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SCIENCE AND THE LIMITS OF ADMINISTRATIVE RULE-MAKING: LESSONS FROM THE OSHA CANCER POLICY

By SHEILA JASANOFF*

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I. INTRODUCTION

At the end of the sixties, Kenneth Davis wrote a seminal book¹ on the problem of securing justice in a legal system that leaves administrators uncontrolled scope for the exercise of discretion. In examining possible techniques for confining and structuring discretion, Davis concluded that:

Administrative rule-making is the key to a large portion of all that needs to be done. To whatever extent is practical and consistent with the need for individualized justice, the discretion of officers in handling individual cases should be guided by administrative rules adopted through procedure like that prescribed by the Administrative Procedure Act. Agencies through rule-making can often move from vague or absent statutory standards, and then, as experience and understanding develop, to guiding principles, and finally, when the subject matter permits, to precise and detailed rules. The constant objective, when discretionary power is excessive, should be for earlier and more elaborate administrative rules.²

Davis regarded open rule-making as an indispensable technique for controlling administrative behavior, for he saw in openness "a natural enemy of arbitrariness, a natural ally in the fight against injustice."³

Since these views were articulated, a succession of laws aimed at protecting public health, safety and the environment have conferred new discretionary duties on administrative agencies in the United States. Federal regulators are required to predict the future impact of new industrial products and processes and to devise measures for mitigating projected risks. Statutory grants of authority are couched in broad and imprecise terms. Laws such as the *Occupational Safety and Health Act*⁴ or the *Toxic Substances Control Act*⁵ instruct administrators to determine "unreasonable risk" or to establish "feasible" safety standards, taking into account the costs and benefits of alternative courses of action.

Inevitably, administrative implementation of these laws moves forward in an atmosphere of uncertainty.⁶ The hazards of modern technology, particularly those related to toxic substances in the environment, often become apparent only after decades of development. Federal health and safety legislation recognizes as a matter of policy that regulators should not wait for harm to materialize before undertaking appropriate remedial action. Accordingly, government agencies must assess the probability of future harm and abate significant risks to health and the environment even when scientific support for their action remains controversial or incomplete. Yet the prospect of regulatory intervention unconstrained either by firm legis-

¹ Davis, *Discretionary Justice* (Baton Rouge: Louisiana State University Press, 1969).

² *Id.* at 219.

³ *Id.* at 226.

⁴ Pub. L. No. 91-596, 29 U.S.C. §§ 651-678 (1970).

⁵ Pub. L. No. 94-469, 15 U.S.C. §§ 2601-2629 (1976).

⁶ Although this paper addresses only the problems associated with scientific uncertainty, administrative agencies have to deal with uncertainty in many other forms as well, for example, in their assessment of the costs and benefits of proposed regulatory action.

lative standards or by definite scientific principles promotes new concern about arbitrary and excessive administrative action.

Given the inescapable need for administrators to contend with uncertainty in health and safety regulation, does Davis' formula for channelling and containing administrative discretion still retain its validity? In particular, does the device of open administrative rule-making offer a sufficient guarantee against arbitrary resolution of scientific and technical controversies? These questions are addressed below in the context of one recent regulatory proceeding: the ambitious attempt by the United States Occupational Safety and Health Administration (OSHA) to establish rules for the identification, classification and regulation of carcinogens in the workplace. In reviewing the history and substance of OSHA's decision-making in this case, it is argued that the agency's effort, although it amply met the standard of "early and elaborate" rule-making, ultimately broke down on two counts. It failed to accommodate crucial differences between administrative and scientific criteria of legitimacy and it paid insufficient heed to the political aspects of the scientific controversies uncovered during the rule-making process.

In the course of developing its regulations on carcinogenic substances⁷—informally known as the "cancer policy"—OSHA was confronted by conflicting expert views on a wide range of theoretical and methodological issues. Areas of significant disagreement included the percentage of cancers attributed to occupational exposure, the criteria used to evaluate animal tests and epidemiological studies, and the factors considered in assigning chemicals to different categories of risk. OSHA attempted to forge a consensus on most of these issues by means of procedural techniques deeply familiar to American administrative agencies: hearings, adversarial testimony, a detailed public record and officially published regulations. Throughout the protracted regulatory proceeding, OSHA seemed to assume that by adhering to the canons of good administrative practice it would produce a workable and socially acceptable policy. But in so doing, the agency overlooked the "mixed" character of its regulatory task. It should have been apparent from the outset that a rule-making process so closely tied to complex scientific considerations would have to meet a dual standard of legitimacy—the scientific as well as the procedural—and that in important ways the two would prove difficult to reconcile. Moreover, in seeking principled solutions to the regulatory debate, OSHA underestimated the strength of the political cleavages underlying what appeared to be conflicts among competing scientific theories of carcinogenesis.

The story of the cancer policy may be told simply as one of regulatory short-sightedness. But in the context of a broader concern with regulatory reform, it is important to ask whether other positive lessons can be drawn from OSHA's experience. Could the agency have used any other institutional or procedural arrangements to fulfil its regulatory purpose more effectively? After examining these issues the paper will conclude with an inquiry into alternative approaches that have been followed in European countries faced

⁷ Identification, Classification and Regulation of Potential Occupational Carcinogens, 45 Fed. Reg. 5001-5296 (1980).

with similar regulatory problems. On the whole, European agencies have been less ambitious than OSHA in defining their regulatory objectives, but more successful in achieving a scientific and political consensus on the control of occupational carcinogens. Though the experiences of regulatory authorities are notoriously difficult to duplicate in other national settings, it is instructive to ask whether the European examples offer any suggestions for regulatory reform in the United States.

II. LEGISLATIVE CONTROL OF CARCINOGENS: THE DELANEY PRINCIPLE

OSHA's concern with carcinogens was rooted in a long-standing pre-occupation of the American regulatory policy with controlling public exposure to such substances. Over the last quarter century, Congress and the courts, as well as several administrative agencies, have devoted considerable energy to the problem of regulating carcinogens in the human environment. OSHA's generic cancer policy can only be understood and evaluated against the backdrop of these earlier efforts; ironically, it appears that the federal government's initial activities in this area achieved a measure of pragmatic success by avoiding the path of open rule-making.

Chemical carcinogens were first identified for special regulatory treatment in 1958 when Congress substantially revised the existing law for controlling food additives. Incorporated in the 1958 amendment to the *Food, Drug, and Cosmetic Act*⁸ was a provision introduced by Representative James Delaney of New York stipulating that no additive should be cleared for use: "[I]f it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal."⁹ The effect of this provision, popularly known as the Delaney Clause,¹⁰ is to ban from the food supply any additive designated as carcinogenic by the Food and Drug Administration (FDA) on the basis of animal or human evidence. The provision has been widely interpreted as laying down a "zero risk" policy for carcinogenic substances used in food preparation.¹¹

The Delaney Clause incorporated a number of assumptions about cancer causation and cancer research that won broad support from the international scientific community in the mid-1950s. Toxicologists generally subscribed to the view that any substance found to cause cancer in animals should also be regarded as a potential human carcinogen. Moreover, it was

⁸ *Food Additives Amendment of 1958*, Pub. L. No. 85-929, codified in scattered sections of the *Food, Drug, and Cosmetic Act*, 21 U.S.C. § 301 *et seq.* (1938).

⁹ 21 U.S.C. § 348(c)(3)(A) (1962).

¹⁰ Originally applicable only to food additives, the Delaney Clause was subsequently added to the colour additive and animal drug provisions of the *Food, Drug, and Cosmetic Act* as well. See 21 U.S.C. § 376(b)(5)(B) (1962) (colour additives) and 21 U.S.C. § 360b(d)(1)(H) (1968) (new animal drugs).

