RISK ASSESSMENT AND REGULATORY PRIORITIES

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A number of surveys taken over time, from the early 1960s through quite recently, show that the public supports a "clean environment."[1] One may say to the public, "Don't you understand that a clean environment is going to cost money? That your utility bill is going to go up?" The public answers, "Yes, we understand that, but we want a clean environment." One replies, "But wait a minute, we may have to shut down some plants and lose some jobs because of it." And the public says, "Yes, but we want a clean environment." Whatever way one asks the question, the public comes back and overwhelmingly answers, "We want a clean environment. Let's get on with it!"

Despite this apparent public support, however, it is clear that legislative goals in the environmental area have not yet been achieved. We continue to discharge pollutants into the waterways of the United States. Air quality levels do not yet "provide an ample margin of safety to protect the public health."[2] While levels of suspended particles and sulfur oxides in the ambient air have been reduced significantly, the ozone problem is worse.[3] Most sewage is treated, but disposal of toxic wastes has proven a more difficult problem than expected and the levels of carcinogens in water do not appear to have been reduced.[4] In general, while it is clear that there has been some improvement in the state

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1. *See, e.g.*, G. GALLUP, FORECAST 2000: GEORGE GALLUP, JR. PREDICTS THE FUTURE OF AMERICA (1984).

2. Clean Air Act, 42 U.S.C. § 7412(b)(1)(B) (1982).

3. CONSERVATION FOUNDATION, THE STATE OF THE ENVIRONMENT: A VIEW TOWARD THE NINETIES (1987).

4. *Id.*; TOXIC SUBSTANCES, HEALTH AND THE ENVIRONMENT (L. Lave & A. Upton eds. 1987).

of the environment, it is also clear that environmental regulation has not completely succeeded. The amount of improvement has probably tended to be overstated.

A great deal of scholarly literature investigating regulatory agencies has found them to be inefficient, if one measures the amount of pollution abatement achieved per dollar expended.[5] Political scientists point out that while a variety of purposes have been served by the creation of regulatory agencies, neither efficiency nor effectiveness were dominant or even important goals to Congress or to agencies historically.[6]

One way of illustrating the problems facing the Environmental Protection Agency is to look at the sheer number of chemicals in the environment. There are currently about 60,000 chemicals in common use.[7] A National Academy of Science panel surveying the extent of scientific knowledge available about these chemicals concluded that in relative terms, science knows absolutely nothing about the human health effects of nearly all of them.[8] There is reasonably complete evidence as to human toxicity for only about 1,000 of these 60,000 chemicals.[9] This lack of data does not indicate indifference on the part of agencies and companies. Rather, it illustrates that toxicological data is extremely expensive to obtain. In all likelihood, therefore, it is technically and economically impossible to get complete data on all 60,000 chemicals currently in use.

For most of the chemicals that we know much about, our knowledge is derived from inadvertent human exposure, that is, human beings have been our test animals.[10] Science has historically obtained its best and most reliable information by using human beings as our "guinea pigs." Unsuspecting workers exposed to asbestos in the workplace played a bigger role than did laboratory rats in discovering the link between asbestos and mesothelioma. Consequently, there has been little controversy

5. *See, e.g.*, J. MENDELOFF, THE DILEMMA OF TOXIC SUBSTANCE REGULATION (1988); CRANDALL, GRUENSPECHT, KEELER & LAVE, REGULATING THE AUTOMOBILE (The Brookings Institution 1986).

6. J.Q. WILSON, THE POLITICS OF REGULATION (1980).

7. NATIONAL RESEARCH COUNCIL, TOXICITY TESTING—STRATEGIES TO DETERMINE NEEDS AND PRIORITIES (1984).

8. *Id.*

9. *Id.*

10. Lave, Ennever, Rosenkranz & Omenn, *Information Value of the Rodent Bioassay*, 336 NATURE 631 (1988).

about the asbestos data and its interpretation, because the data concerned human beings. Asbestos is not an anomaly in this respect. However, the obvious problem with this approach is that while using humans as test subjects for carcinogens gives much information, it is unethical. Using chemicals without prior testing gives rise to social disasters—such as those that occurred with asbestos and thalidomide—which are simply not acceptable.

