CONTROLLING WORKPLACE CARCINOGENS: THE IMPACT OF EVIDENTIARY UNCERTAINTY UPON REGULATORY EFFECTIVENESS

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ABSTRACT

CONTROLLING WORKPLACE CARCINOGENS:
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Even the most casual glance at federal efforts to control carcinogens conveys an impression of ineffectiveness. Few substances have been regulated in the more than ten years since Congress began to direct sustained attention toward the risks posed by cancer-causing substances. One possible explanation for this is that the agencies of the government to which Congress has delegated its power have been unable to reach a consensus among expert opinion regarding the principles of science upon which the evidence for rational and legally defensible regulation must be based.

This dissertation explores this hypothesis by examining three questions. The first question concerns the general structure of the evidence underlying standards controlling exposure to carcinogens. This structure is described and alternative approaches that might be taken within this structure are discussed with a particular emphasis toward identifying and assessing the significance of the sources of uncertainty within each. It is concluded from this examination that any rational scheme of regulating suspected carcinogens must be based upon conspicuous and radical uncertainty.

The second question of the paper is what implications this uncertainty has for effective standard-setting. This question is explored by analyzing the constraints upon standard-setting imposed

through the legal system as well as those imposed by the uncertain character of the evidence. The legal system requires that government actions be based upon enough evidence to ensure that individuals' rights not be violated unfairly. It is argued that by itself, evidentiary uncertainty is not a constraint upon regulatory effectiveness. Rather, it is the relationship between this uncertainty and the requirement of due process that limits the ability of agencies to effectively control suspected carcinogens. The rights of parties who have legal standing to question standards in federal courts has imposed an excessive strain upon every stage of standard-setting. Thus, the constraint on rule-making is not simply scientific, but also social, political, and legal.

The third question of the paper concerns the degree of power of agencies to employ less strict standards of proof than is presently necessary. A case study is presented of what has been the most ambitious attempt by any federal agency to make it easier to regulate suspected carcinogens: OSHA's generic cancer policy. The attempt by the Occupational Safety and Health Administration to issue an effective "generic cancer policy" failed because the Agency was unable to resolve the tension between its dual constraints of radical evidentiary uncertainty and the obligation to respect rights of due process in a way that would make it significantly easier to set standards. Thus we conclude that OSHA effectively did not have the power to shift the "burden of uncertainty."

It is inferred from this, as well as the general inability of federal agencies, that regulators do not possess the effective power to shift the burden of uncertainty sufficiently to permit a concerted and

long-term program that would identify, assess and control the risks from carcinogens. If this is to be done it can only be by the public confronting the political issue of how much protection it wishes the government to offer and by Congress designing administrative mechanisms that will enable this to be realized.

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I was also aided by the generous assistance of several members of the Michigan State University Libraries. Mentioning the particular thoughtfulness of Eleanor Boyles is meant to highlight her unnatural abilities and good nature, not to demean those of a score of other knowledgeable and considerate resource-people whose assistance figured in the final product.

For their words of encouragement and unspoken understanding my parents and brother deserve special mention. I was very fortunate in growing up in an environment in which critical thought and scholarship are held in high esteem and are components of a life well-spent.

I cannot count the ways in which I have benefited and learned from friends and acquaintances. Among these people are Irving Wiesen, Mark Rollins and Bob Proctor. But foremost among them is Lori Indenbaum. Through her extraordinary sensitivity and thoughfulness she helped to make the entire project more fulfilling and less agonizing than I could have expected.

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PART I

BACKGROUND, PROBLEM STATEMENT AND METHODS

CHAPTER ONE

INTRODUCTION

This work stems from the author's perplexity regarding the question of how federal agencies should transfer wealth and create and dispose of rights of private citizens through their regulatory powers when the information that forms the logical basis for the decisions is fundamentally uncertain. When the opinions of experts differ in a fundamental way, how should "life-or-death" decisions be made? Although the thrust of this dissertation is not an attempt to directly answer this question, it will undertake to suggest an answer based on an analysis of the way in which it is done at present.

A. The Cancer Problem: A Dilemma for Regulation

Cancer is arguably the greatest public health problem faced by the more developed countries. After diseases of the circulatory system it claims the most lives of any single cause of death. Four hundred thousand Americans die of cancer each year.[1] It knows no equal in the pain and suffering that accompanies each death. Americans spend more than six billion dollars every year on various forms of cancer treatment.[2] By comparison, the general fund budget of the State of

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1 This figure was obtained by multiplying the cancer death rate (see note 5) by the present population of 225 million.

2 A recent study estimated the average "three year costs" of treatment as $16,700: Abt Associates, Inc., Cancer Insurance Costs and Benefits, Washington: National Credit Union Administration, 1980, p. 44. This number was then multiplied by the estimated number of deaths.

Michigan in 1982 is five billion dollars.[3] Moreover, cancer morbidity and mortality rates have been increasing during most of this century. Whereas the death rate from cancer in 1920 was 83.2 per hundred thousand,[4] by 1977 it had more than doubled to 178.7.[5]

The federal government has a legitimate role in mitigating health hazards.[6] But the regulation of the actions of private citizens by the government needs to proceed with a cautious regard for due process.[7] So, Congress' constitutional power to "provide for the . . . general welfare" is bounded by its obligation to respect the due process rights of individuals. The first principle of due process is that the assignment of responsibility rests with the individual who did in fact

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3 Michigan, Budget Message of the Governor, 1982, page v.

4 U.S. Bureau of the Census, Mortality Statistics 1929, Washington, D.C.: U.S. Government Printing Office, 1932, p. 28.

5 U.S. National Center for Health Statistics, Vital Statistics of the United States, vol. II, Washington, D.C.: U.S. Government Printing Office, 1981, p. 1-7. It is likely, however, that a portion of this reported increase neglects more efficient pathological procedures and reporting techniques.

6 U.S. Constitution, Article I, section 8. Usually, however, Congress does this under its power to regulate interstate commerce (also section 8).

7 The Constitutional basis of this is in the Fifth Amendment.

cause the injury.[8] Thus, a regard for due process in the regulation of carcinogens necessitates an understanding by regulators of scientific evidence adequate (however interpreted) for the ensuring of the rights of due process.

This obligation to adhere to due process produces a dilemma for the regulator. How is he to protect the public health while ensuring that positive findings are based on adequate evidence? He cannot forget that:

> A sanction imposed in the absence of a causal relationship between the prohibited activity and posited adverse consequences would be arbitrary and hence unconstitutional.[9]

What is most conspicuous about the evidence upon which regulations controlling carcinogens must be based is the extreme degree of uncertainty ordinarily attached to it.

Through these regulations government transfers rights and property between individuals and between groups. When it acts to control a carcinogen, government is conferring additional "health rights" upon some and taking away economic rights from others. Certainly, some of the losers will also be beneficiaries, but this will be the exceptional case. In general, the losers and gainers will constitute distinct groups.

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8 Marcia Gelpe and A. Dan Tarlock, "The Uses of Scientific Information in Environmental Decisionmaking," 48 S. Cal. L. Rev. 371, 372 (1974).

9 Ibid., p. 375.

Part of this work will focus on the regulating of carcinogens in the workplace. This is done for several reasons, some of which are detailed later in this Chapter. But there is one general reason that deserves mention at this point. The effects of technological change are often strongest and most immediate in the workplace. This is because technological revolutions are first revolutions in production processes, and secondly in the products themselves. And furthermore, harmful substances and techniques are typically more concentrated and pervasive in the workplace than in the consumption sector of the economy. It is for these reasons that the individual as worker has been less insulated from many of the technological jolts of the past two hundred years than he has been as consumer.

In the present case, that of carcinogens, this is undoubtedly the case. Workers in certain industries and occupations are exposed to vastly higher levels of suspected carcinogens than the typical consumer. Although the population at risk is often relatively small, the risk which these people face is much greater -- according to most exposure/risk models.[10]

In spite of the fact that it cannot be asserted with the same degree of confidence that attaches to most of the inferences which we draw upon in our day-to-day activities, it remains a fact that workers exposed to certain chemicals are contracting cancer and dying with fearful statistical regularity. How is government to respond? The degree of certainty required to permit government to sanction possibly

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10 Inequity of risk, then, is an aspect of the workplace situation. This aspect may be seized upon to justify extra-market mechanisms of risk reduction.

life threatening actions is the sort of concern which admits of no easy rule providing sufficient guidance in specific situations.

B. Problem Statement

Within the last twelve years there has been an explosion of laws designed to protect the public from health risks. This surge of attention by Congress reflects a general concern that the public not suffer undue or excessive harm. Yet, these laws are little more than delegations of authority to one or another agency to employ ambiguously specified powers to attain vague policy goals.

One clear example of this is exemplified by the Occupational Safety and Health Act (OSH Act) which was passed by Congress and signed into law by President Nixon in 1970 after a long and arduous struggle.[11] This law reflects a concern for the healthfulness of the working environment and a belief that then current mechanisms for ensuring it were inadequate.

Yet, as will be shown in Part III, the general vagueness of this law (and others) has contributed to a great deal of uncertainty, misdirection and ineffectiveness by the agencies in which Congress entrusted its powers. For example, whereas the National Institute for Occupational Safety and Health published a list of fifteen hundred "suspected" carcinogens, in the twelve years since the passage of the OSH Act the Secretary of Labor, in whom standard-setting powers are vested, has issued health and safety regulations for only twenty-three

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11 For a concise description of its legislative history see: The Job Safety and Health Act of 1970, Washington, D.C.: Bureau of National Affairs, 1971. For an insider's view see: Lloyd Meeds, "A Legislative History of OSHA," 9 Gonzaga Law Review 327 (1974).

substances. And this is a notable achievement compared to what other agencies have been able to accomplish. The Environmental Protection Agency, for example, has managed to regulate only four substances as "hazardous air pollutants" under the Clean Air Act of 1970 and six chemicals or chemical families as "toxic pollutants" under the 1972 Amendments to the Federal Water Pollution Control Act.[12]

There are two roots of the vagueness. One is that lawmaking in the United States is largely a matter of consensus-building. This property was manifestly present in the framing of the OSH Act. Generally speaking, voluntary agreements among divergent interests can be reached either through compromise, or, if compromise is impossible, by deferring the irreconcilable issues explicitly or through ambiguous language. The last alternative was taken by Congress in developing critical sections of the OSH Act. Because it was politically essential that Congress pass some law, incompatible differences were hidden through equivocation. This will be explained in somewhat greater detail in Chapter Seven. Using a term that will be explained in Chapter Two, this type of equivocation results in uncertainty as to what type of regulatory "framework" should be employed in standard-setting. The agency possesses unclear instructions concerning what decision rule to employ in regulating substances.

The other root of legislative vagueness is insufficient understanding of the object of regulation or of the regulatory environment. This root has been manifestly present in the field of toxic substances. With a better understanding of the mechanisms whereby

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12 These substances are enumerated on page 198.

substances cause cancer and other chronic diseases, Congress would have been able to devise clearer laws. Because the mechanisms were so uncertain, Congress was reluctant to specify the evidence that would be acceptable in rule-makings.

C. Thesis and Purposes of the Work

In the absence of direction by Congress in these two areas, agencies have been obliged to first determine the proper regulatory frameworks under which they should operate to then determine the acceptable standards of evidence.[13] It is the thesis of this dissertation that the regulatory ineffectiveness alluded to earlier has stemmed in large part from an inability by agencies to devise for themselves frameworks and rules for standard-setting.

In investigating this thesis the following descriptive aims will be pursued:

(1) To describe the general structure of the evidence and potential regulatory frameworks underlying standards controlling exposure to carcinogens.

(2) To determine the properties of the evidence that hinder effective standard-setting.

(3) To ascertain the degree of power that agencies possess to make rule-making more effective.

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13 If the rationale for a regulation can be viewed as a syllogism in which the regulation itself is the conclusion, then the framework would be the major premise and the standards of evidence would be the determinants of the minor premise. For example, the hypothetical regulation, "Exposure to vinyl chloride should be limited to one part per million," follows upon the general assumptions: (1) all substances with a certain set of properties should be regulated in a certain specified way and (2) vinyl chloride possesses this set of properties.

D. Research Questions and Format

This dissertation is organized around a set of specific research questions. At this point these questions will be set forth and their significance to the overall thesis and purposes will be explained:

(1) What is the logical structure to which the evidence underlying agency actions to regulate suspected carcinogens must comport?

If this work is to have any general relevance its conclusions must be true of a class of regulations rather than any single one. If the thesis is to be tested for a class of regulations one way of doing it is to determine those properties that are common to all of them and to show that the theorized response occurs as a result of them. With this purpose in mind, the next Chapter outlines a model of the environment for standard-setting for toxic substances, and in Part II certain critical components of this model will be sketched in greater detail. In Part III a case study will be examined through this model.

(2) How does uncertainty enter the process and what is its magnitude?

For reasons which will be explored in Part II of this work the most glaring feature of the evidence to regulate a substance as a carcinogen is the manifest presence of radical uncertainty.[14] In the Introduction to Part II a preliminary model of scientific uncertainty will be offered. Chapters Three, Four and Five, in whole or in part, will then examine the various ways in which uncertainty enters the evidentiary

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[14] By "radical" uncertainty is meant uncertainty of unknown dimensions, whose bounds can at best be approximated.

process for carcinogens and will assess its magnitude. Although attention will focus upon regulating carcinogens, it is suggested, but al argument will not be presented, that many other chronic diseases adhere to the same general model.

(3) Is there a tension between this uncertainty and the legal and political constraints upon standard-setting which hinders rule-making in this area?

It is important for the purposes of this work that the impact of this uncertainty upon rule-making be assessed. This will be done through examining how agencies have dealt with these issues. The focus of this discussion will be upon the standard-setting activities of the Occupational Safety and Health Administration. The discussion in Part III will be directed toward its regulatory experience and will postulate an explanation for its seeming inability to meet the mandate contained in the OSH Act to "assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources."[15] This explanation will be in terms of the interaction between evidentiary uncertainty and the political and legal constraints under which OSHA operates.

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15 The Occupational Safety and Health Act of 1970, 29 U.S.C. et seq. 1651. It is interesting to note that although the law's aim is to assure healthful conditions "so far as possible" OSHA only has the power to set health and safety standards to assure health and safety "to the extent feasible" (section 6 (b)). OSHA's statutory powers and responsibilities will be discussed in greater depth in Part III.

(4) What is the conceptual basis for regulating substances generically as done by the Occupational Safety and Health Administration?

One intriguing idea that would enable regulatory agencies to increase their effectiveness is for them to regulate substances "generically". Under a generic approach framework and evidentiary issues are dealt with once, and in all future rule-makings are considered "settled" to one degree or another. Chapter Six will deal in part with the motivation for this regulatory approach and will offer two justifications for it.

(5) Through a case study examination of OSHA's rule-making process, and from the answers to the earlier questions, what conclusions can be drawn regarding the power of federal agencies to meaningfully and effectively control carcinogens as required under their mandates?

Beginning in 1976 and continuing into the present OSHA has expended a large part of its resources in developing a generic policy to govern future regulations concerning carcinogens. It has proven to be the most ambitious single attempt by any federal agency that would contribute to reducing the risks from toxic substances. It was also significant in being the most explicit attempt by any agency to decide the issues of framework and evidence that Congress had left unresolved. Because of these factors as well as the breadth of public participation in the rule-making, it is expected that some insight can be drawn from it pertaining to the general field of toxic substance regulation.

E. Limitations of the Study

This work is hampered by a pair of limitations. The first is that much of the author's learning in the fields of science which occupy his

attention in Part II has been self-taught. Thus, it is almost certain that he has overlooked points and issues of significance. It is hoped, though, that this naivete has not materially affected the validity of the arguments. To remain silent on issues whose resolution rests on questions of science has been the intention of this work.

But, and this is a key point in the analysis, many of the scientific questions are inherently unanswerable in a scientific framework. Although the questions possess a scientific form — that is, they look like other questions that are amenable to the methods of science -- they cannot be answered because they do not make "logical sense" and "physical sense." This places a decision-maker who must make a decision in an obvious quandary. The question -- and the issue which rests upon it -- will be resolved (whether or not this is recognized) using nonscientific instruments.

Thus, it might even be expected that this naivete has sharpened the acuity with which the distinctions and properties, which might be taken for granted by one who is more expert, are perceived. The author has sought to compensate for this inexperience through extensive reading in the literature. And as these Chapters are not meant to be critical discussions of the science one might expect that the damage is not too great.

Another limitation of this study is its nearly total reliance upon secondary sources of information. The case-study of OSHA's experience in standard-setting contained in Part III is drawn almost completely from published material. Only one of the "players" was interviewed by the author. However, the author did have access to a wealth of printed material. In particular, the weekly Occupational Safety and Health

Reporter, published by the Bureau of National Affairs proved to be most helpful. So, once again, hopefully the study was able to overcome this handicap.

CHAPTER TWO

MODEL SPECIFICATION, INFORMATION COLLECTION, AND METHODS OF INTERPRETATION AND ANALYSIS

A. Model Specification

Care must be exercised in building a model for a system. For once a model is chosen it replaces the object itself as the focus of study. A model that is an inaccurate representation of the system will yield biased conclusions. Although theoretical, this work aims to be descriptive of the conceptual structure which federal decision-making regarding carcinogens should logically comport to. So, it is important that an accurate appraisal of this structure be presented. Because this study is focusing on the conceptual context of decision-making the model minimizes the internal structure of the agency. It can be viewed as a "black box" model. This avoids the necessity of making any assumptions concerning internal agency organization or politics.[1] As a result, the argument should hold for any organization which has the function of regulating carcinogens under the American legal system.

The rule-making process consists of a number of stages. They are a product of administrative and statutory law. As will be seen in Part III, the OSH Act specifies fairly detailed procedural guidelines that must be adhered to in issuing health and safety standards. This degree of specification is routine in the federal statutes that deal with carcinogens.

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1 The seminal discussion of these issues is found in Herbert Simon. Administrative Behavior, (2nd ed.) New York: The Macmillan Company, 1961.

The case study of OSHA's cancer policy is examined as a series of steps each of which is potentially taken by any federal agency prior to a regulation taking effect:

(1) developing and issuing a proposal;
(2) presenting the proposal to the public and allowing comments;
(3) issuing a final standard and responding to comments;
(4) defending that standard in a court of law.

Since, and in large part as a result of, the passage of the Administrative Procedure Act in 1946[2] federal actions have become more open. Parties have increasingly been able to interject their views into individual rule-makings. Clearly, this results in the potential for greater responsiveness on the part of government agencies. It also increases the ability of the public to influence the process. But, at the same time, it raises the amount of "friction" in the process. At several points in the process, parties who wish to thwart a standard are able to delay the process. And under certain circumstances this tactic can bring about the defeat of the standard. In fact, OSHA's cancer policy, which will be the subject of the case study in Chapter Six, is an example of this outcome.

In order to highlight the issues raised in Chapter One, standards are typified as resulting from three "factors" and four "components".

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2 5 U.S.C. 551 et seq.

The factors describe the types of consideration that enter into producing the standard. The three factors are:

(1) politico-economic;
(2) legal;
(3) evidentiary.

Although these will not be discussed in any detail at this point as their interactions are part of this study, a few general comments will be made here.

The politico-economic factor is seen in the influence of interest groups upon the rule-making process. This influence is manifested in various forms, either directly upon the agency responsible or indirectly, by pressing other parts of the government to influence the agency. Granted this is a simplification, but it should suffice for the purposes of this study. As a first approximation, two types of interest groups apply pressure upon OSHA. "Business interests" is one. "Labor" and "public interest" is another. In Part II distinctions will be drawn among these types.

The legal factor is, quite simply, those aspects of the law that have an influence upon the regulation or the rule-making process. There are three parts of the law that are applicable here:

(1) the statutory authority under which action is taken;
(2) procedural requirements governing the form and substance of these actions;
(3) due-process requirements protecting the rights of private parties.

Whereas Congress confers power upon the agency, there are restrictions (usually loosely defined) upon what an agency can do and how it can go about doing it. These powers and limitations will be discussed in Part III.

Depending upon what regulatory framework is employed to set standards, different types of evidence will be necessary. Although every framework requires some types of scientific information, there are other scientific issues that are superfluous. And some, but not all frameworks call for determining the economic costs of the standard.

In principle, the third factor, evidentiary, is the dominant input into agency decisions. According to bureaucratic theories of administrative behavior, the agency executes a closely defined set of functions with little discretion.[3] In reality, however, administrative behavior is heavily influenced by political considerations and forces. Nevertheless, evidence forms a crucial part of any standard. But, as shall be seen, the structure of administrative decision-making is composed in such a way that the other factors acquire greater influence when there is a large degree of uncertainty in the evidence.

Standards controlling the risk from carcinogens stem from a "logical argument" composed of four steps or "components". They are:

(1) Recognizing that a problem exists that warrants regulatory action by the agency.

The first step is a threshold determination. For reasons that will be discussed in Chapter Three, it is based upon epidemiological evidence.

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[3] See Max Weber, The Theory of Social and Economic Organization, New York: The Free Press, 1947.

Based upon this determination Congress may decide to enact a law. For example, the recognition that there was an epidemic of workplace injuries and diseases brought about the passage by Congress of the OSH Act in 1970.[4] Thus, although the agency need not make this determination, for it to have received its authority, it must have been made. It should be noted at this point that the soundness of this determination is irrelevant to the agency. That is to say, OSHA's authority does not stem from the existence of a "workplace health epidemic." Thus, on a macro level, occupation can have very little influence upon the national cancer rate (a debatable point) and OSHA would still be obligated to control individual risks. This very point will be discussed in Part III.

(2) Identifying the source of the risk.

The second step is based upon four types of evidence:

(1) epidemiological studies on humans;
(2) in vivo bioassays in animals under experimental conditions;
(3) in vitro "short-term tests";
(4) tests of structural similarity to "known" carcinogens.

Each of these is grounded in scientific assumptions that will be examined in Part II. They are based to differing degrees on assumptions

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[4] The Act begins, "The Congress finds that personal injuries and illnesses arising out of work situations impose a substantial burden upon, and are a hindrence to, interstate commerce in terms of lost production, wage loss, medical expenses, and disability compensation payments." (§2, 29 U.S.C. § 651 (1975)).

regarding the largely unknown mechanisms of carcinogenesis. They are listed in order of increasing degree of emphasis upon these assumptions (and, for this reason, in order of decreasing evidentiary strength).

(3) Assessing the risks posed by the substance (and, in some schemes, the benefits that it provides, the cost effectiveness and/or feasibility of its control).

Any rational decision rests upon an assessment of its impact. The third step presumes a regulatory framework that is to one degree or another exogenous to the evidence itself. It is given in part by the legal (statutory) mandate within which the agency operates. But within this mandate, the agency will ordinarily have certain discretion in determining the framework within which it will weigh the evidence. It will be argued that there are four frameworks relevant to regulating suspected carcinogens:[5]

(a) the market framework;
(b) the "no-risk" framework;
(c) the technology-based framework;
    (i) economic feasibility
    (ii) technology-forcing
(d) risk-benefit and cost-benefit analysis.

Applying the framework allows the agency to determine a target level of control (a "permissible exposure level").

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5 This framework is adapted from that contained in: Lester Lave, The Strategy of Social Regulation, Washington, D.C.: The Brookings Institution, 1981.

(4) Determining the most effective strategy for control.

Once it arrives at a "PEL" the agency can seek to attain this through any of several strategies. Although they will only be discussed in passing in this study the strategy choices include:

(1) mandating the use of:
   (a) "personal protective devices" and/or
   (b) "engineering controls"
(2) mandating that the exposure level be reached through:
   (a) specific, detailed solutions or
   (b) "performance standards" which can be met through any mechanism that the affected firms choose.

The following table illustrates the relationships between the factors and the components of standard setting:

TABLE 1.

THE INFLUENCE OF THE FACTORS UPON THE COMPONENTS OF THE STANDARD

Steps in Constructing a Standard

Factors	Recognition	Identification	Assessment	Control
Political	Yes	No	Yes	Yes
Legal	No	No	Yes	Yes
Evidentiary	Yes	Yes	Yes	Yes

A health standard is a complex product of a whole series of choices made and decisions taken. This study aims to highlight how these choices are made and the assumptions upon which they are based.

B. Information Collection

The bulk of the information upon which this work is drawn consists of published material. In the discussion of the nature of the evidence that figures into regulations an author was accepted as an informed source if his works were cited by others. With rare exceptions, all of the works that are referred to had been published prior to the publication by OSHA of the final cancer policy. Most of them were cited in the preamble to the final rule.[6]

The sources of information on agency policy are articles in professional and trade journals, and agency publications. In addition, one of the architects of the cancer policy was interviewed. Although the examination in Chapter Seven centers on OSHA policy, it will refer to the policies that other federal agencies have with respect to carcinogens.

C. Interpretation and Analysis

This study is a conceptualization of the evidentiary framework around carcinogen regulation, how it interfaces with the legal framework within which agencies operate, and a short examination of how the dilemmas that arise therefore gave birth to an alternative mode of regulating (generically). So, the tools of interpretation and analysis that will be employed are those of judgment and inductive and deductive reasoning.

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6 U.S. Occupational Safety and Health Administration, "Identification, Classification and Regulation of Potential Occupational Carcinogens," 45 Federal Register 5001 (1/22/80). Hereafter, this will be referred to as "Hearings."

Chapters Three through Five, for example, are centered around two parallel arguments, one deductive and one inductive. There is the deductive argument that any rational carcinogen regulation must be based on a certain train of reasoning that is set forth and termed "identification/assessment." At the same time, there is the inductive argument that the presence of various specific sources of uncertainty in the identification/assessment process lend uncertainty to the process as a whole. Treating these two inferences as premises in a further deductive argument, it can be concluded that any rational carcinogen regulation will necessarily be based on uncertain evidence. So, it is this type of interpretation and analysis that will be employed.

PART II
SOURCES OF UNCERTAINTY

"The conclusions reached in science are always, when looked at closely, far more provisional and tentative than are most of the assumptions arrived at by our colleagues in the humanities. But we do not talk much in public about this, nor do we teach this side of science . . . There are more than seven times seven types of ambiguity in science, all awaiting analysis. The poetry of Wallace Stevens in crystal clear alongside the genetic code."

Lewis Thomas, "The Art of Teaching Science,"
New York Times Magazine, (3/14/82), p. 91.

INTRODUCTION TO PART II

The estimates that form the basis for regulations controlling carcinogenic risk possess a great deal of uncertainty. This evidentiary uncertainty enters into each component of the standard, affecting each one, and thereby the published regulation itself. The adequacy of regulatory responses to this risk is quite sensitive to the degree of uncertainty attached to the estimates.

The objective of Part II is to show that the science of carcinogen identification and assessment is so frail that it can offer little in the way of probable and ampliative knowledge to guide decision makers in Government. At several crucial junctures in the logical decision process "trans-scientific" issues sneak in to muddy the clear waters of scientific discourse. Rarely can a meaningful decision be reached on issues like the human carcinogenicity of substances without retreating into a highly personal conception of what science is that is inherently unscientific.

There is a common misconception that experimental procedure is very much like a recipe in which the researcher follows a series of clearly stated steps to come up with an unambiguous conclusion. In reality, however, nothing could be further from the truth. Experiments, like all research, are very often a matter of trial and error, full of false starts, oversights and mistaken assumptions. But some experiments are "dirtier" than others. The problem with most types of experiments within the field of carcinogen identification is that uncertainty floods in, swamping the evaluations. Because there are no recipes, "scientific judgment" plays a larger role than might be hoped for. And, although there appears to be a consensus in the scientific community on the

appropriateness of many of the assumptions that underlie the evaluation procedure, there are several crucial ones for which a consensus does not exist. Determining their appropriateness is simply "beyond" science. Alvin Weinberg termed these "...questions which can be asked of science and yet which cannot be answered by science . . . trans-scientific."[1]

But judgments must be made. Individuals with scientific credentials are urged from all sides to offer guidance in the name of "Science." Scientific judgments, though, are meant to be made from an attitude of skepticism. An initial attitude of skepticism may be lost in the desire to employ one's knowledge to the perceived greatest good. Thus many of the answers to purportedly scientific questions are laced with a heavy dose of personal bias.

As has been mentioned, one of the most conspicuous features of this process is the manifest presence of uncertainty. There is no getting away from it. Moreover, its presence is not fully appreciated by many participants in the process. It will be suggested later how such a radical degree of uncertainty might distort deliberations. At this point a short schema and description will be presented. For the purposes of this paper, there are three types of questions whose resolutions involve the introduction of a certain amount of uncertainty into the deliberation. They are:

- scientific
- trans-scientific
- normative

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[1] Alvin Weinberg, "Science and Trans-Science," 10 Minerva 209 (1972).

Those individuals whose job it is to make final determinations must be able to recognize and identify by type each question and, to the extent possible, to place bounds around the degree of uncertainty that it imposes.

Scientific Uncertainty

Any question-answering process involves a certain likelihood that study design, procedure or analysis is faulty and biased to a large enough extent as to invalidate the conclusion. Thus, uncertainty is intrinsic to scientific investigation. This is particularly conspicuous when the theoretical underpinning (in physiology and biochemistry) and the logistics (of, most notably, animal studies) provide tenuous bases for reliable estimation.

Trans-scientific Uncertainty

The uncertainty that arises as a result of the intrusion in a study of a trans-scientific question is one that looks as though it is answerable, but is not. Trans-scientific questions can be identified, but the degree of uncertainty that they induce cannot be estimated.

Normative Uncertainty

Normative uncertainty is somewhat different than both of those discussed above. Since the assessment process involves a weighting of the relative desirability of various impacts of a particular strategy, and since nature does not present us with these weights, they must be imposed. Thus, there is not a great deal that can be said objectively regarding the rightness or wrongness of any particular distribution of

impacts. For millenia, thinkers have thrown themselves headlong against this problem. And it has not yet been satisfactorily solved. They all fall prey to G. E. Moore's "naturalistic fallacy": of attempting to derive an "ought" from an "is".[2] But in so far as no distribution can be shown to be optimal, whichever is chosen, the assessment possesses a probability less than one of being so.

It is easy to fall into the belief that the identification/assessment process is free of all value assumptions. But nothing could be more wrong. Indeed, one explanation that shall be offered for the tremendous diversity of opinion among expert viewpoints of the same data is the application to this "raw data" of different value assumptions. It shall be argued that their inevitability suggests that one should not attempt to suppress them, but rather to identify them.

One should look at many of the questions that require "scientific judgment" such as those that are being examined in this part in light of subjective value assumptions. It very well may be that values intrude in the name of scientific judgment, and that they play a role in the identification process as well as the assessment process.

The evaluation of substances as carcinogenic is a complex task. The following three Chapters are meant to suggest just how very complex it is.

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2 F. E. Moore, Principia Ethica, Cambridge: Cambridge University Press, 1956, p. 13.

CHAPTER 3

RECOGNITION

> There is no evidence that industrialization has caused an increase in cancer . . . At the moment there's no hint of a major new cancer threat.
>
> John Cairns[1]

> The role of occupational carcinogens is critical but greatly underrecognized in the recent increases in cancer rates . . . Death rates due to cancer will reach epidemic proportions if they continue at the current rate.
>
> Joel B. Swartz[2]

A. Introduction

It is easy to understand any distress felt by government regulators when they are confronted with such widely disparate views concerning the most fundamental of questions. When basic assumptions that underpin regulatory attitudes are thrown into question, this suggests either a radical subjectivism on the part of one or both advocates, or a radical degree of uncertainty in the descriptive paradigm itself.

At this point the general question of control will be addressed: that is, what is the relative significance of environmental as opposed to genetic factors in determining cancer incidence rates? There is ample evidence that environmental factors are contributory to certain human factors. A first indication is had by observing that cancer incidence varies greatly from one country to another. For example, although cancer of the liver is the most common cancer among men in

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1 Paraphrased from Occupational Safety and Health Reporter, vol. 11, pp. 450-1, (11/5/81) from a statement at the semi-annual meeting of the Chemical Manufacturers Association.

2 Paraphrased from Occupational Safety and Health Reporter, vol. 10, p. 560, (10/23/80) from a statement at the annual meeting of the American Public Health Association.

Mozambique, it is rare in the United States and Europe. The opposite is the case for cancer of the lung. Cancer of the bladder is common in Egypt, and cancer of the stomach is especially common in Japan.[3] And of course, skin cancer is more common in sunny areas. Indeed, a highly significant fact is that it is quite difficult to find a cancer that has a constant incidence rate throughout the world.[4] One study estimated that an imaginary population, which had the lowest recorded incidence rate for each type of cancer would experience an overall incidence rate one-tenth that of most Western countries.[5] This had prompted some to argue that 90% of human cancers are attributable to environmental factors. However, for two reasons which will be discussed below, the evidence is insufficient to support this conclusion.[6]

Different social groups appear to be afflicted with certain cancers to differing degrees. For example, one study suggested that for nearly all common cancers, there is an inverse relationship between the extent of education and incidence rates.[7] This has been explained in terms of diet as well as locality (there being a greater likelihood of a person with little education living in a highly industrialized region than a

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3 John Cairns, Cancer: science and society, San Francisco: W. H. Freeman and Company, 1978, p. 41.

4 There does appear to be a rare form of cancer of the kidney in children that fits in this category, however: R. W. Miller, "Interim report: UICC international study of childhood cancer," 10 International Journal of Cancer 675-677 (1972).

5 John Higginson, "Present Trends in Cancer Epidemiology," 8 Canadian Cancer Conference 40 (1969).

6 The first reason is that these studies make no attempt at all to control for genetic factors, and man is very heterogeneous genetically. The second is that it seems that cancer etiology is multi-causal. Thus, "cause" and "attribute" (in their verbal forms) take on special meaning.

7 A. M. Lilienfled, M. L. Levin, and I. I. Kessler, Cancer in the United States, Cambridge: Harvard University Press, 1972, p. 231.

person who is more well educated - the mediating variable being "income level").

The problem with this type of evidence, however, is that it makes no attempt to control for any effects due to genetic constitution. Much of it is as suggestive of genetic determinants as it is of environmental determinants. Although it certainly is difficult to control for heredity, it can be done. Actually there are two ways of doing it. One can perform a time-series study of a population with a genetic pool that is assumed to be stable and an environment that had undergone (or is presently undergoing) a period of consistent change. The other way of controlling for genetic factors is to study the correlation between differing cancer susceptibility and the degree of heredity similarity.

B. Cross-Sectional Studies

The ideal experimental design that employs the latter study method examines sets of identical twins because it controls perfectly for genetic factors. If heredity were a significant factor then one would expect that there would be a significantly higher correlation in incidence in identical than in non-identical twins. But the evidence seems to suggest otherwise. For example, in a study of 1,528 identical twins and 2,609 fraternal twins of the same sex, the pairwise correlation in incidence rates was similar enough in the two groups for the authors to conclude that "gene differences can only to a limited extent explain the diversity in the population with regard to the

occurance of malignant growth."[8] One author drew the general conclusion that "identical twins were not much more alike in the cancers they suffer than are nonidentical twins."[9]

Of somewhat less elegance are studies of cancer risk among members of family units. Some of these studies suggest a genetic influence in certain particular types of cancer. One study, for example, suggests that cancer of the stomach and large intestine is somewhat more common in "relatives of patients".[10] Another study found that "grandmothers, mothers, aunts, and sisters of women with breast cancer have had breast cancer with a frequency which is significantly greater than that of women in a similar age range in the general population."[11] However, there does not appear to be evidence that many families face a heightened susceptibility to all forms of cancer in general.[12]

Cross-sectional studies are of more than theoretical interest. They provide information upon which to notify members of "high-risk" groups, warning them of their enhanced susceptibility. They can then be advised what lifestyle changes might reduce the risk that they face.

C. Time-Series Studies

Studies of migrants have also provided valuable information regarding the relative importance of environmental and genetic factors

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8 B. Harvald and M. Hauge, "Heredity of Cancer Elucidated by a Study of Unselected Twins," 186 Journal of the American Medical Association 749 (1963).

9 Cairns, supra n. 3 at 53.

10 Ibid., p. 52.

11 Madge Macklin, "Comparison of the Number of Breast Cancer Deaths Observed in Relatives of Breast Cancer Patients and the Number Expected on the Basis of Mortality Rates," 22 Journal of National Cancer Institute 927 (1959).

12 Cairns, supra n. 3 at 52.

in determining an individual's susceptibility to various cancers. The idea is to compare incidence rates of a large migrant group with those of the people who remained at home. Of course, this is best done when the population has fairly homogeneous genetic characteristics. It is also assumed that the migrant groups possesses "typical" genetic qualities. In a sense, it is like performing a controlled experiment on the environmental factors contributory to cancers. One study compared cancer mortality among Japanese and Japanese Americans. It suggests that initial differences between incidence rates of various cancers decline within a generation or two. That is, within one or two generations, these migrants take on the cancer characteristics of the rest of the American population. Stomach cancer declines, and cancer of the large intestine, breast and prostate increases in relative frequency. Since there is little mixing of the genetic pool through intermarriage among first generation Japanese Americans, the conclusion seems to be that these changes stem from the changed environment rather than genetic factors.[13]

In another study, Jewish migrants to Israel were seen to exhibit cancer incidence rates typical of their country of origin. Their children, born in Israel had much lower incidence levels, typical of the native population.[14]

Time series information also seems to indicate that the incidence rates of certain common cancers have changed over the past several

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[13] W. Haenszel, M. Kurihara, M. Segi, and R. K. C. Lee, "Stomach Cancer Among Japanese in Hawaii" 49 Journal of the National Cancer Institute 969-88, (1972); W. Haenszel, et al., "Large-bowel Cancer in Hawaiian Japanese," 51 Journal of the National Cancer Institute 1765-79, (1973).

[14] Cairns, supra n.3 at 51.

decades. For example, the mortality rate from lung cancer has increased more than twelve-fold since 1930. It is believed that most of this change is due to the spread of cigarette smoking throughout society that began in the later years of the nineteenth century for men and during the Great Depression for women.[15] Further, mortality rates from cancer of the pancreas and cancer of the nervous system have risen four to five-fold since 1940. Leukemias have also increased in relative frequency.[16]

Not all changes have been increases, however. The mortality rate from stomach cancer has declined five-fold. And the death rate from cancer of the cervix has been declining since 1950.[17]

Based on this evidence, it is fairly clear that cancer incidence rates are associated with changes in the environment; it is only through environmental changes that changes in cancer rates can be explained. And it is only through differences in environmental factors that different incidence rates can be explained in a fairly homogeneous genetic pool (e.g.; migrant studies, studies with identical twins).

All of these studies seem to indicate that one or another form of cancer is related to environmental factors. And taken together they provide strong grounds for the inference that cancer in general has environmental determinants, and therefore is preventable.

But what is conspicuous about most of these studies is that they do not hypothesize etiologies. They are simply descriptive of the variation in cancer risk as a function of time or geographical location. If

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15 Ibid., pp. 43-5.

16 Ibid., p. 46.

17 Ibid.

epidemiology is ". . . the study of the distribution and determinants of disease prevalence in man,"[18] then these studies partake of the first - and less significant - of the two conjuncts. It is one thing to recognize increased risk; it is entirely another to identify its cause(s).

D. Studies of the Influence of the Workplace on Cancer Rates

Nowhere is the uncertainty that is characteristic of this entire field more evident than in the vast scope of the various projections of the significance of the work environment in the determination of the national cancer incidence rate. From one perspective, the importance of this question is obvious. If society is to expend scarce resources in the general attack on workplace cancer, it only makes sense to inquire what benefit the expenditure will bring about. From another perspective, such estimates are irrelevant at the present time to a justification of any particular control strategy by OSHA. In a static sense, OSHA's mandate has already been determined in the 1970 law. As the Agency argued in the preamble, published with the cancer policy in the Federal Register:

> This regulation was not and is not predicated on the assumption that occupational factors are responsible for any specific fraction of the cancer burden in the U.S. population . . . Even if such groups (of workers at risk) were small, OSHA would be justified, indeed required, to regulate their exposure in order to eliminate their risk of illness and death.[19]

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18 MacMahon and Pugh, Epidemiology: Principles and Methods, Boston: Little Brown and Co., 1970, p. 1.

19 Hearings, supra Ch. 2, n. 6 at 5031.

Although strictly speaking this is true (Congress makes the law and the agencies do its will), each agency has a great deal of discretion over how it interprets the law and the vigor with which it carries it out.

So, the more general question, which may or may not concern OSHA, is addressed here. One can only begin to answer it upon determining the marginal impact that the work environment has upon the cancer rate: how many fewer individuals would contract the disease if the contribution of the work environment were nil. As a first approximation, this figure would represent the total potential benefit of efforts to control workplace carcinogen.

The first thing to consider is that any control strategy would likely create beneficiaries other than the workers themselves. In so far as the workplace is not a closed system, cancer-causing substances have the ability to migrate out of the actual property that the work is being performed on. A molecule of vinyl chloride is as strong a carcinogen beyond the factory walls as it is within them. It is all too easy to undervalue the marginal benefit of a regulation by focusing solely upon its "primary" benefits. This should be avoided by considering "externalities".

