dence of cancer induction by phenacetin-containing analgesic mixtures. As Maugh states, "Virtually all investigators thus agree that chemicals which are carcinogenic in humans are also carcinogenic in animals." Therefore, the change in classification from "associated" with reports of carcinogenicity, as in Tomatis *et al.*, to "chemicals *known* to be carcinogens in man" [emphasis added] introduces an error and gives wide circulation to misinformation.

At a time when serious continuing effort to evaluate risk in drug safety requires effective communication between clinicians, epidemiologists, and laboratory scientists, it is a disservice when assumptions are circulated as fact. The classification of any chemical or drug as a carcinogen is of vital importance and must be related to sound evidence.

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Science and Regulatory Policy

As a health policy consultant to federal regulatory agencies, I agree with Comar (Editorial, 16 June 1978, p. 1225) that bad science is to be deplored. He raises the specter of "bad science" being used to justify unnecessary regulatory policies. Bad science can take another form, that of rejecting findings merely because they challenge accepted beliefs.

It should also be noted that doing science and setting policies are distinct activities. The National Academy of Sciences' committee on decision making for regulating chemicals reported (*1*) in 1975 that there is no absolutely objective way to set many regulatory policies. "All difficult decisions are characterized by inadequate information. . . . Problems of regulating chemicals in the environment are particularly beset with information characterized by a high degree of uncertainty" (*1*, p. 12).

During the past decade, protests about scientific quality and industry costs have been frequently used when regulatory policy is contested, as though regulatory decisions rested exclusively on science and market economics. Every known human carcinogen except arsenic has been demonstrated to be an animal carcinogen. Some suggestive animal and human epidemiological studies have preceded the discovery of serious health problems in humans. It is a policy decision to interpret these kinds of data as grounds for regulation. In the cases of dibromochloropropane (*2*), asbestos (*3*), and anesthetic gases (*4*), we have learned at considerable economic and human cost that reports of their potential hazards for humans should have been followed up earlier.

No one can precisely calculate the total economic costs of bad science leading to the delay of sound environmental and occupational regulation. Surely, however, this accounts for some part of our annual cost of $17.4 billion for cancer and $57 billion for heart, lung, and blood diseases (*5*). Other human costs are greater; for example, those of lives being shortened and diminished by exposure to controllable hazards.

The difficulty with so many preliminary reports of health hazards in animals is that current scientific theory holds that their implications for humans can only be confirmed through human epidemiological studies; hence, the "quick evaluation" that Comar proposes of such reports may not be possible. Even where such evaluation may be made, the regulatory process is often slow (*6*).

In this situation lie fundamental scientific, social, and economic contradictions. Much data relevant for epidemiological analysis were never intended to be so used; problems of noncomparability, disaggregation, and insufficient information abound. Obtaining good epidemiological data that can resolve certain issues will require 20 years or so. To wait for such resolution may expose humans to potential hazards that can lead to even greater burdens and health care costs.

In many instances, current data are sufficiently strong to warrant policies for regulatory intervention. In these cases, the economic and social costs of waiting for more definitive scientific answers outweigh the costs of preventive policies that limit exposure to suspected health hazards. To wait would make the human population mere fodder for epidemiological studies, subjecting the health of this and future generations to potentially grave and irreversible risks. If we are wrong, we can change our regulatory policies. If we are right, we will have saved lives.

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4. V. R. Hunt, *Work and Women's Health* (CRC Press, West Palm Beach, Fla., in press); A. I. Vaisman [*Eksp. Khir. Anesteziol.* **3**, 44 (1967)] reported on increased rates of miscarriage.
5. B. S. Cooper and D. P. Rice, *Soc. Sec. Bull.* **39**, 21 (February 1976).
6. Several billion pounds of the carcinogen vinyl chloride is produced each year. Final regulations for the safer manufacture of vinyl chloride were not in effect until some 3 years after the process of declaring it an "imminent hazard" had begun.

Davis makes several points with which in principle there can be no disagreement, namely: setting regulatory policy is not science; policy is made with inadequate information; bad science and especially inadequate epidemiology should not be used to delay needed regulation; needed regulatory processes should be speeded up.

Obviously, policy-makers will never have enough data; however, "bad science" severely compounds the problem, and premature regulation can have many disbenefits, including the foreclosure of research. But most important is the misconception conveyed that somehow regulatory policy exclusive of science and of market economics could (i) reduce a significant part of the annual $231-billion health bill, (ii) avoid making the human population "mere fodder for epidemiological studies, subjecting the health of this and future generations to potentially grave and irreversible risks," and (iii) save lives.

Matters are just not that simple. Increased industrial costs and inefficiencies mean increased poverty and decreased health which has to be balanced against the health effects avoided in the first place. One example—New York City has spent $200 million a year since 1970 to reduce the average annual concentration of sulfur dioxide in air from 0.06 to 0.03 part per million. Worthwhile? See (*1*). We need less bad science and more regulatory policy based on good science and economics in the interests of individuals and society.

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