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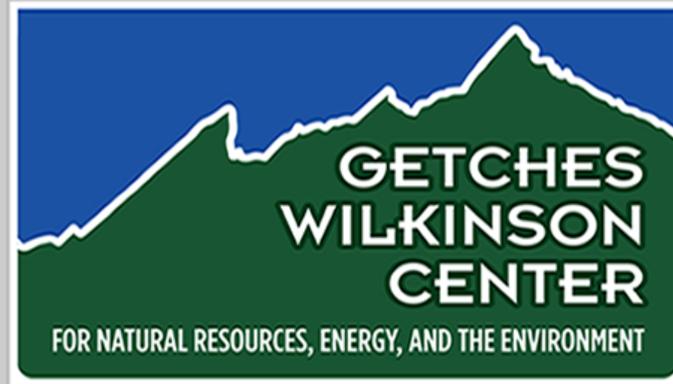
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CHANGING POLICY ROLES OF ENVIRONMENTAL SCIENCE

Dr. Devra Lee Davis*

Environmental scientists are increasingly asked for advice nowadays by the regulatory agencies. We need to be careful to communicate that advice precisely. A colleague of mine reported the following misunderstanding which bears repeating. A patient called and complained that he was very tired and had little energy for his wife. My friend advised him to walk ten miles a day and call back in a month to see how he was doing. He phoned and said "Doc, I feel much better now. I've been walking ten miles a day, and I have much more energy. There's only one problem. I'm 300 miles from home."

REACTIVE AND ANTICIPATORY REGULATORY POLICIES

Environmental scientists can give advice, but such advice is limited by past observations, available data, and typically imperfect understanding of physical and biological systems. It is useful to think of two fundamentally distinct types of environmental policy—those that are reactive, with which we are all familiar as readers of the daily newspaper; and those that are anticipatory. Anticipatory policies are designed to prevent disease or environmental impacts before they occur. In the environmental health field, studies will provide the reactive confirmation of past hazards; for the primary prevention of disease, experimental techniques and models of human risk based on animal data will be essential.

In my remarks today, I will briefly indicate the socio-legal context for the interdependence of environmental health science and environmental law, and discuss their respective evolutions. I will also suggest that recent twists in environmental law and the growth of the animal protection movement have substantially altered the expectations about what environmental health scientists can do; these changed expecta-

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tions may pervert the original intent of much public health legislation. And I will remind you that for the most part, environmental health science is best suited to confirming past risks, and not well equipped to predict, and hence prevent, future risks (see Table 1).

The subject of my talk today is also that of co-development—namely the development of environmental law and environmental science, with the emphasis on epidemiology, in particular. In contrast to those subtle relationships between species that provide fodder for poetic essays, environmental law and science occupy less harmonious ecological relationships.

TABLE 1: ROLE OF RISK ASSESSMENT*

1. The identification of hazard.
This requires an answer to the question, "Does X cause Y in Z?"
2. The assessment of dose-response.
This characterizes the relationship between a specific concentration of a substance and the development of associated health outcomes.
3. Exposure assessment.
This involves the measurement or estimation of the strength, number and pattern of human or environmental exposures to a specific substance.
4. Risk characterization.
This employs all these factors and provides a quantitative range of risks associated with specified exposures in certain populations.

* Data from: National Research Council. *Risk Assessment in the Federal Government: Managing the Process*. Washington, D.C.: National Press, 1983.

BASIC SCIENCE-FORCING LAWS

During its environmental heyday, the United States Congress enacted a number of laws which form the progeny of this wedding and may be thought of as "basic science-forcing." Including the Clean Air Act Amendments of 1970 and the Toxic Substances Control Act, these laws authorize agencies to take regulatory action on the grounds that a given compound poses or may pose an unreasonable risk of causing a host of adverse health effects. In this regard, preventing or reducing exposure to toxic chemicals becomes a form of preventive medicine. For many effects of interest, such as neurological diseases, there are no generally agreed-upon epidemiologic methods for

evaluating the risk. For others, such as cancer, animal models have been generally accepted, but are not without their critics.

Given the anticipatory, preventive thrust of these basic science-forcing environmental laws, toxicology and related experimental techniques for estimating risks were expected to play an important role in identifying priority problems. Courts were especially inclined in earlier stages of environmental law to interpret experimental and theoretical evidence liberally that a given exposure constituted an "unreasonable" risk. Science was pushed and prodded to devise methods for anticipating and predicting harm to public health and environment. As a retrospective science, epidemiology was not expected to play a major role in the development of preventive regulatory policy.

ANTICIPATORY POLICIES

Briefly, consider some of the early case law in this regard. In *Ethyl Corporation v. EPA*, the D.C. Circuit Court of Appeals found that the level of proof required under the Clean Air Act for a finding of endangerment did not require proof of actual harm, but only proof of a "significant risk of harm." (541 F. 2d at 13; *cert. denied*, 426 U.S. 941 (1976)). Indeed, the agency was not even required to prove that harm was "probable," but rather that there was a rational basis for inferring harm. In this case, the inferred harm occurred to the intellectual growth and development of inner city children. EPA based its decision on three types of evidence: theoretical modeling of lead dust, epidemiologic and clinical studies of exposed populations, and laboratory studies of animals. The Court argued that where the risk averted was of major consequence, conclusive proof was not required. In a later case on the same issue (*Lead Industries Association v. EPA*), the D.C. Circuit upheld EPA's air quality standards for lead, commenting that conflicting evidence did not undermine agency action. So long as EPA could show a rational basis for its actions, it could rely on evidence on the frontiers of science.

