42. Environmental Health Risks

Congress should

- repeal statutes that require government registration or notification before new chemical products are put on the market;
- pass the responsibility for the safety of chemical products to manufacturers; and
- examine the expected health benefits from current environmental protection laws and consider elimination of the laws that offer tiny, if any, benefits.

"Risk" has been the most potent word in the enactment of the federal environmental protection laws that now burden the country with more than $150 billion in annual regulatory costs. Risks of cancer, risks of birth defects, risks of other health effects, risks of ecological damage have all been paraded before Congress, and Congress has responded by passing laws that direct the Environmental Protection Agency to ''go forth and eliminate risk."

''Risk assessment'' is the term used to describe the assortment of animal tests, human studies, mathematical extrapolations, and conjectures that go into estimating risks from chemicals and radiation in the environment. Risk assessment, as practiced by the government, has been roundly criticized for depending on assumptions that guarantee exaggerated estimates of risk.

There have been two easy responses to the identified problems with risk assessment: better science and cost/benefit analysis. The fierceness with which proponents of the current system battle against both can be taken to indicate that better science and cost/benefit analysis would make a real difference if adopted. In fact, that's unlikely. Far more definite action is needed to improve risk assessment. That action is to take risk assessment out of the federal government and put it in the private sector.

Science and Risk

Science can't solve the problems because the problems are with risk assessment, not science, and risk assessment is not science. Science involves two processes. The first is proposing hypotheses about how a part of the physical universe works. The second is testing the hypotheses to see if they are indeed predictive. All kinds of hypotheses can be advanced, but a hypothesis without a test has little or no value. Scientists accept and rely on the hypotheses that survive tests, and they use information garnered in the testing of hypotheses in the formulation of new hypotheses. The process continues, and hypotheses that survive testing are used to make further predictions.

An example makes it clear why "better science" will have little effect on risk assessment. Based on information from laboratory animals that are exposed to very high levels of a chemical or, rarely, on the results of studies of workers exposed to high levels of a chemical in the workplace, the product of most risk assessments is a prediction that exposure to a chemical at a particular concentration over a specified length of time will cause an increase in disease. In the language of science, the risk assessment product is a hypothesis. But the hypothesis cannot be tested. It cannot be tested because the predicted risks of cancer or heart disease or neurological disease are such a tiny addition to the usual number of those diseases that the risk, even if realized, cannot be detected against the usual "background" number of cases. For instance, the EPA commonly proposes regulations of chemical exposures that are associated with a one-in-a-million chance of cancer, which is equivalent to three cancers each year in the United States. There in no way that that increase can be detected against the background of more than a million new cancers that occur each year.

The small risk that is predicted cannot be detected, so there is no way to test the prediction. For the same reason, any improvement in health that might accompany any intervention to reduce exposures can't be measured either.

Of course, science does have a role to play in bringing the best techniques and information to risk assessment (that is so even though most estimates of risk cannot be tested). As an example, some chemicals that are known to cause cancer interact directly with DNA and cause mutations, and some do not. There is no reason to think that the model used to predict cancer risks associated with chemicals that interact with DNA works equally well for other chemicals, and essentially all other countries in the world have always used different models for the two kinds of chemicals. Since its

inception, the EPA has resisted that idea and insisted on using a model that predicts the maximum risk for all chemicals. In its 1996 draft revised cancer guidelines, the agency acknowledges that two different risk assessment models are necessary to estimate the risks from the two classes of chemicals. Even so, its "new" model preserves essential characteristics of the old one. In time, the EPA might incorporate better science into its risk assessments, but science has a difficult time against what the EPA calls "science policy choices''—and others call assumptions. So long as the federal government holds a monopoly on risk assessment methods and interpretations, the EPA can brush aside even the most solidly based scientific information as it pursues regulatory aggrandizement.

Cost/Benefit Analysis

Similarly, few significant changes can be expected from requiring more cost/benefit analyses. Such analyses are very data intensive, and the way data are collected can influence the outcome of any assessment. Currently, and probably under any scheme, regulatory agencies gather the data. So long as they have that capacity, cost/benefit analysts will be at the agencies' mercy, whether the analysts are employed by the federal government or by the private sector.