¹¹ See, e.g., Blank, *The Delaney Clause: Technical Naïveté and Scientific Advocacy in the Formulation of Public Health Policies* (1974), 62 Calif. L. Rev. 1084 and Martin, *The Delaney Clause and Zero Risk Tolerance* (1979), 34 Food Drug Cosmetic L.J. 43.

commonly believed that no safe "threshold" limit could be specified for exposure to carcinogens, since such substances were known to produce irreversible effects even at very low doses. These views were summarized in a statement issued by the International Union Against Cancer¹² at its 1956 symposium on chemical food additives: "Any substance which causes cancer in man or which, when tested under (specified) conditions, is shown conclusively to be a carcinogen at any dosage level, for any species of animal, following administration by any route, should not be considered innocuous for human consumption."¹³ In his remarks to the House on August 25, 1958, Delaney introduced this statement into the legislative record as scientific support for his proposed amendment.¹⁴

From the standpoint of later policy, however, it is equally important to stress what was not known or generally agreed upon in 1958. Since no national or international research institution had at that time undertaken systematic testing of chemicals for carcinogenicity,¹⁵ there were no accurate estimates of the number of potentially carcinogenic chemicals actually present in the human environment. Thus, policy-makers could reasonably conclude that it would be economically feasible to exclude *all* such substances from food. The techniques of analytical chemistry were not yet sufficiently developed to permit the detection of chemical substances in food at the parts per billion or parts per trillion level. Available technology supported the view that relatively few carcinogens would ever be subject to regulation under the Delaney Clause. Finally, the mechanisms by which chemicals produce cancerous changes in human and animal tissue were very poorly understood and there was no widespread consensus as to the proper methodology for designing and carrying out long term feeding experiments on test animals.

The formulation of the Delaney Clause implicitly took notice of these scientific unknowns. In contrast to its rigidity on the issue of threshold doses, the provision granted FDA considerable discretion to interpret and, if necessary, ignore experimental evidence of carcinogenicity. Recognizing that experts might differ in evaluating the results of animal bio-assays, the

¹² IUAC is an international non-governmental scientific organization which has consultative status with the World Health Organization. Established in 1935, IUAC became interested in potentially carcinogenic food additives as early as 1939. In 1956, IUAC sponsored a symposium on cancer hazards from chemical additives which provided some of the scientific impetus for the adoption of the Delaney Clause in the U.S.

¹³ See Proceedings of Symposium on Potential Cancer Hazards from Chemical Additives and Contaminants in Foodstuffs (1957), 13 Acta Union International contre le Cancer 179-363.

¹⁴ Extension of remarks by Representative James J. Delaney of New York on the House passage of H.R. 13254 (Cong. Rec. of August 25, 1958, 85th Cong., 2d Sess.), reprinted in Dunn, *Legislative Record of the 1958 Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act* (New York: Commerce Clearing House, 1958) 83-85.

¹⁵ Although the U.S. National Cancer Institute (NCI) was created in 1937, its carcinogenicity testing programme was not systematized or coordinated with federal regulatory priorities until the mid-seventies. NCI's testing activities underwent significant revision and consolidation following an investigation by the General Accounting Office in 1976 and again with the establishment of the National Toxicology Program in 1978.

anti-cancer provision gave FDA great latitude to determine whether such tests were "appropriate" and whether a tested substance in fact "induced" cancer.¹⁶ These escape valves served the agency well in subsequent years. On the whole, FDA has proved remarkably adept at avoiding strict but politically unacceptable applications of the Delaney principle.¹⁷ Only in the case of saccharin was it necessary for Congress to overrule FDA by statute¹⁸ in order to prevent an unwelcome result under the anti-cancer clause.

There is little doubt that FDA's pragmatism in implementing the Delaney provisions of the *Food, Drug, and Cosmetic Act* has helped preserve the agency's credibility in the eyes of the American public. Removing all suspected carcinogens from the food supply no longer seems a reasonable regulatory goal, particularly since modern analytical methods reveal trace amounts of more and more potential carcinogens whose presence in food was previously unsuspected. Some of these additives, such as nitrite, may offer benefits that outweigh their carcinogenic risk. Given these realities, FDA is clearly on politically firmer ground by refusing to ban sodium nitrite in preserved fish, acrylonitrile in beverage containers or lead acetate in hair dyes, than by insisting on rigid controls based on a literal reading of the Delaney Clause.¹⁹

FDA's flexible, pragmatic approach in applying a fairly unbending statute entails obvious costs in terms of administrative regularity and predictability. The agency has succeeded in dealing with carcinogens as well as it has by *not* structuring and confining the discretion it enjoys under the Delaney Clause. In particular, FDA has never issued any rule or policy statement setting forth the criteria by which it evaluates the appropriateness of animal tests. Instead, the agency has resorted to ad hoc procedures and arguments in interpreting scientific evidence so as to reach results consistent with a politically acceptable regulatory outcome.²⁰ In the case of nitrite, for example, the agency submitted the results of a controversial study of the chemical's effects to an independent body of toxicological consultants. This group concluded that the tests carried out at the Massachusetts Institute of Technology showed no statistically significant increases in malignancies in the test animals; accordingly, the study triggered no regulatory action under the Delaney Clause.²¹

III. LITIGATION AND THE EARLY SEARCH FOR CANCER PRINCIPLES

Although the Delaney Clause first focused federal regulatory interest on carcinogens, it was only with the creation of the Environmental Protec-

¹⁶ See, e.g., Comment, *Implementing the Anticancer Clauses of the Food, Drug, and Cosmetic Act* (1977), 44 U. Chi. L. Rev. 817 at 824-37.

¹⁷ *Id.* at 825-27. See also Hutt, *Public Policy Issues in Regulating Carcinogens in Food* (1978), 33 Food Drug Cosmetic L. J. 541 at 544,550.

¹⁸ *Saccharin Study and Labeling Act* of 1977, Pub. L. No. 95-203.

¹⁹ See, e.g., Editorial, "A Carcinogen Passes", *The New York Times*, Nov. 9, 1980 at 18E, col. 1.

²⁰ See authorities cited at note 17, *supra*.

²¹ Smith, *Nitrates: FDA Beats a Surprising Retreat* (1980), 209 Science 1100.

tion Agency (EPA) and its earliest efforts to control environmental pollution that the search for a principled "cancer policy" began in earnest. The effort, first by EPA and then by OSHA, to develop firm principles for identifying and regulating carcinogens owes much of its impetus to the involvement of the federal courts in health and safety policy-making. Judicial activism in this field was largely a product of the 1970s. In the first ten or fifteen years following the enactment of the Delaney Clause FDA's activities under that provision generated little legal controversy. In contrast, EPA became a favoured target of environmental activists who repeatedly brought the agency to court for its alleged failure to take firm action against a variety of chemical pollutants.

A. *The Results of Judicial Intervention*

Frequent litigation over the regulation of suspected carcinogens (especially pesticides) in the early 1970s produced several important side-effects. To begin with, the courts firmly endorsed the view, seemingly shared by Congress and large segments of the public, that chemical carcinogens deserved special attention from federal regulatory agencies charged with protecting public health. The Delaney Clause played a critical role in shaping this judicial attitude. In one early case arising from EPA's failure to issue cancellation notices for DDT, the court noted that the anti-cancer amendment, although not directly applicable to pesticides:

does... indicate the magnitude of Congressional concern about the hazards created by carcinogenic chemicals, and places a heavy burden on any administrative officer to explain the basis for his decision to permit the continued use of a chemical known to produce cancer in experimental animals.²²

The courts also emphasized that administrative decisions to regulate carcinogens would be regarded, to a significant degree, as policy judgments and, as such, would be entitled to great judicial deference.²³

Litigation also had the effect of bringing out into the open many of the scientific and policy issues involved in regulating carcinogens. In several instances, the positions adopted by EPA and other agencies received explicit judicial approval. For example, in sustaining EPA's suspension of the pesticides aldrin and dieldrin, the Court of Appeals for the District of Columbia Circuit approved the agency's view "that the concept of a threshold exposure level has no practical significance where carcinogens are concerned."²⁴ The court also condoned regulation based upon extrapolation from animal evidence to humans:

The long latency period of carcinogens... hinders epidemiological research, and the ethical problems of conducting cancer experiments on human beings are too

²² *EDF v. Ruckelshaus* 439 F.2d 584 at 596n. 41 (D.C. Cir. 1971).