On a conceptual level, failing to do this is a serious oversight. But on account of the vast uncertainty surrounding estimates of the primary impacts of an occupational carcinogen standard, it could be argued that it really does not matter very much whether the external benefits are treated in more than a qualitative, impressionistic way, or

whether they are even treated at all.[20] When there is an extreme degree of uncertainty surrounding a question it makes little practical difference to its proper formulation and resolution whether three-fourths or nine-tenths of the relevant factors are addressed.

The great variability of published estimates of the relative contribution of workplace exposure to the mortal cancer rate makes it very difficult to draw meaningful conclusions. Table 2 illustrates this. The estimates range from 1% to more than 20%. The reasons behind this variability will be outlined presently. It needs to be pointed out here, though, that these numbers hide the significant statistic of the contribution in absolute terms. Since approximately 400,000 people die of cancers in America each year, the "modest" figure of 1% masks the actual impact of 4,000 deaths. It might be interesting to bear in mind that about 40,000 Americans died in the ten years of the Vietnam war, an average also of 4,000 deaths each year.

Reading these studies, one is struck by the acknowledgement of the extreme degree of uncertainty in the projections. One important reason is that there is no logical basis for deriving economy-wide estimates upon the little information that is available concerning the few substances whose carcinogenicity can be estimated. As the last study cited above argued:

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[20] A point to ponder: When all that can be done is to treat a consideration impressionistically, is it better to ignore it entirely? I will suggest here, something different- that it doesn't matter. That is, which tactic distorts the cause of rational decision making less? Impressions can be misleading, contributing to a poor decision. Perhaps, like much else here, even a decision regarding this needs to be guessed at ad hoc.

TABLE 2.

ESTIMATES OF THE RELATIVE CONTRIBUTION OF WORKPLACE EXPOSURE TO THE NATIONAL CANCER RATE

Reference	Estimate of Percent of Cancers That are Occupationally Related
Higginson/1969[21]	1% of mouth cancers 1-2% of lung cancers 10% of bladder cancers 2% of skin cancers
Higginson & Muir/1976[22]	"probably 1-3% of all cancers"
Wynder & Gori/1977[23]	4% for men 2% for women
Doll/1977[24]	"of relatively small importance"
Cole/1977[25]	less than 15% for men less than 5% for women
NCI, NIEHS, NIOSH/1978[26]	"as much as 20% or more"

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21 J. Higginson, "Present Trends in Cancer Epidemiology," 8 Proceedings of the Canadian Cancer Congress 40-75 (1969).

22 J. Higginson & C. S. Muir, "The Role of Epidemiology in Elucidating the Importance of Environmental Factors in Human Caner, 1 Cancer Detection and Prevention 79-105 (1976).

23 E. L. Wynder & G. B. Gori, "Guest Editorial: Contribution of the Environment to Cancer Incidence: An Epidemiological Exercise," 58 Journal of the National Cancer Institute 825-832 (1977).

24 R. Doll, "Strategy for Detection of Cancer Hazards to Man," 265 Nature589-596 (1977).

25 P. Cole, "Cancer and Occupation: Status and Needs of Epidemiological Research," 39 Cancer 1788-1791 (1977).

26 National Cancer Institute, National Institute of Environmental Health Sciences & National Institute for Occupational Safety and Health, Estimates of the Fraction of Cancer in the United States Related to Occupational Factors, (draft report), (9/15/78). The political context of this report will be discussed in Chapter Seven where it is referred to as the "HEW Report".

> . . . in our view, existing methods for such extrapolation leave enough questions open concerning their precision as to make us unwilling to attempt large scale estimates - particularly in the absence of exposure data. Hence we can say nothing firm about the magnitude of future risks attributable to the unquantified present-day exposures. (p. 18)

Yet, this avowed unwillingness did not prevent the authors - among them the most highly respected authorities in the field - from attempting a large scale estimate, albeit one with very broad implied confidence limits.

The report was deeply critical of earlier estimates as being unreasonably conservative. It stated that as a group they are characterized by four pitfalls and it warned that overlooking these pitfalls results in the failure to appreciate the actual significance of occupational factors on the cancer rate:

(a) incomplete data

The data in humans for most substances for which there is evidence that they are animal carcinogens is "either lacking or inadequate to determine whether or not the substances are associated with excess cancer incidence in exposed human populations." (page 2)[27]

(b) the fallacy of "one effect-one cause" explanations

Although the process that results in a malignant tumor is not well understood, it does appear that many (or most) types of cancer have more than one necessary cause. Although this point is discussed in greater

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27 This is based on Lorenzo Tomatis et al., "Evaluation of the Carcinogenicity of Chemicals: A Review of the Monograph Program of the International Agency for Research on Cancer," 38 Cancer Research 877-85 (1978).

detail in Chapter Four, let it suffice to say at this point that one might infer that many cases of cancer that are attributed to other factors (notably smoking) would not have occurred if the individual had not also been exposed to a substance in his place of employment. So, many cancers could very well be misreported.

(c) latent period, age, and duration of exposure

The period of time from the point at which a cancer is "initiated" to that at which a tumor becomes noticeable is measured in years, and sometimes in decades. The "chemical revolution" to which many people attribute a significant portion of today's cancer deaths is fairly young. Thus there may not have been enough time for the full effects of the new workplace technologies to become manifest.

(d) changes in exposure patterns

Occupational exposure data for most suspected carcinogens are insufficient to permit aggregate risk estimation (page 5). A particular problem is that workers who are exposed to a suspected carcinogen are not exposed to only one, but to several over the course of their employment. Since many cancers are associated with more than one factor, this multiple exposure makes it particularly difficult to distinguish a tumor's "cause."

This study is enlightening, not only in what it says (which is important) but also in the way it says it. For the study provides vivid evidence of the non-objectivity of science.

First, the way in which its conclusions are phrased is misleading. For example, asserting that workplace exposure may be marginally

decisive in "as much as 20% or more" of cancers that are yet to be initiated and will result in death means nothing more nor less than that there is little basis at all for any estimate. It is consistent with the "real" figure being higher or lower than 20%. Strictly speaking this phrase means the same as the following: "Occupationally related cancers may comprise as little as or less than 20% (or even 5%) of total cancer mortality in forthcoming decades." But the way in which the conclusion is phrased should be noted. For it transmits a clear sense that enough is known to justifiably make these learned men wary. Although this fear may be justified, as will be shown presently the evidence adduced in the report is insufficient to draw the extreme conclusion that the sense of the statement imparts.

The author's caution is expressed in two of the study's conclusions:

> Patterns and trends in total cancer incidence (and mortality) in the U.S. are consistent with the hypothesis that occupationally-related cancers comprise a substantial and increasing fraction of total cancer incidence. (p. 24)
>
> There is no sound reason to assume that the future consequences of present-day exposure to carcinogens in the workplace will be less than those of exposure in the recent past. (p. 24)

Both of these are true. But they convey a sense that is not true in the same way. For what is left unstated is that the evidence is consistent with other, quite different conclusions as well. One could almost say that the statements express half the truth because of the variety of senses that they convey.

The authors acknowledge that there is a certain measure of imprecision, such as is inherent in any study of this nature, but they

assert that the estimates are approximately correct, and argue that 20% is not an unreasonable projection of that proportion of cancer mortality that is attributable to workplace exposure.

This is an example of subjectivity couched in the garb of "objective" science. To understand these conclusions you need to appreciate not just the science but also the context within which they were written. The only way to understand this obvious slant is as a reaction to what the authors viewed as a dangerous tendency among members of the scientific community to give short shrift to the influence of occupation on the cancer rate. Thus is explained the two levels of meaning contained in these passages. The author's intent can be understood as the desire to present neutral science, whose words convey additional meaning which (as I just argued) is not neutral.

More significant for the purposes of this paper is the inadequacy off the report's methodology. As the last cited conclusion suggests, the authors believed that there was evidence sufficient to estimate what the present consequences are of past exposure to carcinogens in the workplace. And indeed, any projection of the future presumes an ability to do at least this. This estimating procedure forms the crux of the study. But there is good reason to believe that their estimates had insufficient basis in evidence.

To see this, one needs to look at how they were arrived at. The procedure was to look at six widely used substances for which an estimate can be made of a "risk ratio" of certain cancers and then to multiply this factor by the number of workers who come into contact with the substance in an occupational setting. The average number of excess cancers would be equal to (R-1)NI where "R" is the substance's risk

ratio, "N", the number of workers exposed, and "I", the age-adjusted incidence rate of cancer at the sites in question in U.S. males. But their data is very misleading. The data for "N" is very ambiguous. For example, it is stated that two million workers are currently exposed to benzene. This figure is drawn from the National Occupational Hazard Survey undertaken by NIOSH in 1977.[28] Indeed, that survey found that approximately two million Americans are exposed to benzene on the job (p. 218). But this tells only part of the story. For the study also found that of these, about fifty thousand - or one in forty - are exposed "full-time" (p. 232).[29] The survey does not even suggest what the range or distribution is of the concentrations to which any of these workers are exposed. This would not matter if the risk ratio (R) was based upon a survey of a representative sample of these two million workers, but it isn't. The study upon which this risk ratio was based had a cohort of 748 workers occupationally exposed to benzene in the production of a natural rubber cast film at two locations in Ohio.[30] Of these, seven died of cancer whereas fewer than 1.5 would have been expected.[31] Although the published findings do not state it, presumably these workers had been exposed for more than nine hours each day. But the NCI, NIEHS, NIOSH study makes no attempt at presenting a rationale for extrapolating the mortality data from the full-time workers to the two million workers who are exposed to benzene. Yet, in spite of this

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28 National Occupational Hazard Survey, vol. 3, U.S.D.H.E.W., P.H.S., C.D.C., Cincinnati, Ohio, December, 1977.

29 "Full-time" is defined as "in excess of four hours per working day."

30 Peter Infante et al., "Leukemia in Benzene Workers," The Lancet, 1977 (7/9/77), p. 76

31 Ibid., p. 77.

the report infers that all two million workers exposed to benzene face the same risk.

The report can be better understood in the context in which it was prepared, for it was fairly unusual. Many of the scientists who were supportive of OSHA's "cancer policy" regulation were concerned by the impression that the policy's opponents had offered at the public hearing in 1978 that occupational exposure is a negligible contributor to the national cancer rate. They responded by issuing this report which is both a critique of previous "underestimates" and a presentation of a better estimate. It was written as much (or more) to advance the regulation's prospects as to contribute to scientific understanding. Thus, the report can perhaps be better understood as a statement of political or personal values than as a statement of science.

None of this is meant to suggest that the proportion of cancer attributable to occupational exposure is less than the authors hint at (that is, 20%). Rather, all that is intended here is to suggest that they have offered insufficient evidence to warrant the conclusion that it is. One could even make the strong assertion that because they have not shown what the present consequences are of past exposure, the projection that the future will likely be like the past is meaningless.

But the report was not unique in its difficulties. Any estimate of the significance of the workplace on cancer rates must fall prey to the sort of weaknesses that this did; it must be based upon assumptions that are little more than hunches. It appears that there is simply no way to assess the impact of occupation on cancer rates. Even if the question could be operationally defined (which it may not be owing to the general ignorance of the mechanisms of carcinogenesis) the data collection

problems are immense. But this does not mean that there is no reason to control occupational exposure to suspected carcinogens. Whether or not there is an epidemic of occupational cancers, there was a sufficient enough likelihood of there being one to warrant Congress directing its attention to it and conferring authority upon the Department of Labor to identify, assess and control individual carcinogens. The following two Chapters examine the rationale for this process and its significant sources of uncertainty.

CHAPTER 4

IDENTIFICATION

A. Introduction

It is often repeated that man's interaction with the environment is complex. But it may be difficult to really appreciate just how complex the interaction is. Thousands of new chemicals are introduced every year. Each of these poses a risk of various forms of toxicity. The number of possible different toxic reactions multiplies exponentially when additive and synergistic combinations are admitted.

Except for a blanket prohibition of the manufacture of any non-naturally occurring substance, the control of potential carcinogens requires a method to distinguish between substances and combinations. This Chapter will be concerned with elucidating the questions which arise in any such method (or protocol) and different types of solutions to them. The aim is to show that there are several different types of questions calling for different types of answers.

Through an analysis of the models that are employed, the manner in which evidence is accumulated to support a scientific judgment being made that one or another chemical (or substance) is a human carcinogen is explored in this Chapter.[1] Such a judgment rests upon a series of complex inferences which are themselves based upon models that assert to

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[1] This distinction between chemical and substance is an acknowledgment of the present uncertainty surrounding views of the nature of carcinogenesis. Malignant neoplasms have been induced in the laboratory through dermal contact with various solid-state substances. It is also commonly recognized that asbestos fibers have been linked with various forms of cancer. Coke-oven emissions are thought to be carcinogenic. And, of course, forms of energy are thought to be linked with cancer. So, the mechanism may be physical as well as chemical.

being adequate representations of actual components of the regulatory scenario. There are four evidentiary models upon which this judgment could be based. They are outlined in Table 3.

A. Sources of Evidence

1. Epidemiology

In several instances retrospective epidemiological studies have been performed pointing to the carcinogenicity of certain chemicals. The first carefully done study identified the increased risk of scrotal cancer among chimney sweeps in the latter part of the eighteenth century in London, and postulated that it was due to the soot (coal tar) in the chimneys.

It is no coincidence that the bulk of epidemiological studies pointing to the carcinogenicity of chemicals have been of occupational groups. There are two important reasons for this. The first is that workers constitute a relatively easily identifiable study group.[2] The second is that ordinarily, worker exposure to these chemicals is at far higher concentrations and for longer periods of time than for the general population. As a result (assuming that toxicities obey positive exposure/response relationships), their effects among workers are more obvious, with a higher statistical significance. So, although most man-made chemicals are omnipresent, the existence of a readily identifiable study population with a different exposure level permits meaningful cross-sectional study. This largely explains the vivid relationship between reported cancer outbreaks and workers.

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2 Difficulties have been noted in Chapter Three.

TABLE 3.

GENERAL CLASSIFICATION OF TESTS AVAILABLE TO DETERMINE PROPERTIES RELATED TO CARCINOGENICITY[3]

Method	System	Time required	Basis for test	Result	Conclusion, if result is positive
Epidemiology	Human	Months to lifetimes	Chemicals that cause cancer can can be detected in studies of human populations	Chemical is associated (pos) or is not associated (neg) with an increased incidence of cancer	Chemical is recognized as a human carcinogen
Bioassay	Intact animals	2 to 5 years	Chemicals that cause tumors in animals may cause tumors in humans	Chemical causes (pos) or does not cause (neg) increased incidence of tumors[4]	Chemical is recognized as a carcinogen in that species and as a potential human carcinogen
Short-term tests	Bacteria, yeast, cultured cells, intact animals	Generally few weeks	Chemical interaction with DNA can be measured in biological systems	Chemical causes (pos) or does not cause (neg) a response known to be caused by carcinogens	Chemical is a potential carcinogen
Molecular structure analysis	"Paper chemistry"	Days	Chemicals with like structures interact similarly with DNA	Structure resembles (pos) or does not resemble (neg) structure of known carcinogen	Chemical may be hazardous. That determination requires further testing

[3] Reproduced with slight adaptions from Office of Technology Assessment, Assessment of Technologies for Determining Cancer Risks from the Environment, Washington: OTA, 1981, p. 114.

[4] For interpretation of this see the body of the paper

The one clear strength of epidemiological studies stems from the fact that their subjects are human beings. A positive study does not present the further question of extrapolating to human beings (which will be discussed later). Further (and along the same lines), because the test situation is identical - or quite similar - to the regulatory one, potentially significant synergisms and antagonisms which might be overlooked in the laboratory are included. Epidemiology is:

> . . . an extremely important tool in identifying occupational exposures and other hazards because it studies people in the context in which they are exposed. So it identifies excess risk that might have been missed in studying pure exposures.[5]

As should grow clear, no other form of evidence can give reliable estimates of the quantitative risk of human exposure. But there are significant limitations to the method. When a closer look is taken at it, it will be seen that these weaknesses impose severe restrictions on its employment.

(1) Epidemiology is weak in detecting and in identifying the causes of small degrees of excess risk. According to one study, the lowest excess cancer risk that is directly observable in a human population is the 30% risk of childhood leukemia among children who were exposed to radiation <u>in utero</u>[6] It is apparent that a potentially significant degree of <u>absolute</u> risk could exist undetected if the

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5 Hearings, <u>Federal Register</u> 5039 (statement by Dr. Robert Moore of the National Cancer Institute.

6 Earl Diamond et. al., "The Relationship of Intra-Uterine Radiation to Subsequent Mortality and Development of Leukemia in Children," 97 <u>American Journal of Epidemiology</u>, 283-313, (1973)

exposed population were large enough. For example, although it would be difficult to detect the cause of one percent excess risk of death, even in a population of one million, ten thousand people would likely die from the hazard. A related statistical weakness is a hazard common to many occupational studies. Excess risk may be hidden by small sample size.

> Modern technology enables large amounts of particular chemicals or products to be produced by very few people. In these circumstances it might be difficult to recognize the effects of even a relatively potent carcinogen, particularly if the type of cancer hazard involved occurs commonly in unexposed people.[7]

(2) The absolute realism of the test model that was pointed out earlier as being an asset is also a liability. In reality, we all encounter an uncountable number of stresses on our bodies. The trick in any experiment is to determine whether the test sample has responded significantly differently from the control and if so, to determine the cause. When a controlled experiment fixes all factors but one, it has rendered the second step superfluous. But the epidemiologist rarely can isolate a single factor. Indeed, when there is no inkling as to substance's carcinogenicity, he would have little reason to attempt to.[8]

A problem that the epidemiologist faces is that even those people who can be identified as having come into contract with a specific chemical very likely have been exposed to other (known or unknown)

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7 Hearings, Federal Register 5041 (statement of Dr. Francis J.C. Roe, as a witness for the American Industrial Health Council).

8 This underlines the benefit of a screening process in testing that shall be discussed later in this Chapter.

carcinogens. It may be difficult to determine the marginal risk of anyone of them.

This idea was expanded upon in reference to occupational studies in the last Chapter. According to one expert, there is adequate exposure data for only three or four of the known human carcinogens.[9] Causes of this are (i) inadequate exposure records and (ii) increasing worker mobility.

> The observations emanating from epidemiological studies may be suspect because of lack of accurate data and limited or incomplete follow-up from the onset of some remote exposure, even if it was of short duration. In the studies that depend upon recall, the workers may be unaware of the identity of the substances that they have handled. Routine records rarely satisfy the needs of epidemiological research, but rather what may be needed is the development of a standardized comprehensive occupational health information system with prospective monitoring throughout a defined work force. Job titles may not connote a specific exposure, or the same title may encompass a multitude of possible toxic agents that are likely to produce a variety of effects. Each individual worker may have moved through a number of different jobs even within the same manufacturing industry. The task is to attempt to group the various jobs into homogeneous categories of exposure.[10]

In designing epidemiological (or even laboratory) studies it is important to recognize the tradeoff that exists between reducing the number of confounding factors present, and testing for additive, synergistic or antagonistic relationships that might more closely duplicate the real-world environment. This tradeoff was vividly

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9 Testimony of Dr. William Nicholson at the hearing regarding OSHA's generic cancer policy, and included by OSHA in its discussion of the issues accompanying publication of the final regulation. Hearings, supra Ch. 2, n. 6 at 5040.

10 D. Schottenfeld, J. F. Haas, et. al., "The American Petroleum Institute - Memorial Sloan - Kettering Cancer Study of Morbidity and Mortality among Petroleum Refinery Workers," 1978, p. 6 (cited in Ibid. at 5043)

illustrated in Irving Selikoff's studies of shipyard workers handling asbestos. He found that although working with asbestos was a health risk (of lung cancer and other cancers and lung diseases) it was a major risk for those asbestos workers who smoked cigarettes.

In a study of 370 asbestos workers, it was found that whereas the observed mortality rate from bronchogenic carcinoma was 7.6 times the expected rate, the combination of cigarette smoking and working with asbestos increased the risk to 92 times that of men who neither smoked nor worked with asbestos.[11] The study suggested that the additional risk of a non-smoker who works with asbestos dying of bronchogenic carcinoma was negligible (although 3 of the 87 non-smokers died of asbestosis and one of peritoneal mesothelioma). But the authors felt that the small sample size rendered this inconclusive.[12]

This raises the question (that will be discussed later) whether society ought to respond to this threat to health by controlling the substance or by controlling the worker (through voluntary or involuntary restrictions). If, in fact, the threat is to smokers, would an adequate response to the workplace threat be (assuming away, if possible, the environmental threat) to mandate or advise workers not to smoke. This is a difficult question, which will certainly continue to appear - as it already has in connection with fertile women working with suspected

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11 Irving Selikoff, E. C. Hammond & Jacob Churg, "Asbestos Exposure, Smoking and Neoplasia," 104 Journal of the American Medical Association 106, 110 (1968).

12 Ibid.

teratogens.[13] Any response assumes preconceptions of the nature of the relationship between the individual and society, as well as the meaning of "equal treatment" and an understanding of the etiology of these diseases.[14]

Of course, not all occupational health risks can realistically be controlled by adjusting mediating factors. An instance is that of soft-coal miners who were reported to be at increased risk of cancer of the stomach, but when the effects of social class were evaluated, the association was much reduced.[15] Mining companies could attract employees from a different social class by say, adjusting wages sufficiently, but for some reason this seems like an "Alice in Wonderland" solution.

As was pointed out in Chapter Three, perhaps the most decisive weakness of epidemiology in detecting carcinogenic risk is the terrifically long latency periods of most types of cancer and the undetectability (at present) of the disease during this period of time. Coupled with the irreversibility (at present) of most types of cancer, this makes them undefusable time-bombs. By the time a substance were to be indicted,

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13 Apparently a number of companies make a practice of excluding women of child-bearing age from certain jobs: (New York Times, 9/8/80, p. 14). If teratogenicity is indicative of carcinogenicity, which might be a reasonable assumption since they both operate through the genes, then discriminating on this basis could be considered imprudent as well as unjust - to the beneficiaries.

14 On the relationship between notions of disease etiology and political responses cf. Sylvia Tesh, "Disease Causality and Politics," 6 Journal of Health Politics, Policy and Law, 369-90 (1981).

15 Philip Cole and Marlene Goldman, "Occupation", in Persons at High Risk of Cancer, ed. Joseph F. Fraumeni, New York: Academic Press, Inc., 1975, p. 169.

there could be thousands of people who would already be destined to die of the disease.[16]

As a result of all of these weaknesses, it must be concluded that except possibly as an adjunct to other methods, the epidemiological approach forms an inadequate framework for determining the carcinogenicity of substances. The principal problem is the unreliability of negative conclusions. Due to the before-mentioned factors, there is a tendency to overlook the toxicity of many chemicals.

In addition, there is the logical property of epidemiology as science that a negative can not be proven. The most that can be concluded from a study in which the hypothesized result did not occur is that a positive outcome was not indicated. Thus, no study or combination of studies permits the conclusion that the substance under examination <u>is not</u> carcinogenic. Now that this has been pointed out, brackets should be drawn around it. For, in spite of this restriction, methodologically aware scientists have, for centuries, been making statements that have sounded very much like denials of the existence and efficacy of various entities. Did Michelson and Morley prove that there is no ether? Did Copernicus prove that the earth is not the center of the universe?

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16 Along with the observation that the rapid introduction of new substances into the marketplace and, hypothesized increasing rate of obsolescence of newly discovered chemicals, it might be argued that the results of many positive epidemiological studies would be superfluous by the time they were issued.

In essence, this issue is a red herring. We do not expect absolute certainty anyway. One can be perfectly comfortable asserting that there is no ether in spite of the inability to prove it.[17] More importantly, however, for the subject at hand, the chain of reasoning from cause to effect often has many far weaker links than this logical one. Although there should be concern for the inability to prove, as this Chapter will demonstrate, in carcinogen testing there are reasons far more compelling than logical ones.

2. Animal Studies

> It is an inescapable fact that most of the routine screening of chemical substances for carcinogenicity as practiced today is based on completely outdated concepts of cancer and the mechanisms involved in carcinogenesis. . . Poorly designed and poorly executed tests provide little protection for humans and are a waste of valuable resources.[18]

Although direct observation and positive evidence from human studies are the ideal for evaluation of carcinogenic hazard, the role of epidemiology in any conscious screening strategy must necessarily be limited. The weaknesses of an identification procedure that relies solely on evidence from humans have been pointed out. An approach that limited acceptable evidence to epidemiological studies would be

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17 However, an investigator must bear in mind that his assertions are never indisputably true and, more importantly, that they are meaningful only within a very restricted context. Such is the message in Thomas Kuhn's The Structure of Scientific Revolutions, Chicago: University of Chicago Press, 1970.

18 F. J. C. Roe and Mary J. Tucker, "Recent Developments in the Design of Carcinogenicity Tests on Laboratory Animals," Experimental Model Systems in Toxicology and Their Significance in Man: Proceedings of the European Society for the Study of Drug Toxicity, vol. 15, ed. by W. A. M. Duncan, New York: American Elsevier Pub. Co. Inc., 1974, pp. 171, 176.

exceedingly slow and wasteful. In the language of economists, in general it would not be very cost-effective. Furthermore, such a strategy would be insensitive to low-dose risks. It is fortunate, therefore, that there exist other sources of information upon which to base regulatory decisions. Of these, the controlled laboratory animal study is the most highly regarded model. What is done is to substitute other species of mammals whose metabolisms are sufficiently similar to man's to permit the assumption that its reaction to the chemical would also be similar.[19] The animal model avoids or has a greater potential of surmounting four weaknesses of human studies: (1) The potential ethical dilemma of human experimentation in prospective epidemiological studies is avoided.[20] (2) Because these test animals have shorter lives they have shorter latency periods for cancers. Confirmation or disconfirmation is quicker, resulting in a greater potential for prompt decisions being based upon more evidence and a potential saving in lives. (3) By using a large number of test animals it is possible to design studies that can test for a statistically significant response at

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19 As will be discussed later, results are never assumed to be identical; there are various ways of quantifying risk, and ordinarily there is a multiplicative inter-species safety factor (usually 10%) when extrapolating the no-effect dose level to man.

20 This dilemma is replaced by susceptibility to criticism by anti-vivisectionists. Two bases for this criticism will be discussed later in the Chapter. Although there are several valuable discussions, perhaps the most well-known is Peter Singer's Animal Liberation, New York: Random House, 1975. In "Anti-vivisection: The Reluctant Hydra," Robert White defends his use of animals (40 American Scholar 503-512, 1971).

a lower dose level.[21] (4) There is a greater ability to exclude confounding factors from the experiment.[22]

Introduction

Typically, the vast bulk of evidence confirming a substance as a carcinogen is based on the animal model. But this model and all studies based upon it contain certain critical and not indisputable assumptions. It is no wonder, therefore, that a great deal of attention is directed toward determining the relevance of animal studies for identifying a substance as a human carcinogen. One can ask this both of animal studies in general and of particular studies. Although there are assumptions that underlie all of them, there are others that are encountered only on particular occasions. What each of these assumptions does is to lend a measure of uncertainty to the evidence and the rationale for the decision to which it contributes.

This is not the proper forum for an attempt at an in-depth discussion of all of these assumptions and of the science behind them. But because of the great importance that is attached to this approach it is vital that the degree of uncertainty it lends to the policy-making

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21 But there is reason to believe that "mega-mouse" studies will also prove to be inconclusive in the low dose range. For example, the Office of Technology Assessment recently argued that the ED01 study exposing 24,000 female mice at several low doses of acetylaminofluorene (a 'known' human carcinogen) was inconclusive (Assessment of Technologies for Determining Cancer Risks from the Environment, Washington: OTA, 1981, pp. 167-9). Nathan Mantel and Marvin Schneiderman draw the general conclusion that in general 'megamouse' experiments are likely to be futile ("Estimating 'Safe' levels, a Hazardous Undertaking," 35 Cancer Research 1379, 1975).

22 Confounding factors are never totally excluded. There will be more on this point later.

process be established. H. F. Kraybill recognized the animal model as being a primary focus of interest when he wrote:

> It is this area which poses major problems and engages the attention of scientists, consumer activists, regulatory officials, industrial representatives, and legislators. It is an area of science and trans-science that reflects much emotionalism; it abounds with opinions conditioned by prior experiences and scientific indoctrination and opinions reflecting parochial interests and influence, that evolve into controversy until some resolutions can be achieved. In essence, in these developments it is invariably a situation where frequently more "heat is generated than light" and some issues, although apparently resolved by one means or another, are debated, scientifically, for years.[23]

This section focuses upon the injection of uncertainty into the identification process in order to assess the extent of the impact that it has in the overall regulatory process. A practical and illuminating way of viewing these sources of uncertainty is by employing a four dimensional matrix to order them.

The first dimension is that of the source of the question. It describes the branch of knowledge that the question belongs to. The values of this dimension are:

(1) statistical
(2) biological
(3) experimental

The first two should be fairly clear. But the third may require explanation. The proper design and implementation of a chronic animal

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23 H. F. Kraybill, "From Mice to Men: Predictability of Observations in Experimental Systems and Their Significance in Man," Human Epidemiology and Animal Laboratory Correlations in Chemical Carcinogenesis, ed. by Frederick Coulston and Philippe Shubik, Norwood, New Jersey: Apex Pub. Corp., 1980, p. 20

test is exceedingly complex. There are literally hundreds of things that can go wrong, each one throwing the significance of the results into question. Careful attention to biological and statistical considerations will not guarantee that it will be conducted correctly. Common sense and a careful attention to detail is also essential. As shall be seen, the presence of contaminants in the food supply, for example, is one way in which a seemingly successful study can be invalidated. Yet neither an understanding of the biology of the test species nor of statistics and sampling techniques can instruct the researcher on how to evaluate its significance to the study.

The second dimension describes the framework within which the degree of significance of the source of uncertainty can be assessed. This dimension has already been discussed in the Introduction to Part II. Labelled "mode" its values are:

(1) scientific
(2) trans-scientific
(3) normative

The third dimension is important for it describes the stage in the study that the issue typically first arises. The values of this dimension are:

(1) design
(2) experiment
(3) analysis

The fourth dimension is the object of the question. It classifies the question according to the type of objection it raises. Each

question is directed toward either the study's validity or its relevance to men at experienced exposure levels. The first type of object throws into question the validity of its findings (typically, that the test agent was/was not the cause of the excess tumors in the test sample). The second type of object questions the meaningfulness of the results.

This framework is an oversimplification of what, in reality, is an exceedingly complex process. But it should have value as a first attempt at classifying uncertainty in animal studies with the ultimate aim of assessing its impact on regulations.

In this section, the approach of listing and discussing those common questions of most animal tests that are open to debate will be taken, employing the same four dimensional matrix that was referred to earlier.[24] The following table lists and classifies the more conspicuous sources of uncertainty in animal studies.[25]

As a general observation, one notices that none of the questions is normative in nature. However, it very well may be that the trans-scientific questions, if they are to be resolved, can be resolved only in terms of values and an implicit social utility function. But more regarding this point later.

As should grow clear, even the line between science and trans-science is hazy. It is often uncertain whether or not a question is answerable. Of course, this is to be expected since science does not

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[24] From a practical point of view, it is not important merely that they are open to debate, that is that they are debatable. It is enough that they are debated. Whether justified or not, the existence of scientific discussion transforms the regulatory process.

[25] Although they are all discussed in several places, the immediate source for most of them is Kraybill cited supra n. 23.

TABLE 4.

Uncertainty in Animal Studies

Type of uncertainty[26]	Source	Stage	Mode	Object
animal exposure v. human exposure	1	3	2	2
improper test species and strains	2	1	2	2
cellular threshold	2	1	1	1
metabolic overloading	2	1	1	1
time-to-tumor formation	1	1	2	2
dose level	1	1	2	2
benign tumors	2	3	1	1
failures to consider the role of diet, state of nutrition and diet contaminants	2 or 3	1	1 or 2	1
inappropriate route of administration	3	1	1	2
contaminants in the test agent	3	1 or 2	1	1
statistical considerations	1	3	2	1
non-positive results	2	1	1	2

Source		Stage		Mode		Object	
(1)	statistical	(1)	design	(1)	scientific	(1)	reliability
(2)	biological	(2)	experiment	(2)	trans-scientific	(2)	relevance
(3)	experimental	(3)	analysis	(3)	normative		

26 This list does not come close to exhausting all of the different types of uncertainty that enter into carcinogen evaluation via chronic animal testing, It is intended to be a demonstration of its pervasiveness and the importance of paying close attention to it.

stand still. Indeed, science, as a process, is largely the development of methods to answer questions that had been unanswerable.

Care needs to be taken in approaching each of these sources of uncertainty. There is little to be gained in treating them in terms of whether or not they invalidate the study. Rather, it is more fruitful to seek to determine the general degree of uncertainty that they place on the study results and conversely, how much useful information is transmitted in spite of the uncertainty.

When speaking of uncertainties in the scientific process one can draw an analogy to electronics. When transmitting information as electro-magnetic energy one seeks to convey as much information (signal) with as little interference (noise) as possible. No matter how carefully one designs an electronic system there will always be interference. One must reconcile himself to this if he is to communicate at all.[27]

But the problem is not simply how much "noise" to allow into valid research. It is also how to detect the signal from the noise in the first place. This is one way to view many of these questions: as the inability to even determine what is informative in the results.

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27 So, this is true of all information systems including ordinary as well as formal languages. On this general point, one is best referred to Ludwig Wittgenstein's Philosophical Investigations, (tr. G.E.M. Anscombe), New York: The MacMillan Company, 1953.

a. Animal Exposure v. Human Exposure:

> The search for a species comparable to man has been in many instances lip service to a seemingly unattainable ideal, the pursuit of the philosopher's stone.[28]

It was mentioned earlier that our lack of understanding of the relationship between test animals and man as systems within which the test agent acts imposes a severe constraint upon the extrapolation of information concerning the former to the latter. Scientists do not use animals because the results are inherently meaningful for man, but because prospective clinical trials on man of suspected carcinogens are considered unacceptable and unproductive.

The decision to use animals involves an implicit acceptance of the uncertainty involved in drawing inferences between species that are similar but different. Some extrapolations are more acceptable than others. Physicists, for instance, have limited license to infer the kinetics of galactic or subatomic behavior from insights derived from experience with "ordinary" objects. Certain of the rules are taken to apply irrespective of the size or position of the object. On the other hand, it would be wrong to infer from one's experience of one's own consciousness that all objects are conscious.

Not all objects respond to changes in their environment as do humans. This is a result of differences in physiology and anatomy as well as psychology (when it makes sense to draw a comparison on these levels). But some "objects" respond more like people than others. The

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28 Food Safety Council, Proposed System for Food Safety Assessment, Washington: Food Safety Council, 1980, p. 85.

choice of rodents as typical test species involves tradeoffs between degree of similarity, experimental feasibility and ethical considerations. Although rodents' bodies behave like man's there are other animals that are more like man (apes for example). The results of a carefully designed and administered experiment involving one hundred gorillas would very likely be more relevant to man than an experiment with one hundred mice. But such an experiment would be vastly more expensive as well as more difficult to control (since gorillas are more heterogeneous than inbred rodents, and are more difficult to manage). In addition, to seek to induce tumors in gorillas would be considered by most people to be unethical.[29] And, of course, there just aren't that many gorillas.[30]

But in so far as mice are not men, they will not react to suspect carcinogens in quite the same way as humans will, barring any reason to believe otherwise. And, in using another animal as a proxy for man, the results lose a certain indeterminate degree of legitimacy. This needs to be recognized. Although it cannot be eliminated, within certain limits in time this uncertainty can be quantified (transformed from "radical" to "ordinary" uncertainty) through a greater understanding of

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29 There are two roots of this belief. The first stems from our species chauvinism. Because they are quite a bit like us, we invest the Great Apes with a certain human-ness. Secondly, because there exists evidence that they possess a rather rich mental life, one could quite easily offer Kant's argument that they should never be treated solely as means to our own ends, but as ends in themselves.

30 Illustrating the rule that there is never unanimity in the scientific community, one of the witnesses at OSHA's cancer policy bearings argued that there should be experimentation upon primates preliminary to judging a substance to be a carcinogen (James Jandl, testifying on behalf of the trade association, American Industrial Health Council: 8 Occupational Safety and Health Reporter 87, (B.N.A.; 6/22/78).

the differences between the species. But this necessitates a sufficient understanding of contrasting metabolisms as well as of the chemical action of the agent to permit comparisons to be drawn.

In his approach to this question, a scientist is exercising discretion. There are always two criteria to the legitimate exclusive exercise of discretion by an individual or a class of individuals. The first is an opaqueness of proper rules of procedure to the untrained observer. The second is the existence of a class of people to whom by reason of their training or natural ability these rules are more transparent. With one exception only when these two conditions are fulfilled is there a rationale for some people to possess exclusive powers of interpretation.[31]

It can be asked with good reason whether the second condition is fulfilled in the present instance (as well as the other trans-scientific issues). Does their greater knowledge imbue experts with any greater ability to correctly make the tradeoffs among relevance, expense and ethics that were described above?

As a non-expert, it is not at all clear how this question should be answered. It would be naive to expect all reasoning to follow an explicit, clearly marked sequence of steps. That rules cannot be specified does not imply that the process is aimless. Perhaps, by virtue of their training and experience, these people acquire some type of intuition that has not yet crystallized into a set of rules. But if

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31 The exception is when this "separation of powers" serves the broader interests of the society, community or group. Although indefensible in a radical act utilitarian scheme, this rule could be defended in a rule utilitarian or an ontological system of ethics.

the remarks of the experts cited above are to be taken at face value, there is reason to doubt it in this particular case.

b. Improper Test Species and Strains:

There is a certain amount of discussion concerning the nature of restrictions to be placed upon the species and strains to be used in animal tests. If the object of a test is to provide information that can be accurately extrapolated to man, then an animal should be used whose reaction to the substance is thought to be as similar to man as possible. If, on the other hand, the objective is to provide information to enable man to be screened from suspect carcinogens, then there may be a rationale for using animals that are thought to be more sensitive than man. Once more, this determination rests upon an assumption of how science is to be used. Science itself does not present us with a "best" solution.

Certain highly inbred strains of mice, for example, have a high spontaneous tumor incidence. It is interesting to note that this incidence rate may vary from generation to generation. Thus, in one colony it changed from 10% to 80% in a ten year period.[32] So it is important to know the correct rate that tumors are occurring spontaneously (particularly when it is of the same type as that induced by the test agent) so as to be able to correctly infer the contribution of the substance.

It could be inferred that a high incidence of spontaneous tumors suggests an elevated susceptibility to carcinogenesis in general. This

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32 Roe and Tucker, supra n. 18 at 175.

may lead to an unrealistically high incidence of tumors in animals exposed to the test agent. On the one hand, this may be advantageous in leading to protective regulations. But, from the viewpoint of scientific honesty, disguising biases in this way can be considered a questionable practice. It has been characterized as "tantamount to recommending to an analytical chemist that he use a dirty test tube."[33]

But there is even a more fundamental constellation of uncertainties here. It stems from our lack of understanding of the metabolism of the test animals that are used, how it varies from man's, and what are the implications of the differences in terms of the reliability of extrapolating the results.

c. Cellular Threshold:

The issue of whether there is a biological threshold to carcinogenesis is one of the most complex. According to this hypothesis there is a dose below which a proven carcinogen will not produce tumors. It is a difficult question to shed light on, both experimentally and theoretically. To provide reasonably probative evidence, one would need to design an experiment involving thousands of animals subjected to low-dose exposure. And it is reasonable to assume that no experiment could be designed to test whether single low-dose exposures would result in any elevated risk at all. It seems likely that to test for even potent carcinogens would require perhaps millions of animals.

Furthermore, at this stage of our understanding of the processes, theory provides little insight into this question. In the remainder of

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33 Ibid., p. 171.

this section, the major issues involved in determining whether there is in fact a threshold to carcinogenesis will be explored. In addition, anambiguity between two different ways in which the term "threshold" isused will be resolved.

Four different types of argument are offered in support of the threshold. They are:

(1) The apparent existence of threshold effects for other types of toxicity argues for a threshold in carcinogenesis.

(2) The ability of cells to repair damage to their chromosomes is overwhelmed at high dose exposures, thus accounting for mutations which should, therefore, be absent at low dose levels.

(3) The metabolic pathways through which carcinogens pass differ between high and low dose exposure. The chemical that is the proximate cause of the initial reaction is only formed when the normal pathways are bypassed.

(4) There is an inverse relationship between dosage and latency period such that at very low levels of risk there is a "practical threshold." In essence, the individual would die of other causes before the tumor has an "opportunity" to form.

Since, strictly speaking, only the first two are arguments to the existence of a threshold, they alone will be discussed in this section and the other two will be discussed later.