What difference do cost/benefit analyses make, anyway? Regulatory programs of the Federal Aviation Administration, theoretically, provide an additional year of life to one person for every $23,000 in regulatory expenditures; the EPA requires an expenditure of 330 times as much, almost $7,600,000, for the same benefit. In fact, the discrepancy is far, far larger. The FAA calculations are based on information about real airplane accidents that killed real people; the EPA calculations are based on estimated rates of human disease that cannot be tested. Such information has not led to rollbacks in expensive regulations, and there is little reason to expect it to.

Current Regulations

The idea that "Washington knows best" has dominated Congress's efforts to deal with environmental risks. It has produced a patchwork of laws with different criteria, an ever-expanding EPA, increasing regulatory costs, and no demonstrated health benefit from regulating environmental chemicals. Only Congress can alter that course. Ideally, Congress will remove the government from risk assessment and leave it to manufacturers

to certify the safety of their products and to the courts to provide compensation to persons who are injured by faulty products.

Congress can start that process with changes to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA). FIFRA requires that the manufacturer or importer of a pesticide provide the EPA with detailed results of tests for adverse effects on humans and other life forms in the environment, and the EPA then decides whether the agent can be licensed for particular uses. TSCA requires that the manufacturer or importer of any "new" commercial chemical product supply the EPA with whatever testing information is available, and then the EPA can decide whether additional tests are needed before the chemical is introduced into commerce.

Independent Certification

Congress can pass the responsibility for the safety of chemical products to the manufacturers. Most manufacturers would immediately seek expert opinions about the safety of their products as a protection against liability. To supply that need, third-party organizations for testing and certifying chemicals would spring up. Such organizations would be analogous to the Underwriters Laboratories, Inc., which certifies electrical devices as safe without any government intervention. Third-party testing laboratories can conduct and interpret animal tests, and councils of experts, such as the American Council of Government Industrial Hygienists, can provide recommendations about conditions for safe use of the substances. Larger, consensus organizations, such as the American National Standards Institute, would also probably be interested in providing the tests and analysis necessary to certify a substance as safe enough for use. The proper functioning of such a system will require a tort system that compensates people who might be injured.

There would be great differences between the current system in which government does risk assessments and a system from which the government was absent. The assumptions that are based on old information and exaggerate risks and dictate the results of EPA risk assessments would be lifted, and the newest information could be incorporated into risk assessments. More important, the people who carried out tests and did assessments would not be government employees subject to no penalties for foot dragging and sloppy work. They would be working on contract to the manufacturers, which would lead to their completing their work on time, and they would be well aware that sloppy work could result in their

employers becoming known as unreliable and the loss of their own jobs. Wholesalers and retailers would find it in their interests to sell certified chemicals and to base their advertising on the certification. Formulators, who mix chemicals for specific applications, and food processors, who use chemicals, would choose certified chemicals to attract customers. It is entirely possible that some certification marks would come to be associated with more rigorous standards, and the buyer could choose between and among different products on the basis of certification, costs, and other factors.

How Large Are the Risks from Chemicals in the Environment?

Congress will hear that rates of cancer and other diseases will soar if the EPA backs off from its current regulatory course. Congress can take advantage of those claims to hold hearings to investigate just how big the risks are that the EPA is charged with controlling. If those risks are as small as almost all experts agree that they are, the entire panoply of environmental protection laws directed against chemicals can be reconsidered in light of their enormous expenses and tiny, and most uncertain, benefits.

Suggested Readings

Ames, Bruce N., Lois S. Gold, and Walter C. Willett. "The Causes and Prevention of Cancer." *Proceedings of the National Academy of Sciences* 92 (1995): 5258-65.

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Gough, Michael, and Steven Milloy. "EPA's Cancer Guidelines: Guidance to Nowhere." Cato Institute Policy Analysis no. 263, November 12, 1996.

Tengs, Tammy O., et al. "Five-Hundred Life-Saving Interventions and Their Cost-Effectiveness." *Risk Analysis* 15 (1995): 369-90.

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