²³ *Hercules, Inc. v. EPA*, 598 F.2d 91 at 106 (D.C. Cir. 1978); *EDF v. EPA*, 548 F.2d 998 at 1004n. 12 and accompanying text. (D.C. Cir. 1976) (chlordane, heptachlor); *EDF v. EPA*, 489 F.2d 1247 at 1252 (D.C. Cir. 1973) (DDT). On the other hand, the courts have exacted a high level of justification for decisions permitting the continued use of a potential carcinogen. See *EDF v. Ruckelshaus*, *supra* note 22; *EDF v. EPA*, 465 F.2d 528 at 529. (D.C. Cir. 1972).

²⁴ *EDF v. EPA*, 510 F.2d 1292 at 1298 (D.C. Cir. 1975).

obvious to require discussion. Although extrapolation of data from mice to men may be quantitatively imprecise, it is sufficient to establish a "substantial likelihood" that harm will result.²⁵

While litigation spurred EPA to more intensive efforts in regulating carcinogens, on the whole it also strengthened the agency's credibility. Not only were EPA's specific scientific determinations approved by the courts but, taken together, the pesticide cases reinforced the principle of judicial deference to administrative agencies in areas of technically complex decision-making.

B. *The EPA Cancer Principles*

A passage of the *Federal Environmental Pesticide Control Act of 1972*²⁶ assigned to EPA a regulatory task of almost impossible magnitude: to register all new pesticides and to re-register the 35,000 or so pesticides already in use in the United States.²⁷ The law also provided for cancellation of a pesticide registration if the substance was found to cause "unreasonable adverse effects on the environment."²⁸ Strict timetables were laid down for regulatory action. For example, only ninety days were provided for a final decision in a pesticide cancellation proceeding.²⁹ EPA's internal rules further divided this period between the Administrative Law judge and the Administrator, allocating twenty-five days to the former for a recommendation and sixty-five days to the latter for a final decision.³⁰ The tightness of this schedule placed enormous pressure on the agency to develop techniques for streamlining suspension and cancellation proceedings. One response was the attempt to codify the principles the agency would use in evaluating evidence of carcinogenicity.

Since the mid-1950s, a number of scientific and public health institutions have joined the International Union Against Cancer in endorsing the use of animal studies in evaluating chemical carcinogenicity. Expert committees, convened by such bodies as the World Health Organization, the Food and Agriculture Organization and the National Academy of Sciences, agreed on many of the criteria for conducting and interpreting such studies.³¹ When the issue of carcinogenicity was raised, first with respect to DDT and then with respect to the other major organo-chlorine pesticides, EPA sought to extract from the statements and position papers issued by these organizations a set of principles that would simplify its regulatory burden. The results achieved

²⁵ *Id.* at 1299.

²⁶ Pub. L. No. 92-516, 7 U.S.C. § 136 *et seq.* (1972).

²⁷ Pub. L. No. 92-516, 7 U.S.C. § 4(c) (2) (1972).

²⁸ This was defined to mean "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. § 136(bb) (1972).

²⁹ See Karch, "Explicit Criteria and Principles for Identifying Carcinogens: A Focus of Controversy at the Environmental Protection Agency," reprinted in National Academy of Sciences IIA *Decision-Making in the Environmental Protection Agency* (Washington, D.C.: National Academy of Sciences, 1977) 119 at 130.

³⁰ *Id.*

³¹ *Id.* at 161-71.

national prominence during the aldrin/dieldrin suspension proceedings when EPA included in its final brief nine "principles of carcinogenicity" that the agency claimed would be "applied to individual substances to determine their human cancer hazard."³² These are listed below:

- a) A carcinogen is any agent which increases tumor induction in man or animals.
- b) Well-established criteria exist for distinguishing between benign and malignant tumors; however, even the induction of benign tumors is sufficient to characterize a chemical as a carcinogen.
- c) The majority of human cancers are caused by avoidable exposure to carcinogens.
- d) While chemicals can be carcinogenic agents, only a small percentage actually are.
- e) Carcinogenesis is characterized by its irreversibility and long latency period following the initial exposure to the carcinogenic agent.
- f) There is great variation in individual susceptibility to carcinogens.
- g) The concept of a "threshold" exposure level for a carcinogenic agent has no practical significance because there is no valid method for establishing such a level.
- h) A carcinogenic agent may be identified through analysis of tumor induction results with laboratory animals exposed to the agent or on a post hoc basis by properly conducted epidemiological studies.
- i) Any substance which produces tumors in animals must be considered a carcinogenic hazard to man if the results were achieved according to the established parameters of a valid carcinogenesis test.

In the aldrin/dieldrin brief, these principles were accompanied by twenty-seven pages of supporting material from published reports and testimony taken by the agency.³³

Even on a casual reading of the nine principles, one is struck by their hybrid character; with few exceptions, they combine significant elements of both science and policy. The definition of a carcinogen in the first principle, for example, rests on two assumptions that have more the character of policy judgments than scientific findings: first, an agent that increases any type of tumor production (even benign tumors) should be regarded as a carcinogen, and second, carcinogenicity in laboratory animals should be accepted as an indicator of potential human carcinogenicity. The latter assumption is spelled out more explicitly in the ninth principle. Similarly, the seventh principle assumes, largely as a matter of policy, that no threshold levels should be established for carcinogens, because, as a matter of scientific fact, no valid method exists for establishing such levels.

³² EPA, "Respondent's Brief, Proposed Findings and Conclusions on Suspension," (Sept. 16, 1974) at 28-57.

³³ Karch, *supra* note 29, at 134.

As the chemical industry and others began to react to the cancer principles, EPA discovered that public approval would be far from easy to secure. Chemical manufacturers questioned the scientific validity of EPA's approach, correctly perceiving that the principles could become extremely powerful tools in the hands of the regulatory agencies if they were left unchallenged. Unwilling to jeopardize the aldrin/dieldrin suspension by engaging in what promised to be a protracted controversy, EPA substantially weakened its position on the cancer principles. For example, in his final decision the EPA Administrator paraphrased the first principle in the following way:

The once-significant distinction between tumors and cancers, or between tumorigenic and carcinogenic substances, has lost much of its validity with the increasing evidence that many tumors can develop into cancers. Thus, for purposes of carcinogenicity testing, they should be considered synonymous.³⁴

In this more qualified version, the "principle" emerged as nothing more than a policy conclusion backed up by considerable scientific authority. The courts, as we have seen, were quite prepared to defer to the agency in a matter "as sensitive and fright-laden as cancer."³⁵ EPA's watered-down application of the principles aroused no judicial opposition.

In later regulatory proceedings involving heptachlor/chlordane (H/C) and Mirex, EPA again relied on the cancer principles developed during the aldrin/dieldrin case. The original list of nine was extended to seventeen and revised several times, carefully incorporating suggestions made by Dr. Saffiotti of the National Cancer Institute.³⁶ In the H/C and the Mirex administrative proceedings, EPA moved to have the seventeen principles officially noticed as facts,³⁷ but each time without success. The agency eventually fared better at the hands of the judiciary. The Court of Appeals for the District of Columbia Circuit specifically approved EPA's use of the principles in the H/C suspension proceeding, stating that: "EPA's specific enunciation of its underlying analytic principles, derived from its experience in the area, yields meaningful notice and dialogue, enhances the administrative process and further reasoned decision-making."³⁸

Throughout these manoeuvrings, controversy over the status of the cancer principles continued undiminished until EPA abandoned the principles in favour of new procedures for assessing the cancer risk presented by environmental pollutants.³⁹ These included general guidelines for evaluating the evidence of carcinogenicity and were couched in far more cautious and qualified language than the cancer principles. The following brief extract from the guidelines illustrates this point:

³⁴ 39 Fed. Reg. 37267 (1974).

³⁵ *EDF v. EPA*, 510 F.2d 1292, 1298n, 13 and accompanying text (D.C. Cir. 1975).

³⁶ Karch, *supra* note 29, at 146-49.

³⁷ *Id.* at 152, 153.

³⁸ *EDF v. EPA*, 548 F.2d 998 at 1007 (D.C. Cir. 1976).

³⁹ Health Risk and Economic Impact Assessments of Suspected Carcinogens, 41 Fed. Reg. 21402 (1976).