Setting regulatory goals has proven difficult however. In the early 1970s, the Assistant Administrators of EPA would typically have breakfast together every Monday morning to map out their regulatory strategy. Those breakfasts were dominated by discussions of whatever "cancer scare" story had appeared in the *New York Times* or *Washington Post* over the weekend. Nearly every weekend, there was apparently at least one newspaper story identifying a "hot spot" area and the chemicals that might have increased the risk of cancer in that area. At the Monday breakfast meeting attention was directed to that story and agency staff were assigned to spend time working on the problem. This syndrome came to be called the "Carcinogen of the Month." Staff people ran around helter-skelter seeking to address the latest crisis, with little sustained effort among them. While this approach showed EPA to be responsive to public concerns, it did not produce much in the way of "regulatory strategy."

Today we arguably have much more experience with environmental regulation, yet we still have difficulty setting rational policy goals. This is well illustrated by an interesting set of calculations done by Bernard Cohen, a physicist at the University of Pittsburgh. Table 1 shows Cohen's calculations of the reduction in life expectancy in the United States due to a range of causes.

Interestingly, our society spends a great deal of time and resources regulating things that are considered to be very low risk on Table 1, such as environmental chemicals,[11] and not very much time regulating things that are considered to be high risk on Table 1, such as cigarette smoking and obesity. According to Cohen's research, if we could lower the death rate directly attrib-

11. Cohen's assertion that the risk associated with environmental chemicals is relatively small is a view shared by numerous others. *See, e.g.*, Doll & Peto, *The Causes of Cancer: Quantitative Estimates of Avoidable Risks of Cancer in the United States Today*, 66 J. NAT'L. CANCER INST. 1192 (1981) (estimating that only two to four percent of all cancers are associated with environmental chemicals).

utable to heart disease, smoking or obesity by even a little bit, then we could increase longevity in the population by a considerable amount. Instead, we tend to spend our time worrying about things that have relatively minor effects on life expectancy.

TABLE 1.[12]
ESTIMATED LIFE EXPECTANCY REDUCTION
FROM RISKS AND ACTIVITIES

Activity or risk	Days LER
Heart disease	2100
Being unmarried	2000
Cigarette smoking	1600
Cancer	980
Being 30 lbs. overweight	900
Grade school dropout	800
Unskilled laborer	700
Stroke	520
Vietnam army duty	400
Mining or construction work (due to accidents only)	300
Motor vehicle accidents	200
Pneumonia, influenza	130
Homicide	90
Drowning	40
Poison + suffocation + asphyxiation	37
Energy production and use	25
Diet drinks	2
Hurricanes, tornadoes	1
Airline crashes	1
All-nuclear electricity	0.04-2[a]
Harrisburg area residents (from TMI accident)	0.001
Radioactive waste burial ground leaks, risk to nearest neighbors	0.0001
Sky-Lab fall	0.00000002

[a]The lower number is the estimate of government-sponsored scientists, and the higher number is the estimate of nuclear critics.

To illustrate, consider the standard criterion used by the Food and Drug Administration: if a substance causes more than one cancer per million lifetimes among those exposed, then the Agency regards it as a "non-trivial risk."[13] If it causes less than one cancer per million lifetimes, then the FDA regards it as a "trivial risk."[14] A chemical with a one-in-one-million risk of cancer would reduce the life expectancy of the average exposed per-

12. NUCLEAR ENERGY: A SENSIBLE ALTERNATIVE 322 (Ott & Spinrad eds. 1985).

13. 42 Fed. Reg. 10,421 (Feb. 22, 1977). *See also* Hutt, *The Basis and Purpose of Government Regulation of Adulteration and Misbranding of Food*, 33 FOOD DRUG COSM. L.J. 505 (1978); Merrill, *Regulating Carcinogens in Food: A Legislator's Guide to the Food Safety Provisions of the Federal Food, Drug and Cosmetic Act*, 77 MICH. L. REV. 171 (1978).