SOME RESERVATIONS ABOUT USE OF EPIDEMIOLOGY IN ENVIRONMENTAL POLICY TODAY

Basic science-forcing laws laid a framework and stimulated funding for research and development of toxicological tests to predict and anticipate human risks. However, precisely because the animal models on which much environmental regulation rests are models designed to anticipate human and

environmental effects, their validation and development remain the subject of intense debate.

Several basic scientific assumptions form contemporary U.S. laws. Key among these is the policy judgment that studies indicating that a given chemical causes adverse effects in animals should be regarded as implicating this same chemical as a hazard to humans. This tenet rests on scientific evidence amassed to date and also embraces a fundamental principle of preventive medicine and public policy. It is far better, easier, and more cost-effective to prevent diseases from developing than it is to pay the costs of treating those diseases once they become evident. Consider the tremendous investment in clean-up of hazardous wastes in the U.S. today: Whatever it will cost to clean up the thousands of sites now contaminated with previously misused industrial materials, it would have cost far less to have used them prudently in the past.

As to the technical basis for the assumed utility of studies on animals for predicting human effects, all of the compounds found to cause cancer in humans also cause cancer in animals. Moreover, the majority of compounds in commerce have not been adequately tested for their potential human toxicity, nor are data likely to become available based on human exposures, which can be erratic for the purposes of scientific assessment. Consequently, prudent public policy requires that experimental studies become the fulcrum on which regulatory actions rest. In this regard, those charged with environmental protection will continue to develop methods for systematically evaluating the risks of environmental pollution, through the techniques generally referred to as risk assessment. These techniques are driven by the laws that require them, but offer an important tool for evaluating potential, relative hazard of materials of interest.

In the U.S. a number of institutions have taken responsibility for conducting tests on potential hazardous substances. One of these is the toxicology program of the National Institute for Environmental Health Sciences (NIEHS), which supports basic research on chemical toxicity, primarily carcinogenicity. In addition, the regulatory agencies have developed systematic methods for using these data in reaching administrative decisions about risks. Guidelines for the assessment of cancer, reproductive, and neurological toxicity are under development in the U.S. by the EPA. The fundamental scientific principles for these assessments have been reviewed and evaluated by the National Research Council (NRC) in a series of publications, including most recently, *Drinking Water and Health*, volume VI.

EXPANDED ROLE FOR EPIDEMIOLOGY IN RISK ASSESSMENT ACTIVITIES

Questions about quantifying risks for humans, based on the animal data, often lead to calls for epidemiologic confirmation of risk assessments. I want to suggest briefly why this is a mistaken notion.

First of all, many of the compounds of regulatory interest cannot be studied with the tools of epidemiology. Either exposures are erratic, records on exposures cannot be reconstructed, or the exposed population may be too small to permit statistical evaluation of health status.

Secondly, where studies do exist on exposure to toxic chemicals, these commonly involve worker populations, which include healthy, working persons and not the typical U.S. population of young, old, and ill persons, as well as the healthy working population.

Finally, for many compounds of interest, such as ethylene oxide or the new generation of pesticides, chronic health effects with longer latencies may be involved. There has been a doubling in the 1970s, compared to the 1960s, of the production of many synthetic organic chemicals. Chronic effects of these exposures may not be evident until the end of this century.

Unlike many of the sciences which draw on statistics and are permitted relative obscurity, epidemiology captures a lot of public attention. As one researcher put it, "If you ever want to be intensely peer reviewed, produce a study that has millions of dollars of regulatory consequences." Love Canal, Alsea, Times Beach, Woburn, all have in common that they were places of toxic pollution and subjects of multimillion dollar lawsuits. Objective information in these circumstances may be an oxymoron.

EXPANDED ROLE FOR EPIDEMIOLOGY UNDER SUPERFUND

Let me close with a warning about some new directions for epidemiology that may prove to be a new "tar baby." You will recall Brer Fox tried to trick Brer Rabbit into playing with the tar baby, knowing that once he had handled it, he would be so caught up, he would not be able to move. The recently passed Superfund legislation calls for health assessments of proposed superfund sites. These health assessments can include epidemiologic studies of exposed persons. Conventional epidemiologic studies of many potential superfund sites are likely to be of limited value, despite their obvious promise for graduate student training programs. To be effective, such health assessments will need to rely heavily on experimental models of adverse health consequences. No amount of congressional

wishing, nor political jockeying will alter this fact: epidemiologic studies in these situations, as in most others, will confirm past damage, but will do little to prevent or anticipate future harm.

That great philosopher Woody Allen, ended his period piece of the 70s film "Annie Hall" with a story about a guy who loved his brother dearly; but there was only one problem. His brother thought he was a chicken. When asked, "Well, why don't you tell him the truth...that he is not a chicken, help him to face reality?" The fellow replied, "I can't. I need the eggs." Epidemiology may well be the eggs of environmental policy. We cannot strictly speaking ever know the value of our control policies. Because in implementing them, we change the environment, and other factors are certainly important determinants of public health as well; these are beyond our control, and it may be beyond our ability to study them systematically. But, we need the eggs in the sense that we must try to understand what we have done.

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