The best evidence that an agent is a human carcinogen comes from epidemiological studies in conjunction with confirmatory animal tests. Substantial evidence is provided by animal tests that demonstrate the induction of malignant tumors that are generally recognized as early stages of malignancies. Suggestive evidence includes the induction of only those non life-shortening benign tumors which are generally accepted as not progressing to malignancy, and indirect tests of tumorigenic activity. . . .⁴⁰

The EPA Administrator was also careful to point out that carcinogenic risk assessment involves a two-step process: "The first decision is whether a particular substance constitutes a cancer risk. The second decision is what regulatory action, if any, should be taken to reduce that risk."⁴¹ This statement implicitly left open the possibility that a given piece of evidence, for example, induction of benign tumours, could be accorded different weight at the first and second stages of decision-making.

Soon after issuing these guidelines, EPA ceased to play a pre-eminent role in developing federal policy on carcinogens. With the passage of the *Toxic Substances Control Act*, primary jurisdiction over this problem shifted to the Interagency Regulatory Liaison Group (IRLG), a body composed of representatives from the five federal agencies entrusted with major responsibility for co-ordinating toxic substances regulation. Extremely active in the regulatory reform movement of the Carter years, IRLG seems to have died a quiet death with the advent of the Reagan Administration. In the current climate of deregulation, IRLG's demise is unlikely to signal renewed activism by its individual member agencies on the problem of regulating environmental carcinogens.

It is apparent from this complicated history that EPA's attempt to systematize the regulation of carcinogens was neither wholly successful nor a complete failure. The agency probably scored its greatest successes in the courts. Reviewing courts seem to have regarded the cancer principles essentially as open policy statements explaining in advance how the agency would weigh and evaluate conflicting evidence of carcinogenicity. Viewing the principles in this light, the courts agreed that they furthered "reasoned decision-making" by exposing the underlying analytical framework adopted by the agency.⁴² On the other hand, EPA was notably unsuccessful in mustering broad scientific support for the cancer principles. Though the agency asserted that the aldrin/dieldrin principles represented the "most advanced research findings" available,⁴³ their scientific status remained in considerable doubt. Efforts to get the seventeen revised principles officially noticed in the H/C and Mirex proceedings were lost in controversy. As the later guidelines on assessing suspected carcinogens indicate, EPA was eventually forced to substantially modify its position on such issues as the significance of benign tumours.

This analysis suggests that the courts and the scientific community were

⁴⁰ 41 Fed. Reg. 21404 (1976).

⁴¹ 41 Fed. Reg. 21403 (1976).

⁴² 41 Fed. Reg. 21404 (1976).

⁴³ *Id.*

applying very different standards in assessing the validity of the cancer principles. From the standpoint of the federal judiciary, the principles could be accepted as valid decision-making tools because they were openly announced and supported by a respectable body of expert opinion. They also seemed consistent with the agency's apparently pressing mandate to protect public health against the unique hazards presented by carcinogens. Scientists, in contrast, rejected any attempt to develop apparently fixed "principles" on matters that were—and to a large extent still are—being vigorously debated by experts on carcinogenesis. In their view, a search for principles could not be meaningfully undertaken as long as the underlying scientific issues remained so controversial.⁴⁴ A similar tension between scientific and judicial-administrative appraisals of validity precluded the development of OSHA's cancer policy, to which we now turn.

IV. THE REGULATION OF OCCUPATIONAL CARCINOGENS

The Occupational Safety and Health Act (OSH Act) of 1970 established within the Department of Labor a new implementing agency, OSHA,⁴⁵ for the purpose of carrying out the overall objectives of the law, that is: "to assure so far as possible every working man and women in the Nation safe and healthful working conditions."⁴⁶ The agency soon became one of the most controversial regulatory arms of the federal government. In its early years, OSHA was widely ridiculed for adopting thousands of highly specific safety standards dealing with relatively trivial hazards in the work-place. Critics of OSHA pointed to federal standards governing the placement of hooks in toilet stalls or the spacing of rungs on ladders and argued that the agency was doing much more to burden employers than to protect the safety and health of employees.⁴⁷

The need to reform OSHA's image was recognized as a top priority by the Carter Administration. As early as 1977, Eula Bingham, then Assistant Secretary of Labor for Occupational Safety and Health, announced in a policy statement that the agency would "shift to common sense priorities."⁴⁸ Outdated regulations would be eliminated, necessary regulations would be revised and simplified, and renewed emphasis would be placed on the control of serious hazards. Above all, the agency would assign more importance to health issues than to safety. OSHA's celebrated "cancer policy", issued as a final rule in January, 1980,⁴⁹ offered tangible evidence of the agency's determination to reorient its priorities and to set its house in order.

⁴⁴ *Id.*

⁴⁵ Pub. L. No. 91-596, §§ 29 and 30 provided for the appointment of an Assistant Secretary of Labor for Occupational Safety and Health and the creation of twenty-five additional positions in the Department of Labor to implement the Act.

⁴⁶ Pub. L. No. 91-596, § 2(b)(1954), 29 U.S.C. § 651, (b)(3)(1970).

⁴⁷ See, e.g., Smith, *The Occupational Safety and Health Act* (Washington D.C.: American Enterprise Institute, 1976) at 74-77; Shaffer, "Job Health and Safety," *Editorial Research Repts.* (Washington, D.C.: Congressional Quarterly, Inc., 1976) 953 at 965-66.

⁴⁸ OSHA, *The Shift to Common Sense Priorities* (Washington, D.C.: O.S.H.A., 1977).

⁴⁹ 45 Fed. Reg. 5001-5296 (1980).

In the first six years of existence, OSHA exercised its rule-making authority in developing standards for a number of individual carcinogens (asbestos, vinyl chloride, arsenic, coke oven emissions, acrylonitrile) and a group of fourteen organic compounds.⁵⁰ Several factors intervened in 1976-77 to bring about a radical departure from this pattern of substance-by-substance regulation. With the enactment of the *Toxic Substances Control Act* in 1976, public awareness of the long-term health hazards presented by chemicals was at an all-time high, and OSHA was under considerable pressure from its constituents, the labour unions, to speed up its own regulation of toxic substances in the workplace. Chance personnel changes occurring at this time also influenced the agency's course. A senior EPA staff member moved to OSHA, bringing with him the experience gathered at EPA through work on the cancer principles.⁵¹ In all, these circumstances favoured a new approach to the regulation of chemical carcinogens.

A. *Objectives of the Cancer Policy*

By adopting generic rules for the identification, classification and regulation of occupational carcinogens OSHA hoped, in the first instance, to avoid the repetitions that had characterized both its own earlier regulation of carcinogens and EPA's similar initiatives with respect to the organochlorine pesticides. The cancer policy was designed to resolve once and for all the repeatedly debated and litigated issues that seemed to surface in regulatory proceedings involving carcinogens: the validity of using animal studies as a basis for regulation, methodological principles for conducting such tests, and the proper role of epidemiological evidence. OSHA proposed to argue these and related issues fully and openly in one elaborate rule-making process. Its objective was to issue regulations based on these arguments and its own educated policy judgment on matters in dispute. Once the generic rules were in place, OSHA believed it could simplify the regulation of individual substances because many troublesome issues would no longer have to be reopened.

OSHA also hoped that the development of a generic policy would assure consistency over time in the agency's treatment of occupational carcinogens. OSHA's top administration had undergone notoriously frequent changes during the agency's first five years; Assistant Secretaries before Bingham had generally held their positions for no more than eighteen months. Staff members at OSHA believed that a regulation such as the cancer policy was needed to give the agency a stable sense of mission. Their views were expressed in the introduction to the proposed carcinogens regulations issued in October, 1977:

One obvious result of OSHA's current case-by-case approach to the regulation of carcinogens has been the relitigation of certain key issues in each and every rule-making. This taxes witnesses who have in the past been willing to testify in prior rule-makings. In addition, the system hardly guarantees a continuity of approach in every case, whether it be within the Agency or within the Courts.⁵²

⁵⁰ For an account of OSHA's early regulatory action on carcinogens, see Ashford, *Crisis in the Workplace*, (Cambridge, Mass.: MIT Press, 1976) at 154-59.