14. *Id.*

son by 1/100 of a day. Regulatory agencies such as the FDA often set as goals the eliminatation of risks that could reduce an exposed person's life expectancy by as little as one day.

Risk assessment is a tool which is used in this environment of fluctuating and competing priorities. Therefore it is important to understand some of the assumptions behind risk analysis. Risk analysis requires a considerable amount of data. The first task is often to determine what population is at risk. While at first glance this may seem to be a trivial task, it turns out in practice to be an extraordinarily difficult problem. For example, suppose there is a contaminant in the groundwater and we want to assess the health risks it poses. Who is being exposed to it? All the people who get water from that site? But are there people who are pumping water out of their own wells? Is a municipal water treatment plant filtering out the contaminant? Surprisingly, simply figuring out who is exposed is difficult.

The need to determine levels of exposure compounds the difficulty. Some people may be exposed to the contaminant at a one part per million level; other people, at the one part per trillion level. We also need to know what the exposures are like over time, not just at one moment in time, so that we can figure out what the total dose looks like. This requires assumptions about the rate at which the contaminant will be seeping into the groundwater over the next fifty or seventy years.

To determine the likelihood that a contaminant will increase the risk that an exposed population will contract a given disease, we also need to know the dose-response relationship for each relevant disease. The fact that we know very little about dose-response relationships for chronic diseases other than cancer makes it difficult to estimate the increase in risk of those diseases.

When trying to figure out the dose/response relationship for a given disease, we use data either from studying laboratory animals or from epidemiological studies.[15] Each has its own problems. Data from laboratory animals requires extrapolation from mouse to man. We have all heard a bit about this, because when saccharin was an item of front page news, it was reported that in order to ingest the amount of saccharin that the laboratory rats in several studies consumed, a human being would probably

15. M. Pike, *Epidemiology and Risk Assessment: Estimation of GI Cancer Risk from Asbestos in Drinking Water and Lung Cancer Risk from PAHs in Air*, BANBURY REPORT 19: RISK QUANTIFICATION AND REGULATORY POLICY 55 (Hoel, Merrill & Perera eds. 1985).

have to drink extraordinarily large quantities of the soft drink Tab a day. The animal bioassays thus raised questions about whether one could extrapolate to humans and whether the very high doses received by the animals overwhelmed their immune system or otherwise led to an abnormal metabolic uptake.[16]

How can we extrapolate human effects from a mouse, which obviously is not identical to a human being? How can we extrapolate from a very high dose to a very low dose? We make assumptions in order to perform these extrapolations, because we do not know how to do anything better. For instance we reason that a mouse is a mammal and a human being is a mammal. Therefore, we say, anything that causes cancer in a mouse is likely to cause cancer in a human. The wisdom of that assumption is questionable. We also assume that when going from high to low doses, we can simply extrapolate proportionality, another questionable assumption. Again, we do not know what else to do.

Alternatively, we can rely on epidemiological studies, which are usually studies of workers who have been exposed to high levels of a chemical. We are able to detect disease in workers more easily because they are exposed to very high doses. To use this data for environmental or consumer regulation, we extrapolate from the very high doses of workers to the much lower doses of consumers. The usual problem in the epidemiological study is that there is typically little exposure data. There is generally a latency period between the time workers are exposed and the point at which a tumor or other manifestation arises. There are also other confounding factors to consider, such as multiple exposures.