(1) The first is an argument by analogy. It points to threshold effects in other types of toxic reactions and suggests that a similar reaction occurs here. Very often this claim is based on the observation that certain bionutrients that are essential dietary supplements or at least are universally present in minute doses are toxic at higher doses. Mention was made in the cancer policy hearings to Vitamin D as well as nickel, chromium, cobalt, selenium, lactose, maltose and other

substances that are everpresent in trace amounts and are toxic in higher concentrations.[34]

One needs to be careful in pursuing analogical arguments. They are subject to two types of refutation. The first is that the original "observation", although prima facie may appear to be self-evident, upon closer examination may in fact be mistaken. Several witnesses took this tact at the hearings, pointing out that there is no reason to believe that beneficial and harmful effects need be mutually exclusive at different doses. Essentially, this argues that to draw this analogy is to beg the question at hand: of the impossibility of making low-dose inferences. Dr. Arthur Upton argued that:

> I do not see the existence of evidence for essentiality of a material as a trace nutrient is incompatible with the concept that that same material may be carcinogenic in trace amounts. So I don't think that kind of evidence in any way contradicts the notion that there may be in fact no non-carcinogenic or safe level in the cancer risk sense.[35]

The second type of refutatiol iq that the analogy is inappropriate. One current theory of carcinogenesis (the "one-hit" model) is based upon the assumption that a tumor arises from a reaction between a cell and a single molecule of the offending substance. If this is the case, then a cancer would be unlike other types of toxicity in which there exist plausible grounds for believing that there are threshold effects:

> . . . experience teaches us that the kind of toxicity that results in acute renal shutdown, that results in respiratory failure, cardiac arrest, acute hematologic insufficiency, generally

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34 Hearings, supra Ch. 2, n. 6 at 5129-30.

35 Ibid. p. 5130.

> involves a measure of tissue insult that does in fact to all practical intents and purposes represent a threshold; whereas with other kinds of effects, we may be dealing with subtle injury to perhaps only a single cell in the body.[36]

The analogical argument is conditional upon a yet unproven theory of carcinogenesis. Indeed, there appears to be a great deal of evidence to suggest that this theory is incorrect.[37]

(2) It is commonly believed that most (but not necessarily all) cancers start as chromosomal damage. Cells possess mechamisms whose function is to repair this type of cell injury. A properly repaired cell will not lead to a tumor. This argument for the existence of a threshold assumes that at low doses this repair mechanism operates perfectly, but is overwhelmed at a certain level (or rate) of injury. The belief that there is a self-repair mechanism is based on studies that have shown that the rate of genetic alteration is greater than the rate of final mutation.[38] It is believed that cells possess enzymes that can break the abnormal bonds created and restore the DNA to its original state. The longer the period of time before a cell replicates, the greater will be the chance of the damage being repaired. If the alteration is repaired then it will not be passed on as a mutation.

The issue is whether DNA repair is efficient without fail. For there to be an actual threshold then the repair mechanism must operate perfectly. There seems to be some debate on this issue. One witness to OSHA's cancer policy hearings stated that the system is "essentially

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36 Ibid. pp. 5124-25 (Testimony of Dr. Arthur Upton).

37 Ibid., pp. 5129-31.

38 Ibid., p. 5126.

100%" effective.[39] But there is a big difference between being actually and essentially 100% effective. It is the difference between the existence and the non-existence of a threshold. Indeed, those who claim 100% effectiveness are claiming something that they cannot prove. This type of claim falls prey to the inductive fallacy. And, although the author is not a biologist, it seems to make common sense that no biological function is efficient all of the time.

Another protective mechanism cited by witnesses at the cancer policy hearings is the detoxification of carcinogenic metabolites prior to their interaction with DNA. One witness argued that there is in fact a threshold as a result of this mechanism:

> . . . there is a concentration at which detoxification can handle the material in such a way that the reactive metabolites do not get to the critical macromolecules, and therefore you do not get tumorigenicity. So I believe not only in these studies is there a no-effect level. I think there is a real no-effect level.[40]

Again, there is considerable controversy concerning the absolute efficacy of this mechanism.

Although these arguments for the existence of a threshold have perhaps not been given their due at this level of analysis they do not persuade. But that is not to say that the position that they assert is mistaken. For those who argue against it must oppose the arguments rather than the purported existence if the threshold itself. When they do argue against the existence itself, they do so based upon their own

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39 Ibid., p. 5128 (Statement by David Brusick, a witness for the American Industrial Health Council).

40 Ibid., (Dr. Ralph Freudenthal of Stauffer Chemical Co.).

models of carcinogenesis, which may of course be inaccurate in certain critical respects. One cannot observe a threshold, but can only infer its existence. Given the tenuousness of the theory of carcinogenesis, any inference, for or against, is bound to be open to question.

A distinction between thresholds for individuals and thresholds for populations needs to be made. Experience would seem to suggest that individuals have (at least "practical") thresholds for cancer. After all, not everyone exposed to carcinogens gets the disease. But it is not as evident that populations have them. That is, susceptibility will vary among people, and it has not (and perhaps cannot) be shown that there is an exposure level below which no member of a population will get the disease. And given the information so far presented there is no way to determine at what level such a threshold would exist. When focusing on population thresholds (which, after all, is the relevant issue for the government regulator) it must be borne in mind that various members of a population are exposed to differing exposures of various carcinogens some of which may act additively or synergistically. So, the marginal effect of a low exposure to a carcinogen may be greater than one would otherwise expect.

d. Metabolic Overloading:

It has been mentioned that it is common practice for the dose schedule in an experiment to far exceed the exposure levels that humans would likely receive. The rationale for this is statistical. But there is a crucial biological assumption that underpins this practice: that it is possible to predict on the basis of the response at high doses what the response would be at lower (more realistic) exposures.

Mathematically, this is to say that the dose/response curve is continuous over wide intervals.[41] But, what if this assumption is invalid? There is strong evidence that chemicals will take altogether different metabolic pathways at different dose levels. Piper, et al., demonstrated that pharmacokinetic data for different doses of 2,4,5-T argue for the conclusion that at high doses the detoxification processes, such as excretion, are altered.[42]

The biological explanation is that:

> . . . when the dosage for an animal is massive, its natural detoxification systems or defense mechanisms . . . are usually overwhelmed . . . result is that the detoxification mechanisms of the host become incapable of providing the necessary protection.[43]

Because not enough is known of the factors that influence carcinogenesis, one might guess at whether "metabolic overloading" is a relevant uncertainty that should be considered.

Once again, this is a tradeoff between minimizing the risk of false negatives and false positives. This dilemma is reconciled in common practice by testing at high doses and accepting the possibility of false positives. This stems from a sense that chronic toxicity testing is a public health function. But, if indeed there is an alteration of the metabolic pathway, then the results would likely be meaningless. This has to do with the shape of the dose/response cure, an issue which shall

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41 A stronger assumption that the curve possesses a slope of the same sign might also be necessary.

42 W.N. Piper, et al., "The Fate of 2,4,5-Trichlorophenoxyacetic acid (2,4,5-T) Following Oral Administration to Rats and Dogs," 26 Journal of Toxicology and Applied Pharmacology 339 (1973).

43 Hearings, supra Ch. 2, n. 6 at 5089 (Comment by Borden Chemical, Inc.).

be discussed at greater length later. This danger can be minimized somewhat through an understanding of the changes in metabolism from high to low dose.

Weinhouse showed in 1955 that glyoxylic acid conversion to oxalatein rate liver is dose dependent.[44] Although at low doses the oxidation is entirely to carbon dioxide, there is a partial oxidation to oxalate at high doses. If one could draw an analogy to carcinogenesis, this would suggest that in certain instances the proximate cause of the tumor would only be formed when the mediator (the test substance) were present in high concentrations in the animal's system. Under these circumstances the dose/response curve would be discontinuous. One would be able to predict from high dose data what the response to the test agent would be at low doses. So, it is important, when possible, to determine prior to a test that the agent takes the same path in low doses as in the administered dose range for the chronic test.

There is an interesting seeming related paradox.[45] This is that substances that have a higher acute toxicity are more likely to escape detection as potential carcinogens. This is due to the fact that substances that are not acutely toxic can be tested at higher dose levels without incurring short term effects. The estimated maximum tolerated dose (EMTD) is determined during a subchronic test. Clearly, a substance that is acutely toxic at low doses cannot be administered in high doses in a chronic test. Therefore, assuming a dose/response curve

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[44] S. Weinhouse, "The Synthesis and Degradation of Glycine," in A Symposium on Amino Acid Metabolism, ed. William McElroy and M. Bentleyl Glass.

[45] This "seeming" paradox becomes real only if there is a positive relationship between the probability of a substance having acute effects and also being a carcinogen.

that has a positive slope, the researcher would need very many more animals to detect excess tumors at a statistically significant level.

e. Time-To-Tumor Formation:

This is an argument that states that a substance may be carcinogenic, yet not cause cancer. This paradox is resolved through the insight that the period of time during which it is latent may extend past the individual's lifetime. This is certainly a relevant consideration in designing regulations regarding the human carcinogenicity of substances. In a 1967 article H. Druckrey argued that there is an inverse logarithmic relationship between dose/effect and time-to-tumor.[46] Thus, at sufficiently low exposures, the latent period from exposure to tumor would exceed the lifetime of the animal. This has been characterized as a "practical threshold." This theory was clearly articulated by Dr. Hardin B. Jones:

> Both threshold and non-threshold patterns of dose-effect relationships show a further influence of dose on risk of cancer in that the time to the appearance of cancers (the "latent period") increases as a fractional power of the reduction in exposure. When degree of exposure to a carcinogen becomes sufficiently small, the risk of cancer may become zero because there is not enough time, within the life span, for any cancers to develop.[47]

This view has been contested as being a statistical artifact of populations, rather than being true of all members of a population. Druckrey's conclusions were based upon studies comparing the mean values

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46 H. Druckrey, "Quantitative Aspects in Chemical Carcinogenesis," Potential Carcinogenic Hazards from Drugs, ed. Rene Truhaut, Berlin: Springer Verlag, 1967, p. 60.

47 Hearings, supra Ch. 2, n. 6 at 5132.

of latency periods of samples under differing test doses. Statistical inference is not predictive of individuals. Thus, it cannot be inferred that a mouse - or a person - will have a practical threshold at any dose level for a proven (or for that matter, suspected) carcinogen.

> This formulation does not address when the earliest cancers appear but only the median time to appearance. One needs, in addition, information on the distribution of time of appearance to evaluate the concept of a "practical threshold. If the distribution is narrow in time, the concept may have meaning. If the distribution is broad, it will not be meaningful. One might expect in genetically heterogeneous animal, like man, that the distribution will be broad.[48]

f. Dose Level:

While discussing whether it can be determined that a threshold exists for carcinogens the necessary and universal practice of testing at high dose levels was referred to. The rationale for this practice is that in a sample of 50 or 100 animals the test agent would have to be incredibly potent to yield a meaningful (that is, statistically significant) elevation in tumor yields at ordinary dose levels. A substance that was moderately or weakly carcinogenic would require either hundreds or thousands of animals, or unrealistically high dose levels. For reasons of expediency the latter option must be chosen.[49] But this option entails uncertainty.

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48 M.A. Schneiderman et al., Thresholds for Environmental Cancer: Biological and Statistical Considerations, presented at the New York Academy of Sciences Conference on the Scientific Basis for the Public Control of Environmental Health Hazards, 1978, p. 7.

49 For example, to indict a substance that was tumorigenic in 1 out of 1000 individuals exposed would require a group of 5000 test animals and 5000 untreated controls at a .05 level of significance.

In order for this practice to make good scientific sense it must betrue that a substance that is carcinogenic at high (experimental) doses is also carcinogenic at low (realistic) doses. This is a crucial, and controversial, assumption because often the tested dose levels have absolutely no connection to reality. This assumption is vigorously supported by many researchers. Among them is Arthur Upton:

> Contrary to widespread popular belief, there is no evidence that a chemical which is carcinogenic at high doses would not also be carcinogenic at lower doses. The evidence, in fact, is that it is likely to be carcinogenic at any dose, but at a frequency which is much less likely to be detectable at low doses than at high doses.[50]

It is contested by others, largely on the basis of the contention that at such high doses the chemical is metabolized differently in some cases, possibly accounting for the elevation in tumor yield:

> Only relatively high doses can, in practice, yield statistically significant data. But <u>frequently</u> such high doses produce cancer simply because their very immensity overwhelms the biochemical pathways that would detoxify smaller, more realistic doses. (author's italics)[51]

The issues surrounding the possibility of metabolic overloading are discussed in an earlier section. At this point, let it suffice to say that from a raw logical point of view it is conceivable that metabolic over-loading could account for the excess tumors reported in a study. Whether in fact it ever does, the scientific community as a whole is unable to decide.

One is tempted to conclude that absent decisive evidence either way, the issue of whether to test at high doses (EMTD's) pits risk

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50 Hearings, supra Ch. 2, n. 6 at 5085.

51 Hearings, supra Ch. 2, n. 6 at 5088 (statement of Dr. Perry Gehring of Dow Chemical).

TABLE 5.

CORRELATION OF EXPERIMENTAL DOSES IN
ANIMALS TO CALCULATED EQUIVALENT EXPERIMENTAL EXPOSURE IN MAN

Chemicals	Experimental Dose	Equivalency Calculated Human Intake Levels
Cyclamates	5% in diet (2.18 gms/day)	552 bottles of soft drink (max)
Oil of Calamus	5000 ppm in diet	250 qts of vermouth/dry
Saccharin	5% in diet	800 12 ounce bottles of soft drink
DES (Diethylstilbestrol)	1 clinical treatment	5×10^6 lbs. of liver for 50 years
Safrole	5000 ppm	613 bottles of rootbeer per day
TCE (Trichloreothylene)	900 mb/kg BTWT - female	5×10^7 cups per day*
(in decaffeinated coffee)	1200 mg/kg BTWT - male	10×10^7 cups per day
DDT (DDE) - mouse diet		316 mg/lifetime

853 times general population exposure
3 times work exposure

Data from various sources
* Cup of coffee = 9×10^4 mg of TCE for 150 mg cup.

minimalists against risk acceptors. This would be true but for the consideration that just as overloading may result in carcinogenic metabolites being produced, it is conceivable that it could result in non-carcinogens where carcinogens would be produced normally. This was suggested by Hooper, Harris, and Ames. Referring to studies that they saw as suggesting that carcinogenic response at low doses is greater than would be predicted from a linear extrapolation of high dose response they argued that:

> The explanation for this proportionately greater activity at low doses may be that the mechanisms that activate vinyl chloride to the proximate carcinogen are saturated at high doses.[52]

So, high dose testing introduces the uncertainty of overlooking a carcinogen as well as of falsely identifying a substance as one.

g. Benign Tumors:

According to convention, a tumor is not considered a cancer unless it is invasive. These tumors are termed "malignant." What is most terrible about cancer is its ability to spread to multiple and distant sites throughout the body (metastasize). It is this that frustrates any attempt at surgical excision and that can introduce an almost fatalistic acceptance of personal defeat. An abnormal growth tht does not possess the ability to invade normal tissue or to spread to other parts of the body is termed "benign." Generally a benign tumor is less

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52 N. K. Hooper, R. H. Harris and B. N. Ames, "Chemical Carcinogens," (letter) 203 Science 602 (1979).

life-threatening because it can be more easily eliminated through surgery.

It sometimes happens that a chronic toxicity test will yield benign, but not malignant tumors. How is this evidence that the chemical is associated with a statistically significant incidence of benign tumors, to be evaluated?

First of all, the term "benign" is a misnomer since no tumor is really benign.

> In the first instance, benign tumors may cause death in man and animals without ever undergoing malignant transformation. The induction of a benign tumor is, itself, therefore, an indication of a serious adverse reaction.[53]

But because they can be more easily excised, they are not as dangerous in themselves as those that invade normal tissue.

The more important question is whether a benign tumor is indicative of a potential for malignancy. One study concluded that, "There can be no doubt from a survey of experimental studies that benign neoplasms are often precursors of malignancies."[54] Dr. Benjamin Trump took an even stronger position during the cancer policy hearings:

> In all of the examples that we have worked with, what used to be or what some people might have called benign lesions years ago are clearly part of the progression from normal to malignant.[55]

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53 U.S. Food and Drug Administration Advisory Committee on Protocols for Safety Evaluation, "Panel on Carcinogenesis Report on Cancer Testing in the Safety Evaluation of Food Additives and Pesticides," 20 Toxicology and Applied Pharmacology, 419, 420 (1971).

54 Ibid.

55 Hearings, supra Ch. 2, n. 6 at 5100.

This view was also held by Dr. Umberto Saffiotti and Dr. Richard Griesemer. A somewhat weaker view was held by Dr. Curtis Harris who testified that he knew of no chemical that caused only benign tumors.[56]

Yet neither of these postions entails that benign tumors be treated in the same way as malignancies. In the first place, even if the progression from benign to malignant is inevitable, if it takes longer than the individual's lifetime, it might be reasonable to consider it moot from a public health standpoint.[57] After all, cutaneous moles remain benign. Does it make sense to view a substance that induces warts in the same way as one that directly induces metastasizing carcinomas?

But a number of scientists contested even the assumption of the inevitability of the progression from benign to malignant:

> Most of the biological evidence of the behavior of neoplasm comes from man and from clinical experience, and it is evident that the vast majority of benign neoplasm do not progress to malignant and that malignant neoplasm does not develop from benign neoplasm.[58]
>
> Considering all tumors (benign or malignant) equally significant as indicators of carcinogen exposure will neither increase our understanding nor provide information on carcinogenic hazards.[59]

Again, this issue is not readily resolvable because of a lack of understanding of the mechanism of carcinogenesis. Which tumors progress from benign to malignant and how? The distinction between benign and

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56 Ibid.

57 On the related notions of latency and time-to-tumor, see pp. 74-75.

58 Hearings, supra Ch. 2, n. 6 at 5103 (statement by Dr. Richard Bates).

59 Ibid. (statement by Drs. Paul Newberne and Adrienne Rogers).

malignant is viewed by some as artificial; an attempt to make a distinction when the nature of the differences is not known.

> The terms benign and malignant reflected the expected outcome of the presence of the tumor in the individual patient. They bore no relationship to the causal events leading to these tumors and whether or not such events would produce the same or a different kind of tumor in another individual.[60]

Dr. Richard Bates so aptly spoke of the real significance of the issue:

> As with many other questions, the regulator must make a decision before arguments have ceased within the scientific community. These may either lean toward protecting human health or toward protecting economic enterprise. In the former case a significant increase in benign tumors would be considered an index of carcinogenicity. In the latter case less weight would be placed on benign tumors.[61]

h. Failures to Consider the Role of Diet, State of Nutrition and Diet Contaminants:

It is now clearly appreciated that the process of tumor formation is multi-factoral. The carcinogenic mechanism can be enhanced by the presence or absence of any of several different environmental components. Although as a general statement this is known, not enough is known of the nature of the process in specific instances to permit the researcher to determine what portion of excess tumors can be explained by the diet of the animals. This can only be determined by comparing the tumor yields of different groups, each of which had been on a different diet. Yet, clearly, this is an expensive process. But

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60 Hearings, supra Ch. 2, n. 6 at 5013 (statement by Dr. Richard Bates).

61 Hearings, supra Ch. 2, n. 6 at 5104.

it is unarguable that without assessing the potential influence of diet on the test results, the degree of confidence with which they can be accepted is diminished.

How strong an influence might diet have upon excess tumor yield? In 1953 Tannenbaum and Silverstone wrote,

> . . . natural foods contain a number of constituents which have been given little attention in nutrition and cancer research because they are apparently not dietary essentials. In addition, there must be others yet undetected. Perhaps among these unregarded substances are some with carcinogenic activity; and others that potentiate or oppose the action of carcinogenesis.[62]

The Food Safety Council stated that, "Dietary factors are probably among the most important modifiers of carcinogenicity and other forms of toxic manifestations."[63]

There is evidence to suggest that variation of macro-nutrients (protein,fat, carbohydrate) as well as micro-nutrients and contaminants will vary tumor yield. Table 6 contains the results of one study that varied the amount fed to mice. The study indicates a significance difference in tumor yield solely as the result of difference in quantity fed. It is particularly interesting that in this experiment, the ad libitum-fed mice ate very little more (5.8 g. per day) than the mice restricted to 4 or 5 g. per day. The authors thought this persuasive evidence that the difference was <u>not</u> due to the presence of contaminants in the food.

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62 A. Tannenbaum and H. Silverstone, "Nutrition in Relation to Cancer," 1 <u>Advances in Cancer Research</u> 451 (1953).

63 <u>Food Safety Council</u>, supra n. 28 at 125.

TABLE 6.

CANCERS IN AFFLUENT MICE

Group	Number of mice	Number per cage	Weieht of diet per day	Survival to 18 months	Number of tumours
1	40	1	4 g		4
2	40	1	5 g	Similar	4
3	40	1	as libitum		32
4	40	5	as libitum		23

Mice = Outbred Swiss Albino Males
Diet = Standard pelleted

Feeding	Total tumours by 18 months	Liver tumours	Lung tumours	Lympho-reticular neoplasms	Other neoplasms
4 g. diet day 1 mouse cage	4	1	1	2	0
5 g. diet day 1 mouse cage	4	2	0	1	1 testis
Diet ad libitum 1 mouse cage	32	15	2	11	2 testis 1 kidney 1 thyroid
Diet ad libitum 5 mice/cage	23	8	6	9	0

F. J. C. Roe and Mary J. Tucker, "Recent Developments in the Design of Carcinogenicity Tests on Laboratory Animals," Experimental Model Systems in Toxicity and Their Significance in Man, ed. W. A. M. Duncan, New York: Elsevier Publishing Company, Inc., 1974, p. 173.

Absent a fuller understanding of the ways in which carcinogenesis proceeds and the ability to predict, for each cancer type, the influence of the various diets on which test animals will be raised, researchers must be concerned with limiting the presence of non-nutritive contaminants. There are two general strategies toward this end. The first is to use open-formulas or semi-synthetic diets for laboratory animals. Because of their more uniform composition they are preferred. But there is a certain amount of discussion as to whether they are feasible. Although one study argued that, "The increase in cost of feed, although appreciable (from approximately 10 cents a pound to approximately 50-60 cents a pound) represents only a minor fraction of the total cost of a carcinogenesis study,"[64] there were others that considered costs "prohibitive [65] and the diets "expensive and not readily available."[66]

The other strategy is to provide for "the systematic or continuous analysis of the laboratory animal ration. At least this effort provides a profile on the extent and type of contamination that the laboratory must consider and evaluate."[67] One tactic is to subject each batch of mixed feed to analytical chemistry analysis to determine dosage of the test agent as well as to detect the presence of likely contaminants and the concentration of macro and micro-nutrients in the feed. Any

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64 FDA Advisory Committee on Protocols for Safety Evaluation, "Report on Cancer Testing in the Safety Evaluation of Food Additives and Pesticides," 20 Toxicology and Applied Pharmacology 419, 428 (1971).

65 Roe and Tucker, supra n. 18 at 175.

66 Food Safety Council, supra n. 28 at 125.

67 Kraybill, supra n. 23 at 26.

nutrient which exceeds a 10% variation from the desired level could be discarded.[68]

Although less ambitious than providing a semi-synthetic diet, the logistical problems can be awesome. With these complexities come an enhanced risk of experimental error, for example, overlooking a batch or misreading its identification card.

Uncertainty also creeps into the study results as the result of the everpresent possibility of contamination of the animals' environment, as well as through data collection problems. To check the former, one ambitious study:

> . . . included checking food, bedding, and water for bacterial and fungal contamination before they were used on the study, monitoring the environmental conditions (swabs and air samples from the animal rooms, and environmental bedding and water as it as removed from the cage) and monitoring the animal caretakers and animal for evidence of bacterial, fungal, parasitic, or viral infections. In addition, evaluations were performed on numerous biological indicators to assure successful autoclave operation throughout the support areas.[69]

These precautions are very expensive; their opportunity cost must be recognized. It is likely that, assuming fairly fixed budgets for carcinogen assessment, the price of reducing uncertainty in one experiment will be sacrificing another study entirely. Before a decision on the appropriateness of these precautions is made, one would want to

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68 Carol R. Johnson, "Logistics of Conducting a Chronic Study With 24,192 Mice," Innovations in Cancer Risk Assessment, ed. Jeffrey A. Staffa and Myron A. Mehlman, Park Forest South, Ill.: Pathotox Pub., 1979, p. 205.

69 Ibid., p. 206

assess the extent to which instituting them reduces uncertainty as well as the extent to which certainty is desirable in that study.[70]

The risk of data collection problems can never be eliminated. Some of the sources are: skipped cages, incorrect animal identification, inconsistent observations, transcription errors in recording animal weights and food consumption and incomplete recording of data. However, computer assisted techniques have recently been developed to reduce this risk.[71]

Although the risk of experimental error can never be eliminated, some techniques are "safer" than others. An important issue is whether protocols and standards should be established for the design and interpretation of bioassay data. The issue revolves around a tradeoff between guidance and flexibility. This issue arose during the hearings to consider OSHA's generic cancer policy. Arguing that absent explicit guidance (in the form of binding regulations governing acceptable experimentation) "poor scientific practices and the possibility of significant regulatory error" will be encouraged, Drs. Paul Newberne and Adrienne Rogers stated that the policy needs to establish:

> clear criteria for published studies which will be considered acceptable as evidence of carcinogenicity in animals. . . Proper standards of acceptability of data or test protocols should recognize and provide for these factors in advance. . . establishing the scientific criteria on an ad hoc, after the fact basis is highly unsatisfactory from a scientific point of view,

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70 When risk is assessed quantitatively, the actual numbers obtained in this phase are more important than, say, under the Delaney Amendment for food additives. But, on the other hand, because of the all or nothing decision rule for food additives under Delaney, the potential impact of an error is greater.

71 see Johnson, supra n. 68.

> and we would assume the same is also true form a regulatory point of view.[72]

Dr. Rogers testified during the hearings that:

> . . . the proposed regulation should include provisions which to the extent possible assure that regulatory decisions which use it as a framework are based on sound, relevant data. . ."[73]

Advocating pre-specification of bioassay protocols does not, however, eliminate all vestiges of scientific judgment in the interpretation of study results. In response to the question, "If an experiment did not meet your criteria, would you consider it to be an invalid test. . . would you consider any conclusions drawn from that to be invalid with respect to carcinogenicity?", Dr. Rogers replied, "No. It depends on what the conclusions are that one is going to draw."[74]

The opposing point of view is that protocols should be flexible enough to allow scientists leeway in the design of experiments. Implicit in this argument is the assumption that the complexity and diversity of experimental conditions do not permit categorization, much less standardization of protocols:

> . . . the task of distinguishing between. . . valid and relevant tests and . . . invalid and irrelevant tests is not one that can be delegated to a computer. For this purpose, there is no better way than to rely on the collective judgment of a group of

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72 Hearings, supra Ch. 2, n. 6 at 5143.

73 Ibid., p. 5144.

74 Ibid., p. 5141.

> independent, relevantly experienced and well-informed scientists. . .[75]

This argument implies the necessity of having a panel of "the most knowledgeable and experienced experts"[76] to evaluate each study separately.[77] A term that is often used in connnection with this issue is "scientific judgment." There is no need for detailed guidelines when one has adequate faith in the ability of scientists to design, execute and interpret the results of experiments.

> . . .the studies will be validated by scientists of repute or an advisory committee. Therefore, there is no need to write in obvious criteria. . . to suggest that these criteria should be written into the document is excessive material. I think it is a waste of paper.[78]
>
> . . .there will be experiments where the data is interpretable even though it may not fulfill the current NCI bioassay description.[79]

It may be that the field is too complex to allow for meaningful, yet flexible guidelines. One must wonder, however, how much of this aversion to prespecification is the result of the complexity in the object, and how much is due to a recognition that scientists are often unable to agree on the parameters of a protocol. If this is the case (that acceptable experimental conditions can not be consensually prespecified) then why should one expect consensus to be reached on the

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75 Ibid., p. 5143.

76 Even the existence of protocols does not remove the necessity for a panel since experiments may not adhere to even the most rigorously drawn protocols.

77 Hearings, Federal Register 5142 (statement of Dr. Leon Golberg).

78 Ibid., p. 5140 (statement of witnesses for NIOSH).

79 Ibid. (statement of Dr. Bernard Weinstein)

significance of a study ex post? Does hiding behind the cloak of "scientific judgment" mask this inability?[80]

i. Inappropriate Route of Administration:[81]

Here, the issue is how much stock to place on the result of studies in which the agent in question is administered to the test animals along a route different from that by which man is commonly exposed. For example, can we conclude from a study that found elevated tumor rates after adsorbates of industrially polluted water were injected subcutaneously into rodents that these adsorbates are carcinogenic to man when drunk?[82] Although there are several questions here, one of them is how relevant is information from a route of exposure that is different than that which the substance would take in man. There seems to be a general consensus among laboratory scientists that an experimental model should be as similar as possible to the systems that it approximates. That includes route of exposure. But that avoids the question that has been brought up earlier of whether such a study as the one mentioned above contains any extractable information at all. When considering guidelines or regulations governing these adsorbates, ought NIOSH or OSHA to discount entirely a study because it administered them along an "inappropriate" route? A related question is whether, if this

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80 In the last Chapter a connection will be drawn between the limits of scientific judgment and the mandates of regulatory responsibility.

81 The language is Kraybill's. It is not meant to beg the question of whether the technique is inappropriate.

82 It is further complicated when there is no elevated response when rodents are exposed orally. In fact this is what occurred: W. C. Hueper and C. C. Ruchhoft, "Carcinogenic studies on adsorbates of industrially polluted raw and finished water supplies," 9 Archives of Industrial Hygiene and Occupational Medicine 488-495, (1954).

type of study contains some measure of relevant information, it is wrong to pursue this tactic after more relevant models have been explored.

j. Contaminants in the Test Agent:

Just as the belief that a malignancy can be caused by very low exposure to a carcinogen urges caution with regard to the handling by humans of these substances, the potential for the presence in the test environment of a contaminating carcinogen in a very low - and perhaps undetectable - dose may suggest that caution should be taken in interpreting the positive or negative results of a study. If a contaminant occurs in the test agent itself, as opposed to the diet, it will selectively affect the test animals. The control will be unaffected. The results will be biased.

There have been numerous reports that call attention to the fact that the biological response was frequently altered when impurities or contaminants in the chemical to be tested were removed by purification or a different synthesis.[83] It is reasonable to presume that there are also instances when this contamination goes undetected.

Unlike the other sources of uncertainty, this does not involve, at least prima facie, a clear bias toward false positives. For some contaminants, if present, might suppress the initial carcinogenic reaction, thereby lowering response rate. But it is not unreasonable to expect that most contaminants would raise it.

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83 Kraybill, supra n. 23 at 28.

k. Satistical Considerations:

Perhaps the most under-appreciated aspect of carcinogen testing is its inherently statistical character. Although necessary, the raw data is insufficient to determining whether a substance causes - or is correlated with - a certain type of cancer.[84] An integral part of scientific method involves the analysis of the data obtained in the actual experiment. In the fields of toxicity testing this analysis will be statistical.

Mechanical laws are generally contrasted with statistical laws on the basis that the first "assert universal or invariant connections in nature."[85] Experience has shown that any two particles attract each other with a force inversely proportional to the square of the distance separating them. A single counterexample would serve to invalidate this principle.

Statistical laws are different in asserting tendencies rather than invariant connections in nature. As a result they are not predictive of individual events. Michael Scriven argued that "statistical statements are too weak - they abandon the hold on the individual case . . . An event can rattle around inside a network of statistical laws."[86] So, they can be disposed of only by demonstrating that the asserted tendency is false. The proposition that 75% of Americans are over 5'6" in height

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84 This distinction between "causation" and "correlation" is commonly attributed to Hume who held that the first term is epistemogically meaningless and ontologically moot. All that the world discloses is that events have occurred in a certain order; and from this we infer that they will continue to do so; they are correlated.

85 M. R. Cohen, A Preface to Logic, Cleveland: World Publishing Company, 1944, p. 143.

86 Michael Scriven, "Truisms as the Grounds for Historical Explanations," in Gardiner, ed., Theories of History, New York: The Free Press, 1959, p. 467.

does not give warrant to the conclusion that a particular American is over 5'6" and observing that a person is shorter does not provide evidence of any kind against the proposition; indeed the law predicts that certain people will be shorter.

Sight must not be lost of the fact that statements that are phrased as conclusions are nothing more than inferences. The statement that 75% of Americans are so tall is based upon evidence culled as data from studies of the height of Americans. Its reliability will be based upon a number of considerations. One, clearly, is the sample size. The larger the sample the more realistic will be the conclusion reached. In the ultimate case, the sample is coextensive with the population. Then it can be said with certainty that at that point in time "X"% of the population is taller than 5'6".[87]

But in the typical case a sample is tested, and is taken to be representative of the population. This assumption of representativeness is basic; it underlies all scientific inference, nomological as well as statistical. In animal tests, the 50 or 100 mice chosen in the test group are thought to be typical of the class of mice. In the language of statistics, it is an unbiased sample. But of course, there is really no way of <u>testing</u> for bias. It can only be guarded against, through randomization or by increasing the size of the sample.

The aim of chronic toxicity testing is not to determine whether particular individuals will become ill as a result of contact with the substance. Rather, it is to correctly identify a substance as capable

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87 Assuming, of course, that the data is collected in a span of time during which there are neither births and deaths, nor height changes across the line of demarcation.

or incapable of causing cancer in humans, and to provide the basis for determining how many people would likely be harmed. The method that is employed is to administer the test substance under carefully controlled conditions to a group of animals.

The normal procedure is to perform a hypothesis test with a single level of significance attached. It is not necessary to go into the mechanism of how a test is constructed since there is no single best methodology. According to one approach used by the National Cancer Institute the chemical is administered over a period of eighteen to twenty months to male and female mice and over a period of twenty to twenty-four months to male and female rats. Each of the four species/sex combinations has two treated groups of fifty animals each and a control group of fifty animals. One of the treated groups is administered the substance at the estimated maximum tolerated dose and one group at half that dose.[88]

The null hypothesis is that the substance has no effect. The data will be consistent to one degree or another with the truth of the null hypothesis. The object is to determine to what degree it is consistent. Within this framework there are two kinds of error.[89] One can wrongly reject the null hypothesis - that there is no difference, accepting the alternative that (in this instance) the substance does account for the excess tumors. This is termed a type I error. On the other hand, one

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88 T. R. Fears & R. E. Tarone, "Response to 'Use of Statistics When Examining Lifetime Studies in Rodents to Detect Carcinogens,'" 3 Journal of Toxicology and Environmental Health 629,630 (1977).

89 This method is referred to as the Neyman-Pearson formulation of hypothesis testing. Among other places, it was advanced in: J. Neyman & E. S. Pearson, "The Testing of Statistical Hypotheses in Relation to Probabilities 'A Priori'," 24 Proceedings of the Cambridge Philosophical Society 492-510 (1933).

can fail to reject the null hypothesis when, in fact, there is a difference. This is termed a type II error. The following table illustrates the possibilities:

TABLE 7.
TEST RESULTS

Test Concludes:	UNKNOWN TRUE STATE OF NATURE H_0 true	H_0 false
Do not reject H_0	Correct	Wrong (type II error)
Reject H_0	Wrong (type I error)	Correct

There is a tradeoff between these two types of error. If one wishes, the probability of a type II (or type I) error can be reduced to zero. That is to say, the possibility that a substance did in actuality account for the differences was not indicted can be avoided by calling any substance "tumorigenic" regardless of what the data shows. But that stance presumes a philosophical orientation that is never taken, for it renders the test itself superfluous. Most people would consider it an unbearably restrictive attitude, for it ascribes infinitely greater utility upon the protection from the use of a suspected carcinogen than upon the potential benefit of that substance in use.

Even accepting the reasonableness of ascribing infinitely greater worth to the restrictive practice because it leads to (presumably) to less risk (which is wrong since there are risks to health in either option) the decision-maker would need <u>some</u> evidence upon which to base his decision. It only makes sense to protect the public from those

substances for which there is reason to be protective. The evidence to base these suspicions on must come from somewhere. Even Descartes would not believe that such complex ideas as these would be a priori. These suspicions must rest upon tests such as those in question here. The purpose of assessing the probabilities of type I and II errors is to provide a rational basis for suspicions.

These reflections bear a number of points. First, the extent to which we are willing to accept on type of error affects that to which we are forced to accept the other type. Minimizing type II error increases the probability of type I error. Second, the determination involves a tradeoff between incommensurable risks. Thus, science cannot offer any "right" answer. Third, determining the error that we are willing to accept is normative as well as descriptive.

When scientists test for statistical significance at a 5% level, they are really setting the probability of a type I error at 5%. What this means is that the null hypothesis would be wrongly rejected in about five out of one hundred independent tests. Increasing the level of significance would increase the probability of wrongly failing to reject it.[90] The chart on the following page illustrates the nature of the tradeoff.

The point here, as in most of the other questions, is how to trade off the probability of false negatives against that of false positives. In so far as (1) there is no best ratio of one to the other and (2) the nature of the uncertainty is itself so uncertain, there will rarely be a consensus among knowledgeable scientists on whether to design this

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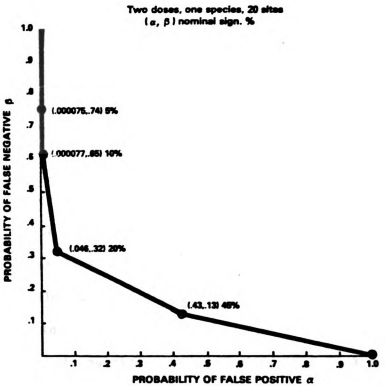
90 The only way of decreasing the probability of both type I and type II errors is to increase sample size.

FIGURE 1.



Fifty animal bioassay. Test positive for a site if positive for both doses. Excess risk 10%. True tumor rate in controls 2%. Nominal critical values from one-tailed Fisher exact test.

Source: Talbot Page, infra n. 92 at 149.

uncertainty in or out.[91] It is my contention that the first conjunct necessitates a valuational process; assessing the relative importance of measures to protect public health on the one hand and the protection of the economic property of flexibility in developing and marketing industrial products on the other.

Although the curriculum vita of Science does not mention expertise at conducting such valuations, any study necessarily involves several. On one level this may seem rather shocking. After all, we do not expect scientists to go around making the ethical judgments implicit in this type of assessment: trading off the likelihood of the detection of one type of risk to one segment of society against that of another type of risk to a different segment. But this is just what they must necessarily be doing. [But furthermore, it is possible that the way in which scientists perceive and judge the nature of the uncertainty itself is partially determined by their approach to this tradeoff.]

Clearly, the level of significance at which a test is performed is a very important aspect of experimental design.[92] If analysis was simply a matter of counting tumors, then testing at a 10% significance level would reject some null hypotheses that a 5% level would not. Some substances would be better classified as carcinogenic according to one level but not the other.

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91 By "consensus" is meant the existence of agreement among the bulk of informed individuals.

92 Talbot Page argued that under certain realistic conditions, the tradeoff can become highly skewed. Setting a 5% level of significance can result in a true false positive considerably less than 1% and a true false negative as high as 74% (see Figure 1). "A Framework for Unreasonable Risk in the Toxic Substances Control Act," in Management of Assessed Risk for Carcinogens, ed. William Nicholson, New York: New York Academy of Sciences, 1981, p. 148.

The beauty of statistical inference rests in its ability to quantify one aspect of uncertainty. But the reader must be careful not to attach too much confidence in its capacity to quantify uncertainty per se. One should be careful not to attach unwarranted importance to the issue of significance levels. If analyzing an animal test was simply or largely a matter of counting tumors (and if all tumors were homogeneous) then significance levels would be very important. But there is not recipe for this type of analysis. As Fears ald Tarone pointed out:

> Evaluation of the carcinogenic properties of a test compound is not strictly a statistical decision process. No two animal experiments are exactly alike, because there are differences in survival patterns, differences in the selection of dose levels, different modes of chemical administration and different laboratory techniques. We cannot define one set of rejection criteria that can be applied to every experiment. Any decision concerning the carcinogenic potential of a test chemical must also incorporate the experience and knowledge of the participating veterinarian, pathologist, toxicologist, and pharmacologist. The role of the statistician in this process is to examine carefully the observed survival and tumor patterns and to quantify the strength of the evidence concerning the null hypothesis that the chemical under test has no tumorigenic effect. This quantification can be obtained through the judicious use of the significance tests.[93]

Yet, although it would be naive to attach very great import to the statistical issue of the level of significance, that and other statistical issues such as the proper study size do contribute to the conduct of animal experiments. There are statistical uncertainties which simply cannot be obviated, and must be reckoned with in the only

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93 Fears and Tarone, supra n. 88 at 630.

way that any of the uncertainties can be dealt with in this field: by identifying them and seeking to determine how they affect the decision process.

1. Non-Positive Results:

It is incontestable that the object of animal tests is to determine whether the test agent is a human carcinogen. A human carcinogen is a substance that will induce tumors in man. Not all human carcinogens will induce tumors in all men. So, a human carcinogen is a substance that will induce tumors in some men.