⁵¹ Anson Keller became Special Assistant for Regulatory Affairs at OSHA.

⁵² 42 Fed. Reg. 54154 (1977).

The cancer policy was designed not only to identify potential carcinogens, but also to classify them according to the degree of risk they presented to worker health. By this technique, OSHA expected to establish a rational system of priorities for regulating the thousands of chemicals, many of them suspected carcinogens, present in the American workplace. For all substances assigned to the highest risk category, OSHA proposed to set control standards at the lowest "feasible" level, as authorized by the *Occupational Safety and Health Act*.⁵³ Section 655(b)(5)⁵⁴ of the Act provides that for toxic materials or harmful physical agents the appropriate standard is the one:

[W]hich most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.

By tying the proposed classification scheme to different levels of control, OSHA blurred the line between decisions as to whether a substance presents a cancer risk and decisions as to what regulatory action should be taken. This was a distinction which EPA, as noted above,⁵⁵ had been careful to introduce in its own guidelines on carcinogenic risk assessment. OSHA's departure from the EPA precedent was consistent with its desire to speed up the regulation of occupational carcinogens, but in retrospect there is little doubt that this decision increased the cancer policy's vulnerability to political challenge.

B. *Values in Conflict: Good Administration vs. Good Science*

Issued as a final rule in January 1980, OSHA's cancer policy covered almost 300 pages in the Federal Register, of which more than half were devoted to the agency's analysis of specific scientific issues. The publication capped more than three years of regulatory development, distilling the views of at least fifty-four experts in the field of carcinogenesis and summarizing a total record of over 250,000 pages.⁵⁶ At least on the surface, there could be no question that OSHA had fully complied with the dictates of good administrative practice. The agency had listened to experts from government, industry and independent institutions. The decision-making record carefully described their conflicting viewpoints and justified the agency's decision to accept one or another position. Nevertheless, the publication of the cancer policy drew an instant, hostile reaction from the chemical industry, whose representatives immediately filed suit against OSHA. The reasons for this outcome are examined in detail below.

1. Maximum Tolerated Dose: A False Impression of Consensus

At public hearings on the cancer policy held in May-July, 1978, OSHA considered more than a dozen specific issues related to the conduct and interpretation of carcinogenesis bio-assays. One of the more controversial

⁵³ 42 Fed. Reg. 54185 (1977) (proposed rule); 45 Fed. Reg. 5286 (1980) (final rule).

⁵⁴ 29 U.S.C. § 655(b)(5) (1970).

⁵⁵ See text accompanying note 41, *supra*.

⁵⁶ 45 Fed. Reg. 5008 (1980).

was the propriety of testing at high doses. OSHA's handling of this issue is analysed here in some depth, because it is symptomatic of the difficulties encountered by the agency in resolving serious scientific disputes.

A key question posed by the agency to its expert witnesses concerned the appropriateness of testing laboratory animals at the maximum tolerated dose (MTD), usually defined as the highest dose administered during a chronic study "that can be predicted not to alter the treated animals' normal longevity from toxic effects other than carcinogenicity."⁵⁷ Establishing the MTD for any tested substance and any species of test animal involves a prediction and experts may differ or simply err in making this judgment. In spite of the possibility of variant opinions or outright error, however, many of OSHA's witnesses approved the use of the MTD as one of the doses in a cancer bio-assay. The opinion was frequently expressed that testing at the highest tolerated dose offers the only practical alternative to tests using unmanageably large numbers of animals at doses much closer to the levels of expected human exposure.⁵⁸

Though the principle of testing at the MTD was widely supported on practical grounds, several experts suggested that unavoidable biological effects produced at such high doses could lead to distortions in the dose-response curve. One theory that received considerable support, especially from industry scientists,⁵⁹ was that *any* chemical can induce cancer through "metabolic overloading" of the body's natural detoxification mechanisms. A witness for Dow Chemical summed up this hypothesis as follows: "Only relatively high doses can, in practice, yield statistically significant data. But *frequently* such high doses produce cancer simply because their very immensity overwhelms the biochemical pathways that would detoxify smaller, more realistic doses."⁶⁰ Others suggested that the metabolic effects of high doses might interfere with protective mechanisms, such as DNA repair, or cause the formation of carcinogenic agents not formed at lower doses. The possibility of "secondary carcinogenesis" at high doses, caused by tissue damage rather than direct carcinogenic action (for example, through induction of bladder stones), was also discussed by some scientists from the chemical industry.⁶¹

OSHA cited a number of scientific reasons for not accepting these arguments at face value. The agency noted, for example, that empirical evidence in support of the "metabolic overloading" theory was generally limited.⁶² Bio-assay results on vinyl chloride actually seemed to contradict the hypothesis that detoxification mechanisms were overwhelmed at high doses. The agency also dismissed the evidence of "secondary carcinogenesis" as not entirely convincing, noting that in most cases the alleged causal link between

⁵⁷ *Id.* at 5084.

⁵⁸ *Id.* at 5085-5088.

⁵⁹ *Id.* at 5088. OSHA's listing of some of the participants who supported this theory reads like a who's who of the chemical industry.

⁶⁰ *Id.* (emphasis added).

⁶¹ *Id.*

⁶² *Id.*

tissue damage and cancer was either inconclusive or non-existent.⁶³ OSHA concluded, therefore, that it would continue to accept data from tests conducted at high doses, although it expressed a willingness to evaluate any "truly substantial scientific data" to support the "metabolic over-loading" or "secondary carcinogenesis" hypotheses.⁶⁴

From the regulatory standpoint, the most noteworthy consequence of this decision was that OSHA proposed three criteria that proponents of rival mechanisms of carcinogenesis would have to meet before they could present evidence in support of their theories.⁶⁵ The agency stipulated that arguments about special mechanisms of carcinogenesis at high doses would only be heard if accompanied by evidence showing that:

- a) The tested substance produced metabolic products at high doses that are not present at lower doses;
- b) The metabolites produced at high doses were ultimate carcinogens while those produced at lower doses were not;
- c) The metabolites produced at high doses in animals were not produced in humans at lower doses.

Industry representatives interpreted this provision as an attempt by OSHA to take back with one hand what it seemed to have granted with the other, for they correctly perceived that the criteria would be impossible to meet in the current state of scientific knowledge.⁶⁶ Although OSHA admitted that evidence of metabolic disorders at high doses could be relevant to a determination of carcinogenesis, the stringency of the criteria essentially ruled out any possibility of introducing the "metabolic overloading" hypothesis. In sum, the agency appeared to be arbitrarily foreclosing from further consideration an area of potentially important scientific development. This was a result that most scientists, whatever their political affiliations, would not easily be prepared to accept.

The approach taken by OSHA to the MTD question also illustrates the agency's relative insensitivity to the political character of the controversy before it. The criteria for admitting evidence of metabolic overloading were unilaterally developed by the agency without seeking an accommodation with the parties most likely to disagree. Instead of functioning as a mediator between conflicting expert viewpoints, OSHA, by this action, positioned itself as a clear adversary to industry interests. Spokesmen for the Chemical industry could claim with some justice that the criteria were more a legal stratagem to curtail their rights than a reasoned response to disputed scientific issues.

It is important to recognize, however, that OSHA had strong reasons for its relative inflexibility in this matter. On strictly scientific grounds, the

⁶³ *Id.*

⁶⁴ *Id.* at 5093.

⁶⁵ *Id.* at 5094.

⁶⁶ Personal interview with Ronald Lang, Executive Director at American Industrial Health Council, Scarsdale, N.Y. (June 25, 1981).

agency found the secondary carcinogenesis theories unimpressive. Moreover, OSHA had reason to expect that, given any opportunity to do so, industry would continue to challenge the validity of high dosage testing, even on the basis of weak empirical evidence. In light of the federal judiciary's record of deference to the administrative agencies, OSHA could perhaps have counted on upholding its position at the end of the day in court. But the need to litigate these issues at all would bring back to the regulatory process precisely the kinds of delay that the generic policy was designed to prevent. Under the circumstances, the establishment of strict threshold criteria for the introduction of certain types of evidence made very good administrative sense.

