispute. Union Carbide abandoned its early efforts to shift the blame to its Indian affiliate and decided to settle the claims, initially totaling several billion dollars, for $400 million, a small price to pay for the human suffering that resulted.

The claims of shipyard workers and others who have handled asbestos for many years against the Johns Manville company and several other manufacturers of asbestos are reaching billions of dollars. Eventually many of these claims will probably be settled. However, reflecting the difficulty in proving that asbestos was the cause of cancer and related lung injuries, a large portion of the payments will go for legal fees with one estimate being that the victims and their survivors will receive less than one-third of the total payments.

For many years the Congress has debated the desirability of dictating wide-ranging compensation for victims of exposures to toxic chemicals. The long-standing law providing for government arbitration in resolving compensation cases of black lung among coal miners is often cited as a possible model. However, applying the precepts of this legislation and other approaches to worker's compensation to the problems of compensation for exposure of the general population to environmental chemicals needs to be approached with great caution. There are relatively few coal miners, but there are tens of millions of Americans who are exposed to trace levels of toxic chemicals.

Clearly, the courts are dealing with issues which should be of concern to all officials responsible for the control of toxic chemicals. However, many of their decisions are retrieved from law libraries only as new cases reach the courtrooms. Their rulings deserve much greater immediate attention from everyone involved in preventing as well as reacting to toxic chemical problems. Dealing with claims which are tied very directly to personal harm is an excellent way to underscore the many aspects of chemical risks, and particularly the many uncertainties.

Reducing Risks during the 1990s

In 1850, the average life expectancy in the United States was less than 45 years. Now it is over 70 years. The industrial revolution was at the core of this change in the health of the population.

Living in the industrial age we have become preoccupied with types of risks that didn't seem important a century ago, including risks posed by some man-made chemicals. All institutions—regulatory agencies, industrial companies, research laboratories—have a responsibility to join in the national effort to reduce chemical risks. Even if they all strive toward this goal, some level of risk will persist. The definition of "safe" in *Webster's Ninth New Collegiate Dictionary* as "without risk" is obsolete. During the next decade, an important challenge facing our institutions is to develop mechanisms which will permit all elements of society to participate more fully in deciding the levels of safety, or "acceptable" risk, for specific situations.

Given the embryonic state of risk assessment, a key in responding to this challenge will be major educational efforts—efforts to improve the expertise of specialists and the sophistication of the public. All participants in the national environmental effort need to understand better the potential and limitations of science and how to incorporate high levels of scientific uncertainty into responsible public policy. Education about risk must begin in the schools, receive far greater attention in universities and colleges, and continue into the town meetings where practical problems are addressed.

As this educational process proceeds, public perceptions of risk will continue to be a driving force in environmental protection programs. Risks that are difficult to understand, and particularly the probability of harm from intermittent exposures to low levels of chemicals, are often much more threatening to the public than more familiar, and even more serious, risks such as automobile accidents. Scientific studies will help in reducing the mystique of chemical risks. Also, improved estimates of the economic costs in reducing risk levels to zero will convince some people that certain risks may not be as bad as they seem. Still, the public wants to be exposed to a minimum of involuntary risks, and chemicals in the environment will remain an easy target for public outrage.

Meanwhile, concerned citizens grudgingly accept the argument that every chemical problem cannot be solved immediately. They want to be certain, however, that the procedures for determining priorities and for resolving each problem will be fair. The public needs to be constantly reassured that governmental agencies are responsible and free from scandals and favoritism. Unfortunately, a few regions of the

country, such as those embroiled in debates over disposal of nuclear waste, may never see the day when the public believes there is veracity in governmental pronouncements about environmental risks.

Increasingly, risk assessments, whether sponsored by government agencies or by local institutions, must stand up as "objective" under rigorous scrutiny by all concerned parties. The assessments can then play important roles in educating policy makers, in determining priorities, and in reaching conclusions on the most appropriate actions to reduce risks. However, scientific studies which blur the known facts with untested hypotheses, which fail to clearly articulate the uncertainties, or which subsume and hide value judgments are best left in the desk drawers of their authors.

At the present time, hundreds of institutions and thousands of specialists are busy assessing chemical risks. These experts work for federal and state agencies and their contractors. They are employed by insurance and financial institutions. They are full-time researchers at universities and think tanks. They are specialists engaged by labor unions and professional associations.

Some of these risk specialists are attempting to improve the methodological approaches to risk assessment. Frequently they share their experiences at scientific meetings and through the pages of scientific journals. However, much experience is simply forgotten after each problem is solved. Newcomers streaming to the field usually spend many months and years climbing the learning curve, often unaware of pitfalls encountered many times before by their predecessors.

In financial terms, government and industry spend billions of dollars each year developing scientific data which can be used in assessing chemical risks. The federal government alone earmarks tens of millions of dollars annually for improving risk assessment techniques. Given these large expenditures and the currently fragmented efforts for assessing risks, a modest investment by the Congress of a few million dollars each year to provide an effective focal point in Washington to coordinate and improve the risk assessment process on a nationwide scale seems long overdue.

The EPA and other agencies will argue that they are already the focal points. But each speaks with a different voice. None adequately recognizes the vital roles that state agencies, private sector organizations, and the courts should play in setting the national direction for

assessing risks. A new congressionally mandated forum, with representation from a broad spectrum of decision officials and other interested parties within and outside Washington, could play a useful role in reaching a consensus on how to approach risk decisions. They could sponsor educational and information-sharing activities that in a relatively short time would have considerable payoff in reducing risks and saving dollars.

We will see in a later chapter that the most effective way to reduce future risks from pollutants is to stop the generation of pollutants in the first place: for example, through the use of more efficient manufacturing processes, by the promotion of energy conservation measures, and through reduced reliance on chemicals known to cause problems, such as pesticides. A second line of defense is recycling and reuse of products and wastes which cause trouble—including the remelting of metals and the reclaiming of solvents, for example. If wastes still persist, then more effective controls on liquid effluents and atmospheric emissions and tighter containment of solid refuse are clearly needed.

While industrialists and agriculturalists can reduce the generation and spread of chemical pollutants, they will not be able to reduce leakages into the environment to zero. Also, we must cope with the chemicals which are already in the countryside. Therefore, identifying and assessing chemical risks will continue to undergird environmental protection efforts for the indefinite future.

Finally, the uncertainties surrounding risks from chemicals are enormous. At the same time, the costs of placing restrictions on commercial activities which are responsible for such uncertain risks can be substantial. But the cost of not taking action to reduce risks can be devastating in the long run. The experts often debate the cost of scrubbers and incinerators, of cleaning up spills and waste sites, and of developing nontoxic substitute products. They discuss far less frequently the increased cost of health care for pollution victims. They neglect the cost of finding alternative drinking water sources after aquifers are polluted. They forget the lost productivity and the beauty of land abandoned to contamination.

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