The evidence for the conclusion that a substance is a human carcinogen is drawn from the results of certain tests on animals. Implicit is the drawing of an analogy between the response of the animals and that of man. If, in a properly designed and performed test, there is a statistically significant elevation in the tumor yield, it is inferred that the substance is carcinogenic in that species (or that strain).[94] Ordinarily, assuming away other questions of the possible hyper-susceptibility of the species (or strain), these results would be taken to provide evidence that the substance is a human carcinogen.

But it is certainly very possible that an experiment involving a substance that is carcinogenic in the test species (or strain) would not yield statistically significant results. Individual mice may have varying susceptibilities. It could be that the animals in the test group are resistant. Thus, although it is possible to show that a substance is a carcinogen to the species (strain), it is not possible to

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[94] On the role of "statistical significance in animal experiments, see p. 93.

demonstrate that it is not a carcinogen.[95] It is therefore not possible to demonstrate from an animal test that a substance is not a human carcinogen.

It is for this reason that it is preferable to speak of this type of result as being "non-positive" as opposed to "negative." For reasons of scientific logic, no experiment or set of experiments can show that a substance is not a carcinogen.

It is not immediately clear, however, what type of evidence such a result provides. To simply label the results "non-positive" might suggest to some that they provide no information whatsoever - and perhaps that they can be ignored. There are many who hold to a weaker variant of this position.[96]

There are other researchers who see a difficulty with this position. They argue that although a non-positive result cannot be taken to be demonstrative of non-carcinogenicity, it does impart useful information. Rather than label it "non-positive" they might prefer to label it "suggested negative" to signal the type of information that they see in the results. This position starts with a reductio ad absurdum of the strict view that negative results should be ignored.[97] Would twenty studies with non-positive results be as uninformative as one? If you were committed to saying that one holds absolutely no

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95 Notice how the inductive fallacy is avoided for positive results: by construing a carcinogen as a substance that yields tumors in some (not all) individuals.

96 According to this variant positive results should generally supersede negative findings. In connection with this point see Hearings, supra Ch. 2, n. 6 at 5079-84.

97 The more widely held view is that negative results should be treated less seriously than positive results are. However, once one accepts that they should be respected at all he is faced with determining the difficult question of degree: how much less.

information, then you must be equally committed to the position that twenty impart no information either. But somehow this does not make sense. Unless one is prepared to assert that the informativeness is emergent (in the same way as some would argue that "mind" is emergent in "brain") he would be forced to hold that even one study with a non-positive result contains some information. But how much?

This issue (and other related ones) was discussed in the cancer policy hearings. Several witnesses spoke of the inherent insensitivity of current practice. There is a high probability that a test will yield a false negative. This offers reason to believe that an indeterminate, but large, proportion of all negative results will be false, not informative, largely as a result of relatively small sample sizes. One of the witnesses at the cancer policy hearings spoke to this issue:

> In actual practice, statistical considerations only permit the detection of a risk several fold large than this for rare tumors and considerably larger if the types of tumors induced are those found with significant frequency in untreated control animals.[98]

These tests will very likely not detect the carcinogenicity of substances that impose a smaller, but real, risk.

The other perspective argues that the <u>biological</u> design of animal experiments minimizes the risk of false-negatives (thereby making non-positive results more meaningful than one might expect). Although the small samples used limit the ability to detect carcinogens in the test species, the determination of <u>human</u> carcinogenicity which is based upon this earlier determination is severely biased in the other

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98 Hearings, supra Ch. 2, n. 6 at 5081 (statement of Dr. Richard Bates).

direction, toward increasing the probability of false-positives -- and reducing the probability of false-negatives. This bias is a result of the tendency to choosing species that are highly susceptible to carcinogenesis.

> It is sometimes suggested that man may be more sensitive than laboratory animals to the induction of cancer by a particular agent. This possibility certainly exists just as does the possibility that a particular agent that does not cause cancer in animals will do so in man. Either situation could arise, for instance because the metabolism of an agent in man is different from its metabolism in laboratory animals. However, by far the more likely situation is that laboratory animal test systems are more sensitive than man. I say this because of the greater likelihood that the laboratory animals used for tests will have been selected for genetically-determined or virus-determined high sensitivity to tumor induction. Also, several aspects of the laboratory environment (e.g. over-feeding, abnormal hormonal status . . .) increase the risk of tumor development in response to non-specific factors.[99]

However non-positive results are interpreted when deciding to regulate a substance as a carcinogen, there will always remain a danger that they are being misinterpreted. Uncertainty arises with respect to the decision taken because it will not be known whether they are being interpreted correctly.

3. Short Term Tests

Although *in vivo* tests constitute the bulk of the evidence used to identify carcinogens, as a group they are not without weaknesses. Several of them were examined in the preceeding pages. These weaknesses lead to the conclusion that even under optimal conditions the evaluation

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99 Hearings, supra Ch. 2, n. 6 at 5081 (statement by Dr. F. J. C. Roe).

of the results of a study calls for careful scientific judgment to be employed. This type of judgment is not rule-based in the same way as other routines are. There is room for dispute, both in the proper design of a study and in the evaluation of one already performed.

Yet, because of the great similarity between man and the animals used it is commonly felt that they constitute signals with significant import for man. However, another weakness that has been spoken of only in passing is less easily reconcilable with the regulatory aims of the Federal agencies. This is the tremendous amount of time and expense involved in animal tests. A typical chronic test can take three years and cost hundreds of thousands of dollars. Quite simply, it is not possible at this point in time to perform a rigorous enough test on every controllable substance that man comes into contact with.[100] There is a need, therefore, for additional sources of evidence to serve either as an adjunct to or as a substitute for *in vivo* methods.

Within the past decade several different models have been developed that respond to this need for cheap and quick assays. These include *in vitro* tests for mutagenesis in bacteria (notably in *Salmonella typhimurium* using the 'Ames test'), fungi (notably yeast), insects (notably *Drosophila melanogaster*) or in mammalian somatic cell cultures.

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100 Inserting the modifier "controllable" is based on the belief that it does not make any sense to test those components of our environment that we have no power to protect ourselves from. (Although I suspect that this is merely an intellectual exercise, since there may, in reality, be no members of this class). I am not even sure of my initial intuition (to ignore uncontrollable components) since the knowledge of carcinogenicity may, it itself, have utility.

These tests are inexpensive and fast. The Ames test, for example, can be completed in two to three days.[101]

These tests operate by seeking to induce gene mutations in the in vitro test system. There is a great deal of evidence suggesting a correlation between mutagenesis and carcinogenesis.[102] In particular, experimental evidence suggests that initiation (recognized as the first stage of carcinogenesis) often involves a mutation event.[103]

In two studies of 152 chemicals, at least 80% of the known chemical carcinogens were found to be mutagens and less than 10% of the chemicals believed to be non-carcinogenic were indicated to be mutagens.[104] This is the rationale for using mutagenicity assays. In one publication the Salmonella/Ames was described in the following terms:

> This test is currently the most widely used of the short term tests. A large number of known carcinogens have been tested and shown to be mutagens in this system. The method is very efficient for detection of organic chemical carcinogens (about 90% of those tested can be detected), but it does not detect all classes of carcinogens with equal efficiency. . .
> The procedure uses several specially constructed strains of the bacterium Salmonella typhimurium. These strains contain different mutations that inactivate the genes necessary for the synthesis of the amino acid histidine, and as a result that bacteria cannot grow unless this amino acid is added to the growth medium. The test is carried out by exposing the bacteria to the chemical to be tested and measuring the number of bacterial colonies that are able to grow in the absence of histidine. Each such bacterial colony is the product of a mutational event. A correlation between increasing dosage of a chemical and increasing numbers of colonies shows the chemical to be mutagenic. The method also incorporates rodent (or human) liver extracts into the assay

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101 Food Safety Council, supra n. 28 at 51.

102 Cairns, supra Ch. 3, n. 3 at 91.

103 Food Safety Council, supra n. 28 at 51.

104 Frederick DeSerres, "The Utility of Short-Term Tests for Mutagenicity as Predictive Tests for Carcinogenic Activity," in The Prediction of Chronic Toxicity from Short Term Studies, ed. by Duncan et al., Amsterdam: Excerpta Medica, 1976, p. 113.

> mixture to provide 'activating enzymes' which are necessary to metabolize some carcinogens to their active forms.[105]

But this is a mixed bag. Some important carcinogens, e.g. asbestos and carcinogenic hormones, may not operate directly through genetic mechanisms; they would therefore give rise to negative results in mutagenicity assays.[106] Further, these tests are vast oversimplifications of (1) the complexity of the in vivo system and (2) the multi-stage process involved. In the animal there are many factors that could mediate or accelerate the activity that the mutation gives rise to.

> It is impossible in mutagenicity assays to duplicate the concentration of the ultimate reactive metabolite, organ-specific release, biological half-life, organ specific DNA repair or replication frequency and immuno-surveillance.[107]

However, one of two authors willing to hold that at the present these tests are well enough understood to offer sufficient evidence that a substance is a carcinogen stated that:

> Positive results in several, valid short-term tests indicate that, without waiting for the results of long-term animal exposure studies, operations involving the chemical should be immediately examined and human exposure reduced to as far as is practical.[108]

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105 Office of Technology Assessment, Cancer Testing Technology and Saccharin, Washington: Government Printing Office, 1977, P. 101.

106 Food Safety Council, supra n. 28 at 53.

107 Ibid., p. 53.

108 Hearings, supra Ch. 2, n. 6 at 5173 (comments by the Chemical Industry Institute of Technology).

But there are several who considered it to be a possibility in the future.[109] That, in general, this is not considered viable today is due to two factors. Along with the probability of false positive and false negative results, another mitigating factor is the inability of these tests at present to give quantitative results. Referring to the Ames test one researcher concluded:

> We are not really sure whether the difference in the frequency of revertants obtained with two different chemicals means that they have different degrees of potency with regard to mutagenic activity.[110]

It shall be seen in the next Chapter that for the purposes of regulation, it is not enough that science identify the substance as a human carcinogen.[111] The enabling statutes of most of the Federal agencies giving power to regulate carcinogens also mandate that in some way or other this be done based upon an assessment of the risk that their use possesses. This assessment can only be performed after determining how potent is the carcinogenicity of the substance. The Ames test, if it is unable to determine mutagenic potency, is also unable to determine carcinogenic potency. Indeed, considering how simplified a representation of the in vivo situation is this short-term test, one would wonder how valuable information on mutagenicity would be even if it were available.

Thus, it seems more reasonable to treat short-term tests as adjuncts to animal tests. The two roles that have been proposed for it

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109 Food Safety Council, supra n. 28 at 54.

110 DeSerres, supra n. 104 at 114.

111 The law makes an exception for food additives for which this identification is sufficient to regulate the substance.

are as a pre-screen, to select those substances which warrant the additional time and expense of a chronic test and as an additional (albeit, a small) piece in the evidentiary puzzle indicating (and to a lesser extent acquitting) the substance in question. How this latter function would be fulfilled operationally (that is, how these tests would be evaluated and how much weight they would be seen to carry to support or refute the results of an in vivo test) is unclear, but it seems reasonable that they should possess some weight. Dr. David Rall argued this point during the generic cancer hearings:

> There is no question that positive results in short-term tests (such as the Ames test, induction of unscheduled DNA repair, or malignant cell transformation in vitro) add to the confidence that one would have in a single positive animal test. This is not to say that these short-term tests are equivalent to lifetime bioassays in rodents: it merely reflects the fact that most carcinogens give positive results in short-term tests. Hence, if there is any reluctance to accept the result of a single animal bioassay, positive results in short-term tests would add sufficient evidence to overcome this reluctance. Certainly, it seems reasonable to use them in this way rather than to demand a second lifetime test in a rodent, which would be lengthy and expensive.[112]

Most proposals to employ in vitro tests as a preliminary step in the identification/assessment process envision using a "battery" of several different assays. Depending on the scheme, one or two positive results would trigger a chronic test.

A possible weakness of a multi-stage screening procedure is that each stage increases the amount of uncertainty of the entire assessment process. The extent to which false positives and false negatives impact on the ultimate decision will be magnified by each additional step

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112 Hearings, supra Ch. 2, n. 6 at 5170.

taken. For example, in a two-stage screening procedure with each step having a 10% probability of false positives, the probability of a false positive of the entire scheme would be 19% (assuming that these probabilities were independent).

4. Structural Similarity to Known Human Carcinogens

According to some scientists, if two chemicals have sufficiently similar structures, that one is a carcinogen constitutes presumptive evidence that the other is as well. This belief is based upon the "structure-function theory." This holds that,

> "It is the structural properties of the carcinogen which determine its pathway of activation, and our knowledge of the structural similarities enables us in many cases to predict which pathway will be followed for the activation of a particular compound."[113]

Like that from short-term tests, the evidence from this method can be used in either of two ways. It can be used either to set priorities for further testing or as evidence in itself for regulations. To illustrate the second use, Dr. David Groth of NIOSH stated during the cancer policy hearings that:

> The fact that nickel sulfide has been found to be carcinogenic in rats by inhalation would indicate that nickel compounds in general are probably carcinogenic, and we would like to recommend that nickel compounds should be regulated as such.[114](Italics added)

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[113] Written comments of Dr. Peter Goldman into the record of the generic cancer policy, Hearings, Ibid., p. 5176.

[114] Oral comments during the generic cancer policy, Hearings, Ibid., p. 5177.

One of the difficulties with regulating a substance on these grounds is that even if it is a carcinogen, this evidence from "paper chemistry" does not offer any insight into its potency. There would be no grounds for postulating a dose/response curve, unless it too were done by analogy with the "parent carcinogen." The tenuousness of the evidence for conventionally derived dose/response curves shall be discussed in Chapter Five. Basing it on that of another chemical simply builds another source of uncertainty into the derivation.

The real problem with this type of evidence is that even closely related chemicals may differ with respect to carcinogenicity. The clearest instance of this is that although 2-acetylaminofluorene is a well documented carcinogen, its close relative, 4-acetylaminofluorene is not.[115]

In 1980 EPA used evidence of strutural similarity to regulate six chemicals under section 5(e) of the Toxic Substances Control Act.[116] Based on the National Cancer Institute bioassay that had shown a related chemical to be carcinogenic, EPA stipulated that the manufacturer provide more information regarding their toxicity before manufacture could begin. Interestingly, although this is an instance of the use of the first mentioned type of use of structural similarity, i.e., to set priorities for further testing. Because it resulted in the company's

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115 This is reproduced from Office of Technology Assessment, Assessment of Technologies for Determining Cancer Risks from the Environment, p. 115.

116 David Dickson, "More Tests Required on New Chemicals," 285 Nature 60 (1980).

eventual discontinuation of testing and marketing, it had the same effect as a substantive regulation banning the chemicals.[117]

Examining this from a legal perspective, this illustrates a potential danger in regulation. When animal bioassays can cost up to one million dollars, it is important that the grounds for requiring them be meaningful. If EPA were to require that expensive tests be performed on weak suspicions of a chemical which is only marginally profitable to begin with, this could have the same result of banning the substance on these same limited grounds, an action which if itself taken would likely be overturned in Court. This simply argues for the paramount importance of Federal Agencies using these methods of inference with great care.

E. Conclusion

If regulation is to be rational it must be based upon acceptable evidence. At the present time, evidence for the carcinogenicity of a substance comes from four sources. Each of these sources used individually, or jointly, is typified by glaring sources of uncertainty. At a first level of approximation, this uncertainty in experimental design, conduct and analysis necessitates the employment in even the most carefully specified study of "scientific judgment" in deciding how to deal with it. Moreover, in many instances there is not the type of consensus among practitioners of how these issues are to be dealt with that is characteristic of "normal" science. As a result, it is presently impossible to specify a "correct" protocol.

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117 Ibid.

The net effect of this is to seriously hinder regulatory rule-making. Agencies are hampered in their efforts to promulgate regulations, fulfilling their legislative mandates, by the ability of people to raise meaningful and sometimes irresolvable questions regarding the evidence on which these rules are based. Federal Courts have been forced to play a large, and largely unwanted role in this framing of regulations.

An indication that the entire field is a quandary is the ability of what had been considered to be unassailable assumptions to be rejected. This is amply illustrated in a recent reversal of position with the EPA on two fundamental and long-held positions:

> . . . known as the Clay Memorandum, (this document) reverses ten years of EPA and federal regulatory policy affirming the principle that positive animal studies predict for carcinogenicity in man with an acceptable degree of certainty and that no threshold can be established for a carcinogen below which it can be considered to be safe.[118]

Whether this action is legally defensible is unclear. It is based as much on questions of law as on the scientific issues themselves. But that such a radical turnaround can even be proposed is significant in itself. If retained, the implications for the number of substances regulated are immense.

The issue of how evidence is used to assess the degree of control appropriate for substances that the evidence has shown to cause cancer will be examined in the next Chapter. The operative uncertainties are even more significant.

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118 Jacqueline Warren and Ross Sandler, "EPA's Failure to Regulate Toxic Chemicals," Environment, vol. 23, no. 10, (Dec. 1981), p. 4.

CHAPTER FIVE

THE ART OF ASSESSMENT

A. Introduction

Assume that the substance in question has been identified to an adequate definite degree of satisfaction as a human carcinogen. That is to say, the determination has been made that exposure to the substance would present at least some people with a finite risk of developing malignant tumors. There are many reasonable ways of proceeding on this information. The substance can be removed from all further economic transactions, exposure to it by workers and or the public can be limited, controls can be placed upon the ways in which it is used, and doing nothing are some of the types of actions that government can make with respect to a substance that it has identified as posing some risk of being a human carcinogen. It seems clear that any of these (and others) in many of their variants and in combination with others presents a rational response to this piece of information. Absent some

additional act of judgment, no one of these options can be considered "better" than any of the others.[1]

One strategy can be shown to be better than the others only after it has been shown to offer a more rational response to the risks presented. The risks and benefits of the strategy need to be assessed. Any rational solution must be based upon such an assessment. By no means is this a fundamentalism with respect to risk-benefit analysis, sensitivity analysis and other formal methodologies.[2]

B. Four Frameworks for Regulation

There are several frameworks that can be employed for guiding government action with respect to protecting the public from human carcinogens. There will be briefly described in this Chapter and it

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1 In the absence of any information whatsoever, one is bound only by the dictates of pure reason. As one acquires more and more knowledge, his realm of rational choice becomes increasingly circumscribed. Conversely, with more knowledge we should be better able to make the correct decision. (There are two exceptions to this that are highly relevant to the present discussion: when valuational assumptions are manifestly present; and when there are factual determinations that are conspicuously irresolvable.) The identification of the substance as a human carcinogen can logically endorse any and all of these responses. I totally disagree with those who see underdetermination as sanctioning one or another particular strategy over its competitors. And I particularly object to those arguments that lead to the conclusion on a priori ethical grounds. One writer, for example, argued for the "immortality" of risk benefit analysis because it is counter to "objective individual necessity." (Sheldon Samuels, "The Uncertainty Factor," in The Management of Assessed Risk for Carcinogens, ed. William Nicholson, New York: The New York Academy of Sciences, 1981, p. 276.)

2 With regard to these tools I am in agreement with Baruch Fischhoff: "We would be kidding ourselves . . . to believe that cost-benefit analysis, or any technique is going to save us from confronting our uncertainty and conflicts about what we know and what we want. Excellent cost-benefit analyses can help guide and order our thinking: however, we seldom should put much faith in their bottom line." (Testimony before the Committee on Interstate and Foreign Commerce, U.S. House, "Use of Cost-Benefit Analysis by Regulatory Agencies," 96th Cong., 2nd sess., 26-7 (1980).

will be suggested how they would be used. Each stems from a different philosophy of the proper role of government, and from a different vision of the amenability of the problem to solution. It must be kept in mind that an agency does not possess absolute freedom to determine which framework it chooses. Although they may all make sense prima facie, the agency is constrained by its statutory direction to a more limited range of choices. Certain statutes are quite specific in the degree to which they guide substantive rule-making. Other statutes grant the agency more opportunity to shape its own approach in meeting its mandated responsibilities.[3]

One conspicuous property of these statutes is the ambiguity contained within the language itself. Even where they clearly direct that one of the frameworks be used, it shall be seen that in almost every case they leave undetermined how it should be used. This indicates a property of the frameworks in themselves (with the two exceptions of the market framework and the no-risk framework). They are under-specified in that each one permits a great deal of leeway. The frameworks that shall be discussed in this Chapter are[4]:

(1) Market regulation
(2) No-risk
(3) Technology-based standards
(4) Risk-benefit and Cost-benefit analysis

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3 Whether this freedom stemmed from a political decision by Congress that the Agency ought to possess it or rather to the political inability for it to achieve a consensus is another question. Whether such a decision (to allow discretion) is properly that of Congress or of the Agency is yet another issue.

4 Adapted from Lester Lave, The Strategy of Social Regulation, Washington: The Brookings Institution, 1981.

(1) Under the market regulation framework, the assumption is that the government should act only to insure the proper functioning of a competetive market, notably through correcting externalities and providing complete information to individual economic agents. One way of limiting conventional pollutants is to institute a system of effluent charges wherein the damage is given a price and then polluters' behavior will be subject to the incentive mechanisms of the market. In the area of carcinogens, the most effective tactic within the market framework is for government to provide more complete information to the "consumers" of the substance. When it ordered the labelling of cigarette packages it was relying on each consumer to make an informed - and rational - choice for himself. OSHA's recurrent attempts to issue a regulation requiring the labelling of hazardous substances (when viewed alone) also assume that total utility will be maximized through the market. Within the market framework there are two limitations in the labelling approach. First, it will be effective only when the substance imposes costs solely on the decision maker. Providing information to cigarette smokers may permit them to make the correct choice for themselves (although one might question even this) but non-smokers who find themselves forced to inhale the smoke have not been provided with the ability to make a choice correct for themselves.[5]

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5 As a response to this realization, witness the movement by local governments to limit smoking in public places. An example of an externality that the market system cannot correct is exposure to fertile men and women of suspected teratogens. The unborn cannot decide. The question reduces to who should decide for them: government or the prospective parents.

The second limitation is that it may be difficult to decide how to phrase the information so that it offers a fair statement of the facts. Any statement of this sort, such as, "Cigarette smoking may be hazardous to your health," presumes that those substances within cigarettes have been identified as hazardous. It was shown in the previous Chapter that it is not difficult to consider most identifications conjectural. Thus, any label that is more than a bare recital of the laboratory results (and perhaps even this) would be less than the unvarnished truth. And it would be unrealistic to expect the "consumers" of the hazardous substances to be able to understand the technical language of science. So, there arises a dilemma regarding how to be "fair" to the facts and also fair to the consumer.

The virtue of a system of market regulation is that when it operates effectively it grants individuals freedom to make decisions for themselves: to smoke or not to smoke; to work with hazardous chemicals or not to. But it is not easy to design regulations that accurately inform the individual of the risks that he faces.

The market model also assumes that given adequate and accurate information, individuals will choose that action that most furthers their own interests. Admitting the possibility, though, that people will not always act rationally, it must be granted that merely informing people will not guarantee that they will correctly act to maximize their own welfare. This instance of market failure is more difficult to remedy. It may be seen as suggesting the need for some rational agent to act on behalf of the irrational individual. This is one of the rationales for the other frameworks that shall be discussed, in which

government performs the risk assessment on behalf of the people at risk.[6]

The market framework, as it has been construed here, is one in which government action is restricted to keeping the system of voluntary change of economic resources and goods and services smoothly functioning. One of the avenues individuals have for resolving complaints within the market framework as well as the others that will be examined in turn is to sue for damages. The possibility of successful suits could serve to affect decision-making by firms. If it could be shown by an individual, to the satisfaction of a Court, that he had been legally damaged by the actions of the company marketing the suspected carcinogen, then he could possibly receive monetary damages. Further, if it could be shown that the firm's actions are likely to endanger individuals in the future, then these actions could be enjoined.

For example, the American Tobacco Co. was sued by a person who had smoked Lucky Strike cigarettes for fifty-six years until his physicians told him that he had contracted lung cancer.[7] Although the case was ultimately decided against the plaintiff, this illustrates one remedy open to individuals, and thereby to society as a whole to alleviate suspected risks. The fact that although the jury had made the finding that smoking was a proximate case of the development of the lung cancer, the case was still decided against the plaintiff illustrates the

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6 The other rationale is the non-excludibility of pollution control. Carcinogen protection is a public good. The degree to which it is for workers depends upon how effective personal protection devices are in preventing cancer.

7 Green v. American Tobacco Co., 304 F.2d 70 (5th Cir. 1962), rev'd on rehearing, 325 F. 2d 673 (5th Cir. 1963) cert. denied 377 U.S. 943 (1964), aff'd on rehearing per curiam, 409 F. 2d 116 (5th Cir. 1969).

weakness of this legal recourse.[8] The fact that, more recently, a former shipyard employee won a voluntary settlement from Johns-Manville for asbestos related injuries illustrates that it can be successful.[9]

In principle, of course, firms' behavior will be influenced by the possibility of such settlements. Thus, if it feels that the evidence suggests that manufacturing substance X will introduce a likelihood of suits for negligence in the future, it may decide not to proceed. But there are two reasons to discount the effectiveness of this with respect to carcinogens or other chronically toxic substances. The first is that the firm may believe that it will not be in business by the time that the damage has been manifested, a decision handed down. Just as one cannot sue a dead person, he cannot sue a corporation that no longer exists. Second, the net present value of a sum of damages awarded twenty or forty years in the future will be greatly discounted by most corporation managers. So, for both of these reasons, if the firm's objective function is to maximize the net present value of profits, then it may well be rational for it to disregard the risk of monetary settlements in the far future. This is particularly the case in present American business structure. For management decisions, to market or not to market substances, are typically made by individuals whose performance is evaluated by how well they perform <u>today</u> with little

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8 The Court held that the manufacturer could not be held liable without a breach of an implied warranty that such cigarettes were "reasonably wholesome or fit for the purpose for which they were sold." 325 F. 2d at 676 (dissenting opinion).

9 11 <u>Occupational Safety and Health Reporter</u> 544 (12/17/81); More than 12,000 asbestos actions have been filed in federal courts. According to a spokesperson for the insurance industry, "The sheer volume of these lawsuits threatens to bring the American judicial system to a standstill" [11 <u>OSH Rptr</u> 524 (12/10/81)].

concern for the future. These decision-makers are likely not to remain with the same firm for twenty or thirty years, so they may feel no personal incentive to minimize the risk of costs incurred far in the future.[10]

The effectiveness of this common law remedy in influencing decisions is also mitigated by the possibility that far in the future the firm will not have funds sufficient to repair the damage done. With reference to this, EPA recently promulgated a regulation requiring hazardous waste management facilities to have liability insurance.[11] Although it has been criticized as being inadequate, it does suggest another way of Government intervening to keep the system well-oiled.[12]

The other remedy that was mentioned earlier is that of injunctions. Based upon the way in which the Court reads the evidence and applies legal standards of proof, this remedy can either be effective or ineffective. However, based on past experience, there is reason to believe that the burden of persuasion for the plaintiff seeking injunctive relief in environmental lawsuits is very high.[13]

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10 Reynolds Sachs argues that manufacturers are likely to design products of more or less the same degree of safety, regardless of how liability is assigned. (Neglieelce or Strict Product Liability: Is There Really a Difference in Law or Economics?" 8 International and Comparative Law 259, 276-7 n. 36 (1978). Also see Michael Baram and Kevin McAllister, Alternatives to Regulation, Lexington, Mass.: Lexington Books, 1982, esp. Chapter 2.)

11 12 Environment Reporter 1635 (4/16/82).

12 The criticism was mentioned in Ibid., p. 1636.

13 Donald Large and Preston Michie, "Proving that the Strength of the British Navy Depends on the Number of Old Maids in England: A Comparison of Scientific Proof with Legal Proof," 11 Environmental Law 555 (1981).

(2) Under the no-risk framework, government acts to exclude from circulation any substance that is found to present any risk at all. This is the operating philosophy behind only one section of the law. The "Delaney Clause" of the Food, Drug and Cosmetic Act stipulates that a food additive may not be considered safe and may not be used in any amount if 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.[14] No conceivable benefit could outweigh the risk, however minimal, of a carcinogen.

There are several ways of designing a no-risk system. Under the Delaney Clause a substance is identified as posing a risk if it is tumorigenic in any animal at any dose level. Congress could also, if it wished, define a risk as existing only when the substance was found to induce cancer in man. If it then excluded that substance from circulation, that too would constitute a no-risk system. Positive evidence from animal tests would not be considered suggestive of a risk to humans. Furthermore, there are many considerations that are left up to the Food and Drug Administration in evaluating tests that are submitted to it. The issues that were discussed in the preceeding Chapter are very influential in determining the results of a study -- that is, whether or not the substance is "found" to cause cancer. A no-risk framework will prescribe strict treatment of carcinogens. But

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[14] The section states, "That no additive shall be deemed safe if it is found to induce cancer when injested 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." (21 U.S.C. 348 (c)(3)(A)). Elsewhere, the Act states that any food that is not deemed safe is to be banned.

this will be largely meaningless if a high threshold must be reached before a substance is determined to pose a risk. In addition, administrative oversight may allow carcinogens to remain in circulation, and they could be bureaucratically redefined as not being food additives.[15]

This view that no risk will be condoned has a two-fold root. On the one hand, there is a pervasive lack of confidence on the part of scientists in their ability to actually quantify the level of risk that a human carcinogen presents.[16] It is one thing to identify a substance as posing some risk. But it is entirely something else to measure this degree of risk. The Office of Technology Assessment referred to this in its report on saccharin:

> The "Delaney clause" reflects the present state of technology in which laboratory methods can predict that a specific substance is likely to cause cancer in humans, but cannot reliably quantify this potential.[17]

The second ingredient is a strongly aversive attitude toward risk in the presence of uncertainty. An infinitely greater weight is given to protect from risk than from the benefits that the substance offers. But there is no logical reason why the uncertainty that results from an inability to quantify risk need be approached hesitantly. If one knows that there is some risk that he will drown if he goes rafting down the Snake River, but has absolutely no idea of the magnitude of that risk,

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15 William Lowrance, Of Acceptable Risk, Los Altos, Calif.: William Kaufmann, Inc., 1976, p. 83.

16 The methodology of risk quantification will be discussed later in this Chapter.

17 Cancer Testing Technology and Saccharin, supra Ch. 4, n. 105 at 5.

prima facie it makes equally good (and bad) sense to go as it does not to go. In order to decide he needs to possess some decision-rule instructing him how to act in the presence of uncertainty. Conversely, how he acts will be as much a reflection of that decision-rule as of anything else.

The Delaney Clause can be viewed as a decision-rule, guiding action in the presence of uncertainty. But also, as an act itself, it is a reflection of the attitude of Congress toward quantification of uncertainty. It reflects a hesitant, risk minimizing attitude. Looking at various statutes to decipher Congress' attitude toward various risks one finds the attitude that more care should be taken to guard against ingested carcinogens than those inhaled. But this attitude had changed when sixteen years after the drafting of the Delaney Amendment to FDCA Congress passed the Safe Drinking Water Act of 1974 which stipulated that contaminants in the drinking water be reduced "to the extent feasible. . . (taking costs into consideration)."[18] This apparent inconsistency might be taken to suggest a weakness in the risk aversiveness of the Delaney Amendment.

The no-risk framework can be attacked for both of these ingredients. First, as we shall see later, it is asserted by some that although not an exact science, quantification does offer some generally reliable information. Why throw out the baby with the bath water? The second root can be attacked for naivete. Such absolutism has no place in rational regulation. In purchasing diet soda with saccharin, consumers express their preferences. Presumably the saccharin is

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18 42 U.S.C. 300g-1(a)(2) (1978)

offering some benefit to these consumers. To disregard this benefit is to consciously misallocate resources, unless the value of even the smallest risk is at least as large as the value of any benefit foregone by its exclusion from the market.

The response to these arguments is that the value of risk quantification if largely illusory and, as such, it is too easy to be lulled into a (false) sense that the numbers are more certain than they are. Forbidding the quantification of risks guards against this numerical fallacy. This dispute will be examined in some greater detail in connection with the treatment of the risk-benefit framework.

The no-risk framework confronts a difficult conceptual dilemma with regard to a substance that is both a carcinogen and performs a health function for which there is no substitute. This dilemma is not simply hypothetical. FDA has had to meet it with regard to sodium nitrite. Sodium nitrite is added to cured meats to inhibit the growth of C. botulinum. "Without the protection of nitrite in cured meats, botulism could become a common disease causing many deaths."[19] Furthermore, there is no known substitute for nitrite.[20] Moreover, it is estimated that at least eighty percent of the total body burden comes from other sources.

Although nitrites themselves are suspected to be carcinogens, a common metabolite - nitrosamines - are considered "extremely potent carcinogens."[21] The regulatory fates of sodium nitrite and saccharin illustrate the principle that ways will be devised to get around strict

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19 Lave, supra n. 4 at 55.

20 However, there are compounds, eg. potassium sorbate, that enhance its effects so that less need be used.

21 Lave, supra n. 4 at 49.

rules. In 1980 FDA terminated its proposal to eliminate nitrite additives.[22] And beginning in 1977 Congress has set moratoria on the power of the Commissioner of FDA with respect to saccharin. The Saccharin Study and Labeling Act Amendments of 1981 provide a 24 month moratorium with respect to the authority of the Secretary of Health and Human Services to amend or revoke the certification of saccharin.

There appears to be a broad consensus that the Delaney Amendment is unworkable. But it is politically difficult, or impossible, for Congress to actually revoke it since it really has taken on a larger-than-life significance. It symbolizes the concern of Government for protecting the American people. Voting to revoke it could be considered callous by constituents. So, it is politically wiser to find solutions for each problem as it arises, as was done for saccharin.[23]

(3) The technology-based standards framework is a response to the criticism than the no-risk framework mandates that unreasonable sacrifices be made to respond to uncertain risks from carcinogens. It finds its most explicit expression in sections of the Clean Air Act and Clean Water Act.[24]

The primary advantage of this framework is that while it is a more meaningful decision-rule than the two frameworks discussed above, it entails a less rigorous examination of benefits and costs than does

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22 Ibid., p. 54.

23 The dilemma for saccharin arose on account of its being the only non-nutritive sweetener that was known since cyclamates had been taken off the market.

24 42 U.S.C. 7401 et seq. (1982) and 33 U.S.C.1251 et seq. (1978).

risk-benefit or cost-benefit analysis. Three variants have been used thus far. The first is an "economic feasibility" interpretation. It is found in § 6(b) of the OSH Act. It is meant to be protective, yet not to the extent of eliminating risks. Its chief disadvantage is that it does not offer a logical connection between the evidence of risks and strategies for reducing them. Under this approach, standards would be based upon the level of control that an industry could afford. Yet, there is no logical reason why society would benefit more from the higher level of risk reduction that an affluent industry can afford to implement simply because it is feasible.

Further, it acts as a disincentive to innovation and efficient management insofar as it "taxes" profitable polluters at a higher level than unprofitable ones. Let us imagine an industry comprised of small, marginal firms operating with a very small profit margin. This industry is involved in producing a potent carcinogen. Under an "economic feasibility" variant of technology-based standards this industry would not be bound to any degree of control.

Another variant of technology-based standards is "technology-feasibility." Under this variant the ultimate profitability of the firm is not directly considered. For example, section 301 of the Clean Water Act (which does not govern carcinogens) sets effluent limitations for point sources. It requires that "the best practicable control technology currently available" be applied.[25] This was interpreted by the Eighth Circuit Court of Appeals as "intend(ing) to limit the use of available technology only where additional technology

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25 33 U.S.C. 1311(b)(1)(A) (1978).

necessary to achieve a marginal level of effluent reduction is wholly out of proportion to the cost realized."[26] [The only way to understand this is by adding "the benefits of" before the phrase "additional technology necessary."] According to this interpretation of the statute, Congress is mandating that EPA weigh health improvements more heavily than economic costs. EPA should force industry to introduce technologies that have lower marginal social benefits than privately incurred costs. Regulation should stop only when the marginal cost bears absolutely no resemblance to the benefit that it brings about.

The Court seems to be saying that regulators should act irrationally; impose restrictions past the point where marginal benefits equal marginal costs. The statement could have been worded differently with better results by mandating that health benefits be accorded a large weight. Both interpretations would be extensionally equivalent, but the latter one is consistent with a view that regulations "make sense." This is mentioned here because it is important to counter the view, that decisions like this might further, that strict environmental regulation is irrational. Whether or not it is rational depends upon what value is placed upon the prevention of a marginal decline in health.

Even more strict is a "technology-forcing" interpretation. A unique instance of this occurs in Title II of the 1970 Amendments to the

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26 CPC International, Inc. v. Train, 540 F. 2d 1329, 1341 (8th Circuit 1976). Certiorari was denied by the Supreme Court (430 U.S. 966 (1977). It appears that the Court was confusing two variants of the technology-based framework. For on the following page it stated, "What is required for new source standards is a thorough study of initial and annual costs and an affirmative conclusion that these costs can be reasonably borne by the industry." (at 1342) Clearly, these passages mean different things.

Clean Air Act. So concerned was Congress with pollution from automobile emissions that it mandated a 90 percent reduction by 1975 in the maximum allowable emissions of hydrocarbons and carbon monoxide from automobiles allowed in 1970.[27] This was to be followed one year later by a similar reduction in nitrogen oxide emissions.

> Although the Act was not the first federal statutory attempt to control air quality, its perspective was unique: rather than regulate from the standpoint of what was technically feasible, it started from a point of determining what air standards were necessary to protect the public health, and it required technology to meet those standards.[28]

The concept of "technology-forcing" presumes that the means for meeting the standard, although they do not yet exist, are attainable, and that the achievement of that standard is paramount.

There are three roots of technology-based standards. First is that health is something important, and so should be protected as strongly as is reasonable. Whether or not this is a rational intuition depends upon how you set up the decision. But at base, the technology-based framework reflects a strong (perhaps overriding) concern for health protection. Secondly, it also reflects a distrust of the absolute protectiveness that is implicit in the no-risk framework. Health protection is a scarce good, and should be rationed (to one degree or another), as are other economic goods.

The third root of the technology-based framework is a distrust of the more explicit comparisons between benefits and costs that are part

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27 42 U.S.C. 7521(b).

28 Cynthia J. Bolbach, "The Courts and the Clean Air Act," Environment Reporter, Monograph No. 19, 7/12/74, p. 1.

of the risk-benefit and cost-benefit frameworks. These frameworks will presently be discussed and the reasons for this distrust assessed.

Although the technology-based framework is motivated by a rejection of an emphasis upon numerical exactitude it has been interpreted (even in its technology-forcing version) to require an accounting of regulatory feasibility. Congress did not intend to bankrupt American enterprise.[29] But even these cost data are highly uncertain. The best example of this is seen in the widely inflated estimates that the vinyl chloride industry had made of the cost of complying with a one ppm standard. The industry claimed that not only would a one ppm standard force most companies out of the business, but moreover, it was technologically impossible to meet.[30] On these, as well as other grounds, the standard was challenged and ultimately the Courts upheld it.[31] And neither of the predictions came to pass.[32] It seemed to have had little impact on capital costs.

Nicholas Ashford traced the roots of this uncertainty as to cost estimates:

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29 It is reasonable to ask, though, why not. If a firm is performing a harmful act, why should government be constrained in its response to allowing that firm to retain a profit? The answer is ultimately answerable only on a political level that it is impossible to reach a consensus in Congress to support a more radical (in the sense of being disruptive of the status quo) alternative.

30 David Doniger, "Federal Regulation of Vinyl Chloride: A Short Course in the Land and Policy of Toxic Substances Control," 7 Ecology Law Quarterly 497, 552 (1978).

31 Society of the Plastics Industries, Inc. v. OSHA, 509 F 2d 1301 (2d Cir. 1975), cert. denied sub nom, Firestone Plastics Co. v. United States Dep't of Labor, 421 U.S. 992 (1975).

32 Doniger, supra n. 30 at 63.

Agencies depend to a large extent upon industry data to derive estimates of compliance costs. I do not believe I am being too unkind in questioning the bias of those estimates. The regulatory agencies themselves do not have access to the information concerning alternative products and processes and resulting costs which would enable them to come up with the best estimates of the cost of compliance.

In addition, compliance costs often fail to take three crucial issues into account. First, their economies of scale which arise in the demand induced increases in the production of compliance technology. Second, is the ability of the regulated industrial segment to learn over time to comply more cost effectively - what the management scientists call the learning curve.

Third - and this is a critical issue - compliance costs based on present technological capabilities ignore the crucial role played by technological innovation, which yields benefits to both the regulated firms and the public intended to be protected.[33]

But the technology-based framework is vastly more complicated to administer than the no risk framework. It takes a prodigious amount of resources to evaluate all the many categories of production in a single industry, and to determine for each that standard which is economically or technologically feasible. As an example, EPA issued guidelines for the Canned and Preserved Seafood Processing Point Source Category. There were 33 separate categories, from "Non-remote alaskan crab meat processing" to "Southern non-breaded shrimp processing in the contiguous states."[34]

The technology-based framework is clearly a compromise between more extreme solutions. Like the other frameworks it occupies an area on a spectrum. At one end, it approaches the no-risk framework. In its technology-forcing version, it could be given a strict interpretation.