2. Negative Epidemiological Studies

The classification of carcinogens under the cancer policy depends on an assessment of the relative risks presented by large numbers of candidate substances. This, in turn, requires the evaluation of different types of evidence, both positive and negative, from a variety of sources: human epidemiological studies, long-term bio-assays involving laboratory animals and supportive evidence from other sources, such as short-term mutagenicity studies. From its prior regulatory experience, OSHA was well aware of a strong possibility of conflicts among results obtained from different types of studies. Such contradictions, the agency recognized, would have to be consistently resolved to make possible a reasoned classification of carcinogens by degree of risk.

The evaluation of epidemiological studies in relation to animal tests posed a specially critical problem for OSHA in this connection, particularly since negative evidence from the studies was frequently in conflict with positive results from the tests. Again, the agency adopted what appeared to be a flexible position. In general, positive results from either human or mammalian animal studies would supersede negative epidemiological evidence, but the latter would still be considered if it conformed to certain criteria.⁶⁷ The difficulty with this approach lay, as before, in the nature of the criteria developed by OSHA for passing on the adequacy of "non-positive" human epidemiological studies.

In its final form, the cancer policy provided that non-positive human epidemiological studies would have to meet the following minimum criteria to merit consideration by the agency:

- a) The study should involve a group of subjects exposed to the substance for at least 20 years; the group should have been observed for at least 30 years following exposure.
- b) Documented reasons should be provided for predicting the sites at which the substance would be expected to induce cancer.
- c) The group of subjects should be large enough to permit detection of an increase in cancer incidence of 50% above that in unexposed controls.⁶⁸

⁶⁷ 45 Fed. Reg. 5059 (1980).

⁶⁸ *Id.* at 5059-5060.

It requires no more than a passing familiarity with the current state of epidemiology to recognize that these conditions would be practically impossible to satisfy in practice. At the same time, these criteria as well reflect legitimate concerns about the quality of scientific evidence routinely submitted to the regulatory agencies by industry. Epidemiological studies, in particular, are frequently flawed; among their most common shortcomings are the inadequate size of the exposed group and the inconclusive length of the observation period. One could argue from the agency's point of view, therefore, that the criteria represented a valid device for screening out such methodologically faulty surveys from the outset.⁶⁹ By excluding inadequate and incomplete epidemiological data, OSHA could save valuable resources that would otherwise be spent in evaluating and rebutting inconclusive evidence.

The technique of using impossibly stringent criteria as an exclusionary tool nonetheless raises troublesome questions from both an administrative and a scientific viewpoint. OSHA's evidentiary criteria were designed only for epidemiological studies indicating *no* positive correlation between exposure and increased incidence of cancer. No parallel methodological constraints were proposed for studies tending to show positive evidence of cancer risk. The criteria thus reflected an agency policy not only to accord greater weight to positive than to non-positive studies, but also to apply a lower standard of quality in evaluating the former than the latter.

Such an approach is perhaps legally defensible as being in accord with the *Occupational Safety and Health Act's* highly protective mandate concerning worker health. But clothing a basic policy judgment in the guise of seemingly objective evidentiary "criteria" is more difficult to justify by the standards of fair administrative practice. The use of such a technique suggests that the agency is hiding a politically vulnerable decision behind a façade of scientific rationality. This is a far cry from Davis' vision of an agency structuring its discretion through open rule-making.

There is another, deeper problem with OSHA's effort to exclude certain types of evidence by means of criteria for quality control. Few decisions in the field of carcinogenic risk assessment rest on certain knowledge. The mechanisms of carcinogenesis, the methodology and interpretation of animal and epidemiological studies, and the development of quantitative risk assessments are all matters on which experts may differ. Sifting through conflicting and uncertain evidence on such issues presents regulatory agencies with problems not encountered in more ordinary factual inquiries. As the District of Columbia Court of Appeals noted in reviewing one of EPA's early regulatory decisions:

Looking to the future, and commanded by Congress to make policy, a rule-making agency necessarily deals less with "evidentiary" disputes than with normative conflicts, projections from imperfect data, experiments and simulations,

⁶⁹ It should be noted as well that the proper methodology for conducting epidemiological studies is still a matter of debate in national and international scientific circles. OSHA therefore could not fall back upon any ready-made scientific consensus in designing its minimum criteria for non-positive studies.

educated predictions, differing assessments of possible risks, and the like. The process is *quasi*-legislative in character, and one will search it in vain for those intermediate "findings" of fact which mark the midway point in an adjudicator's linear march from raw evidence to single ultimate conclusion.⁷⁰

If this is an accurate description of modern regulatory decision-making, then the legitimacy of the result depends in large part on how carefully the agency considers and balances the probabilities before it. Indeed, the more predictive and subjective the process becomes, the greater is the agency's obligation to consider all factors relevant to a decision, regardless of the direction in which they tend. In such a calculation, both the quantity and quality of evidence may become crucial, for one moderately persuasive positive study may be offset by several negative ones, each less conclusive but cumulatively compelling. A fair assessment of the data would require consideration of the complete dossier, making due allowance for the shortcomings of each individual study. Summary exclusion of certain types of evidence from this delicate evaluation process, though supportable on grounds of administrative convenience, could lead to distorted results that no technical expert would find tenable.

3. The "Freezing of Science" Issue

The two examples discussed thus far reveal the extent of the conflict between the purposes of the rule-making agency and the requirements of sound scientific practice, as well as the tendency for technical disputes to take on political overtones in regulatory proceedings. The conflict between administrative efficiency and scientific credibility was openly discussed during the cancer policy proceedings under the heading "freezing of science." The central problem can best be stated in the agency's own language. Noting that the purpose of the cancer policy was to improve the efficiency of rule-making, ensure uniformity, and avoid relitigation of key issues, OSHA observed that: "[I]t is necessary to strike a balance between some limitation of scientific discussion, which is necessary to avoid regulatory paralysis, and the flexibility to consider exceptional cases and to accommodate new scientific advances."⁷¹

In its proposed regulations of 1977, OSHA attempted to strike this balance through a system of rebuttable presumptions and a mechanism for amending the generic regulations on the basis of new scientific evidence. These devices, however, were criticized by pro-labour interests for permitting a too easy reopening of supposedly foreclosed issues and by the chemical industry for not providing sufficient opportunity to incorporate scientific advances.

The final regulations promulgated by OSHA make significant concessions to the position adopted by the chemical industry. Two major procedures were provided for ensuring that the cancer policy would remain abreast of recent developments and incorporate the "best available evidence" as required by section 655(b)(5) of the Act. First, the regulations would

⁷⁰ *Amoco Oil Co. v. EPA*, 501 F.2d 722 at 735 (D.C. Cir. 1974).

⁷¹ 45 Fed. Reg. 5212.

be subject to periodic review, at least once every three years, by the National Cancer Institute (NCI), the National Institute for Environmental Health Sciences (NIEHS) and the National Institute for Occupational Safety and Health (NIOSH).⁷² OSHA was required to consider proposed amendments to the policy under four circumstances:

- (1) A recommendation for amendment made individually or collectively by each of the Directors of NCI, NIEHS and NIOSH after a required periodic review;
- (2) a recommendation for amendment made individually or collectively by each of the Directors of these Institutes, on their own motion; (3) a petition submitted by the public which demonstrates new evidence or issues; and (4) the Secretary's own motion.⁷³

In addition, the regulations permitted amendments to the cancer policy during standard-setting proceedings on individual carcinogenic substances. Such amendments were to be based on "substantial new evidence" or "substantial new issues" related to the substance under regulatory consideration.⁷⁴

The provision for amending the generic regulations during particular rule-making proceedings, not included in the 1977 proposal, represented a positive response to the chemical industry's demand for "flexibility". In the final rule, the right to initiate an amendment proceeding during an individual standard-setting process was constrained principally by the requirement that issues or evidence in support of such a petition be "substantial". If not strictly construed, this provision could simply serve as an open door to every available scientific counter-argument, thus undermining OSHA's fundamental objective of insulating key issues from continual debate.