In regulation and in litigation, whenever one is using a risk analysis, whether using data from a laboratory animal or from epidemiology, there are thus many uncertainties. That fact leads to a more basic question: how accurate are risk assessments? Are they accurate to plus or minus ten percent or are they off by a factor of ten million? The answer depends on the particular situation. For risk estimates associated with cigarette smoking, the uncertainty is probably within the ten percent range.[17] A risk estimate of saccharin is probably uncertain by about a factor of ten million.[18]

16. L. LAVE, THE STRATEGY OF SOCIAL REGULATION: DECISION FRAMEWORKS FOR POLICY (The Brookings Institution 1981).

17. L. Lave, *Health and Safety Risk Analysis*, 236 SCIENCE 291 (1987).

18. *Id.*

Unfortunately, many risk assessments are more like saccharin than they are like cigarette smoking.[19]

Generally, risk assessment methodological procedures are designed to provide "reasonable upper-bound estimates"[20] of a given risk. Thus, by design, the point estimate of the risk derived from risk assessment is at the top of the actual risk distribution curve. The usual risk assessment procedures choose an estimate so high that it is unlikely to actually occur. To illustrate, think of 100 similar chemicals. Rather than choosing an estimate representing the middle of the distribution, the estimate chosen by risk assessment is, for example, fifth from the top.

In virtually every case, the reasonable lower-bound estimate of a given risk is zero.[21] In other words, for chemicals that are carcinogenic in rodents, but for which there is no human evidence of carcinogenicity, it is a reasonable assumption that the chemical may not be a human carcinogen. Even when a chemical is known to be a human carcinogen, the relationship has only been shown to exist at much higher doses than those to which humans are usually exposed. A reasonable lower-bound assumption is that there is a threshold dose below which the risk to an exposed person is zero. It follows from this that in virtually every case, the reasonable range of uncertainty extends from zero to the point estimate derived from risk analysis. This range can be quite broad, as in the example of saccharin.

Recognition of this broad range of uncertainty leads to another question: how useful is risk assessment? I believe it is useful for several purposes. First, risk estimates help to focus public debate. They are an excellent tool to guide inquiry, because they show very quickly the crucial assumptions, and the need for additional data or interpretation. Risk analysis improves science by focusing on what we need to know in the future. However, it does not answer the most basic questions about what should and should not be regulated in the present. As we present this information it is important that we acknowledge the uncertainty explicitly.

These methodological obstacles aside, however, I believe that the most difficult and important step in risk management is set-

19. BANBURY REPORT 19, *supra* note 15.

20. E. Anderson, *The Risk Analysis Process*, in CARCINOGENIC RISK ASSESSMENT (C. Travis ed. 1988).

21. U.S. NATIONAL CANCER INSTITUTE, CANCER CONTROL OBJECTIVES FOR THE NATION 1985-2000 (1986).

ting policy goals. In the past, risk management was regarded as the province of "professionals." These professionals generally did not know and did not care to know public concerns. They believed that the public did not understand the nature of risk and thus had little to contribute. This led the system, through its risk managers, to address a number of concerns of little importance to the public and to ignore a number of concerns of great importance to the public. Consequently, we have spent far too much time in this country worrying about what scientists or professionals think ought to be done and far too little time worrying about what the public thinks ought to be done.

What risk assessment provides us is a systematic approach to analyzing complex problems. As long as we are trying to set policy in a scientific and systematic way, there is nothing better at our disposal than these admittedly imperfect risk assessments, no matter how uncertain they are. Scientific knowledge is not in a position, at this stage, to give confident answers as to how risky it is to drink water that has a certain contaminant in it at a certain dose. At least at the moment, and probably for any foreseeable future, uncertainty is ubiquitous and inevitable. Litigators will have much material for litigation. We will undoubtedly continue to be faced with difficult questions to resolve, and scientific experts alone will not be able to resolve them. But with risk assessment we can provide the best available health effects data and a systematic approach to estimating that risk so that more informed decisions are made by the public and its appointed decisionmakers. Risk assessment is a tool that should be used to present the evidence to the population.

As professionals, whether lawyers, scientists, managers or regulators, we thus need to concern ourselves a lot more with risk communication. Unfortunately, the previous attempts at risk communication have been terrible. When we are speaking to the public, risk communication must be a two-way street. We must seek to uncover the public's concerns, and make those concerns the primary source of regulatory priorities. What the public wants, in the end, is what should prevail. Risk assessment is not so much a means of convincing scientists or even judges. Rather it is a tool that should be used to present the evidence to the jury, the population in general, so that more informed policy decisions can be made.