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33 U.S. Congress, House, Committee on Interstate and Foreign Commerce, Cost-Benefit Analysis: Wonder Tool or Mirage?, 96th Cong., 2nd sess., 11 (1980).

34 U.S. Environmental Protection Agency, "Canned and Preserved Seafood Processing Point Source Category," 40 Code of Federal Regulations 408 (1981)

On the other hand, it is more commonly seen as a vehicle for informally and implicitly expressing society's preferences for trading off the alleviation of health risks against the sacrifice necessary to bring this about.

(4) Risk-Benefit and Cost-Benefit Analysis

Risk-benefit analysis offers many faces. To one person it is "in the same class of endeavor as alchemy and astrology."[35] To another, it is "the only reasonable mechanism for evaluating and selecting among regulatory options."[36] What will be suggested in this section is that the truth falls somewhere in between.

What risk-benefit analysis is in actuality is a tool to assist decision makers to identify and compare the benefits and costs of an action. Whether its aims are achievable is an important question, as is whether it is intrinsically biased, distorting rather than aiding the cause of rational decision making. These are two of several questions that shall be addressed in this section.

Risk-benefit analysis is related to cost-benefit analysis. The notion of making public policy decisions on the basis of a comparison of benefits and costs was operative during the nineteenth century. "The Federal Government used this type of analysis for evaluating public works projects."[37] But interest has intensified within the past twenty years, largely as a result of three influences. First, it is a response

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35 Sheldon Samuels, "The Uncertainty Factor," in Nicholson, supra Ch. 4, n. 92 at 269.

36 U.S. Congress. House. Committee on Interstate and Foreign Comerce, Use of Cost-Benefit Analysis by Regulatory Agencies, 96th Cong., 1st sess., 56 (1979). Statement by Robert Crandall

37 Cost-Benefit Analysis: Wonder Tool or Mirage?, supra n. 33 at 3.

to the call for greater public accountability by Federal agencies in rulemaking. When pursued, it is one way of shaping a decision to meet the mandates of the Administrative Procedure Act. It can be appealed to in response to the contention that an action was "arbitrary and capricious." It gives an aura of objectivity and careful scientific logic. The second part of the explanation for the increasing use of these methodologies is simply that they are part of a general increase in the level of appreciation within the social sciences of a systems perspective and the rising stature of economics with its central notion of "opportunity cost." Third is the nature of the problems that the government is being called upon to respond to. Rule-of-thumb calculations fail to provide intellectually satisfying and defensible solutions when the implications of decisions are varied and the recipients of these effects diverse. If nothing else, these methods offer a framework to structure a scenario around.[38] These factors are interconnected. The rise in complexity of public policy issues creates a demand for sophisticated modelling techniques which in turn enable greater power and control to be exercised over the real environment, creating additional complex issues requiring further efforts at modelling. The calls for public acountability of agency actions which have been expressed in many appeals to the Judiciary may also be influenced by the growing complexity of the issues in which the government immerses itself in.

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38 It is interesting that the great majority of criticisms that are levelled against cost-benefit are on account of its weaknesses as a method, not for the inappropriateness of methodological rigor to public policy issues. I will discuss both types of criticism later in this Chapter.

Of all of the frameworks that are being examined, they are most an art. In a sense this is ironic, since they have the highest aspiration to the logical consistency of science. But, as shall be seen, this is an inevitable result of their sophistication. What gets in the way of these good intentions?

First, as was mentioned before, they are motivated by the (perhaps naive) desire to rationalize public decisionmaking. If the rational decisionmaker is someone who operates on Bayesian principles, then nature frustrates the desire. As Jerome Cornfield pointed out:

> The strict Bayesian decision procedure, which requires assignment of prior probabilities to all the possible scientific hypotheses, utilities to all the possible consequences, the computation of an expected utility for each possible decision, and the selection of the decision with maximum expected utility may be well beyond the capacity of any scientifically, legally, or politically oriented decision-maker short of Plato's philosopher king, even though it is the only coherent one.[39]

The philosophy behind risk-benefit and cost-benefit analysis is one of practicality. Exponents advocate them as making good common sense. Very often analogies are drawn comparing the assessment decision with more mundane choice situations. In these ordinary situations we decide after comparing risks and benefits. That we rarely are conscious of the "calculations" does not mitigate the fact that we perform them. Indeed, we perform them because it is rational to do so. Moreover, we judge a person "sane" by the degree to which he acts upon the results of this utility calculus. Should not the federal government strive toward sanity?

There is more than one way of performing risk-benefit and

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39 "Carcinogenic Risk Assessment," 198 Science 693, 699n (1977).

cost-benefit analyses. And there is more than one attitude of support for them. In fact, there is a range of confidence with which one can consider them of value in decision making. These positions will be brought out in the following pages.

There are four components of risk-benefit analysis. They are listed below:

(a) quantify risk
(b) place a value on this risk
(c) determine the cost of regulating in terms of the
    (i) benefit foregone
    (ii) cost of control
(d) compare (b) and (c)

Some risk-benefit methodologies do not employ step (b). Rather than being oriented toward maximizing utility they are cost-effectiveness criteria. It will be seen that they thereby avoid some of the difficulties of the "full" theory (at the price of diminished "sophistication").

(a) Quantifying risk:

The first logical step in any carcinogen risk-benefit assessment is to determine the extent of the danger that the substance poses (measured as the expected number of lives that would be lost) and to ascertain the degree to which various control strategies would mitigate that danger. The mechanisms for identifying a substance as a human carcinogen were outlined in the preceeding Chapter. The model that, at the present time, is most valuable in this is based on administering the substances in high doses to test animals. The judgment that a substance that

induces excess tumors in animals at abnormally high doses under artificial experimental conditions will also do so in humans at much lower doses under ordinary conditions is based upon a number of assumptions that were discussed in the previous Chapter. The universally admitted tenuousness of these assumptions attaches a fair amount of uncertainty onto any conclusions reached. What it involves is a qualitative judgment. But assessing the degree of risk is a numerical judgment. As such, it is more sensitive to the types of assumptions that are made. One would expect, therefore, a greater degree of uncertainty in this evaluation. If the determination that a substance is a human carcinogen is sensitive to all of the assumptions of design, procedure and analysis, how much more sensitive to these assumptions would be the assessment of the degree of risk that the substance poses?

Generally speaking, there are two approaches to assessing the degree of risk posed to humans by a carcinogen. One type performs the extrapolation by assuming ad hoc that test parameters lend a certain factor of uncertainty and thereby (making the risk averse assumption that greater uncertainty calls for greater protectiveness) derive "acceptable daily intake" or "virtually safe dose" levels that purport to incorporate some of these sources of uncertainty. The second bases its extrapolation on more elaborate models, that it is claimed fairly closely represent carcinogenic processes.

(i) Safety factors:

This methodology incorporates the first two steps of the assessment process. For it seeks to determine an acceptable exposure level, and in so doing implicitly ascribes valuational weights to the objective "risk" magnitudes. According to one proponent it operates "by the application of common sense."[40] It stems from a sense of dissatisfaction with the standard method of extrapolating risk downward by means of one or another mathematical model (which is discussed in greater detail in the following subsection). It is asserted that these techniques are unreliable when their predictions can be tested, and (what is worse) often untestable.

> It is common knowledge that the extrapolation of values beyond the region covered by the data is very dangerous. The uncertainty of approximation increases with the remoteness of the estimated point from the midpoint of the curve.[41]

The safety factor method is presented as a reasonable approach in the face of "extrapolative uncertainty."

> The use of a factor of safety based upon informed scientific judgment is the only practical method of determining a safe level of intake for man from the results of tests upon animals.[42]

It has a deceptively simple three-step procedure. In the first step, an experiment that will offer results relevant to man is designed. The next step is to ascertain the "minimum measured cancer-producing

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40 Carrol S. Weil, "Statistics vs Safety Factors and Scientific Judgment in the Evaluation of Safety for Man," 21 Toxicology and Applied Pharmacology 454, 460 (1972).

41 Ibid., p. 459.

42 Ibid., pp. 462-3.

dose level" (MiE). This is the lowest dose at which a significant tumorigenic effect is observed. Certainly this level will be dependent upon the experiment design (eg. how many animals are used, for how long a period of time the substance was administered, nutritional factors, and levels of significance) and for this reason the first step is very important. In the last step, the MiE is divided by a certain factor to yield a "virtually safe dose," or "acceptable daily intake" for humans.

The magnitude of this factor will, in each proposed scheme, reflect both the objective uncertainties attached to extrapolating risk to animals under experimental conditions to human beings under actual conditions of exposure. To illustrate how this operates, one scientist's proposal that a factor of 5000 be attached to the MiE will be outlined. His proposal consists of four components:

(a) a factor of 10 to reflect "animal to animal variation."

(b) a factor of 10 "to translate the results from animal to man."

(c) a factor of 10 to allow for certain complicating factors in carcinogenesis such as irreversibility and potential co-carcinogenesis and initiation-promotion that may be present due to the exposure to other materials.

(d) a factor of 5 because the minimum-effect level will be greater than the no-effect dose level.[43]

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43 Ibid., pp. 461-2; this was a proposal for the maximum allowable in food. Similar reasoning could lead to proposals for exposure in other media as well. Weil suggests that MiE rather than NoEL be used because it is "more respectable" (p. 462). This is a conservative assumption since he points out that typically MiE will be less than 5 times as large as NoEL.

If, for example, the MiE is 100mg/kg, then under Weil's proposal the maximum acceptable exposure would be set at .02 mg/kg. As has been suggested, even this type of procedure "must be regarded as (a) mathematical formalism. . ."[44] It assumes "a specification of a theoretical dose-response curve and a procedure for estimating its parameters from responses at all dose levels."[45] For example, Weil's proposal would be consistent with a "one-hit" model having a virtually safe dose at 2×10^{-4} of the MiE. Rather than pretending simplicity and burying biological and statistical assumptions, is it not better to base the model upon meaningful assumptions? The problem with the safety factor method is that it is theoretically too casual. But proponents possess a meaningful response that is, perhaps, too easily dismissed. The response is based upon an observation that has already been mentioned and that forms a thread throughout this dissertation; that theoretical robustness is no substitute for explanatory meaningfulness. If the test of the pie is in the eating, not the baking, then the test of a risk assessment model is in the predicting, not in the specification.[46]

The argument is on a philosophical level. It asks why needless theoretical clutter should be added to an already hopelessly untidy regulatory environment. The response, again, must be on a philosophical

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44 Cornfield, supra n. 39 at 698.

45 Food Safety Council, supra Ch. 4, n. 28 at 138.

46 This analogy is only meant to be suggestive. For history has judged theories on criteria other than predictive efficacy. Indeed, the Ptolemaic paradigm was overturned in part because the Copernican view predicted the same phenomena that the other did, but with greater simplicity.

level. It reflects a view (perhaps naively[47]) stressing regulatory accountability. The more fully the model is specified, the more open it is to criticism.

(ii) Explicit Mathematical Models:

The second tactic toward quantifying risk is to prespecify a dose/response curve having a slope that has its justification in biological and statistical theory, and then to extrapolate downward from experimentally observed (d,r) coordinates to a realistic dose range in order to determine a risk associated with it. The following table taken from a study on risk assessment lists several of the biological factors that should be considered:[48]

Evaluation of Chronic Cancer Bioassay Data
- Number of Species and Stains Affected
- Number of Tissue Sites at Which Tumors Occur
- Latency Period
- Dose Level and Duration of Exposure Required to Induce Tumors (potency)
- Proportion of Malignant vs. Benign vs. Pre-Neoplasm Change

Evaluation of Characteristics of the Compound
- Chemical Similarity to Other Known Carcinogens
- Metabolic and Pharmacokinetic Data
- Binding to DNA, RNA, and Protein
- Physiological, Pharmacological and Biochemical Properties
- Genotoxicity and Activity in Short Term Tests for Carcinogenicity

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47 "Naively" because as shall be seen, a strong argument can be made for the view that these models are not "falsifiable" (even the "mathematizers" grant this) and therefore do not meet Popper's criterion of a proper scientific theory. Indeed, in one document the authors advocated "the development of orderly and systematic procedures for low-dose risk assessment which utilize all available biological and statistical information" two paragraphs after they had conceded that these models were essentially untestable, (Food Safety Council, supra Ch. 4, n. 28 at 144).

48 Ibid., p. 138.

Population At Risk
- Age
- Sex
- Physiologic State
- Conditions of Exposure

Much of this information will be available to the assessor. What will not be available, however, are rules detailing how this information is to be used. Thus, this information is of limited value to decision-making.

What is also absent from this list is one factor that is especially troublesome: the variation in response between test species and man. It is particularly troublesome because there is little basis at present for any sort of interspecies comparison between average susceptibilities. Although it is reasonable to believe, for instance, that there is a positive or a negative relationship between potency and certain of the factors listed in the table, not even this much can be foretold regarding the animal/man extrapolation for any particular substance. As was seen in the previous Chapter, epidemiological data will suggest one type of relationship ex post. One substance implicated through epidemiological study will have been predicted in mice for example, but not in rats, while the reverse will hold for another substance. And at this time, there is no way of explaining why this should happen. How much more sensitive is risk quantification to this fundamental uncertainty?

But "the extrapolators" feel that however questionable their estimates of risk may be, they are less tenuous than any estimate that has absolutely no basis in theory. How questionable are they though? One might think that there would be no way to determine this. In fact,

it is quite simple to do so by examining the variability among estimates, each one equally well-entrenched in theory. A number of different models have been proposed. What is interesting about them is that, based on different biological assumptions, they offer vastly different predictions of low-dose response rates based on the same experimental results. Futhermore, there is no way to distinguish among them, theoretically or experimentally, on the basis of predictive accuracy.

> While a variety of mathematical models have been discussed for the recommendation in favor of any one of these models for all applications cannot be made at this time. Because the mechanisms of carcinogenesis are not understood, even those mathematical models drawing on biological theory cannot claim to be universally correct. Similarly, statistical considerations alone cannot lead to the adoption of one particular model for purposes of risk assessment. Even an optimally designed experiment involving a moderately large number of experimental animals will have only limited power to discriminate between two plausible models.[49]

The graph on the following page illustrates the range of predictions of four models based on the same experimental evidence:

> For any population exposed, it is generally impossible to estimate within a factor of five or six the expected future cancers from a given dose of the suspected carcinogen. Evidence from animal studies and limited epidemiological evidence are simply inadequate to draw very precise conclusion concerning the effect of the doses encountered by human beings.[50]

So, if all of the models are equally well entrenched in theory, then the subjective uncertainty presently attached to the extrapolative

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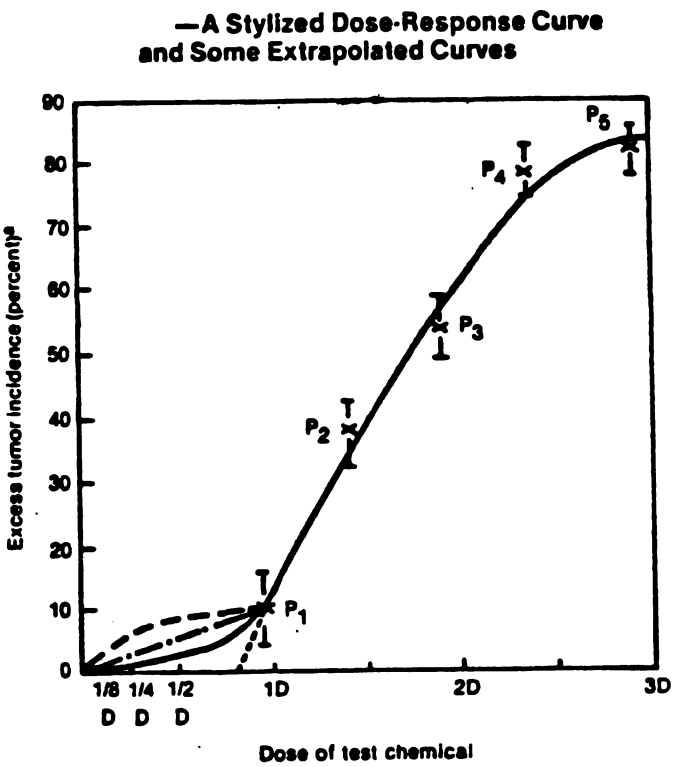
49 Ibid., pp. 143-4.

50 Robert W. Crandall, "The Use of Cost-Benefit Analysis in Regulatory Decision-Making," in Nicholson, supra Ch. 4, n. 92 at 101.

FIGURE 2.



Source: Office of Technology Assessment, supra Ch. 4, n. 21 at 158.

method as a whole is a function of the variability of the predictions of low-dose response, based upon the same experimental data. If the estimates are closely clustered, this argues for the reliability of any one of them or all of them. Table 9 reports the results of 14 bioassays of 13 substances. Table 10 presents the estimates for widely used models of the "virtually safe dose" for risk levels of 10^{-4} and 10^{-6}.

With one exception, the ratio between high and low estimates is always greater than a factor of ten (the exception is hexachlorobenzene). And in one instance, that of vinyl chloride at a VSD of 10^{-6} it was as high as 10^{8}. So, if the government aims to protect 99.99% of all individuals exposed to vinyl chloride, it would presumably make equally good sense to limit exposure to either 2 ppm or 3.0×10^{-5} ppm (or anything in between). Under these circumstances, it is reasonable to question the value to rule-making of quantitative risk assessment.

A report of the National Academy of Sciences concerning saccharin described the lack of consistency of risk projections. It reported the risk of ingesting 0.12 grams per day of saccharin:[51]

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51 Marvin Schneiderman, "Regulation of Carcinogens in an Imprecise World," in Nicholson, supra Ch. 4, n. 92 at 227. Moreover, in these projections rat dose was adjusted to human dose by comparing skin surface area. It is interesting that different results would be obtained were the adjustment done on the basis of a constant ratio of saccharin to food injested.

TABLE 8.

DIVERSE ESTIMATES OF RISK

Model	Lifetime Cases Per 10^6 Exposed
One-hit model (Hoel)	1,200
Two-stage model (Hoel)	5
Multi-hit model (Food Safety Council)	0.001
Probit (Mantel/Bryan)	450

Typically, the linear extrapolation to zero (one-hit) model leads to the lowest VSD, the multi-hit model to the highest. It must be understood that the quantitative extrapolation of risk, through the models that generate these estimates, disguise a great number of scientific and normative assumptions. By way of illustration, one might focus upon the one-hit model. A hit is "any event necessary for the production of an observable consequence."[52] So, according to the one-hit model, a malignant tumor arises from a single (irreversible) biological event. That event is a sufficient cause for the tumor. On a cellular level, we "picture" that once this event occurs, the remaining steps are inexorable, i.e., the sequence occurs with a probability equal to one. This single hit need not be a unique event-type. It can occur in any one of several ways. However, all of these logically distinguishable events can be grouped together given the name "X". An event is "X" if and only if:

52 Cornfield, supra n. 39 at 698n.

TABLE 9.

EXPERIMENTAL RESULTS FOR FOURTEEN SUBSTANCES

Substance	Species	Type of Response	Dose Units	Response Data				Dose No. of responses/No. of animals						
1. NTA	Rat	Kidney Tumor	% in diet	0 0/127	.02 0/48	.20 0/48	.75 1/91	1.50 2/91	2.00 12/48					
2. Aflatoxin B_1	Rat	Liver Tumor	ppb.	0 0/18	1 2/22	5 1/22	15 4/21	50 20/25	100 28/28					
3. Ethylenethiourea	Rat	Fetal Anomalies	mg./kg.	0 0/167	5 0/132	10 1/130	20 14/81	40 142/178	80 24/24					
4. 2,3,7,8-tetrachlorodibenzo-p-dioxin	Rat	Intestinal Anomaly (fetuses)	mg./kg.	0 0/24	.125 0/18	.25 1/33	.50 3/31	1.00 1/10						
5. Dimethyl-nitrosamine [1]	Rat	Liver Tumors	ppm.	0 0/29	2 0/18	5 4/62	10 2/5	20 15/21						
6. Vinyl Chloride[2]	Rat	Liver Angiosarcoma	ppm.	0 0/58	50 1/59	250 4/59	500 7/59	2500 13/59	6000 11/60					
7. Hexachlorobenzene	Rat	14th rib Anomaly (fetuses)	mg./kg.	0 0/80	10 4/79	20 8/91	40 15/87	60 25/96						
8. Botulinum toxin – Type A[3]	Mouse	Death due to botulism	ng.	.010 0/30	.015 0/30	.020 0/30	.024 0/30	.027 11/30	.030 4/30	.034 11/30	.037 10/30	.040 16/30	.045 26/30	.050 26/30
9. Bis Chloromethyl Ether	Rat	Respiratory Tumor	No. of 6 hr. exposures by inhalation of 100 ppb.	10 1/41	20 3/46	40 4/18	60 4/18	80 15/34	100 12/20					
10. Sodium Saccharin	Rat	Bladder Tumors	% in diet	.01 0/25	10 0/27	1.0 0/27	5.0 1/25	7.5 7/29						
11. Ethylenethiourea	Rat	Thyroid Carcinoma	ppm.	0 2/72	5 2/75	25 1/73	125 2/73	250 16/69	500 62/70					
12. Dieldrin[4]	Mouse	Liver Tumor	ppm	0 17/156	1.25 11/60	2.50 25/58	5.00 44/60							
13. DDT	Mouse	Liver Hepatoma	ppm.	0 4/111	2 4/105	10 11/124	50 11/104	250 60/90						
14. Reserpine (spontaneous)	Rat	Cardiac Lesion	% in diet	0 1/10	5 1/10	10 4/10	15 4/10	20 5/10						

(1) Results at 50 ppm. omitted.
(2) Results at 10,000 ppm. omitted.
(3) Results at .001, .005, .055, .060, .065 ng. omitted.
(4) Results at 10, 20 ppm omitted.

Source: Food Safety Council, supra Ch. 4, n. 28 at 147.

TABLE 10.

ESTIMATED VIRTUAL SAFE DOSE (VSD) FOR FOUR MODELS FOR FOURTEEN SUBSTANCES

Substance	Dose Unit	Estimated VSD at Risk Level 10^{-4}				Estimated VSD at Risk Level 10^{-6}			
		One-Hit	Armitage-Doll	Weibull	Multi-Hit	One-Hit	Armitage-Doll	Weibull	Multi-Hit
1	% in diet	2.0×10^{-3}	1.9×10^{-2}	.85	1.0	2.0×10^{-5}	1.9×10^{-4}	.52	.80
2	ppb.	3.4×10^{-3}	7.6×10^{-2}	.40	1.2	3.4×10^{-5}	7.9×10^{-4}	4.0×10^{-2}	.28
3	mg./kg.	4.5×10^{-3}	1.6	2.3	4.7	4.5×10^{-5}	.35	.59	2.3
4	mg./kg.	5.2×10^{-4}	1.6×10^{-2}	1.7×10^{-2}	2.5×10^{-2}	5.2×10^{-6}	1.6×10^{-3}	1.7×10^{-3}	3.8×10^{-3}
5	ppm.	3.2×10^{-3}	.19	.19	.41	3.2×10^{-5}	1.9×10^{-2}	1.9×10^{-2}	7.7×10^{-2}
6	ppm.	2.0	2.0	7.4×10^{-5}	3.0×10^{-5}	2.0×10^{-2}	2.0×10^{-2}	2.1×10^{-9}	3.9×10^{-10}
7	mg./kg.	2.1×10^{-2}	2.2×10^{-2}	2.4×10^{-2}	2.4×10^{-2}	2.1×10^{-4}	2.2×10^{-4}	2.6×10^{-4}	2.6×10^{-4}
8	ng.	8.4×10^{-6}	9.1×10^{-3}	9.2×10^{-3}	1.7×10^{-2}	8.4×10^{-8}	4.2×10^{-3}	4.3×10^{-3}	1.3×10^{-2}
9	No. of 6 hr. exposures by inhalation of 100 ppb.	1.6×10^{-2}	4.0×10^{-2}	.47	.48	1.6×10^{-4}	4.0×10^{-4}	3.1×10^{-2}	3.7×10^{-2}
10	% in diet	4.3×10^{-3}	1.1	1.4	2.0	4.3×10^{-5}	.33	.53	1.1
11	ppm.	5.5×10^{-2}	20.8	24.4	63.0	5.5×10^{-4}	4.5	6.0	33.5
12	ppm.	5.7×10^{-4}	2.2×10^{-3}	1.8×10^{-2}	5.1×10^{-2}	5.7×10^{-6}	2.2×10^{-5}	1.2×10^{-3}	6.7×10^{-3}
13	ppm.	2.8×10^{-2}	6.4×10^{-2}	.41	.76	2.8×10^{-4}	6.4×10^{-4}	1.7×10^{-2}	4.9×10^{-2}
14	% in diet	3.7×10^{-3}	5.7×10^{-3}	3.2×10^{-2}	6.7×10^{-2}	3.7×10^{-5}	5.7×10^{-5}	1.1×10^{-3}	3.8×10^{-3}

Source: Food Safety Council, supra Ch. 4, n. 28 at 149.

(1) It occurs of a single event.[53]

(2) Its occurring is a sufficient condition for the prediction of a tumor

That the carcinogenic mechanism is "one-hit" is unprovable at the present time for any particular chemical or for all chemicals. There is epidemiological evidence that at low doses risk from cigarette smoking is linear with respect to dose.[54] But difficulties associated with epidemiological data-collection make this only suggestive.[55] In any event, proven linearity for any one or set of substances would at best suggest linearity for another.

It seems reasonable that different biological sequences might occur, all with the same endpoints (exposure to a carcinogen, development of a tumor) but with different event-sequences in between. Perhaps the common popular simplification fallacy of "forgetting this" is the result of our grouping all of these widely divergent diseases under the single name "cancer". This linguistic simplification is itself the result of our lack of understanding of what distinguishes one

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53 It is difficult to get a handle on this without going into more detail than it is worth to this paper. What I mean, though, can perhaps be illustrated through an analogy with an electrical switch. Either the switch is closed, allowing current to "flow" or it is open, preventing current from "flowing." In a sense this is a single event. But in another sense, it is not (for it can be analyzed as consisting of a set of lesser events).

54 Harold A. Kahn, "The Dorn Study of Smoking and Mortality Among U.S. Veterans: Report on Eight and One-Half Years of Observations," in Epidemiological Approaches to the Study of Cancer and Other Chronic Diseases, ed. William Haenszel, (NCI Monograph #19), Bethesda, Md: National Cancer Institute, 1966, p. 1 (esp. chart on p. 7).

55 It is also asserted that radiation induced cancer is linear with respect to dose. But even this has been questioned. (see Bertram Wolfe, "Low-Level Radiation: Predicting the Effects," 196 Science 1387 (1977)). And, in any event, one thing that seems clear regarding chemical carcinogenesis is that it differs from radiation induced carcinogenesis.

from another. So really, what it comes down to is the impossibility of demonstrating the appropriateness of any one extrapolative model, not simply because of the poverty of scientific theory, but also, because it can be proven only once it becomes superfluous. This last argument is applicable not only to the one-hit model, but to any extrapolation risk model.

Risk-benefit analysis, and indeed any procedure for assessing risk, is incapable at the present time of appreciating the extent to which exposure to more than one carcinogen at the same time or in sequence may influence the degree of risk that any one of them poses individually. Although a weakness in experimental design, rather than of analysis, it is expressed in the assessment.

In actuality, humans are exposed to many substances which according to some widely held views of carcinogenesis, may act synergistically. A laboratory experiment that did not test substances together would overlook this possibility. And an analysis based on these studies would be unable to assess its influence on the degree of risk presented.

It was mentioned earlier that the one-hit model typically leads to the lowest estimate for VSD. An argument for its use makes use of this tendency, pointing out that adopting this model is a way of compensating for the uncertainty attached to the risk assessment process.[56] The problem with this, though, is that it confuses the first two steps of risk assessment. It is not for statisticians to distort the assessment process by incorporating into the first step a risk averse attitude

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56 Cornfield, supra n. 39 at 695.

toward uncertainty. That is not to say that the uncertainty should be ignored either.

Any estimate of risk should include two components.[57] First, it should include a best estimate of the probability of harm that is to be expected at various dose levels. It should be kept as free as possible from purposeful bias. Secondly, it should include an estimate of the uncertainty associated with this estimate. Although experimental data will not have been collected at these low doses, and so there cannot be a standard deviation in the classical statistical sense, it is essential that some verbal description be offered of the degree of faith that should be attached to the estimate of the "mean" probability. With these two pieces of information, it will be suggested in the following section that the decision of how the second should affect the manner in which the first is treated is to be made within the political sphere.[58]

In certain instances, there will be reason to believe that the probability estimates are more uncertain than at others. There is little doubt, for example, that aflatoxin is a more potent carcinogen than sodium saccharin.

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57 William B. Upholt, "Models for Extrapolation of Health Risk," in Environmental Modeling and Simulation, ed. Wayne Ott, Washington: U.S. Environmental Protection Agency, 1976, p. 184.

58 When I speak of uncertainty in this connection I am referring to all of the sources of uncertainty that I have identified so far in these Chapters that are present in the evidence (and those that I have omitted). So, the possibility of metabolic overloading and nutrient contamination, for example, usher in the possibility of bias, and thereby create uncertainty in any estimate reached, whatever it may be. I have not come across any suggestions for a procedure for quantifying this uncertainty. Moreover, I suspect that the absence of a method is more than temporary. For, as I have sought to show, it is unquantifiable. Indeed, the huge variability of low-dose extrapolations, indicating the unknowable uncertainty of just this last step in the risk assessment process, demonstrates this.

An additional complication is that there is no reason to believe that the uncertainty is symmetrical. Indeed, it is logical that in individual instances it be asymmetrical. The evidence may suggest that the VSD (10^{-4}) of vinyl chloride is 6 X 10^{-3} ppm (a made up number). All of the terrifically complex information has been analyzed. 6 X 10^{-3} may be the best estimate. But it probably is not the least unbiased estimate. As an estimate it is reached by analyzing the data statistically, and making judgments as to how each recognized source of uncertainty should be dealt with, while ignoring those that are not recognized. Each judgment imposes a certain strain upon the final probability estimate that is impossible to quantify. Most of the time, this strain of uncertainty will be either positive (that the mean results in an understatement of risk) or negative (that it results in an overstatement of risk). But rarely will this uncertainty be neutral. For example, if a time-to-tumor model is used in risk quantification, then <u>if it is wrong</u> it is more likely to underestimate than overestimate risk. What is the sum total of all of this uncertainty?[59] Perhaps there is an equal amount of strain biasing the estimate upward and downward. But this is not likely, particularly when the evidence relating to the substance's carcinogenicity has been gathered, judgments made, by a relatively small group of individuals, each person with certain attitudes toward proper scientific method and the role of carcinogen screening. Under these circumstances one would expect a certain consistency of bias.

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[59] It is not meant that a downward bias counters an upward bias, resulting in less uncertainty overall. I am not sure to what degree it would. I am merely saying that the sign of the uncertainty is affected.

Each model yields coefficients that represent the degree of risk that an individual who is exposed to the substance faces at each level of exposure. To arrive at the total risk that the substance poses, this coefficient is factored by the number of people exposed at each level. In order to be able to determine the optimal strategy of control, the extent of risk expected at each level of controllable exposure should be evaluated. The various control strategies would likely reduce the present risk to varying degrees. All of these considerations could be summarized as in the table on the following page describing the risk at various control levels posed by a hypothetical substance "XXX."

In light of these very serious doubts regarding the value of quantitative risk assessment, what role should it play in the regulatory process? One position was expressed by Arthur Upton in 1979, who at the time was the Director of the National Cancer Institute:

> Current scientific knowledge is not sufficiently advanced to the use of quantitative risk assessments as a primary basis for the regulatory decisions involving human exposure to carcinogens.[60]

Part II contains a discussion of OSHA's response to these and related uncertainties as it was expressed through its "generic" cancer policy. It is hoped to show that the cancer policy provides a focus for examining issues of proper regulatory responses to the manifest presence of uncertainty in risk assessment in light of the other constitutional and statutory obligations of these federal agencies.

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60 As reported in 8 Occupational Safety and Health Reporter 1800 (5/31/79).

TABLE 11.

RISK QUANTIFICATION FOR SUBSTANCE XXX

	# of people exposed	level of exposure	probability of lost life (per year)	expected # of deaths (per year)	degree of uncertainty
at present	10,000	100 ppm	10^{-3}	10	very large
with control strategy 1	10,000	1 ppm	10^{-5}	.1	very large
with control strategy 2	10,000	.1 ppm	10^{-7}	.001	very large

(b) Placing a Value on Risk:[61]

The quantification of risk associated with a type of action (such as the action of being exposed to vinyl chloride in a factory) is quite different from condemning or accepting its presence. To do the latter presupposes a moral attitude toward the action.[62] How that risk is to be viewed requires a distinctly ethical judgment. But like any ethical judgment it can be mapped with only a fair amount of distinctness.

There is no getting around the fact that the science of morals is radically incomplete. This has great significance for risk-benefit analysis. Whereas the motivation elsewhere in this process is the desire to achieve a fuller "understanding of," a searching outward to discover how the world works, this step involves a very different type of activity. The ascription of moral indicators upon actions does not involve knowledge per se. G.E. Moore argued that "Good" is a non-natural category.[63] It is not found in objects, but rather placed onto them. As a result, there is no uncertainty more radical than that examined in this section.

If Moore is correct, then methodologies for attaching ethical ascriptions operate through an act of inference from natural categories. Broadly speaking, there are two ways in which this can be done. In the first, risk activities are classified according to pre-stated criteria, and values are attached to them by how they fulfill these criteria. The

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61 Not all risk-benefit strategies include this step.

62 Even cost effectiveness criteria involve an implicit valuation. It is not more natural to aim for the highest ratio of deaths averted/costs incurred than some other ratio.

63 Principia Ethica, Cambridge: Cambridge University Press, 1956, p. 13.

best example of this methodology is valuing a death or injury by the amount of the explicit costs that society incurs as a result.

In the second methodology, evidence for the ascription is obtained from subjective empirical input. The evidence for the acceptability of a risk is taken from people's judgments. For instance, according to the "willingness-to-pay" criterion, the value of a risk is equal to the maximum amount of money that an individual would be willing to pay to avoid it.[64]

Also falling within this subjectivist methodology is the system employing "revealed preferences." In this, evidence for the ascription is obtained from the ways in which people make judgments in similar situations in which they find themselves. This methodology stems from the assumption that the rules that the government composes to bind the activities of its citizens should not be dissimilar to those that they bind themselves by. That people consider these other risks acceptable would constitute prima facie evidence that government should consider comparable risks within its regulatory purview acceptable.

In actuality, people do not base choices solely on the attendant risks, but on whether the potential benefits justify taking the risks. So studying people's risk-taking behavior reveals the nature of this tradeoff rather than the value that they attach to risk quanta. But, in spite of this, the method of "revealed preferences" is dealt with in this section.

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64 Or, in a slightly different formulation, the minimum amount of money that a person would accept to incur it. Theory suggest that these would yield different numbers. And evidence supports it. For a fuller discussion, see "willingness-to-pay" below.

(i) The Direct Method of Analysis:

The value that this method places upon avoiding a risk is equal to the expected value of costs the mitigating the risk would avoid. So, the trick is to identify and place a value upon the negative effects of the "average" occupational cancer.

For example, the "costs" of an occupationally induced cancer include the costs of medical care, but also lost wages as well as the pain and suffering of the worker, and the anguish felt by the family and friends. The employer loses the services of a (presumably) productive and experienced worker.[65] Further, there is likely to be a "leveraging effect." To avoid future conflicts with the rule-making agencies, firms are likely to internalize aspects of a health rationale. So there will be unknown beneficiaries. The extent of the marginal impact of the regulation upon future decisions may be difficult to gauge.[66]

There are serious limitations in even the most sophisticated analysis. The difficulty of placing a value on amenities for which the market does not fix one has been extensively discussed in the literature. What is the value of pain and suffering averted? Two methods that are employed to approach this question will be discussed.

But what is often overlooked in market economies is that price as an index of value is a fiction. That the interaction of supply and demand or relative scarcity should determine the worth of a good is a

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65 U.S. Congress, Senate, Committee on Governmental Affairs, Benefits of Environmental, Health and Safety Regulation, (Prepared by the Center for Policy Alternatives), 96th Cong., 2nd sess., 6 (1980).

66 Although if it is as efficient as the leveraging effect of prosecuting tax offenders, it is probably significant.

convention.[67] It may be acceptable to use "price" as a proxy for "value."[68] But if it is used in this way it should be understood that this decision is arbitrary.

A list of the harmful effects due to carcinogenic risk on the job could include:

(1) health care costs and associated losses
(2) lost earnings[69]
(3) psychological costs

It might also be appropriate to view the more pervasive occupational carcinogens from a macro-economic perspective to determine their influence upon the national economy. For example, it was estimated in one study that occupational exposure to asbestos will be associated with between 58,000 and 75,000 cancer deaths per year.[70] If correct, this would certainly have an impact on the following parameters:

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67 The alternative preferred by neo-classical economists employs the notion of consumer's surplus. I will discuss this in connection with the willingness-to-pay criterion. Marxist economists, of course, accept the labor theory of value (according to which, as a first approximation, the value of a good is based on the amount of labor that went into its production). The labor theory would have a very difficult time of recognizing, and of placing value on, the pain and suffering averted through a regulation (although this does not say that Marxists would).

68 This ignores the possibility of price distortions which distance the concept of "value" even further from that of "price."

69 Lost earnings are used simply because as a measure it is easier to estimate: T.C. Schelling, "The Life You Save May Be Your Own," in Problems in Public Expenditure Analysis, ed. Samuel B. Chase, Washington: The Brookings Institution, 1968, p. 135. But it confuses "life" and "livelihood." Among the paradoxical results (some of which will be considered later) that follow is that the value of death avoided is no different from the value of unemployment avoided.

70 HEW report, supra Ch. 3, n. 26 at 10.

(1) employment
(2) productivity
(3) prices
(4) investment
(5) GNP

A recent study estimated average direct costs for the first three years of cancer treatment at $16,700.[71] Using data from a study by the National Center for Health Statistics, the average amount of lost earnings that are foregone as a result of a cancer death is approximately $43,000 (at a 6 per cent discount rate).[72] The choice of discount rate, although a technical issue, can very significantly alter net present value as is shown in the figure on the following page. Whether or not average lost earnings for occupationally induced cancers is larger or smaller than this is highly uncertain. There is reason to believe that it is higher, and reason to believe that it is lower. $43,000 would reflect the lost earnings of all cancer deaths whether or not these people were employed or would have been employed. But, on the other hand, a reasonable suspicion is that the bulk of the burden of risk is faced by lower paid workers. So the average would be biased upward and downward.

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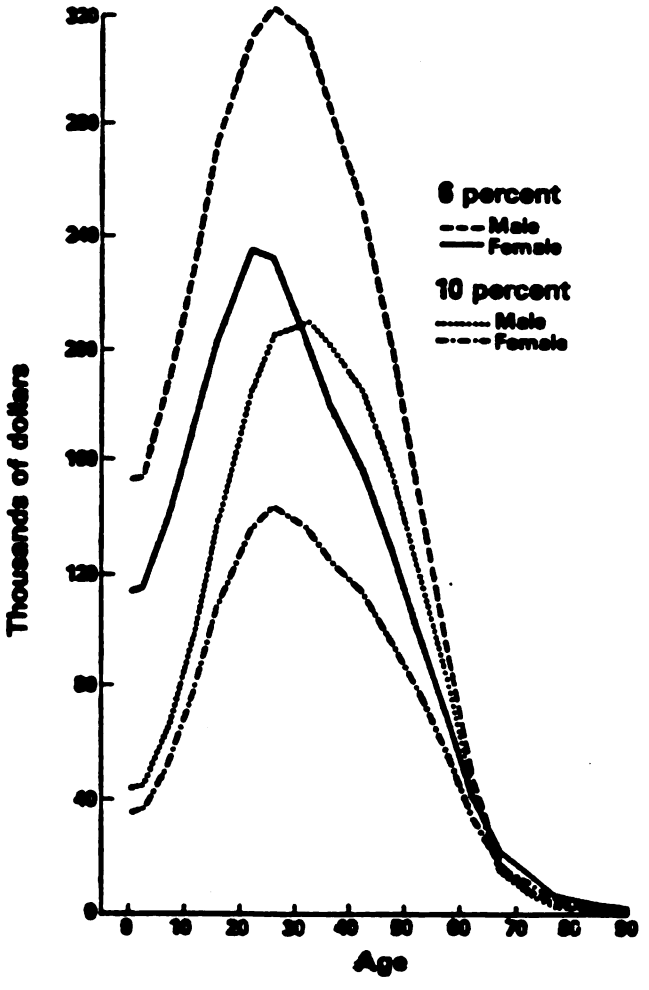
71 Abt Associates, p. 44. It stated that "three year costs" are a "modest understatement of lifetime costs." (p. 45).