This extended discussion of the OSHA cancer policy has highlighted some of the principal dilemmas that now confront American regulators in their evaluation of complex scientific and technical issues. Values cherished by American administrative agencies—uniformity, continuity, certainty—seem frequently at odds with the demands of science, particularly in areas of rapidly developing knowledge. Entrusted with increasingly complicated tasks, and working under stringent timetables and the ever present threat of litigation, agencies like OSHA and EPA find more and more attractive the possibility of simplifying the issues in dispute and, if possible, permanently foreclosing debate on some of them. But as the examples of high-dosage testing and negative epidemiological studies show, agencies may have to engage in arbitrary exercises of discretionary power in carrying out such simplification. In particular, a decision to systematically exclude certain categories of evidence may be impossible to justify either on scientific grounds or from the standpoint of fair and rational decision-making.

Equally important, the procedural safeguards accompanying rule-making in the United States do not provide the means for striking a genuine compromise between conflicting scientific viewpoints. American courts and administrative agencies have long subscribed to the idea that rule-making

⁷² *Id.* at 5204.

⁷³ *Id.*

⁷⁴ *Id.*

permits complex scientific questions to be "resolved in the crucible of debate through the clash of informed but opposing scientific and technological viewpoints."⁷⁵ The proliferation of hybrid rule-making procedures and the development of the "hard look" doctrine of review⁷⁶ both reflect the assumption that scientific controversies can be resolved through a full airing of the disputed issues. The record of OSHA's cancer policy rule-making suggests, however, that procedures alone cannot resolve conflicts in which scientific issues are linked to deeper economic and political interests. Indeed, a stable consensus in such cases may sooner be achieved in an atmosphere of mediation and conciliation than in the crucible of public debate. But if rule-making under appropriate procedures does not provide a satisfactory answer to the problems of technically complex decision-making, are there any reasonable alternatives? This question is addressed below by way of a brief comparative analysis of European approaches to the regulation of occupational carcinogens.

V. INTERNATIONAL COMPARISONS

The problem of protecting workers against occupational exposure to carcinogens is, of course, endemic to all industrial societies, particularly those with a developed capacity for chemical production. The methods used in West Germany and Britain to deal with this problem are briefly considered here in order to determine whether significantly different regulatory systems can better resolve the tensions between science, politics and administrative practices experienced by OSHA.

West Germany's legal and institutional structure for regulating carcinogens in the workplace limits administrative discretion in ways that minimize the need for procedural rigour. To begin with, the governing law⁷⁷ authorizes public officials to take action against occupational hazards related to toxic substances, but does not place upon any administrative agency an affirmative obligation to develop protective health and safety standards for such agents.⁷⁸ The German regulatory process also bypasses the need for government to referee scientific disagreements by delegating the responsibility for resolving

⁷⁵ *Int'l Harvester Co. v. Ruckelshaus*, 478 F.2d 615 at 652 (D.C. Cir. 1973) (concurring opinion of Chief Judge Bazelon).

⁷⁶ This doctrine, perhaps most ably propounded by the late Judge Harold Leventhal of the U.S. Court of Appeals for the D.C. Circuit, requires reviewing courts to ensure that agencies have taken a "hard look" at the problems before them. See *e.g.*, Leventhal, *Environmental Decisionmaking and the Role of the Courts* (1974), 122 U. Pa. L. Rev. 509 at 511-12.

⁷⁷ *Act on Protection against Dangerous Substances (Gesetz Zum Schutz vor gefährlichen Stossen)*, vom 16 Sept. 1980 (BG-BLI I.S. 1718). Short title: *Chemicals Act (Chemikaliengesetz)*.

⁷⁸ Section 19 of the *Chemicals Act* provides generally that the federal government may regulate hazardous substances in the workplace "insofar as it is necessary to protect human life or health including worker protection and humane job planning." Beyond this, the provision lists a variety of specific control measures that may be prescribed by federal regulation, such as controls on the condition and layout of the workplace, packaging and labeling requirements and ambient standards.

such conflicts to experts committees representing labour, management, government and academic scientists.

Two technical advisory bodies play a dominant role in setting Germany's occupational safety and health standards for chemicals. The first, an independent group formed under the auspices of the Deutsche Forschungsgemeinschaft (DFG),⁷⁹ determines safe levels of exposure for most toxic substances in the workplace. Maximum exposure standards⁸⁰ established by the DFG committee are officially published by the Ministry of Labour, thus achieving the character of binding standards for industry. This committee also prepares a separate, annually updated list of carcinogens found in the German workplace.⁸¹ For these substances, the committee does not undertake to establish standards, endorsing the widely-held view that there is no valid method for determining safe exposure levels for carcinogens. To develop enforceable standards for these substances, the labour ministry makes use of a supplementary rule-making process supervised by a second pluralistic advisory committee. Following the designation of a substance as a carcinogen, the ministry's own advisory committee on toxic substances⁸² assigns to it a so-called "technically directed standard",⁸³ taking into consideration economic and technical factors, as well as information about risk.

Both expert committees involved in the process of setting standards for occupational carcinogens represent divergent political interests. The DFG committee consists of scientists from industry and academic research institutions; the committee formed by the Ministry of Labour is even more elaborately representative, drawing its members from labour unions and the medical establishment, as well as from industry. The pluralistic structure of these committees serves an important political purpose, permitting scientists affiliated with different political interests to iron out their technical and policy differences without having to expose their disputes to public view. Since membership remains fairly stable over time, the committees provide a relatively consistent approach to regulatory problems. Above all, the committee system makes it possible to avoid the tensions between administrative and scientific principles that surfaced during OSHA's effort to develop the generic cancer policy. Composed primarily of scientists and operating without specific statutory authorization, the committees are protected against both legal and political pressure to act according to prescribed procedures, or to produce regulatory results within a mandatory timetable. Since decision-making is governed by scientific rather than administrative criteria, chemicals tend

⁷⁹ The group is officially known as the Senate Commission on the Testing of Workplace Substances Posing a Danger to Health (Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe).

⁸⁰ The standards are known as "maximum workplace concentrations" (Maximale Arbeitsplatzkonzentrationen, MAK-Werte).

⁸¹ A revised list of carcinogens is published each year along with the annually updated list of MAK-Werte.

⁸² Committee for Dangerous Substances in the Workplace (Ausschuss für gefährliche Arbeitsstoffe, AGA).

⁸³ Technische Richtkonzentrationen, TRK-Werte.

to be regulated on a case-by-case basis, with new findings accommodated as they become available. Such an incremental process generates no demand for generic policy-making or for the closure of debate on controversial scientific issues in the interests of administrative efficiency.

The British regulatory system for toxic hazards in the work place resembles the German system in several important features, though there are significant differences of philosophy between regulators in the two countries. The *Health and Safety at Work etc. Act*⁸⁴ of 1974, which controls all danger to worker health from toxic substances, states the obligations of government officials even less explicitly than the corresponding German law. The basic duty to design and implement control measures against carcinogens or other chemicals is assigned to manufacturers and users of such substances.⁸⁵ Government plays a facilitating role in the policy process, developing regulations where necessary, but generally relying on negotiated standards and voluntary codes of practice to achieve health and safety objectives. Nothing in the British law forces a departure from case-by-case evaluation of chemical hazards; an approach that avoids direct conflict between scientific flexibility and administrative efficiency.

As in the German case, the British regulatory framework has little need of formal procedural rules to promote consensus. Under the *Health and Safety at Work etc. Act* the concept of representative decision-making has been institutionalized through the creation of several "tripartite" bodies, such as the Health and Safety Commission and the Advisory Committee on Toxic Substances (ACTS), composed of representatives from labour, management and government. ACTS (with the assistance of technical subcommittees as needed) is primarily responsible for hearing and resolving disputes related to specific hazardous substances. Like the comparable German expert committees, it operates out of the public eye and without recourse to formal administrative procedures. Its members can resolve their differences of opinion, whether motivated by scientific or political considerations, through direct negotiation and compromise.