72 Dorothy Rice and Thomas Hodgson, "Social and Economic Implications of Cancer in the Untied States," in U.S. Congress. Senate Committee on Labor and Human Resources. National Cancer Program, 1979. 96th Congress, 1st Session, 1979. This estimate is very tenuous. I derived it by dividing their estimate of total lost earnings due to mortality from neoplasms (p. 51) by the estimated number of cancer deaths (p. 70). Both of these estimates are questionable, but hopefully they are "in the ballpark."

FIGURE 3.

Present Value of Lifetime Earnings, Discounted at 6 Percent and 10 Percent, By Age According to Sex, 1977



SOURCE: Present values of lifetime earnings in 1975 calculated by the Public Services Laboratory of Georgetown University, Washington, D.C., have been adjusted by changes in earnings, work experience, and housekeeping rates between 1975 and 1977 to obtain estimates of present values for 1977.

Source: Thomas Hodgson, "Social and Economic Implications of Cancer in the United States," in Nicholson, supra Ch. 4, n. 92 at 201.

Thus, the version of the direct method that has been presented here would estimate the average value of a cancer death at something like $60,000. From society's standpoint it would make sense to expend up to $60,000 of its resources in preventing that death (if strategies would be absolutely certain of success).[73] Prevention would save approximately $17,000 worth of health care resources and spare a laborer whose lifetime marginal revenue produced (discounted at 6 per cent) is approximately $43,000.

The chief objection to this way of placing value on risk is that in effect it views a person's value simply as a means of producing a stream of output whose contribution is measured by his earnings. This is referred to as the human capital approach. The primary complaint is that it is counter-intuitive. For example, it excludes all intangibles and non-wage related activities. Each of us likes to think that we are "worth" more than what we can produce and market. Moreover, since the average discounted lifetime earnings of the very young and the elderly are lower than of middle-aged people risks to them could be valued lower. Furthermore, if women and blacks are discriminated against in wages, then their product would not even reflect the value of their product.

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73 A variant of this with repugnant implications is to consider output net of consumption, since the loss also frees up goods and services. But since we would not want to be forced into the position of arguing that a person who would consume more than he would contribute to national produce would possess negative value, and therefore it would be of value to society that he die, most people would not consider this framework acceptable. But, perhaps a "cold-blooded" utilitarian might. (For a "cold-blooded utilitarian" view see Burton Weisbrod, Economics of Public Health, Philadelphia: University of Pennsylvania Press, 1961, p. 35.)

Cancer has a cost in pain and suffering that cannot be disregarded. People are not indifferent to whether or not they suffer and encounter pain in life. So, it is important to somehow include these intangibles as costs of cancer risk.[74]

One of the most intractable problems is whether, and if so, how to discount future benefits. Nicholas Ashfold suggests that health benefits be discounted at a lower than market rate, reflecting the "belief that certain amenities, such as health, become more valuable relative to other goods in this society as time passes and the standard of living improves."[75]

Because it is counter-intuitive, the direct method of valuing risks would be considered by most people to be inappropriate. By confusing the value of a life and the market value of one's product it leads to paradox. It disregards those products of life, including thoughts and feelings, that are not traded on the market.[76]

ii. Indirect Methods of Valuing Risks

Because it is counter-intuitive, the direct method outlined above fails to adequately value the risk manifested in exposure to carcinogens. Another valuational method is to infer these values from people's behavior or from their intuitions regarding the acceptability

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74 For a reasonable argument that the psychic costs to others of a person's death are sufficiently correlated with monetary costs so as to permit the latter to be used as an index for the former, see Ibid., pp. 96-98.

75 "Alternatives to Cost Benefit Analysis in Regulatory Decisions," in Nicholson, supra Ch. 4, n. 92 at 138.

76 The ready reply to this objection is to ask why we should trust our intuitions. To discuss these issues in any greater depth would be inappropriate in this paper.

of risk.[77] Two instances of this method are "revealed preferences" and "willingness-to-pay."

(α) revealed preferences:

The method of revealed preferences has received an increasing amount of attention recently.[78] Technically, it sidesteps the question of how to place a value on risk. It is based on the insight that all activities involve a certain amount of risk and that society expresses socially acceptable tradeoffs between the benefits conveyed through and the risks entailed by those activities that are considered acceptable. Measuring risk and benefit data for hazardous, yet common activities will reveal risk-benefit tradeoffs that can be used to set permissible exposure levels for carcinogens. "Acceptable risk for a new technology is defined as that level of safety associated with ongoing activities having similar benefit to society."[79]

In an early study Chauncey Starr drew the following conclusions about society's risk preferences:[80]

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77 U.S. Congress, Senate, Committee on Governmental Affairs. Benefits of Environmental, Health and Safety Regulation, supra n. 65 at 17.

78 Chauncey Starr, "Social Benefit versus Technological Risk," 165 Science 1232-38 (1969). Harry Otway and J.J. Cohen, "Revealed Preferences: Comments on the Starr Benefit-Risk Relationships," IIASA RM 75-5, Laxenburg, Austria: International Institute for Applied Systems Analysis, March 1975. W.D. Rowe, An Anatomy of Risk, New York: John Wiley & Sons, pp. 261-66, 1977, Baruch Fischhoff et al.; "Weighing the Risks," Environment, vol. 21, no. 4 (May 1979), pp. 20, 32.

79 Fischhoff et al., supra n. 78 at 20.

80 Starr, supra n. 78 at 1237.

(1) The indications are that the public is willing to accept "voluntary" risks roughly 1000 times greater than "involuntary risks.

(2) The statistical risk of death from disease appears to be a psychological yardstick for establishing the level of acceptability of other risks.

(3) The acceptability of risk appears to be crudely proportional to the third power of the benefits (real or imagined).

(4) The social acceptability of risk is directly influenced by public awareness of the benefits of an activity, as determined by advertising, usefulness, and the number of people participating.

(5) In a sample application of these criteria to atomic power plant safety, it appears that an engineering design objective determined by economic criteria would result in a design-target risk level very much lower than the present socially accepted risk for electric power plants.

The following chart compares risk and benefit to American society from various sources. Risk is measured as fatalities per person-hour of exposure. Benefits reflect the average contribution of an activity to the participant's income or the average amount of money spent on the activity.

There are several weaknesses in this approach that limit its relevance to public decision making:

(1) It ignores distributive considerations (although they could be considered)

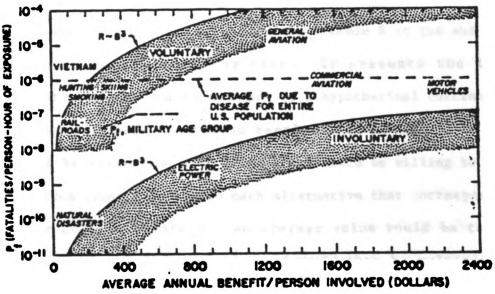
(2) It ignores external benefits of the activity (although, in principle, they could be included).

(3) It assumes that past behavior is a valid predictor of present preferences.

(4) It overlooks imperfections in information, and the ability to analyze information. People do not always understand the implications of their actions. If they did, they might act differently.

FIGURE 4.

Risk (R) Plotted Relative to Benefit (B) for Various Kinds of Voluntary and Involuntary Exposure



Source: Starr, supra n. 78 at 1234.

(β) willingness-to-pay:

An extensive literature has arisen around the concept of "consumer surplus."[81] Implicit in this is the belief that the value of a good to a person is equal to the maximum that that person would be willing to pay for it.[82] This is termed "compensating variation." This compensating variation would be equal to the area below the demand curve and above the price line (the difference between what he would pay and what he has to pay).

To see how it might be used, consider Table 8 at the end of the preceding section on quantifying risk. It presents the likely probability of mortality due to exposure to a hypothetical carcinogen at different exposure levels. A random sample could be taken, in which people would be asked how much money they would be willing to pay to reduce risk from present levels to each alternative that corresponds to a particular control strategy. An average value would be taken to represent a social preference function and would then be multiplied by the number of workers exposed to obtain the value of reducing the risk to each of these levels. For example, if the poll yields the conclusion that people would be willing to pay $10,000 to reduce the risk from present levels to 10^{-5} per year of exposure (corresponding to control strategy "1") then the value of the risk that would be averted by instituting this strategy would be $100,000,000.

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81 See John Currie, John Murphy and Andrew Schmidt, "The Concept of Economic Surplus and its Use in Economic Analysis," 81 Economic Journal 741 (1971).

82 Because most demand curves are downward sloping (the exception being those of "Giffen goods", for which the substitution effect is outweighed by a negative income effect) people would ordinarily be willing to pay a price that is higher than that determined through the market.

An alternative measure of consumer surplus is the minimum amount of money that a person would accept to forego the benefit (known as "equivalent variation").[83] Mishan pointed out that for non-Giffen goods (which "health" would seem to be an instance) the amount of money that a person will have to accept before he will forego it (its equivalent variation) will be greater than the amount that a person will pay to acquire it (its compensating variation).[84] Which alternative is preferable is partly a matter of judgment. But it would seem to make more sense, when seeking to determine the impact of a regulation, to measure the benefit of the risk averted (through the compensating variation variant).

There are a number of theoretical difficulties in a willingness-to-pay criterion. First, any pretension to being an objective measure of value is mitigated by the great variability of derived estimates as a function of changes in non-relevant factors. People will offer different estimates depending on whether they are asked early in the morning or late at night, after they've eaten a satisfying meal or when they are hungry, or whether they feel sick or healthy. "The values they express may be highly unstable."[85] Further, how the question is worded will likely have an impact on how it is answered:

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83 J.R. Hicks, "The Four Consumer's Surpluses," 11 The Review of Economic Studies 31, 35 (1944).

84 E.J. Mishan, Cost-Benefit Analysis, New York: Praeger Publishers, 1971, p. 328.

85 Fischhoff, et al., supra n. 78 at 34.

> Subtle changes in how issues are presented - how questions are phrased and responses are elicited - can have marked effects on their expressed preferences.[86]

This ushers in the crucial question that has been sidestepped until now, of whether it even makes sense to base Government action upon people's own "naive" or "uninformed" preferences. Of course this is a question for philosophers and political scientists, but it is still a question: Would it necessarily not make sense for Government to be more or less protective than the average citizen?

The second objection to willingness-to-pay approaches is that people may be irrational. That is, they may have "contradictory values (a strong aversion to catastrophic losses of life and a realization that they are not more moved by a plane crash with 500 fatalities than one with 300)."[87] This argument adds additional weight to a contention that people's preferences should not be used as a guide to public decision making.

The third objection is that it does not allow for the fact that costs and benefits are falling on different parties. The risks of occupational exposure to carcinogens, for instance, are shared by only a small portion of the population. It is one thing to argue that willingness-to-pay promotes economic efficiency, it is another to argue that it promotes the "just" solution. One or another study employing this criterion may achieve the just solution, but only by accident.

The import of all of these objections is that willingness-to-pay can serve only a restricted role to determine the value of quantifiable

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86 Ibid.

87 Ibid., pp. 33-34.

risk. It is the author's belief that none of the methods presented offers an effective and fair approach to fulfilling this function. The implication of this for the attempt to construct a rational process for regulating suspected carcinogens should be obvious.

(c) Determining Costs:

Ordinarily, any risk reduction will involve an opportunity cost. Acquiring the economic good of increased health will reduce the amount that can be acquired of other goods. When it chooses to "purchase" a reduced risk of cancer for industrial workers, OSHA is also deciding that other purchases must be foregone.

On the firm level, this is manifested by lower profit levels and or price increases (for those of its goods whose demand is inelastic) which have the effect of reducing the real incomes of those consumers who purchase those goods. On the national level, the regulation results in a transfer of income from consumers (who can purchase a smaller value of goods and services) to workers (who have acquired a larger "amount" of health).[88]

That portion of costs that cannot be passed along via higher prices (because demand is elastic) must be absorbed by the firm if it is to remain in business. It can cut costs and/or reduce profits. Workers may be laid off or investment reduced. But because of increases in

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88 If the following two assumptions are satisfied the increase in capital spending will be counteracted at least in part by a corresponding decrease in real wages for the affected workers: (1) If the wage rate reflects the magnitude of the attendant risks; (2) If the supply of labor is perfectly elastic. If both assumptions are met, once the risks are mitigated, workers will be willing to accept lower wages.

employment and investment in the economic sector that is producing this equipment, national investment and employment may be growing.

The bare statement of costs will not convey the nature of these economic effects. To do that requires an understanding of the market structure of the directly affected industry as well as those with economic linkages to it.

This is the rationale for estimating the costs of health and safety regulations. They will ordinarily have a negative impact on the firm and industry (by decreasing supply, thereby causing equilibrium price of the good to increase and equilibrium quantity to decrease). However, for two reasons this is an oversimplification of reality. First, if the firm offers more than one good, it will likely increase the price of that good whose demand is most inelastic, which may be different from that directly affected by the regulation.[89] Secondly, the amntrol technology may actually permit the firm to operate more efficiently than before. Being required to control ambient air quality will also force the firm to operate more cleanly, reducing the amount of process waste. The net cost of control would be reduced by the value of the material that can be recovered and recycled. For example, the most cost-effective way of reducing airborne cotton dust "consists of dust capture devices. . ., ducts for transporting the contaminant, and a filtration system for eliminating the dust from the airstream."[90] It would be a fairly simple matter to recover it. The net cost of the

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89 Or it may price discriminate, raising the price only in those markets whose demand for the good is most inelastic.

90 Research Triangle Institute, Cotton Dust: Technological Feasibility Assessment and Final Inflationary Impact Statement, Washington, U.S. D.O.L., 1976, p. V-3.

regulation would be equal to the marginal cost of control and recovery minus the marginal value of the product recovered. However, this accounting technique would not apply to those carcinogens, like coke-oven emissions, that have little or no recoverable value.

It was pointed out in connection with the discussion of the technology-based framework that some of the sources of uncertainty may bias estimates of regulatory cost. These sources are also present in cost estimation in this framework. And there are additional uncertainties not considered at this point that may also bias these estimates. John Morrall discusses them in his treatment of the cotton dust standards issued by OSHA on June 23, 1978.[91] What is particularly revealing about the standards, from an economist's perspective, is the wide variability between the projections of costs of three OSHA contracted studies.

Although large in magnitude, this variability is not indicative of the radical uncertainty this is characteristic of the estimation of benefits. For most of the variability can be traced to different ways of measuring variables. The additional uncertainty that is a function of the estimation weaknesses that Ashford pointed out is quantifiable within limits. For example, based on past experience, one could

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91 "Cotton Dust: An Economist's View," in The Scientific Basis of Health and Safety Regulation, ed. Robert Crandall and Lester Lave, Washington: Brookings Institution, 1981, p. 93.

TABLE 12.

ESTIMATES OF TOTAL COMPLIANCE COSTS FOR THE TEXTILE INDUSTRY[92]
(in millions of dollars)

	Hocutt-Thomas	RTI I	RTI II
Capital costs:			
Engineering controls	543.0	986.5	692.9
Other provisions	7.0	7.0	7.0
Total	550.0	993.5	699.9
Annualized costs:[93]			
Capital, total	109.2	197.3	139.0
Operating, maintenance and engineering controls	8.5	10.1	7.0
Other provisions	4.3	4.3	4.3
Energy	49.0	67.9	47.5
Total	171.0	279.6	197.8

92 "Occupational Safety and Health Standards: Occupational Exposure to Cotton Dust," 43 Federal Register 27350, 80 (6/23/78).

93 Capital costs annualized by a factor of 0.19864 to reflect 9 year depreciation period, 10% discount rate and allowances for equipment taxes and other costs.

estimate that technological improvement could cause costs to decline at a rate of 5 to 10 percent per year for five years.[94]

But estimates of costs will vary, and as a result, making a reasoned decision on how to regulate the substance under consideration is made more difficult. It is another source of uncertainty.

(d) Comparing Benefits and Costs:

Remembering that risk-benefit analysis arises from the intuition that rational action requires rational methods of inference, the goal is to be able to compare the costs and the benefits of an action, for example, that of setting a one ppm permissible exposure level for ambient concentrations of vinyl chloride in the workplace. The real benefits are in probabilities of deaths and suffering averted, medical costs avoided, productive members of society spared, as well as a manifold number of other implications. What an analysis attempts to do is to identify at least the more conspicuous and significant of these effects and to place values upon them. And it seeks to do the same things for the costs of the action. So, risk-benefit analysis seeks to identify and place values on the gains and losses to society of the action under consideration. It also seeks to compare them. An act is rational only if the agent is better off by performing it than not performing it. So, using the same criterion to judge regulations, it must be determined how well off the nation is made by it. And that requires at least a consideration of its benefits and costs.

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94 Ibid., p. 106.

There is an old saw that "one can't add apples and oranges." And it is true, but only in a restricted sense. On one level they are incommensurable, but on another, because each can be exchanged at (albeit arbitrary) certain rates for a common entity (money), they can be added. In one important sense, a dozen apples and a dozen oranges are (say) $3.50. Proponents of a strong form of risk-benefit analysis argue that the same operation can and must be performed, allowing the apparently incommensurable goods that are "traded" via government regulation to be compared. We view the effects, benefits and costs, within an economic framework in which they all possess a value in terms of what they can be exchanged for. The advocates of an explicit rationality point out that it is foolish to pretend that health does not have an exchange value. In so far as it is scarce, if it is to be acquired, something must be given up. To fail to recognize this is both naive and wasteful.

There are two important and related reasons why this argument should be discounted. In effect, the first has already been presented. It is that the manifest presence of radical, illimitable uncertainty frustrates any attempt to rationally trade-off risks against benefits. Part II of this dissertation has been devoted to examining the logical steps that are implicit in regulations governing people's exposure to substances on the basis of their posing a risk to health. Carcinogens have been focused on because they have received the most attention from the public, Government and the scientific community. It is hoped that it has been shown that the radical uncertainty that was referred to above cannot be extracted from the evidence. It is as much a part of

the evidence as the nominal conclusions themselves. It is self-deluding, therefore, to accept these conclusions at face value.

With respect to risk-benefit analysis, is it not also self-deluding to pursue without hesitation what very well may be the mirage of perfect rationality in decision making? It is as if a person spent all of his time shoring up the walls of his house to keep out the elements, forgetting that it has no roof. Pursuing the rationality of a limited part of the logical foundation of regulation does not guarantee the rationality of the whole structure. What is not always appreciated, even by those well-versed in regulatory issues, is how intractable this uncertainty is. One advocate of cost-benefit analysis misconstrued the nature of this uncertainty:

> . . . costs and benefits are inevitably prospective; hence, data are often not available from past experience with such a regulatory standard. This means that uncertainty enters the calculation, just as uncertainty enters into business planning, family budgeting, and selecting the final roster for the Washington Redskins. Social scientists have been developing tools for dealing with uncertainty for generations. The Department of Defense uses them. Regulators could use them.[95]

Unfortunately, however, there are no tools to identify, much less quantify, much of the uncertainty that, under a rational scheme of regulation, must be quantified.

There is no way to prove empirically that, because of this uncertainty, regulations obtained through this process will be "incorrect." That is, assuming that the purpose of a rule is to

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95 Use of Cost Benefit Analysis by Regulatory Agencies, supra n. 36 at 58 (prepared remarks of Robert Crandall).

maximize utility (however this is construed), then it cannot be shown exante or ex post that the regulatory strategy pursued succeeds in this.

The second general objection to risk-benefit analysis is that it leads to biased decisions. It falls prey to Gresham's law. Greater notice will be paid to quantifiable results, to the exclusion of unquantified results and caveats regarding the uncertainty of the estimates. Because regulatory costs are more easily quantified, there is a tendency to base decisions on them, placing less emphasis on the (less certain) benefits. This is a real danger of techniques that strive toward complete rationality.

Lester Lave sees more limited objectives for risk-benefit analysis.[96] Rather than being a decision rule for risk assessment, he views its proper role as being that of a heuristic:

> This framework is intended to be somewhat vague, with all effects being enumerated, but with full quantification and valuation being left to the general wisdom of the regulators. . . (It) makes no pretense at being an automatic decision making tool. It forces regulators to consider a broad set of costs and outcomes.[97]

If these are its aims, though, it is very limited. And Lave wonders this out loud: "Is it more than an injunction that decision makers ought to think broadly about the risks and benefits of their decisions?"[98] But if this is all that it is, then a tremendous amount of intellectual energy, in this paper and elsewhere, has been misdirected. In actuality, however, its aims are more ambitious. It champions systematic investigation, including quantification and valuation (under certain circumstances). Otherwise, it would be little

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96 Lave, supra n. 4 at 17-19.

97 Ibid., pp. 18-19.

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different from a call for "common sense." And this is certainly something that it does not do.

C. Conclusion

If health and safety regulation is to be rational it must be based upon an assessment of the risk which it is designed to minimize. There are a number of ways in which an assessment can be performed. This Chapter has contained an examination of the general characteristics and significant weaknesses of the most widely regarded schemes.

Each of these frameworks for assessment is a formula for standard-setting. The "variables" of each formula are those factors of the regulatory environment that are considered to be relevant in guiding government action. The "variables" possess relative weights in the "equation" that are also based on implicit value assumptions of the relative importance of the factors.

The market framework is a strategy of relative government inaction. Allowing the "consumers" of carcinogens to act for themselves, this model would have government provide them with information upon which to make a reasoned independent choice and allow them to exercise their common law rights in the courts. The government would not necessarily even have to determine that a risk exists. It might only present test findings, leaving their analysis to the public.

The no-risk framework is somewhat more sophisticated. Under this scheme government makes the threshold determination that the substance does or does not constitute a risk to the exposed population. The determination that it does present a risk would trigger action to eliminate it. The no-risk framework can be criticized because it turns

a blind eye toward useful and relevant information that could contribute to more rational decisions and because it reflects an unnaturally aversive attitude toward risk.[99] The virtue of the no-risk framework is that it is simple to apply (because it offers a simplistic solution).

The technology-based framework is yet more sophisticated. Once a risk were determined to exist it would mandate the highest level of protection that would be economically feasible (under one interpretation) or the greatest protection up until the point at which the marginal cost of an additional increment of protection is "wholly out of proportion" to its value (under another interpretation). Under yet another variant of the technology-based framework health benefits would be considered to be paramount and that although it cannot be met at present the specified standard can be met through innovation. There are a number of difficulties with this framework not the least of which is that it requires cost data whose certainty typically cannot be relied upon. But it offers a more rational solution to the regulatory question because it bases its answer upon more information than does "no-risk." The price of greater theoretical sophistication is additional evidentiary uncertainty.

The risk-benefit and cost-benefit frameworks are most sophisticated of all. To varying degrees they seek to base the regulatory decision upon a complete description and valuation of the implications, both positive and negative, of the action. To the extent that they succeed they contribute to more rational decisions. It is foolish to assert that government should not try to make well-informed decisions. But, at

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[99] Methods of mediating this extremism consistent with a no-risk formula are noted above.

the same time, the limitations of any decisions-rule should be kept well in mind and, when these limitations are significant, their implications should occupy a significant place in the evaluation.

However sophisticated the decision model it rests upon a very uncertain assessment of the magnitude of the effects of the action. The vast uncertainty of determining the regulatory costs and benefits places severe constraints on the rationality of any decision-rule. This needs to be recognized by students of regulation. Moreover, because any single point estimate of "risk" or "benefit" will probably be biased decisions based upon them which do not correct for the bias will themselves be biased. But very often bias, if it exists, will be impossible to identify.

Risk-benefit and cost-benefit need to be used carefully in decision-making for toxic substances, perhaps more carefully than the other frameworks discussed. This is because they lend an aura of objectivity and truth which the others do not, and which is largely a mirage.

Every decision-rule contains assumptions of a normative nature. Each rule has a different view of the rights of individuals and groups vis a vis the government, and the acceptable limits of government action. Although, to a certain extent, Congress makes these normative decisions, agencies have a fair amount of discretion in determining how they will utilize the often ambiguous instructions contained in the statute. Furthermore, every decision-rule will employ uncertain evidence. The more sophisticated the rule, the greater will be the absolute value of this uncertainty simply because it employs more evidence (of a more uncertain character). And, since this uncertainty

will rarely be neutral, it is reasonable to ask whether better informed decisions are necessarily better decisions.

CONCLUSION TO PART II

For several reasons federal agencies with responsibilities for controlling carcinogens find themselves in an impossible situation. This Part has examined a number of them. The universal presence of uncertainties in the evidence for regulations makes it very difficult to evaluate the reliability of test results. A high degree of sophistication is necessary to even identify for a study what acts omitted or committed could invalidate its stated conclusion. And it will often be impossible to determine with certainty whether in fact any of them do invalidate it.

Moreover, even if the reliability of a test were reasonably certain, some people might question its relevance to man. Of the twelve types of uncertainty discussed in connection with the animal model of carcinogen identification, six pertain to the relevance of test results to man at experienced exposure levels.

Under most regulatory decision-rules, the uncertainties only begin with the identification step. Determining a "permissible exposure level" from experimental results using the more sophisticated "technology-based" and "risk-benefit" frameworks is filled with even more extreme uncertainties. The "market" and "no-risk" frameworks may offer fairly unambiguous guidance, but at the expense of a smaller degree of reasonableness.

Wherever the regulator turns, he is confronted with questions for which the evidence is insufficient to allow him to make a confident and unbiased decision. Yet, decisions will be made, either through action or inaction.

Bearing in mind that absolute certainty is unattainable, two questions become relevant:

(1) What degree of certainty is necessary to control a substance as a carcinogenic risk?

(2) What models should be used for quantifying risk and/or determining regulatory costs?

An agency's effectiveness in controlling risks from carcinogens will largely be a function of its answer to the first and in some cases the second of these.

Among other things, the correspondence between politico-economic interests and various answers to these questions are examined in Part III. It also examines the experience of the Occupational Safety and Health Administration in regulating suspected carcinogens, evaluating its effectiveness in terms of the answers that it has given to the first question.

PART III
THE IMPACT OF EVIDENTIARY UNCERTAINTY UPON REGULATORY EFFECTIVENESS

It must. . . be recognized that the state of science and technology is not adequate to fulfill the legal burdens of proof which the Occupational Safety and Health Review Commission and the Courts have been requiring of the Agency. In most cases, a dose-response curve does not exist for the effects of the agent on the population at risk. Also, in the real world the population at risk is exposed to a multiplicity of hazards and the effects produced in the human body by the various agents are often in the form of a general medical, i.e., emphysema, bronchitis, cancer. These medical conditions cannot be uniquely associated with the agent that is being regulated. All of these uncertainties, which we attempt to treat in our standards documents, are fertile grounds for legal challenges by those who are not committed to abiding by the standard in question.

Morton Corn, "Report on OSHA," in U.S. House, Committee on Government Operations, Performance of the Occupational Safety and Health Administration, 95th Cong., 1st sess. 154 (1977).

INTRODUCTION TO PART III

Regulations are the products of complex processes, often involving a multitude of issues and scores of participants. Nearly all of the parties enter the process voluntarily, with the common aim of influencing the agency to adopt a standard that is as close as possible to its own point of view or interest.[1]

Inherent to the process that produces carcinogen regulations is the extreme evidentiary uncertainty that was mapped in Part II. In this respect, it is different form most other types of rule making that the federal government engages in. This uncertainty plays an important role in determining the effectiveness of various regulatory strategies. The fact that there is so much uncertainty is appealed to by those parties in the proceedings who assert that government action must be based upon a high standard of proof. Other parties claim that the need for a high degree of certainty must give way before the demands of protecting the public from potential health risks. What type of evidence is considered to be acceptable and what amount is required to base a standard on are issues which have great bearing upon the effectiveness of regulatory efforts.

The requirement that standards limiting permissible exposure levels be based upon adequate evidence can impose a "burden of uncertainty" on those who are exposed to suspected carcinogens and stand to benefit from government control if the standard of adequacy is difficult to attain.

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[1] There is an extensive literature on interest group politics. See, for example, Harmon Zeigler, Interest Groups in American Society, Englewood Cliffs, New Jersey: Prentice-Hall, Inc., 1964.

bearing upon how heavily the burden of uncertainty weighs upon the various parties.

Agencies possess a certain amount of freedom in designing control strategies. The extent to which this freedom permits them to effectively govern the impact of uncertainty is an important issue. The attempt by the Occupational Safety and Health Administration to issue a generic cancer policy was the most ambitious made by any federal agency to reduce the burden of uncertainty. A study of it is also an examination of the limits of the power of agencies to carry out the mandates conferred upon them by Congress to protect the public from cancer and other chronic diseases associated with environmental contaminants.

CHAPTER SIX
OSHA'S EXPERIENCE IN SETTING HEALTH STANDARDS, AND TWO RATIONALES FOR A RULE-BASED CANCER POLICY

> Reports which I have had from my district indicated that your people are operating under this law in a highhanded dictatorial manner which is reminiscent of the days of Mr. Hitler in Germany.[1]
>
> Now the hopes of this Congress and their (sic) constituents have been undermined by the inept and lax administration of important parts of the occupational safety and health law. A spirit of protecting the lives of our workers is barely discernible.[2]

A. Introduction

In passing the Occupational Safety and Health Act of 1970 Congress' stated purpose was "to assure as far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources."[3] It gave responsibility to the Secretary of Labor to promulgate standards to this end. This standard-setting authority was viewed to be the most significant aspect of the Act. Underlining the importance that it placed upon controlling toxic substances, Congress devoted a subsection of the law to setting forth the standard of proof and the considerations to be taken account of in setting forth standards governing toxic substances.

The newly-created Occupational Safety and Health Administration faced a tremendous responsibility from the outset. Waiving notice and comment guidelines contained in the Administrative Procedure Act, § 6(a) of the OSH Act mandated that national consensus standards be promulgated as occupational safety and health regulations within two years.

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1 Unidentified Congressman, U.S. Congress, House, Committee on Appropriations, Departments of Labor and Health, Education and Welfare Appropriations for 1973, pt. 6, 92nd Cong., 2nd sess. 61 (1972).

2 Rep. Dominick Daniels, Ibid.

3 29 U.S.C. 1651.

From its inception OSHA was a political football. The same interests that had fought over the Act continued the battle, to influence how it would be administered. The Nixon Administration, that had supported a weaker bill than that which ultimately passed Congress, was accused of sabotaging it. Less than one year after its effective date one of the Act's authors accused:

> All too often it has appeared that the only priority this Administration has adopted with regard to this Act is to turn enforcement over to the individual States, whose past failures were the real reason this Act was passed in the first place.[4]

Organized labor shared a similar disillusionment. Less than eight months after the effective date of the Act the AFL-CIO biennial convention adopted a resolution pointing out that:

> It is quite clear that the Administration has adopted policies whereby the discretionary powers accorded to the Secretary of Labor are being applied to delay implementation of standards, soften the impact of enforcement on employers, weaken the act's provisions setting forth the rights and protections for workers, and moving with unseemly haste to abandon federal responsibilities to the various state governments.[5]

"This Act of Congress. . . is in the hands of an Administration which does not believe in the Law's philosophy and purpose, despite White House rhetoric."[6] According to the director of the Industrial Union

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4 Senator Harrison Williams speaking on April 18, 1972; Charles Cullhane, "Labor Report/Administration Works to Shift Safety, Health Programs to States Despite Labor Criticism;" 4 National Journal 1041, 42 (6/24/72).

5 1 Occupational Safety and Health Reporter 592 (11/25/71).

6 A statement by the AFL-CIO executive council (5/2/72); Charles Culhane, "Labor Report/Labor, Business Press Administration to Change Safety and Health Program," 4 National Journal 1093 (7/1/72).

Department of the AFL-CIO, "The Labor Department and HEW [within which the newly-formed National Institute for Occupational Safety and Health, the research arm of the regulatory effort, found itself] have done an exceedingly poor job of standard setting in the first year."[7]

In what was to prove indicative of the character of organized labor's relationship with OSHA, on November 4, 1971 the AFL-CIO submitted a report to Labor Secretary Hodgson urging that an emergency temporary standard be promulgated under section 6(c) limiting exposure to asbestos in order to head off a "massive epidemic of cancer among workers exposed to asbestos dust."[8] On the advice of NIOSH scientists (NIOSH would not submit a formal criteria document on the toxicity of asbestos until January 21, 1972 -- its first such document) the Department of Labor issued an emergency standard on December 7.[9] In what would be one of its quickest rule-makings, OSHA would publish the final standard on the following June 7, just six months later.[10] This process of union pressure inciting OSHA action would be repeated for other standards.[11]

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7 A statement by Jacob Clayman, Ibid., p, 1094.

8 1 OSH Rptr. 581 (11/18/71).

9 36 Fed. Reg. 23207.

10 37 Fed. Reg. 11318; the proposed permanent rule had been published on January 12 (37 Fed. Reg. 466).

11 Regarding the political impetus behind the standard for the fourteen carcinogens of 5 Nat. J. 567-70 (4/21/73); and for that for vinyl chloride 6 Nat. J. 1831,33 (12/7/74).

While organized labor interests were condemning OSHA for moving too slowly in standard-setting, some business interests assailed it for acting recklessly.[12] The complaints centered on OSHA's adoption of the consensus standards, many of which were viewed as uneconomical, unnecessary or unachievable. An attorney for the Chamber of Commerce argued that too little attention had been paid to them before they were promulgated.[13] And a spokesperson for the Manufacturing Chemists Association felt that OSHA "moved pretty fast in the first year, possibly faster than it was possible to do and achieve accurate standards."[14] This last is a revealing statement, for it discloses what proved to be the primary tactic used to oppose all of OSHA's health standards that decade. Less effort would be made in arguing that control was unnecessary in principle, than that the evidence was insufficient to support the regulation itself. Although the waiver of the provisions of the APA left critics less able to contest the promulgation of national consensus standards for a two-year period, with two exceptions every final health standard that OSHA would issue under section 6(b) would be challenged for being based on insufficient evidence.[15] This was to be a very effective means of paralyzing OSHA efforts to regulate under section 6(b).

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12 "Business interests" refers to the Chamber of Commerce, and certain other powerful trade associations, in addition to individual industrial firms.

13 A statement by Richard Berman, in Culhane, supra n. 6 at 1095.

14 Ibid., p. 1096.

15 As was a national consensus standard that was partially revised after the two year period under section 6(b); the successful challenge was based on OSHA's failure to provide grounds for not amending a section of the standard, Associated Industries of N.Y.S., Inc. v. U.S. Department of Labor, 487 F. 2d 342 (2nd Cir. 1973).

In a hearing before the Labor-HEW subcommittee of the House Appropriations Committee, Assistant Labor Secretary George Guenther (the head of OSHA) acknowledged the problem that the Agency was having in issuing health regulations:

> We are the first to concede that there are thousands and thousands of toxic substances for which we do not have standards at the present time. The development of these standards may, some day, catch up to the development of those substances.[16]

Just two days later, Ralph Nader's Center for the Study of Responsive Law issued a 420 page report critical of government, industry and sections of organized labor.[17]

The relationships between OSHA and each of these interest groups have persisted up until the present. Business interests have chided OSHA for issuing meaningless safety regulations, and the Agency has been the butt of a good many jokes for its warning to farmers not to fall when walking in manure, the latter of which has deflected attention away from it's potentially valuable "Cancer Alert Series"[18] designed to inform workers of the real risks they face on the job. At the same time, business has resorted to the Courts, seeking to overturn health regulations issued under sections 6(b) and 6(c).

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16 1973 Appropriations Hearings, supra n. 1 at 448.

17 Published under: Joseph Page and Mary-Win O'Brian, Bitter Wages, New York: Grossman Publishers, 1973. In the introduction Nader writes, "Union leaders with swollen treasuries and shrunken imaginations, have almost uniformly failed to equip their staffs with the skills to locate and detect the full range of job hazards and develop strategies for prevention" (p. xiv). As a footnote, OSHA's solicitor's office hired O'Brian several months after the report appeared (Culhane, supra n. 6 at 1101).

18 Begun in 1978 with More Than A Paycheck: An Introduction to Occupational Cancer.

The AFL-CIO and several of the larger labor unions have acted as gadflies, instigating OSHA to speed up its regulatory agenda. Although critical of the Agency in the early years, organized labor grew less restive when Morton Corn and Eula Bingham were Assistant Secretary (1975-1977, 1977-1981). They were justifiably viewed as being more sympathetic to Labor interests than Nixon's appointees (John Guenther and John Stender) had been.[19] And it seems reasonable to assume that organized labor began to appreciate the regulatory impasse that OSHA found itself in, which was in large part not of its own making.

B. An Informal Evaluation of OSHA's Effectiveness Prior to the Cancer Policy

Determining the effectiveness of government agencies is a very difficult task. In the private sector market price serves as a proxy for "value" and "efficiency" can be interpreted in terms of short and long-run cost curves. Moreover, "consumer sovereignty" argues that what is produced is in response to consumers' expressed demand.[20] None of this is the case for most "goods and services" produced by government since they are exchanged outside the market. Moreover, "demand" is expressed with votes and petitions taking the place of dollars. A vote

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19 According to Sheldon Samuels (director of health, safety and environment of the AFL-CIO's Industrial Union Department), "Corn's exactly the kind of Assistant Secretary designed for the job" (7 National Journal 1725, 12/27/75).

20 The extent to which these are realized is another matter. The assumptions of the competetive model are seldom if ever realized. Moreover, as Galbraith has pointed out, consumers' preferences are often created through misinformation by producers. Thus, although the consumer may be sovereign the producer is regent.

is an insufficient indicator of preference since it is non-differentiable.

For it to be given operational meaning, "administrative effectiveness" must be accorded another interpretation. Effectiveness will be discussed in terms of the following indices:[21]

(1) The number of final standards issued and the length of time of the standard-setting process.

(2) The relationship between the number of criteria documents issued by NIOSH and final health standards issued by OSHA.

(3) The number of standards begun but not completed.

(4) Comments by OSHA officials and the public regarding its effectiveness.

(5) The relationship between the number of health standards issued by OSHA and those issued by other federal agencies with similar powers and constraints.

Even in these terms, it will be difficult to extract a conclusion with the degree of objective certainty which is hoped for. There is no logical and objective standard against which to measure the evidence proffered by each criterion. And there is no reason to believe that there may not exist other, more effective, criteria. One might, for example, compare the ratio of budgetary dollars to regulations issued or lives spared in OSHA to that of other Federal Agencies with similar mandates and constraints.

Although largely self-explanatory, a word should be said concerning these criteria. The evidence from the first four can <u>at most</u> be suggestive of either obstacles in the way of regulating occupational carcinogens or of regulatory inertia on the part of OSHA. But, in

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21 These indices are the authors'.

offering a standard external to OSHA itself, the fifth criterion is somewhat different. For, if it can be shown that the Environmental Protection Agency as well as OSHA has been a lax regulator, then there would be more reason to believe that there is some property exogenous to both (perhaps in the nature of the evidence itself) that has hampered effectiveness.[22] The explanation might be sought elsewhere.

1. There is little doubt that OSHA has spent more time in developing each standard than Congress had envisioned, and than is permitted in the Act. Section 6(b) specifies a timetable according to which the period of time between the issuing of a proposed rule and the final rule should be no more than approximately six months.[23] The listing of a timetable can be taken to suggest that Congress was concerned that standards be issued promptly.

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22 Alternatively, both OSHA and EPA were inefficient regulators, a pmssibility that will be dispegarded. But this observation should reinforce suspicions the reader may have had concerning the difficulty of measuring the effectiveless of government programs.

23 The law is somewhat unclear as to what the period of time should be. Section 6(b) does not mandate a six month period, but rather 120 days plus (by inference) the period of time necessary to announce and hold a public hearing. However, section 6(c) which governs the issuance of emergency temporary standards mandates that the ETS serve as a proposed rule and that, "The Secretary ((of Labor)) shall promulgate a standard under this paragraph no later than six months after publication of the emergency standard as provided in paragraph (2) of this subsection" (emphasis added). Whether this should be read as implying a six month period for 6(b) standards is unclear. In Florida Peach Growers Assoc. v. U.S. Dep't of Labor, the Court does draw this inference (without offering a rationale, however), [489 F.2d 120, 124 (5th Cir. 1974)]. For two contrasting judicial views of whether the timetable is mandatory see National Congress of Hispanic American Citizens v. Usery [554 F.2d 1196 (D.C. Cir. 1977)] ruling that it does not, and overturning National Congress of Hispanic American Citizens v. Dunlop [425 F.Supp. 900 (D.C. Cir. 1975)].

The table on the following page presents the actual schedule that OSHA adhered to in issuing its ten health standards under section 6(b).[24] A number of points can be made with regard to the information contained in this table. First, only four of the rules were issued within an approximate six month limit. Interestingly, these were the four that followed emergency temporary standards. To determine whether this promptness was the result of the ETS, or the ETS itself the result of different political circumstances would require further study however.

The great length suggested by the average, 15.4 months, was largely the result of the arsenic and lead standards. The average of the other eight was less than eight months. Thus, it would be true to say that with these two exceptions standard-setting has been relatively prompt. And it would be fair to say that in general it has been prompt.

OSHA has been criticized even more roundly for the small number of standards that it has issued. Six out of the ten were issued in 1978 based on work performed when Morton Corn and Eula Bingham headed the Agency. With the exception of the generic cancer policy, not one final health standard has been issued since November 1978. One of the concerns of organized labor during the early stages of the development of the cancer policy was that while the policy was in the process of being developed, limited resources would be diverted from regulating individual chemicals. OSHA officials sought to assuage this fear (see following Chapter). But the fear may have been realized.

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[24] By disregarding the often tedious and time-consuming pre-regulatory steps, this table understates the actual time and effort required.

TABLE 13.

REGULATORY HISTORIES OF THE TEN HEALTH STANDARDS ISSUED PRIOR TO THE CANCER POLICY

Substance Name	Type of Action	Date of Publication	Federal Register Citation	Elapsed Time[24]
Asbestos	ETS	12/07/71	36 Fed. Reg. 23207	
	prop. perm rule	01/12/72	37 Fed. Reg. 466	
	final rule	06/07/72	37 Fed. Reg. 11318	6 months
14 Carcinogens	ETS	05/03/73	38 Fed. Reg. 10929	
	final rule	01/29/74	39 Fed. Reg. 3756	9 months
Vinyl Chloride	ETS	04/05/74	39 Fed. Reg. 12341	
	proposed fule	05/10/74	39 Fed. Reg. 16896	
	final rule	10/04/74	39 Fed. Reg. 35890	6 months
Coke-oven Emissions	proposed rule	07/31/75	40 Fed. Reg. 32268	
	final rule	10/22/76	41 Fed. Reg. 46742	15 months
Benzene	ETS	05/03/77	42 Fed. Reg. 22516	
	proposed rule	05/27/77	42 Fed. Reg. 27452	
	final rule	02/10/78	43 Fed. Reg. 5918	9 months
DBCP	ETS	09/09/77	42 Fed. Reg. 45536	
	proposed rule	11/01/77	42 Fed. Reg. 57266	
	final rule	03/17/78	43 Fed. Reg. 11514	6 months
Arsenic	proposed rule	01/21/75	40 Fed. Reg. 3592	
	final rule	05/05/78	43 Fed. Reg. 19584	39 months
Cotton Dust	(ANPR)	(12/27/74)	(39 Fed. Reg. 44769)	
	proposed rule	12/28/76	41 Fed. Reg. 56498	
	final rule	06/23/78	43 Fed. Reg. 27350	18 months
Acrylonitrile	ETS	01/17/78	43 Fed. Reg. 2586	
	proposed rule	01/17/78	43 Fed. Reg. 2608	
	final rule	10/03/78	43 Fed. Reg. 45762	9 months
Lead	proposed rule	10/03/75	40 Fed. Reg. 45934	
	final rule	11/14/78	43 Fed. Reg. 52952	37 months

24 The period of time between the publication of the ETS or the proposed rule (if no ETS was filed) and the final rule.

2. In the OSH Act Congress had envisioned a close working relationship between NIOSH and OSHA. NIOSH, through the Secretary of HEW, was given power to "develop criteria dealing with toxic materials. . . "[25] Section 6(b) authorized the Secretary of Labor to base proposed standards in part upon information provided by NIOSH. As illustrative of the close cooperation envisioned, section 6(b) refers to the Secretary of HEW eight times. Although the standard-setting power rests in the Department of Labor, one might expect that OSHA standards would follow from recommendations of NIOSH. However, through 1978 NIOSH had published entries on at least eighty-nine substances in its series, "Criteria for a Recommended Standard: Occupational Exposure to. . ."[26] Although OSHA has proposed rules for more substances, it has issued final standards for only twenty-three. As further indication of the gap between research and regulation, while the cancer policy was being considered by OSHA, NIOSH prepared for "internal institute review" a list of over three hundred chemical substances that were felt would likely appear as "Category I" carcinogens under the policy.[27] And in 1975 NIOSH published a list of 1500 "suspected carcinogens."[28] Thus, OSHA had been able to set standards for fewer than ten percent of all substances that in the opinion of sections of NIOSH would be regulated under a coherent carcinogen policy.

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25 29 U.S.C.669(a)(3)(1976).

26 U.S. Department of Health and Human Services, NIOSH Publications Catalogue, 4th ed., Cincinnati: NIOSH 1980, pp. 71-78.

27 8 OSH Rptr. 211 (7/13/78).

28 5 OSH Rptr. 129 (6/26/75).

3. Another measure of the effectiveness of standard-setting is the ratio of the number of completed standards to that of total standards proposed or envisioned by the Agency. In March 1974 NIOSH and OSHA announced the "Standards Completion Project."[29] Its goal was to issue completed standards governing monitoring methods, medical surveillance, recordkeeping and housekeeping requirements for the four hundred toxic materials for which consensus standards had been accepted via section 6(a) in 1971.[30] It was also announced that an initial package of forty standards would be released as a pilot program.[31] These were never issued.[32]

In April 1976 OSHA announced drafts of standards for seventeen of the substances.[33] As of the present time a final standard has been issued for only one of them (acrylonitrile).

Guidelines for the seventeen were ultimately published in May 1979 as a purely informational guide after "over a year of delay due to disputes between the Institute and OSHA. NIOSH decided to publish the information after OSHA failed to take regulatory action on recommended

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29 3 OSH Rptr. 1725 (3/21/74).

30 41 C.F.R. 50-204.50 (36 Fed. Reg. 23217; 12/7/71). The consensus standards are listed in Tables Z-1, Z-2, and Z-3 of 29 C.F.R.1910.1000.

31 3 OSH Rptr. 1725.

32 Proposed standards were issued for eleven substances on 10/8/75.

33 41 Fed. Reg. 17640 (4/27/76).

standards for the substances submitted by NIOSH to the Labor Department in 1976."[34]

Another example of the difficulties that OSHA has had in setting standards is its experience with 4,4'methylene bis(2-chloroaniline) (MOCA). One of the fourteen carcinogens for which a standard had been issued in January 1974, the Third Circuit Court of Appeals struck down for procedural reasons the standard governing MOCA.[35] Although reproposed in 1975, it was not reissued. In April 1976 the General Accounting Office sent a letter to Morton Corn asking why OSHA was "taking so long" to republish the standard.[36] In June 1978 a spokesperson for OSHA announced that the Agency was working on a new proposed rule for MOCA. He admitted that there has been "a tremendous underutilization and misutilization of data with regard to MOCA" and that the Government has failed to "properly and expeditiously handle this agent."[37] In January 1979, the Department of Labor included the publication of a proposed rule governing exposure to MOCA within its first semiannual agenda as one of its anticipated actions within the

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34 8 OSH Rptr. 1797 (5/31/79).

35 Synthetic Organic Chemical Manufacturers Assoc. v. Brennan, 506 F.2d 385 (3rd Cir. 1974); cert. den., 95 S. Ct. 1396 (1975).

36 6 OSH Rptr. 268 (7/29/76). The Department of Labor responded by asserting that a standard for MOCA was not a priority, and in any event workers were protected through the "general duty clause" (section 5(a)(1)) of the OSH Act since MOCA is a "recognized hazard."

37 8 OSH Rptr. 179 (7/6/78).

following six months.[38] It was also included in the second and third agendas.[39] A standard has not yet been reproposed.

As indicative of the failure to meet schedules, in February 1978 Grover Wrenn (then director of Health Standards) testified before the House Appropriations Committee regarding the following year's budget. He projected that OSHA would issue eleven health standards in 1978 and seventeen in 1979.[40] In actuality OSHA would publish standards for six substances in 1978 and none in 1979. But as an indication of true expectations on the part of rule-makers in OSHA, these projections should be discounted to a certain extent. It is natural that inflated expectations be offered when seeking funding.[41] But it is illustrative of a certain degree of regulatory inertia.[42] In December 1974 Daniel Boyd who was the Director of Standards at the time promised that by the following March most of the nineteen NIOSH criteria documents will have

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38 44 Fed. Reg. 5578, 83 (1/26/79).

39 44 Fed. Reg.65566, 72 (11/13/79) and 45 Fed. Reg. 37648, 54 (6/3/80). The agenda was required under President Carter's Executive Order 12044 on Improving Government Regulation.

40 U.S. House Committee on Appropriations, Departments of Labor and Health, Education and Welfare Appropriation for 1979, pt. 1, 95th Cong., 2nd sess. 639.

41 Aaron Wildavsky speaks of the opportunity that hearings present for an agency to create a favorable portrait of itself. But he also warns of the danger of an agency's making predictions to which it can be called account to (The Politics of the Budgetary Process, Boston: Little, Brown & Co. 1964, pp. 87, 97).

42 Another indication is the number of rules proposed but not finalized.

been acted upon. "And then we will stay caught up, because we'll have the resources."[43]

4. The promises were never fulfilled. Over time there has grown a realization on the part of many of these same people that the obstacles are almost inexorable. But it is not for lack of will that OSHA has been able to issue only eleven health standards.[44]

In 1974 Bert Cottine was a staff attorney with Ralph Nader's Health Research Group, which was perhaps, OSHA's most unrelenting critic. In an interview Cottine mentioned that there should not be more than nine months between the release of a criteria document by NIOSH and the final standard by OSHA.[45] In 1977 Cottin was appointed Eula Bingham's special assistant to help her "in developing OSHA policy."[46] Eula Bingham herself was dedicated to improving the quality of health of the American worker. Yet, after the flurry of standard-setting in 1978 (which was significant, largely in comparison to what had preceded) OSHA issued no additional final standards aside from the cancer policy.

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43 Linda Demkovich, "Labor Report/OSHA Launches Dual Effort to Reduce Job Health Hazards," 6 National Journal 1831, 35 (12/7/74).

44 But this may have been the case during the Nixon Administration (and perhaps also during the present Administration). Evidence for this during the Nixon Administration is had from the "Guenther memo" from Assistant Secretary Guenther to Laurence Silberman, Undersecretary of Labor. This memo discussed "the great potential of OSHA as a sales point for fund raising and general support by employers" and sought suggestions "as to how to promote the advantages of four more years of properly managed OSHA for use in the campaign." (Ibid.).

45 Demkovich, supra note, at 1833.

46 U.S. House, Committee on Government Operations, Performance of the Occupational Safety and Health Administration, (Hearings), 95th Cong., 1st sess., 74 (1977).

5. OSHA is not the only federal agency with a mandate to control toxic substances. It is not even the principal agency with this directive. Without a doubt this distinction is held by the Environmental Protection Agency.[47] Its budget for promulgating regulations is far larger. Examining EPA's experience issuing standards for toxic pollutants under the Clean Air Act and the Federal Water Pollution Control Act, one sees that OSHA's experience is not unique. Section 112 of the Clean Air Act (enacted in 1970) gives the Administrator of EPA the power to regulate "hazardous air pollutants." Yet only four substances are controlled under it (asbestos, beryllium, mercury and vinyl chloride).[48] Section 307(a) of the 1972 Amendments to the Water Act gives the Administrator the power to control toxic pollutants entering the nation's waterways. Yet, at present, only six chemicals or chemical families are controlled thereunder (aldrin/dieldrin; DDT, DDD, DDE; endrin; toxaphene; benzidine; and PCB's).[49] This provides evidence of a sort that "blame" for OSHA's apparent inactivity does not lie wholly on the Agency itself, but in some property of the general regulatory environment.

C. Analysis

The important question is what caused standard-setting under section 6(b) to move so slowly, and then to stop completely. One important explanation lies in the fact that every standard issued under section 6(b), with the exception of two, was challenged in the Courts by

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47 EPA administers six laws dealing with exposure to carcinogens: The Clean Air Act, the Water Act, the Resource Conservation and Recovery Act, the Safe Drinking Water Act, the Toxic Substances Control Act, and the Federal Insecticide, Fungicide, and Rodenticide Act.

48 40 C.F.R. 61 (1981).

49 40 C.F.R. 129 (1981).

either industry or labor interests. One journalist wrote in 1974, "About the only thing that can be said with any certainty concerning the health standards program of the Occupational Safety and Health Administration is that legal challenges. . . will result."[50] This prediction has proven to be fairly accurate. With the exception of the standards for DBCP and acrylonitrile every one has been challenged. One explanation why the DBCP standard was not is that it was no longer in production in the United States in 1978.[51] Following are the ultimate decisions of the nine standards that have been challenged:

asbestos:	Industrial Union Dep't v. Hodgson, 499 F.2d 467 (D.C. Cir. 1974): upheld in general.
14 carcinogens:	Dry Color Manufacturers' Assoc., Inc. v. Dep't of Labor, 486 F.2d 98 (3rd Cir. 1973): reversed; Synthetic Organic Chemical Manufacturers' Assoc. (SOCMA) v. Brennan, 503 F.2d 1155 (3rd Cir. 1974): upheld in general; SOCMA v. Brennan, 506 F.2d 385 (3rd Cir. 1974): reversed in part (MOCA).
vinyl chloride:	Society of Plastics Industries v. OSHA, 509 F.2d 1301 (2nd Cir. 1975): upheld.
coke-oven:	American Iron and Steel Institute v. OSHA, 577 F.2d 825 (3rd Cir. 1978): upheld.
lead:	United Steelworkers of America v. Marshall, 647 F.2d 1189 (D.C. Cir. 1980): upheld in part, reversed in part.
arsenic:	ASARCO, Inc. v. OSHA, 647 F.2d 1 (9th Cir. 1981): reversed.
benzene:	Industrial Union Dep't v. American Petroleum Institute 448 U.S. 607 (1980): reversed.
cotton dust:	American Textile Manufacturers' Institute v. Donovan, 452 U.S. 490 (1981): upheld.
cancer policy:	American Petroleum Institute v. OSHA, No. 80-3018 (5th Cir.): pending.

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50 Linda Demkovich, supra n. 42 at 1839.

51 The ETS for acrylonitrile has been unsuccessfully challenged in Vistron Corp. v. OSHA, 6 OSHC 1483 (6th Cir. March 28, 1978).

The pressure that this places is not only on the Solicitor's Officeto meet the legal challenge in Court. It also places a strain on the authors of the rules, to write standards with sufficient basis in fact as well as law to be successfully defended. An indication of a growing concern in the Agency is in the increasing length of the preambles to the health standards over time. Normally a preamble is published along with the regulation in the Federal Register. It is meant to serve as explanation of and justification for the regulation itself. Whereas the preamble to the asbestos standard took up barely one page in the Federal Register (37 Fed. Reg. 11318-19), the preamble to the lead standard occupied fifty-five pages (43 Fed. Reg.52952-53007). The cancer policy merited a preamble of three hundred pages.

The strict scrutiny that courts of appeal direct toward Agency decisions has forced the decisionmaking process to evolve during the decade of the seventies. There is no denying that courts of appeal have played an active role in reviewing the procedural ingredients of many rulemakings.[52] It has been suggested that this has contributed to a less than optimally efficient rulemaking procedure.[53] Whether this close scrutiny will continue is a subject of debate. Referring to the

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52 See International Harvester v. Ruckelshaus, 478 F.2d 615, 30-31 (D.C. Cir. 1973); Portland Cement Assoc. v. Ruckelshaus, 486 F.2d 375, 400 (D.C. Cir. 1973); Mobil Oil Corp. v. FPC, 483 F.2d 1238, 57 (D.C. Cir. 1973).

53 Paul Verkuil, "The Emerging Concept of Administrative Procedure," 78 Columbia Law Review 258, 310 (1978); Thomas McGarity, "Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA." 67 Georgetown Law Journal 729, 54 (1979). Also generally, Stephen Williams, "'Hybrid Rulemaking' Under the Administrative Procedure Act: A Legal and Empirical Analysis," 42 U. Chicago Law Review 401 (1975).

unanimous opinion of the Supreme Court in Vermont Yankee Nuclear Power Corp. v. NRDC,[54] one commentator suggests that "Monday morning quarterbacking" of agency procedural choices will not be tolerated any longer.[55] However, a noted environmental lawyer views close scrutiny as persisting, the decision in Vermont Yankee notwithstanding.[56] Whatever may happen in the future, OSHA has adopted procedural requirements for standard-setting which begin to bridge the gap between informal rulemaking and adjudication, with corresponding loss of efficiency. Although not required, the public hearings under section 6(b) are held before an administrative law judge.[57] Cross examination of witnesses is permitted and extensive.[58] According to a source in OSHA, only loosely

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54 435 U.S. 519 (1977). The Court concluded that in the face of this judicial activism agencies "would undoubtedly adopt full adjudicatory procedures in every instance" and that "not only would this totally disrupt the statutory scheme. . . but all the inherent advantages of informal rulemaking would be totally lost." (at 547).

55 Verkuil at 310n.

56 William Rogers, "A Hard Look at Vermont Yankee: Environmental Law Under Close Scrutiny," 67 Georgetown Law Journal 699 (1979).

57 29 C.F.R. 1911.15(b)(1)(1981).

58 29 C.F.R. 1911.15(b)(2)(1981).

imposed constraints exist on repetition and relevancy.[59] Rule-makings grow longer.

All rulemaking procedures by federal agencies must seek a balance between the fair treatment of claims of individuals and the interests of government or society as expressed in the statutory mandate of the Agency. However, in concrete instances it is rarely entirely clear what rights of "due process" entail.

> What procedures are required [for due process] must reflect a careful balance between, on one scale, the nature of the right affected and the consequences to the right-holder of its loss, and on the other, the administrative burden imposed on the agency.[60]

"Individual rights" is an amorphous concept. In reviewing administrative decisions, therefore, Courts have by and large, sought to preserve these rights by constructing an elaborate and flexible web of procedural responsibilities within which agencies must operate in informal as well as formal rulemaking. But this is based on the belief that the Agency possesses greater expertise in reasoning on the facts. Moreover, even where special expertise is not required to make the decision, the Supreme Court has ruled that, "[A] court may [not] displace the [agency's] choice between two fairly conflicting views, even though the court would justifiably have made a different choice had the matter been before it de novo."[61] Underlying it is the assumption that procedures that conform to this structure will thereby conform to

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59 Verkuil, p. 308: referring to an interview (11/14/77).

60 City of Santa Clara, Cal. v. Kleppe, 418 F. Supp. 1243, 60 (N.D. Cal. 1976).

61 Universal Camera Corp. v. NLRB, 340 U.S. 474, 88 (1951).

due process mandates.[62] Or, to be more exact, that this structure offers the best combination of governmental efficiency and individual rights.

> Judicial review must operate to ensure that the administrative process itself will confine and control the exercise of discretion. . . When administrators provide a framework for principled decisionmaking, the result will be to diminish the importance of judicial review by enhancing the integrity of the administrative process, and to improve the quality of judicial review in those cases where judicial review is sought.[63]

When nearly every standard is challenged in the Courts the review process becomes an extension of the administrative process. OSHA issued the final standard for organic arsenic in May 1978, to take effect three months later. Yet, the fact that the Court did not reach an opinion until 1981 (and then vacated the standard) demonstrates this clearly. It was for this reason that OSHA experimented with the generic cancer policy. The motivation is discussed in somewhat greater detail in the next section. The Conclusion to Part III will suggest that the desire was based upon a misperception of the nature of the rulemaking/judicial review process. In part, the error rests on the observation just made that the judicial review process is largely directed toward procedural rather than factual issues. But the motivations and the rationales for generic rulemaking are nevertheless significant.

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62 Not to beg the question, it must be granted that there are Courts that have ruled that in informal rulemaking due process does not demand procedures more rigorous than those delineated by Congress eg. Association of Nat. Advertisers, Inc. v. FTC, 627 F.2d 1151, 65 (D.C. Cir. 1979).

63 Environmental Defense Fund v. Ruckelshaus, 439 F.2d 584, 98 (D.C. Cir. 1971).

D. The Motivation for Generic Standards

As stated above, one of the motivations behind generic rulemaking is the desire to "disenfranchise" federal courts. The architects of OSHA's generic cancer policy saw the ability of parties to seek judicial review of evidentiary questions as the root cause of the Agency's apparent failure to meet the mandate of the OSH Act. As will be discussed in the following Chapter there was a belief that once the policy was in place, standards would almost issue themselves. This is a natural belief to hold in the face of the widespread depiction of the courts as being the primary cause of regulatory delay.

OSHA was not the first federal agency to have the idea of regulating generically. The effectiveness of Emergency Core Cooling Systems (ECS) in nuclear power plants has been contested very often. In at least two instances (Shoreham and Indian Point Unit No. 2) there were lengthy suits regarding core-cooling criteria.[64] In November 1971, the Atomic Energy Commission proposed criteria to govern ECCS's. The final rule was issued in January 1974.[65] "But the result, agency officials find, has been to remove this time-consuming issue from contention in subsequent licensing proceedings."[66] The attempt of the Consumer Product Safety Commission to propose a generic regulation under the

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64 U.S. Congress, Senate, Committee on Government Affairs, Study on Federal Regulation: vol. iv, "Delay in the Regulatory Process," 95th Cong., 1st sess., 1977, p. 160.

65 10 C.F.R. 50.46; 39 Fed. Reg. 1002 (1/4/74).

66 Study on Federal Regulation, supra n. 64 at 160; referring to a letter from I.C. Roberts, Assistant Director for Site and Health Standards, Office of Standards Development, NRC (4/22/77). But the relevant question is how this has affected the efficiency of the overall licensing process (including judicial review). As will be suggested in the next Chapter, there are innumerable ways to slow down standard-setting, if that is one's desire.

Child Protection and Toy Safety Act has been less successful.[67] McGarity refers to "numerous occasions in which Federal Courts have encouraged Agencies to issue general rules."[68]

Any generic rule stems from a belief that, spaped from having to decide empirical issues in rulemaking and to repetitively defend decisions in the judicial system, the standard-setting process will run faster and more smoothly. Yet a distinction should be drawn between two types of generic policy processes. One, like the potential toy safety standard, would expedite both standard-setting and litigation by making an initial determination to group specific objects of regulation together. Thus, all dolls would be regulated in the same standard. The advantages to efficiency would likely be great. The second type of policy, like OSHA's (as shall be seen in the following Chapter) would possess more restricted advantages because it would not dispense with the necessity to issue separate standards for each object of regulation. OSHA would still need to adhere to the procedural provisions of section 6(b) for each substance. What such a policy seeks to do is simply answer by regulatory fiat several of the evidentiary questions (that were discussed in earlier Chapters of this paper) that have recurred in judicial review of OSHA (and EPA) actions and thereby to render them non-justiciable in future challenges to standards. What the policy does not do is seek to expedite standard-setting by, say, issuing one regulation governing all halogenated compounds. Regulations will not be

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67 Ibid., pp. 17-20. A generic rule was never issued in spite of the ruling by a Federal Court that the Commission was "under an obligation to attempt to promulgate general prospective regulations" (p. 18).

68 McGarity, supra n. 53 at 756.

based on less evidence.[69] Data will still need to be gathered and analyzed. In the following Chapter, it will be suggested that these objectives are modest to a fault (and that the furor over the policy has been a tempest in a teapot).

Following is a brief presentation of two rationales for a generic cancer policy, each one based on a different conception of justice. The first is consistent with utilitarian principles, the latter is not.

E. Two Rationales for "Rule-Based" Standards

Two rationales can be given for "rule-based" standards. One is that they contribute to effectiveness in rulemaking. The other is that they can contribute to a greater degree of justice. These rationales are now discussed.

1. As John Rawls pointed out in "Two Concepts of Rules," the distinction between justifying a practice and justifying a particular action falling under it is central to many discussions of justice.[70] However, it has not yet been clearly applied to discussions of regulatory justice. In this section, some aspects of the problem will be sketched out.

At present, the justification for regulatory actions restricting the use of suspect carcinogens is ordinarily sought in the extent of the

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69 However, they would be subject to less flexible of an interpretation.

70 John Rawls, "Two Concepts of Rules," 64 Philosophical Review 3 (1955).

utility and or justice achieved through each particular action.[71] This Chapter has already shown that seeking to justify its health regulations substance-by-substance has contributed to an effective inability on the part of OSHA to control workplace health hazards. It has been unable to meet its mandate to protect the American worker.

But most human behavior follows a different logic than that applied by OSHA to regulate substance-by-substance. Most of our behavior, and many of our actions, is generated by applying an independently derived rule to an individual fact situation. We get out of bed in the morning in response to the alarm without giving a thought to the consequences. We greet our friends when we see them, not because each time we do we decide that it makes sense to, but because we follow a rule that in general it makes sense to.

Groups of people, from fraternities to nations, also institute rules to order behavior.[72] As Rawls points out, behind this version (which he terms the "summary view") of rule-based actions lies a two-fold rationale. First of all, "The point of having rules derives from the fact that similar cases tend to recur and that one can decide cases more quickly if one records past decision in the form of rules."[73] It is simply more practical to base action upon pre-specified rules than

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71 As the next Chapter should demonstrate, section 6(b) attempts to juggle both aspects of justice. The ambiguity of Congress' intentions has contributed to the confusion. Through a reading of the regulatory histories of various OSHA health standards, one finds one set of interest groups arguing its substantive position using a utility-based rationale, and another set of groups its position with one stressing distributive justice.

72 The nature of the distinction that Rawls draws between the summary view and the practice view is not relevant here. Suffice it to say that for Rawls there are certain rules whose justification is of a different sort.

73 Rawls, supra n. 69 at 22.

to judge each choice independently. In the language of economics, the information costs are lower. In the case of toxic substance regulation, rules governing individual substances can be promulgated more quickly, at least prima facie.

Secondly, acting from a rule will make sense under the following conditions:

> One is pictured as estimating on what percentage of the cases likely to arise a given rule may be relied upon to express the correct decision, that is, the decision that would be arrived at if one were to correctly apply the utilitarian principle case by case. If one estimates that by and large the rule will give the correct decision, or if one estimates that the likelihood of making a mistake by applying the utilitarian principle directly on one's own is greater than the likelihood of making a mistake by following the rule, and if these considerations held of persons generally, then one would be justified in urging its adoption as a general rule.[74]

In the situation that Rawls depicts the decision-maker is faced with a set of choices $(x_1, \ldots, x_n)$ which he can judge individually on their merits or apply a rule to. For two reasons the case of applying a rule to regulating suspect carcinogens (or toxic substances in general) is quite complex and argues persuasively for deciding with a rule.

First, as was argued in Part II, information costs for making a well-reasoned decision on the carcinogenicity of a substance are exorbitant. Indeed, if the estimate of the dimensions of evidentiary uncertainty is correct, this information is unattainable. If so, the most that can ordinarily be expected from a substance-by-substance approach is an identification of "X" as a carcinogen or a non-carcinogen (for regulatory purposes) with at least a fair amount of certainty, a

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74 Ibid., p. 23.

choice of a framework for regulating it containing conspicuous value assumptions and (if appropriate) a measurement of the degree of risk and benefit posed by the substance with a large degree of uncertainty attached. The opportunity cost of deciding with an informed rule is less than it would be were a substance-by-substance approach more reliable.

The second reason why the case of regulating toxic substances is more complex than might be suspected from Rawls' depiction also argues more strongly for a "generic" approach to regulation. The reason should be apparent from the history of regulatory inertia that was presented in the first sections of this Chapter. The choice of whether to regulate generically or not is not between whether $(x_1, \ldots, x_n)$ should be judged on their merits or according to a pre-specified rule. Rather, it is whether more than a few of them will be judged at all.

Ignoring distributional considerations for the moment, prima facie it involves a choice between whether to make a small number of regulatory determinations with the great amount of uncertainty that was sketched in the preceding Chapters or to make a much larger number of determinations, each with a somewhat larger degree of uncertainty. Accepting a generic (or rule-based) approach involves a tradeoff between additional evidentiary uncertainty and greater protection of workers for the added cost that such protection involves. Unfortunately, it is impossible to decide whether this tradeoff is beneficial since none of these parameters is quantifiable (as was demonstrated earlier).

2. In principle, there are likely to be radical distributional consequences in any generic cancer policy.[75] That is, the benefits and costs of a successful policy will be large and will fall on different individuals. As will become apparent in the following Chapter, it is this that has motivated most of the comment on OSHA's policy. Typically, OSHA's cancer policy has been viewed negatively by most business interests and favorably by most labor unions.[76] A reasonable explanation is that the policy has been perceived by "industry" as potentially adding to the costs of doing business (lowering production levels and profit rates). "Labor" has perceived it as potentially mitigating occupational risks. To the extent that the benefits and costs of a decision fall on different parties, are non-transferable, these parties are aware of them, and they possess a political voice, being self-interested each will seek to influence the decision to its own ends. Each "side" will appeal to principles of justice in stating its case (as will be illustrated in the following Chapter). In effect, each "side" seeks to shift the burden of evidentiary uncertainty off its own shoulders. And it is politically more acceptable to do this by

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75 The extent of the consequences will depend upon how "radical" the policy is.

76 Exceptions will be discussed in the next Chapter.

appealing to universal standards of justice and fair play that are on its side.[77]

Organized labor interests argue that justice is not served when small groups within society face unreasonable risks to health that others do not. Although disagreement may arise over the criteria of relevance, it seems to be generally agreed that justice involves "treating equals equally and unequals according to their relevant inequalities."[78] It is this principle of justice that is appealed to in support of strong regulation of suspected workplace risks. Government action that served to mitigate even probable unequal treatment would be a just act. An effective generic policy would shift some of the unequal burden of risk off of the shoulders of workers by shifting away a greater share of the burden of evidentiary uncertainty.

Seeing a generic policy as a means of circumventing a full and careful hearing of the issues of each unique case, business interests argue that it is a violation of the principle of justice contained in the Fifth Amendment's prohibition of Government action that deprives people of property without due process of law.[79] The Fifth Amendment seeks to guarantee that there will be no harm from reckless behavior on

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77 How do people arrive at the principles of justice that they espouse? By observing that most principles tend to be self-serving, it is hard not to arrive at the conclusion that they are meant to be. Do business people go into business because they believe in due process of law?

78 See S.I. Benn, "Justice," Encyclopedia of Philosophy, vol. 4, New York: The MacMillan Company and The Free Press, 1967, p. 301. This is the principle of distributive justice expressed by Aristotle in Nicomachean Ethics, Book V., Chapter 3.

79 "The impartial and consistent administration of laws and institutions, whatever their substantive principles, we may call formal justice." (John Rawls, A Theory of Justice, Cambridge: Harvard University Press, 1971 p. 58.

the part of Government. This has the result of shifting the burden of uncertainty off the shoulders of those who believe that they stand to lose through more effective Government control of carcinogens and onto the shoulders of those who stand to gain.

Distributional implications of a regulation like the cancer policy are significant in principle. It might be wondered, therefore, why greater attention is not paid to the questions of distributive justice. These questions are of even greater significance than normal when the actual extent of the effect of the regulation on utility is less certain (as is the case here) than of the distributional efforts.

3. This section has offered two rationales for a "generic" policy to control workplace health hazards. The first, along the lines of a rule utilitarian justification argues for the greater efficiency of a rule-based policy. The second justification is that of its leading to greater distributive justice. Also mentioned was the potential violation by the policy of the principle of due process of law and the dilemma that arises in theory between enforcing this principle and mitigating the burden of evidentiary uncertainty that rests largely on the shoulders of the worker exposed to suspect carcinogens. This is not intended to be more than suggestive of what in actuality deserves a much fuller discussion.

Through this Chapter the regulatory predicament that OSHA found itself in in its attempts to control workplace health hazards has been sketched. Also discussed has been the motivation for developing a generic policy and two rationales behind regulating carcinogens according to a rule-based system. The following Chapter contains a discussion of the development of the generic cancer policy by OSHA. The

conclusion of this Part contains a short evaluation of the likely limits of generic rulemaking of the sort envisioned by the policy's architects.

CHAPTER SEVEN

THE RISE AND FALL OF OSHA'S "GENERIC" CARCINOGEN POLICY[1]

A. Introduction

In its generic cancer policy OSHA sought to expedite rulemaking by "solving" through regulatory fiat the evidentiary uncertainty which the Agency felt, left unanswered, was the major cause of the growing backlog of suspect carcinogens for which standards had not been issued. In this Chapter the development of the policy will be examined and its potential significance to rulemaking will be assessed.

Judging from the rhetoric of the involved parties, it was a politically significant rulemaking. Testifying in support of the proposal's rejection of cost-benefit analysis as a means of determining "permissible exposure levels" an economist from the United Steelworkers of America invoked the Ten Commandments:

> What we are involved in is a simple but meaningful thing, the commandment that in civilized society thou shalt not kill. The proponents of cost-benefit analysis would have us believe that it is all right to kill if not killing is too expensive.[2]

Using language that could serve equally well to express the views of the policy's opponents the President of Clement Associates, a consulting firm that was intimately involved in the policy's development asserted (perhaps self-servingly) that it had the "potential to be the most

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1 This Chapter should be read with Tables 15-17.

2 James Smith as quoted in Timothy Clark, "Cracking Down on the Causes of Cancer," 10 National Journal 2056 (12/30/78).

important federal declaration [on carcinogens] since the Delaney Clause."[3]

The policy's critics were just as insistent, arguing that it was the "single most important regulation industry has faced this year" and that the "implications are monumental."[4] A spokesperson for the Chamber of Commerce criticized it as an example of "regulatory extremism" and called it the "king pin" of federal health regulations because of its broad impact on business.[5] Moreover, it spawned its own trade association, the American Industrial Health Council (hereafter, "Council" or "AIHC"), with the single aim of influencing OSHA to produce a policy favorable to the interests of its members.

It has been a significant rulemaking in many other respects as well. It marked the first attempt by any of the federal Agencies charged with controlling carcinogens to institute a coherent policy that would govern its activities in this area. It was a forum for the discussion and debate of the regulatory framework, and an examination of the proper role of Agencies toward carrying out their mandates in the presence of radical uncertainty.

It was also significant in terms of sheer time and effort involved. Three years elapsed form the issuance of the draft proposal in January 1977 to the publication of the final rule in January 1980. The formal

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3 John Kolojeski as quoted in "Carcinogen rule seen equal to Delaney," Chemical Marketing Report, vol. 211, (6/6/77), p. 3.

4 Ronald Lang of the Synthetic Organic Chemical Manufacturers' Association (SOCMA) as quoted in "Carcinogen Crackdown Proposed," Chemical Week, vol. 121, (10/12/77), p. 18. Lang was to be active in the American Industrial Health Council.

5 Mark de Bernardo at a Chamber of Commerce conference in Chicago on December 6, 1979, as cited in 9 Occupational Safety and Health Reporter 670 (12/13/79).

hearings lasted for over two months, producing a record of 250,000 pages. Moreover, the quality of the testimony at the hearings was peerless. The list of witnesses reads like a veritable Who's Who of cancer researchers.[6] The preamble of the final rule, which presents OSHA's position on many of the issues of evidence and law that had been continually discussed and debated by both experts and non-experts, and which presents the Agency's reasoning on these issues covers three-hundred pages in the Federal Register.

The final rule, which is presently being reconsidered by the Reagan Administration, has now spanned three Administrations in its development, and is likely to reach into a fourth before it becomes effective.[7]

B. The Genesis of the Idea and the Draft Proposal

For all of the hoopla accompanying its birth and public development, the policy had a deceptively ordinary period of gestation after an accidental conception. In 1976 Morton Corn was Assistant Secretary of Labor for Occupational Safety and Health and Grover Wrenn was Director of Health Standards. In early 1976 CBS aired a series on cancer. One of the programs was called "The Politics of Cancer." A reporter who came to interview Corn prior to taping asked him, "What's OSHA's policy for regulating carcinogens?" Corn went to Wrenn asking

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6 It almost has a flavor of being a recasting of "Showdown at the OK Corral" in which witnesses ("hired guns") for and against refute ("gun down") the testimony of their opponents.

7 Although most of the policy is nominally in effect (and has been since April 1980) it has remained unused (the immediate reason being that there have been no new rulemakings regarding carcinogens since then).

him the same question. According to one account by Wrenn he responded, "We don't really have a policy, though there are common threads in the standards we've issued so far."[8] According to another account he responded that the Agency had one "implicitly."[9]

> That question from CBS really got us started on developing a cancer policy. We saw that with different chemicals and different situations the agency had come to the same general policy conclusions. So we decided to try to answer some questions conclusively. It doesn't make sense to revisit - and re-litigate - the same questions over and over again. It appeared there was an ultimate truth, that we could deal with some questions in a generic, conceptual way.[10]

The chief architect of the policy was Anson Keller who had been involved in the aldrin/dieldrin rulemaking while at EPA.[11] In the spring of 1976 Wrenn and Keller assembled a group of scientists "in a motel room in Bethesda" to begin to design a cancer policy for OSHA.[12]

Explaining the decision to act, Ray Marshall, who was Secretary of Labor in the Carter Administration, observed that "trying to control carcinogenic substances on a case-by-case basis is like trying to put

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8 10 National Journal 2056, 57 (12/30/78).

9 Personal interview of the author with Grover Wrenn (1/11/81).

10 10 National Journal 2056, 58 (12/30/78).

11 EPA suspended the registrations of the pesticides aldrin and dieldrin on October 1, 1974 under section 6(b) of the Federal Insecticide, Fungicide and Rodenticide Act, 7 USC 136d(b). The suspension was upheld in Environmental Defense Fund v. EPA, 510 F.2d 1292 D.C. Cir. (1975). In 1977 EPA prohibited their discharge into the Nation's waters, 40 C.F.R. 129.100; 42 Fed. Reg. 2613 (1/12/77) under section 307(a) of the Federal Water Pollution Control Act, 33 USC 1317(a).

12 Personal interview with Grover Wrenn (1/11/81).

out a forest fire one tree at a time."[13] OSHA had been receiving a great deal of criticism from both business and labor interests for a perceived set of misplaced priorities in enforcement as well as rulemaking, which stressed safety "at the expense of health." The Agency was ripe for a radical change.

In an interview in 1981, several months after he had left the Agency to work for Clement Associates, Grover Wrenn responded to the question of why OSHA, as opposed to EPA, had been the first agency to seek to develop a coherent cancer policy by citing several reasons.[14] He replied that first, OSHA was much smaller. As a result, there was less bureaucratic inertia. Lines of communication were more direct. It only administers one law, and as a result the case law is more consistent and easier to design a policy around. Furthermore, both Morton Corn and Eula Bingham were scientists. Lastly, Wrenn gave chief responsibility and credit for the policy to Anson Keller whom he termed "literally a brilliant individual." Also, because Keller was in contact with many of the leading researchers, he was able to obtain advice and support when necessary.[15]

The remainder of the year was spent developing a draft proposal. In September the House Committee on Government Operations issued a

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13 "Carcinogen Crackdown Proposed," Chemical Week, vol. 121, (10/12/77), p. 18.

14 Interview of 1/11/81.

15 One last reason Wrenn offered was that the Executive as a whole was not well-disposed to generic policies. As he pointed out, the Interagency Regulatory Liaison Group (IRLG) which was comprised of, and was intended to coordinate the policies of EPA, OSHA, CPSC, and FDA did not advocate the adoption of explicit policies. Its position was that the regulatory response should be flexible.

report entitled Chemical Dangers in the Workplace.[16] The report was critical of OSHA's performance regulating carcinogens and it suggested that the Agency develop a mandatory system of identifying toxic substances in the workplace, rather than waiting for the tortuous process of issuing standards on an agent-by-agent basis.

In November the nation elected a new President. However, in OSHA there probably was not the anxiety and indecision that normally would accompany a change of Administration.[17] There appeared to be broad support for Morton Corn among both labor and business interests. And there was even reported to be uncertainty whether the Democratic Administration would replace him.[18] But ultimately he did resign. In a press conference on January 13, 1977 Corn announced his resignation and, pointing out that a substance-by-substance method was "self-limiting," disclosed that OSHA was on the verge of issuing a draft of a comprehensive generic proposal.[19]

The draft was formally announced a week and a half later on January 24.[20] After presenting the rationale for the policy, Grover Wrenn predicted that it could be in use within a year. This was to be the first of the serious underestimates by OSHA officials of how long the process would take. The final rule would not be issued for three years. Wrenn also predicted that the policy could result in a permanent

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16 U.S. House, Committee on Government Operations, Chemical Dangers in the Workplace, 94th cong., 2nd sess., 1976.

17 The contrast with the following change of Administration could not be starker.

18 6 OSH Rptr. 947 (12/30/76).

19 6 OSH Rptr. 1075 (1/20/77); He returned to the faculty of the University of Pittsburg School of Public Health. Bert Concklin continued as Deputy Assistant Secretary.

20 6 OSH Rptr. 1107-8 (1/27/77).

standard being issued within eight months of the proposal as opposed to the more than two years it took to issue the coke-oven standard.[21]

The draft was immediately sent to the National Advisory Committee on Occupational Safety and Health (NACOSH) for its comments.[22] The standards subcommittee began its consideration three days later on January 27.[23] But the discussion wasn't very focused since not all of the members had had time to study it. Apparently, the chairperson of the subcommittee had not received a copy until only a short time before the session began. But not everyone was at this disadvantage. Nicholas Ashford, while commending OSHA for "such a vigorous attempt" criticized its underemphasis on mutagenicity tests as a criterion for categorizing substances and the failure to include structural similarity as another criterion.[24]

NACOSH continued its discussions at a meeting of the standards and policy budget subcommittees on February 17.[25] Spokespersons for

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21 In fact, 15 months had elapsed between the proposed rule and the final rule for coke-oven emissions.