In comparison with the United States, both Germany and Britain have displayed a remarkable facility for circumventing potential conflicts among the scientific, administrative and political considerations involved in regulating occupational carcinogens. Despite their fundamentally different legal and political traditions, the two European countries have employed the same basic techniques to avoid the regulatory dilemmas confronted by OSHA in the United States. In the first place, the occupational safety and health laws

⁸⁴ *Health and Safety at Work etc. Act*, 1974, c. 37 (U.K.).

⁸⁵ Section 6 of the *Health and Safety at Work etc. Act*, 1974, c. 37 (U.K.) imposes a general duty on "any person who designs, manufactures, imports or supplies any article for use at work —

(a) to ensure, so far as is reasonably practicable, that the article is so designed and constructed as to be safe and without risks to health when properly used."

The provision also requires manufacturers to test products to the extent necessary for compliance with the general duty clause and to provide information to users.

of Germany and Britain sketch out a more modest regulatory agenda with respect to chemicals than the American *Occupational Safety & Health Act*. Neither explicitly nor implicitly are administrative agencies in either country required to undertake systematic control of *all* toxic substances to which workers are exposed. Regulation of such hazards can therefore proceed through case-by-case review of individual chemicals suspected of damaging worker health. The idea of a generic policy for identifying, classifying and regulating all carcinogens has attracted little support in this context.

Further, the legal and institutional systems of both Germany and Britain minimize the need for government to establish and explain its regulatory priorities through rule-making. British legislation, for example, assigns the duty to guard against cancer risks principally to those who create and, to a lesser extent, those who are exposed to such risks: manufacturers, employers and employees.⁸⁶ The general duty clauses of the *Health and Safety at Work etc. Act* require, in effect, that these private parties, rather than the competent public regulatory authority, should assume responsibility for identifying and controlling potential carcinogenic hazards in the workplace.⁸⁷ Though German law does not expressly endorse the concept of self-regulation, the task of establishing regulatory priorities in that country is tacitly assumed by a non-governmental body, the DFG expert committee, which identifies targets of regulation for the labour ministry through its annually published list of occupational carcinogens.

Finally, the representative expert committees of both European countries provide an effective forum for resolving political as well as scientific controversies. Implicitly recognizing the linkage between science and politics in the regulatory environment, both Germany and Britain have created institutions capable of mediating technical differences among experts holding different political allegiances. Constrained neither by procedural rules nor publication requirements, these committees can achieve consensus on disputed issues with greater ease than is ordinarily possible in the open and adversarial setting of administrative rule-making in the United States.

VI. CONCLUSION

This brief detour through two European regulatory systems throws into relief the special complexity of the American administrative process and underscores the difficulty of proposing for the United States any simple guidelines for regulatory reform. The structure of the American regulatory system requires, in effect, that administrative decision-making in areas of scientific complexity, such as the control of occupational carcinogens, must meet a three-way standard of legitimacy: the administrative, the scientific

⁸⁶ *Health and Safety at Work etc. Act*, 1974, c. 37 ss. 2-7 (U.K.).

⁸⁷ In placing greater emphasis on private regulatory behaviour, the *Health and Safety at Work etc. Act*, 1974, c. 37 (U.K.) simply followed the recommendation of the influential Robens Committee, which proposed in its 1972 report that a new occupational safety and health law should encourage more "personal responsibility and voluntary, self-generating effort." See Robens, *Safety and Health at Work — Report of the Committee 1970-72* (London: Her Majesty's Stationary Office, 1972) 7.

and, ultimately, the political. Confronted with broad or vaguely worded statutory mandates, administrators are expected to structure their discretion through rule-making in accordance with the dictates of good administrative practice. At the same time, their decisions are required by law to incorporate the best available scientific evidence and, as a practical matter, to satisfy the political demands of affected interest groups. The problems encountered by OSHA in promulgating its generic cancer policy illustrate in a particularly acute form the tensions and contradictions among these conflicting requirements.

For administrative officials in Britain and West Germany, the task of regulating risks to worker health presents itself from the outset in a much more simplified form. In contrast to the *Occupational Safety & Health Act*, the applicable laws of both European countries are noticeably reluctant to spell out in explicit terms the nature and scope of governmental responsibility in the field of worker protection. Although they confer substantial regulatory powers on administrators, the European statutes are generally silent as to the circumstances in which this authority should be invoked and the substantive and procedural limits within which it should be exercised.⁸⁸ Accordingly, regulators in both European countries enjoy a large measure of discretion which they, unlike their American counterparts, are not required to narrow through the techniques of administrative rule-making.

Relieved of the pressure to comply with procedural requirements, administrators in Britain and West Germany need only meet the dual standards of scientific and political acceptability in fulfilling their regulatory objectives. Their success is ensured to a considerable extent through the creation of representative expert groups which permit scientific and political disputes to be resolved within a single institutional forum. By restricting membership on these committees to acknowledged scientific experts, the regulatory process guarantees, at a minimum, that decisions will conform to established norms of scientific validity. At the same time, interest group representation on these key decision-making bodies promotes the formation of a stable consensus on genuinely controversial issues.

The lessons that American regulatory reformers can draw from these European examples are necessarily limited by the unique legal and political context of administrative decision-making in the United States. In particular, the two most important preconditions for continued elaborate rule-making—delegation of unstructured discretion and political demands for its subsequent curtailment—seem to occupy a permanent place in the American legislative and administrative process. It thus appears inevitable that American administrators, more than their European counterparts, must keep contending with the triple claims of science, politics and administrative procedure in their effort to develop new regulations. But the case of OSHA's cancer policy suggests that a simple application of Davis' formula for rule-

⁸⁸ By contrast, American environmental and public health legislation in recent years has frequently fallen back on complex procedural requirements as a device for constraining agency discretion. See Scalia, *Vermont Yankee: The APA, the D.C. Circuit and the Supreme Court*, (1978), Sup. Ct. Rev. 345 at 386-88.

making cannot adequately handle the problems created by scientific complexity and uncertainty during this process. OSHA's attempt to codify the scientific issues under consideration and to foreclose debate not only failed to silence controversy, but resulted, ironically, in arbitrary rule-making that violated even the standards of legitimate administrative practice.

What, then, are the choices that realistically face an agency like OSHA in the future? One course that runs counter to the Davis prescription is to eschew rule-making except where it is absolutely necessary and to adopt a pragmatic, case-by-case approach to most regulatory decisions. This is the route that FDA selected in implementing the Delaney Clause with, as indicated above, considerable political success. It is also the preferred avenue for regulators dealing with occupational safety and health problems in Germany and Britain. EPA's cancer principles suggest an alternative course that satisfies some of the functions of generic rule-making, but does not "freeze" science to the extent contemplated in OSHA's original cancer policy proposal. Basically, EPA's approach relies on clearly articulated decision-making principles, rather than formal rules, to structure administrative discretion and to provide a rational basis for future decisions. This technique appears particularly well-suited to the context of chemical control, since it permits an open declaration of policy without necessitating too great a loss of flexibility.

The combined experiences of FDA, EPA and OSHA in regulating carcinogens suggest that in areas of pronounced scientific controversy, rule-making may introduce an unacceptable rigidity into the administrative process.⁸⁹ But a more flexible approach is unlikely, by itself, to produce the kind of political accommodation that is needed to regulate effectively in the face of great scientific uncertainty. At least two European governments have attempted to solve this dilemma through the use of "representative expertise" and their policies merit closer study by American regulators.⁹⁰ The pressing task for federal administrators is to design for such groups an effective role in resolving controversy, without sacrificing the openness and public accountability that characterize the American regulatory process at its best.

⁸⁹ An analysis of the OSHA cancer policy that reaches somewhat different conclusions about the value of generic rules may be found in McGarity, *Substantive and Precedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA* (1979), 67 *Georgetown L.J.* 729.

⁹⁰ It should be noted in this connection that the American Industrial Health Council (AIHC), an influential chemical industry trade association, has proposed the establishment of a scientific review panel with sole responsibility for identifying and classifying occupational carcinogens. However, the proposal does not explicitly provide for an equal representation of labour and management interests on the panel. OSHA's reasons for rejecting AIHC's proposal in its original form are discussed at 45 *Fed. Reg.* 5203-5204 (1980).