22 NACOSH was formed through section 7(a) of the OSH Act to "advise, consult with, and make recommendations" related to administering the Act. It is composed of twelve members appointed by the Secretary of Labor and must meet at least twice a year.

23 6 OSH Rptr. 1136-7 (2/3/77).

24 OSHA responded to both these criticisms in the final rule. A word of clarification is necessary with regard to the first of these objections. In the discussion of "short-term" tests in Chapter Four. I referred to the distinction between their use as a priority-setting device on the one hand, and as a standard-setting mechanism on the other. I pointed out that the inherent uncertainty surrounding this mechanism makes it a more appropriate tool for the first function than for the second. In OSHA's draft proposal, these two functions were blurred. For once a substance is classified into Category I, a standard will issue without any further scientific evidence. So, using short-term tests as a priority-setting (categorizing) mechanism under the scheme would be tantamount to using them to set the standard itself. And Ashford's criticism needs to be read with this in mind.

25 6 OSH Rptr. 1229-30 (2/24/77).

business and labor offered comments. The comments of industry representatives fmaused ml a perceived failure of the policy to appreciate the complexities of carcinogen identification and assessment. The proposal ignores "the difficulties and the complexities of evaluating occupational risk relating to carcinogens." Each substance "must be considered on its own and the criteria appropriate for one agent may not necessarily apply to another."[26] Another spokesperson argued that the details of an experiment are important mediating factors of the nominal conclusion reached. Dosage and duration of exposure, for example, have an impact on the sensitivity of the test, and provides information that can be used to infer the substance's potency. In refusing to consider this evidence OSHA is, in effect, throwing away information.[27]

This criticism will recur over and over again. The reader is referred to Part II where other mediating factors were discussed and the degree of uncertainty surrounding each was assessed. OSHA's rationale for discounting most of them was its conclusion that the information that they offer is unreliable due to a perceived uncertainty.

Eula Bingham took office as Assistant Secretary of Labor for Occupational Safety and Health on March 23.[28] In her confirmation hearings before the Senate Human Resources Committee she had taken a strong stand in favor of OSHA's responsibility to protect workers against health hazards.[29] Without endorsing the draft in particular, she did support the generic approach: "I intend to review this proposal

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26 Ibid., p. 1229. (a comment by a spokesperson for SOCMA).

27 Ibid.

28 6 OSH Rptr. 1323-4 (3/24/77).

29 Ibid.

very carefully and would be favorably disposed to any such [generic] approach which would significantly improve OSHA's ability to act in this area."[30]

Meanwhile, interested parties were seeking to influence NACOSH. In a letter on April 1, the Manufacturing Chemists Association presented its case for a substance-by-substance approach to standard setting.[31]

On May 5, based on a recommendation of the standards and policy/budget subcommittees, NACOSH suggested that the draft be published "solely for the purpose of information gathering" and then issued as a statement of policy.[32] Although endorsing "OSHA's general attempt" the subcommittees had declined to endorse the policy itself.[33]

On May 27 Eula Bingham spoke before the National Press Club. In her speech she strongly supported the policy. "We must go the generic standards route."[34] She also predicted that the proposal would be ready for publication in September.

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30 Ibid., p. 1324. Bert Concklin announced that he would resign within 2 to 3 months (on 1325).

31 6 OSH Rptr. 1418 (4/14/77).

32 6 OSH Rptr. 1545 (5/12/77).

33 6 OSH Rptr. 1388 (4/7/77). NACOSH is composed of both labor and business interests. It might be expected to be, therefore, somewhat conservative and consensus-seeking.

34 7 OSH Rptr. 3 (6/2/77).

The Society for Occupational and Environmental Health held a conference in Washington on June 2 to discuss the cancer policy.[35] Put into the position of defending the policy against objections from both business and labor representatives, Grover Wrenn had perhaps the impossible job of making it appear reasonable to both interests. In response to the fears of industry that the policy represented an unfair and scientifically unjustifiable short-cut to mass producing standards, Wrenn explained that it is "not intended to be a cookie-cutter approach to turning out regulations in a large number." Moreover, it would make regulations more predictable. This last comment was a response to a concern for the indirect, yet potent effect of regulatory uncertainty upon business decisions. Doniger suggests that in some instances uncertainty regarding the scope of a regulation can be a significant concern for those potentially affected.[36] And, perhaps because of this realization, most of the vocal trade associations would ultimately embrace the concept of a general policy to control workplace carcinogens, but they would not support OSHA's proposal.[37]

Wrenn also sought to counter part of John Sheehan's two-fold criticism of the policy. Sheehan, the legislative director of the United Steelworkers, had already examined the policy in his role as chairperson of the policy subgroup of NACOSH. At the conference he predicted that while the policy would not materially speed-up the effective regulation of carcinogens, the resources necessary to put it

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35 7 OSH Rptr. 53 (6/9/77).

36 Doniger, supra Ch. 5 n. 28 at 505.

37 The author offers a more cynical explanation later in the Chapter.

through rulemaking would hinder standard-setting during the process.[38] No generic policy would be able to dispose of all justiciable issues. Thus, parties who opposed a standard would always be able to prolong the process by seeking judicial review. Although there does not seem to be a record of Wrenn's response to the second (and, it seems, more potent) criticism, he did answer the first by pointing to the ETS and proposed standard for benzene which had just been issued in May. To a certain extent this response is inadequate when viewed from the present time. If the reader looks at the table of health standards (page 192) issued by OSHA, two things jump right off the page. First is the disproportionate number of standards (ETS, proposed, and final) issued in 1977 and 1978. And second is the fact that none was issued after November 1978. It seems as if the Agency finished all of the projects that had been in the works and then waited for the policy to become effective. The policy would not actually become effective for nearly one and one half years. Although in the author's opinion, both of Sheehan's criticisms were extremely accurate, four months later when the proposed rule was issued he did an about-face and publicly supported it.[39]

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38 The first of these predictions will be discussed in greater detail in a later section of this Chapter.

39 One wonders whether this shift stemmed from a genuine change of opinion or from a belief that on such an important issue labor must support OSHA's efforts, however flawed they may be.

C. The Proposed Rule

On October 4, 1977 OSHA issued the policy as a proposed standard under section 6(b) of the OSH Act.[40] In rejecting the recommendation of NACOSH and deciding to put the policy through rulemaking, the Agency was trading off the opportunity cost of the diminished resources available for other functions for the added legal strength of a regulation. But even aside from this, there is some doubt whether it even could have been issued as a policy (skirting procedural rulemaking provisions) and still have had any legality. The Consumer Product Safety Commission would issue a cancer policy in 1978 but be forced to withdraw it because a Court had construed it as a regulation, thus requiring procedures that the Commission had hoped to avoid.[41]

OSHA scheduled the hearings to begin on March 14. [It would be later moved back, first to April and then to May.] Eula Bingham said that she hoped it would be adopted within a year.[42] In major details the proposal was identical to the draft.

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40 42 Fed. Reg. 54148 (10/4/77).

41 "Interim Policy and Procedure for Classifying, Evaluating, and Regulating Carcinogens in Consumer Products" (16 C.F.R. 1040, 43 Fed. Reg. 25659, 6/13/78). An injunction was issued against the policy in Dow Chemical, U.S.A. v CPSC, 459 F. Supp. 378 (W.D. La. 1978). The Commission withdrew the policy on April 23, 1979 (44 Fed. Reg. 23821).

42 7 OSH Rptr. 555 (10/6/77).

The policy was immediately condemned by the Society of the Plastics Industry[43], SOCMA[44], and a spokesperson for Du Pont.[45] It was applauded by Anthony Mazzocchi, of the Oil, Chemical and Atomic Workers Union, who termed it "a justification of our past expressions of indignation"[46] and "the only logical means to use in regulating the nearly 1500 known and suspected carcinogens in the workplace."[47]

On October 5, Eula Bingham placed her full support behind the policy in a videotaped speech before the Joint Conference on

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43 Ibid.; "Carcinogen Crackdown Proposed," Chemical Week, vol. 121, (10/12/77), p. 18; "OSHA proposes New Carcinogen Policy," Chemical and Engineering News, vol. 55, (10/10/77), p. 7; "OSHA Wants Generic Rule for Carcinogens in Workplace," Chemical Marketing Report, vol. 212, (10/10/77), p. 3.

44 "Carcinogen Crackdown Proposed," Chemical Week, vol. 121, (10/12/77), p. 18.

45 Ibid.

46 Ibid.

47 "OSHA Wants Generic Rule for Carcinogens in Workplace," Chemical Marketing Report, vol. 212, (10/10/77), p. 3.

Occupational Health in Denver. She pledged that it wouldn't become "bogged down in bureaucracy."[48]

On October 7, OSHA released a draft environmental impact statement on the policy.[49] Two pages long, it asserted that significant effects on the environment would occur only when a specific substance would be regulated under the policy, and that an impact statement would be issued at that time. Why, then, did the Agency even bother to file a statement? One can infer that at least going through the motions was viewed as having some utility, in forestalling a legal challenge based on the failure to conform with the procedural mandate of the National Environmental Policy Act.[50]

On November 22, the creation of the American Industrial Health Council (AIHC) was announced at a semiannual meeting of the Manufacturing Chemists Association.[51] The epitome of a "single issue" organization, it was formed to "assess basic health assurance and economic issues raised by OSHA's recently proposed regulations for carcinogens in the workplace" and to "assist OSHA in developing a rational, practical, and effective policy." It was composed of firms and trade associations (mostly in field of chemical production).

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48 7 OSH Rptr. 677 (10/13/77).

49 7 OSH Rptr. 713 (10/20/77).

50 However, OSHA could have made a "Finding of No Significant Impact" describing why an EIS is not necessary (40 C.F.R. 1508.13, 1980). In Dry Color Mfrs Ass'n v. Dept. of Labor, 486 F.2d 98, 107 (3rd Cir. 1973) the Court ruled that an EIS is required for "ordinary standards" (as opposed to ETS's). Regarding the necessity to file for "generic" actions, in 1980 a district court ruled that "a regulatory program requiring hundreds or perhaps thousands of actions each significantly affecting the environment must itself be regarded as significantly affecting the environment" - and thus necessitating the filing of an EIS [American Public Trans. Ass'n v. Goldschmidt, 485 F. Supp. 811, 33 (D.D.C. 1980)].

51 7 OSH Rptr. 915 (12/1/77).

Indicating its dependence upon an already existent infrastructure, the Council worked out of the offices of SOCMA in Scarsdale, N.Y. Moreover, it was co-chaired by Paul Oreffice, the President of Dow Chemical, U.S.A. and William Bricker, the Chief Executive Officer of Diamond Shamrock Corporation.

From the start, AIHC adopted a sophisticated strategy. In spite of this, there was a fairly common perception of it as a foil for industry (and indeed it may have been). Congressman Obey (D-Wis) would call it "a fancy name for protecting industry profits even if it means workers' lives."[52]

Rather than condemning the generic approach (indeed, most segments of business conceded the value, or at least the inevitability of a generic policy - they just wanted one on their terms) AIHC urged that it be altered.[53] The statement cited in the previous paragraph suggests a desire to be "helpful", as did William Hoerger's explanation that, "We want to present information that will give a perspective on cancer. The overall picture is badly muddled."[54] Chemical Week, one of the widely circulated trade publications of the chemical industry, printed an open letter by Oreffice with the amicable title: "New Proposal by OSHA - An Opportunity for Cooperation" in which Oreffice notes the importance of the policy to business interests and solicits their membership in AIHC.[55] By the middle of January, the Council had increased its

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52 8 OSH Rptr. 799 (11/2/78).

53 The nature of these alterations will be discussed later, as will the question of whether they indicated a genuine desire by the membership to control occupational carcinogens or merely a change in tactics designed to emasculate standard-setting by OSHA.

54 7 OSH Rptr. 1189 (1/5/78).

55 Chemical Week, vol. 122, (1/18/78), p. 5.

membership to more than 75 companies and trade associations.[56] And it had surpassed its initial fundraising goal of one million dollars.

Judging from the public record, there was a confusion at first within the organization as to what degree of significance to place on occupational exposure as a cause of cancer. One perspective was dramatically opposed to that of OSHA and of every other Federal Agency or Institute with dealings on the subject.[57] At root was a disagreement concerning the origins of the disease that was sometimes hidden by rhetoric. In a revealing statement, Elwood Blanchard, the head of AIHC's "alternatives committee" (and director of Du Pont's Dyes and Chemicals Division) pointed out that industry does not accept the "building belief that the elimination of carcinogens in the workplace will eliminate the major causes of cancer."[58] Of course, in actuality no scientist or policy-maker believed that the workplace is the only source of exposure to carcinogens. So Blanchard was setting up a straw man to knock down. But there was an actual disagreement concerning the significance of the workplace to the overall cancer rate.[59] Spokespeople for the chemical industry have consistently taken the position that the role of the workplace is insignificant. And they point out that it is foolish for society to expend scarce resources chasing a solution to an insignificant problem.

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56 7 OSH Rptr. 1189 (1/5/78).

57 This will become apparent when OSHA will be able to gather unanimity of Agency and Institute heads in support of the scientific assumptions upon which the proposal was based (with the partial exception of EPA).

58 "Cancer Policy Revealed," Chemical Week, vol. 122, (1/18/78), p. 14.

59 This issue is discussed in Chapter Three. At that point, the author concluded that there is no way to determine its overall significance.

OSHA would respond to this objection in the preamble to the final rule (which would be issued two years later). Citing the study performed by the National Cancer Institute, National Institute for Environmental Health Sciences and NIOSH (which was written in the first place to support OSHA's position), the Agency argued that occupational exposure is an important component of the overall cancer rate.[60] But, it also pointed out that regardless of the overall contribution of the workplace to the cancer rate, it is charged with promulgating health standards to protect workers. The justification of a standard rests on the degree to which it protects workers, not the degree to which it lowers the national cancer rate.[61] Thus, even if true, Blanchard's contention was considered a non sequiter.

Yet, in its eighty-five page alternative proposal (issued in January 1978) AIHC pointed out the significance of workplace exposure:

> Identifying and regulating carcinogens in the workplace is a formidable but most necessary task, one that requires the best thinking of the most informed representatives of science, government, labor, business, and public interest groups.[62]

And AIHC made its stand on the types of evidence sufficient to identify and regulate a substance as a carcinogen. For example, unlike OSHA's

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60 The significance of this study is discussed in Chapter Three. The politics surrounding it is examined in somewhat greater detail later in this Chapter. AIHC was involved in a bit of a scandal in its reception to it.

61 The argument of industry has the same logical structure as the assertion that urban mass transit does not fulfill a legitimate function since a minority of the population uses it (or, for that matter, that business tax write-offs are illegitimate since only a few directly benefit).

62 "Industry Group Offers Carcinogens Policy," Chemical and Engineering News, vol. 56, (1/23/78), p. 6.

proposal, AIHC's alternative would not allow animal data to influence a "Category I" decision. Category I ("Known Human Carcinogens") would be classified solely on the basis of epidemiology "or other human data."[63] Moreover, the proposal would determine a permissible exposure level from dose/response data, thereby seeking to quantify risk. And it would also perform a risk-benefit analysis.[64] There were other differences between the two proposals, but these three alone would result in dramatically different regulatory strategies.[65]

Since studies on humans are basically ineffective in identifying carcinogens, stipulating that studies be based on human evidence would completely cripple the Agency. Moreover, it involves an implicit, yet altogether real, transfer of the burden of evidentiary uncertainty onto the shoulders of those who are at risk. For the Council was not implying that animal studies are of no predictive value at all. Rather, its position could only have been that they are not reliable enough to be used in proceedings that would result in a redistribution of resources from one segment of society to another. And since the

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63 7 OSH Rptr. 1259, 60 (1/19/78). Concerning the value and hazards of using animal evidence, see Chapter Four.

64 Concerning these issues see Chapter Five.

65 Other differences were an emphasis by AIHC on the issue of "personal protective devices" (masks and suits) rather than "engineering controls," accepting the existence of a threshold (see Chapter Four) and forbidding an outright ban of a carcinogen because a substitute exists for it. Another aspect of the proposal was the suggestion that an independent scientific review panel be established to oversee the evidence for individual standards. In the spring a group of chemical industry executives met with Donald Kennedy (FDA), Eula Bingham (OSHA), Barbara Blum (EPA) and John Byington (CPSC) to advocate this last idea. They received a "mixed reaction." According to a memorandum of conference after a May 24 meeting with these executives Kennedy was "not in favor of an additional group of scientists to independently evaluate each compound. That merely creates an additional layer of bureaucracy" ["Little Headway on Cancer Policy," Chemical Week, vol. 122, (7/21/78), p. 13.]

uncertainty must be borne, the authors of AIHC's policy advocated it being borne largely (one is tempted to say "entirely") by workers. Not using animal studies radically increases the probability of false negatives, and decreases the probability of false positives.

There is a revealing inconsistency in the Council's position that, nevertheless, is easy to overlook. Proposing that animal tests never be used to classify a substance into Category I involved throwing away information. It is little more than an oversimplification to ensure that Agency action conform to AIHC's vision of "due process." And yet, all through the debate over the cancer policy AIHC condemned the Agency for "oversimplifying" the science of carcinogenesis. But is this not what the Council's suggestion amounted to?[66]

In its acceptance of risk quantification and risk-benefit analysis, AIHC implicitly took the opposite methodological tact by accepting the added uncertainty that they involve in order to gain the additional information that they convey. The stated rationale, however, was that not weighing risks against benefits would be socially irrational.[67] And, it does not seem unfair to presume that the actual reason was, as before, to shift the burden of uncertainty onto workers. To the degree that they are accurate, risk quantification and risk-benefit analysis lead to more efficient regulations.[68] But to the extent that they are

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66 Of course, the Council could respond that there is a crucial difference between simplification for the purpose of preventing individuals' rights from being unlawfully interfered with through Government action and simplification in order to make life easier for Government regulators. To do justice to this response would call for a treatise in political philosophy, an effort that will not be made in this footnote.

67 For a more complete discussion see Chapter Five.

68 Although perhaps at the price of a diminished degree of justice.

invalid, they will tend to result in permissible exposure levels that are too high; are underprotective rather than overprotective.[69]

AIHC spent the remainder of the winter coordinating the responses of all of its members in preparation for the hearings that would begin in May. According to a spokesperson for the Society of the Plastics Industry, the Council was compiling "exhaustive documentation" and gathering "as large a procession as possible" of witnesses to appear at the hearing.[70]

More than 260 comments were received concerning the policy.[71] Of these, more than 200 were written in opposition to it.[72] Objections touched on most of the particulars of the policy. And the American Petroleum Institute argued that the adoption of "generic policy judgments" irrebutably applicable in all substance-by-substance proceedings would be "unlawful if enacted."[73] API offered an alternative to answering questions like the acceptability of evidence from animal tests generically. Under the alternative, whenever OSHA issued a health standard it would attach the statement of "facts not in controversy" similar to that which persons seeking summary judgment in civil cases do. The statement would cover facts that it believed were uncontrovertible as well as issues that it believed were irresolvable. These matters would not be dealt with during the hearings. API concluded that this method would "save time and resources in those areas

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69 For an explanation why this would be the case, see Chapter Five.

70 7 OSH Rptr. 1463 (2/23/78).

71 7 OSH Rptr. 1523-4 (3/9/78).

72 7 OSH Rptr. 1505-6 (3/2/78).

73 7 OSH Rptr. 1523, 4 (3/9/78). API would later become converted to the virtues of generic rulemaking, but not OSHA's variant.

where no one in the public disputed the issues for which OSHA sought 'summary judgment'"[74]

In actuality, though, the true extent of the saving would be minimal. For, as long as parties with standing were not precluded from disputing factual issues in substance-by-substance rulemaking (as the generic approach would do) there would be no reason to believe that they would voluntarily refrain. Thus, the issues would not be considered to be incontrovertible. As a proposal to expedite standard-setting this was little more than an empty gesture. But it should not be surprising since the only way to expedite OSHA's rule-making would involve limiting the broad rights of interested parties to challenge individual standards, an approach which API and industry in general find counter to their interests and (perhaps for this reason) philosophically repugnant as a dimunition of legal (and moral) rights guaranteed by the Constitution.

The policy found support from several areas. The California Department of Industrial Relations, administrator of that state's occupational safety and health program, termed it "comprehensive enough to deal with general and specific problem areas. We believe it is a step in the right direction, is urgently needed, and will work for the benefit of workers' health."[75] The cmmments of the AFL-CIO also were strongly favorable.[76] But the labor federation did have reservations on

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74 Ibid.; quoted from the language of the article.

75 7 OSH Rptr. 1505 (3/2/78).

76 7 OSH Rptr.1523, 4 (7/9/78).

particular issues and suggested some ways to strengthen the proposal.[77]

There were 162 requests to testify at the hearing which was to be held in Washington.[78] Approximately 100 parties requested the customary 15 minutes.[79] Another 20 asked for approximately 80 hours. Neither estimate includes the time necessary for questioning witnesses and procedural matters. AIHC requested 20 hours for three separate presentations on the scientific, regulatory and economic aspects of the policy. Reserve Mining requested 6 hours. Eight labor unions and eight trade associations also requested time to testify, as did the Environmental Defense Fund and Public Citizen Health Research Group.[80]

On March 27, 1978 AIHC announced the release of the economic analysis of the policy which it had contracted with Foster D. Snell, Division of Booz-Allen and Hamilton to perform.[81] The study took 3-1/2 months to complete and cost AIHC $750,000. The report constructed three regulatory scenarios based on the number of substances to be regulated and two exposure targets (10 ppm and 1 ppm) and estimated the capital and annual costs required to comply.

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77 For example, a substance could be classified in Category I on the evidence of a single well-conducted animal experiment. The AFL-CIO also suggested that a substance be classified in Category I if it metabolizes in the human body to a substance that had at one time been in Category I.

78 7 OSH Rptr. 1892-3 (5/18/78).

79 7 OSH Rptr. 1566-7 (3/16/78).

80 Ibid.

81 7 OSH Rptr. 1636-7 (3/30/78).

TABLE 14.

ESTIMATES OF THE POLICY'S COST

Scenario	Capital Cost ($ Billion, 1977)	Annual Cost
Low scenario (38 high volume substances)	9-23	6-11
Medium scenario (1870 substances	17-47	10-20
High scenario (2415 substances	30-88	18-36

Paul Deisler, vice president of Shell Oil Co., argued that the policy would impose a greater cost than necessary to effectively control workplace carcinogens.[82] However, he did nOt estimate the savings that AIHC's alternative would offer. Richard Fleming, executive vice president of Air Products Company conceded that although "the basic idea of appropriate controls is supported by AIHC. . . socially acceptable risk is the only practical means of dealing with" the cancer problem.[83]

The study caused a storm of debate. George Taylor of the AFL-CIO suggested that its authors "have been smoking economic opium."[84] It was questionable on at least four grounds. First, the study failed to address the marginal cost of regulating generically. Assuming that substances would be regulated even without a policy, the true social cost of regulating according to an explicit policy is the added cost of regulating those substances for which standards would not have been set otherwise.

Second, the medium and high scenarios are gross exaggerations since OSHA officials had estimated that roughly 270 substances would be classified in Category I.[85] Third, because they exclude regulatory benefits, these estimates are not of the costs that society faces. For example, the fact that society diverts tens of billions of dollars worth of resources every year to the education of its youth does not in itself

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82 Ibid.

83 Ibid.

84 Ibid., p. 1637.

85 Later that year OSHA would publish a "Candidate List" for Category I which included 269 substances (8 OSH Rptr. 237, 7/20/78). Upon hearing Grover Wrenn's projection of 261 substances, Foster Snell would delete the "high scenario" from its testimony at the hearing: Testimony, Preliminary Estimates of District Direct Compliance Costs and Other Economic Effects of OSHA's Generic Carcinogen Proposal, OSHA Docket No. H-090, (6/22/78), p. 33.

make it a bad investment. So, the expenditure of resources to prevent early deaths of workers is not necessarily unwise. Determining whether or not it is a bad investment is a complex decision in which costs cannot be examined alone. But, examining it solely as an investment in the first place begs the important question of distributive justice that the previous Chapter alluded to. Furthermore, a discussion of costs is meaningful only if the OSH Act permits their consideration in standard-setting. At the time, decision makers in OSHA believed (or claimed) that the Agency was not permitted to consider costs.[86] And, as Chapter Five discusses, cost estimation of toxic substances regulation is notoriously inaccurate. As is pointed out in that Chapter, there is a tendency for these estimates to be overstated by industry. So, for these four reasons the Foster Snell study was not particularly informative. Yet it would play a central role in the political debate around the policy.

In the first week of April, 1978 OSHA announced that forty-eight witnesses would offer testimony in support of the policy, and placed copies of their statements on file in the docket room.[87] Anyone who had initially commented on the policy had until April 25 to submit supplementary written comments on this testimony.

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86 This would be tested in the legal review of the cotton-dust standard. In 1981 the Supreme Court ruled that the Agency need not perform a risk-benefit analysis since the Statute seems to mandate a feasibility analysis. (American Textile Mfrs' Inst. v. Donovan, 452 U.S. 490 (1981).

87 7 OSH Rptr. 1676-8 (4/13/78).

D. The Hearing

The first day of the hearing on May 16 drew several hundred people into the Departmental Auditorium of the Department of Labor.[88] This would be the longest hearing and draw more participants than any other OSHA standard hearing. Because of its sheer size, guidelines had to be made to keep it manageable. At the start, the Administrative Law Judge, J.F. Greene, who would preside over the entire process which would not end until the hearing record would be certified the following January, announced a set of rules to keep the hearing from getting bogged down. She placed the participants into six groups such as "trade associations," "individual companies," "federal agencies," and "labor unions." Each group was asked to indicate in advance which witnesses they wished to question and who would represent their group. Each group would then be limited to forty minutes for cross-examination. Yet, if each of the 162 witnesses would be cross-examined for forty minutes by each of five groups, cross-examination alone would take 540 hours (or nearly 70 eight hour days). But even this minimal restriction was objected to by attorneys for API and AIHC.[89] Witnesses were scheduled through the end of July, but according to one source this was an overly hopeful timetable.[90]

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88 7 OSH Rptr. 1892 (5/18/78).

89 Ibid. In informal hearings the A.L.J. has broader powers to restrict cross-examination than in adjudication. Yet these restrictions did not seem overly burdensome. With so many witnesses the same issues could be raised time after time if the parties desired. But it is indisputable that greater care needs to be taken to examine issues when they are to be decided generically since the decisions will have broader impact.

90 All the more surprising that it did finish on schedule.

OSHA would present its witnesses first, to be followed by AIHC,industry groups, and then labor unions and advocacy groups. As the leadoff witness, and representing the Agency itself, Grover Wrenn sought to make the policy palatable to groups that considered it another example of capricious bureaucratic meddling as well as to those that felt that the policy was not taking the cancer problem seriously enough.

Wrenn denied the common charge of industry that the policy was intended to make the American workplace "risk free." Rather it is intended to ensure that "workers should not be subject to the risk of irreversible illness, when it is feasible for that risk to be reduced or eliminated."[91] He responded to the objection that the policy would "freeze science" by promising that OSHA would amend it when scientific advances warranted, but that to consider such issues as the existence of a threshold and the reliability of animal evidence in individual rulemakings would destroy the purpose of the policy. But, to the question of whether its substitute need be economically feasible before OSHA would ban a substance Wrenn answered that, "We have in mind primarily its technical suitability."[92] However, unless it was economically feasible, then effectively it would not be a substitute since it would not be used.

Jacqueline Warren of the Environmental Defense Fund asked Wrenn why a Category I classification should not be triggered by a single positive animal test. Wrenn replied that the Secretary of Labor would have that flexibility, but that the classification is "automatic" given positive results from two studies.

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91 7 OSH Rptr. 1892 (5/18/78).

92 Ibid., p. 1893.

On May 17 the heads of the National Cancer Institute, the National Institute of Environmental Health Sciences and the Food and Drug Administration testified in support of the policy.[93] All of them agreed with OSHA's principle to employ animal studies. Indeed, they seemed to agree on all major principles of science. But Donald Kennedy (FDA) urged that the Agency seek to quantify risk (and presumably perform a risk-benefit assessment) rather than limit exposure to the extent feasible as the proposal would. "I have no suggestion about the best way to quantify risk, but it is clear to me that, from a scientific view it is important to do so."[94] But the following week when the hearing renewed, Harold Stewart, a scientist emeritus at the National Institutes of Health gave the opinion that risk quantification is impossible.[95] On the issue of risk quantification, most of the witnesses called by OSHA thought it unacceptable except (notably) for Kennedy and Stephen Jellinek (EPA), who offered testimony on June 6.[96] Perhaps as regulators they had a greater sense of the politics and or economic implications of the issue. On the other hand, however, John Byington of CPSC supported OSHA's rejection of risk quantification in his testimony on June 5.[97]

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93 7 OSH Rptr. 1924-6 (5/25/78).

94 Ibid., p. 1925.

95 For a discussion of the limitations of risk quantification see Chapter Five.

96 8 OSH Rptr. 65 (6/15/78).

97 8 OSH Rptr. 33 (6/8/78).

OSHA concluded its presentation on June 13, and AIHC started on June 20. By this time the Council had grown to include 100 companies and 60 trade associations.[98] Paul Oreffice explained that:

> Some of our members believed initially that we should take a strong adversary position, including commencement of legal action, to obtain the changes important to us. . . AIHC decided instead to take a positive and open stance, stating adequately what improvements we felt were essential for a useful policy, and seeking dialogue and cooperation as a means for achieving our objectives.[99]

Presumably the governing body of the Council felt that it had a better chance influencing OSHA and the public by appearing reasonable than conforming to the popular image of the "Big Bad Corporation." AIHC witnesses criticized the policy's heavy reliance upon animal data,[100] disputed the significance of occupational exposures to the national cancer rate,[101] and promoted the case for risk-benefit analysis.[102] Richard Zeckhauser, an economist at Harvard University, also promoted

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98 8 OSH Rptr. 86-7 (6/22/78).

99 Ibid. Once the final rule was issued a year and a half later, AIHC would take legal action. Of course, the real reason why it did not before that point was that it could not - the issue was not yet ripe for judicial review.

100 8 OSH Rptr. 87, by Robert Olson and James Jandl (on this issue see pages 54-61).

101 Ibid., by James Jandl.

the use of risk-benefit analysis in his testimony for the American Petroleum Institute on June 26.[103]

The President of Monsanto testified on June 29. Placing his faith in American business, he urged OSHA to also:

> We wholeheartedly support the idea that these employees deserve a workplace with hazards as low as prudently possible. . . But let me stress that the primary responsibility for insuring a safe workplace rests with industry - with companies like Monsanto.[104]

Apparently the decision of what hazards are imprudent lies with Monsanto as well as the responsibility for mitigating them. Yet, should not Monsanto stockholders drum him out of office if he were to needlessly spend their money to prevent worker injury and disease when it would not benefit the company? This is the dilemma facing those who work for individual companies, hoping to be able to alter those firms' behavior from the "inside," inducing them to place a value on amenities that do not have a market price - like worker safety and health, or environmental externalities. For one thing, it is against the "nature" of companies, which is primarily or solely, that of profit maximization; asking that they voluntarily diminish profits is like teaching a fish to fly. But also, to be perfectly just, it must be conceded that firms ordinarily ought not to do otherwise. In the American system at present the managers of a corporation are trustees of the stockholders' investment. Thus, ethically, they themselves ought to have little initiative aside from determining the best way to maximize the rate of return of their charges' investment. So, unless the corporation's

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103 8 OSH Rptr. 103-4 (6/29/78).

104 Testimony of John Hanley, 8 OSH Rptr. 186 (7/6/78).

stockholders indicate otherwise, the managers have a moral obligation to do as little as possible to provide for the health and safety of employees and citizens "downstream."[105] The dilemma arises for those managers who also feel a moral obligation to serve these other parties in the production process. But, in an important sense, this obligation is subservient. The managers are participants in the game, and while playing must obey the rules - one of which is that they obey the wishes of their stockholders.[106] So, for these reasons it is not likely and, moreover, it is immoral for American corporation managers to "needlessly" expend resources when it is not in the interest of the firm as expressed by its stockholders.[107] And this explains why "primary responsibility for insuring a safe workplace" cannot rest with industry.

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105 There has been dissatisfaction with the implications of this view among segments of the intellectual community. For example, one early critique, written during the Great Depression, predicted that, "It is conceivable, - indeed it seems almost essential if the corporate system is to survive, - that the 'control' of the great corporations should develop into a purely neutral technocracy, balancing a variety of claims by various groups in the community and assigning to each a portion of the income stream on the basis of public policy rather than private cupidity." However, in an earlier Chapter the authors had described the status quo as being one in which "corporate power. . . must. . . be judged in relation to the existing facts with a view toward discovering whether under all the circumstances the result fairly protects the interests of the shareholders." [Adolf Berle and Gardiner Means, The Modern Corporation and Private Property, New York: The Macmillan Co., 1932, pp. 356, 275.] Berle and Means are not counseling altruism. The "claims" of "various groups" can only be exercised once they are embedded within some institutional framework of laws and expectations based upon a system of incentives and penalties. Neither firms nor people can be expected to act against their own interests. On these issues see John Kenneth Galbraith, The New Industrial State, Boston: Houghton Mifflin Company, 1967.

106 This is a question of the ethics of promise-keeping and promise-breaking. An act-utilitarian might, however, view the matter differently, placing no intrinsic value on promise-keeping.

107 These same arguments apply, but in weaker form, to explain why firms do not police themselves through trade associations.

If workers are to be protected it can only be through their own means or with the help of Government.[108]

Labor unions began testimony in the second week of July.[109] Although supporting the proposal in essence, many witnesses did offer suggestions for fine-tuning it.[110] However, there were several suggestions of a more fundamental nature. Sheldon Samuels of the Industrial Union Department of the AFL-CIO and Sidney Wolfe of the Health Research Group advocated a permit system whereby firms that wish to use Category I carcinogens (according to Wolfe) or selected "virulent" carcinogens (according to Samuels) would first need to obtain a permit from OSHA.[111] For Samuels, permits would be granted only for necessary uses. An example of a trivial and unnecessary use according to Samuels is using benzidine derived dyes to obtain certain shades of color "for a lady's Easter bonnet."[112] For Wolfe, they would be granted only after showing that worker exposure would be kept to zero.

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108 Perhaps during Eula Bingham's administration OSHA can be viewed as a collaboration of unions and Government (although this is meant more as a question than as an assertion).

109 8 OSH Rptr. 214-5 (7/13/78).

110 For example, instituting earnings protection for workers removed from their jobs because of exposure (a provision of the cotton dust standard that was later vacated), and setting an action level of one-fourth the permissible exposure level that would trigger monitoring and medical surveillance.

111 8 OSH Rptr. 242, 3 (7/20/78).

112 Ibid., p. 244.

The hearing ended on July 25.[113] Anson Keller did not attempt to estimate how long it would be before OSHA issued a final rule. The OSH Act mandates that one be issued within 60 days of the close of the hearing. But there was little likelihood of this deadline being met considering that the deadline for post-hearing evidence was September 15, and for final briefs October 10.[114]

E. Post Hearing Comments and Developments

But OSHA was involved in a lawsuit over the policy even before the hearing was over. On July 6, 1976 the American Petroleum Institute filed suit under the Freedom of Information Act, asking for items which it had requested on March 24 but had not yet received.[115] The suit was dismissed without prejudice on September 21, after OSHA released several, but not all of the documents.[116]

At the end of July, OSHA announced that it would do a regulatory analysis of the policy.[117] In March, Organization Resources Counselor, a Washington, D.C. consulting firm had written to Eula Bingham asking that the hearing be postponed until the analysis was performed in accordance with President Carter's Executive Order 12044 ("Improving

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113 8 OSH Rptr. 294 (7/27/78).

114 8 OSH Rptr. 294, 6. Later that summer the deadlines would be extended.

115 The suit was field in the District Court for the District of Columbia (Docket No. 78-1235).

116 8 OSH Rptr. 668 (10/19/78).

117 8 OSH Rptr. 323-4 (8/3/78).

Government Regulation").[118] Bingham wrote back in May, that an analysis was unnecessary because by itself the policy would not "impose any regulatory burden on industry."[119] But by July OSHA's position had changed, quite possibly under pressure from the Council of Economic Advisors and the Office of Management and Budget (and apparently with at least the knowledge of the White House staff).[120] For, after receiving Bingham's initial response ORC and the Chamber of Commerce wrote a letter to OMB. The Office replied:

> You have highlighted an important concern which could have fundamental effects on the way agencies make regulatory decisions. . . It is a complicated issue which we have discussed with Dr. Bingham's staff. They have agreed that a regulatory analysis will be done for the generic standards and we will continue to work with them on the design of the analysis.[121]

This episode raises the issue of mapping the proper relationship of the President to executive agencies when they are acting under the explicit mandate of Congress (as OSHA under section 6(b) of the OSH Act). In principle, at least, the latter are meant to be insulated from political influences; to act in a Weberian bureaucratic manner carrying out the expressed political wishes of Congress. Although this is rarely, if ever, possible, in some sense it is an ideal. Insofar as the Office of the President is a political entity, responding to immediate political forces (as expressed in the ORC letter), pressure that it applies via CEA, OMB and the Council on Wage and Price Stability is likely to

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118 Ibid., p. 324.

119 Ibid.

120 Ibid.

121 Ibid., pp. 323-4.

possess an influence unintended and unwished for by the framers of the statute.

Further pressure was applied on OSHA late in August when Barry Bosworth, the director of CWPS informed the Agency that the Regulatory Analysis Review Group (RARG) would do its own study of the policy.[122] In a letter to Bingham on September 26, Bosworth outlined several of the aspects on which the RARG study would focus.[123] Among them were "the OSHA carcinogenic decision-making process" to determine what role, if any, is given to risk estimation, hazard analysis, risk-benefit analysis, economic impact and cost-effectiveness in the policy. So, two studies of the economic impact of the policy would be issued that fall, one by OSHA and the other by RARG. They were to arrive at vastly different conclusions.

A question of proper administrative procedure arose in September when ORC requested that the hearings be re-opened so that the study by NIOSH, NIEHS, and NCI (hereafter, "HEW report") could be formally considered.[124] This study (which is examined in Chapter Four) was released in September, more than one month after the hearing had concluded. Written by employees of these three institutes, many of whom had testified in support of the policy, it was a response to the common accusation that had arisen during the hearing that workplace exposure is an insignificant contributor to the national cancer rate. Although OSHA considered this argument a non sequiter (for reasons discussed earlier in this Chapter), the Agency did make the report part of the record,

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122 8 OSH Rptr. 517-8 (9/21/78).

123 8 OSH Rptr. 565 (10/5/78).

124 8 OSH Rptr. 667 (10/19/78).

asserting that it buoyed its assumption "of the magnitude and importance of overcoming the problems of occupational cancer."[125] OSHA did not re-open the hearing (in response to ORC's request) but extended the post-hearing comment period by two weeks to October 24.[126] An additional sixty day extension would be granted to permit comments on OSHA's regulatory analysis which would be issued on October 24. RARG's analysis would be released one day later.

The RARG report termed the policy inflexible and not cost-effective.[127] The study claimed that, because potency is disregarded in categorizing chemicals, agency resources will not be directed toward the most serious hazards first.[128] Moreover, the study suggested that cost-effective control strategies be advanced. Two ways to do this are (1) through performance, rather than specification, standards which would permit firms to meet permissible exposure levels through the least-cost option[129] and (2) to vary PEL's from industry to

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125 8 OSH Rptr. 517 (9/21/78).

126 The Courts have held that re-opening hearings is a matter of discretion for the Agency [Bowan Transp. v. Ark. Best Freight System, 419 U.S. 281, 94-5, (1974)]. Only once did the Supreme Court remand a case for re-opening of evidentiary proceedings, in 1932 [Atchison, T. & S. F. R. Co. v. United States, (284 U.S. 284)].

127 U.S. Regulatory Analysis Review Group, Occupational Safety and Health Admnistration's Proposal for the Identification, Classification and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk, Washington: Council on Wage and Price Stability, 10/24/78, p. 8.

128 Ibid., p. 20.

129 Ibid, pp. 34-5.

industry and by processes.[130] Industries for which control is inexpensive would be held to a stricter standard than others. RARG also urged the use of risk-benefit analysis to set exposure levels: "Such information [concerning "potency, exposure levels and duration, and the degree of confidence that the substance is a true human carcinogen"] is nevertheless essential if "the benefits of the standards are to be assessed and the standards are to be set so that they are commensurate with costs."[131] (emphasis added).

Underlying these suggestions was a radically different regulatory philosophy than that underpinning OSHA's proposal. OSHA's philosophy was based on two assumptions; that there is no known threshold to carcinogenesis, and that the OSH Act requires the Agency to protect workers from toxic substances under the sole constraint that regulations be feasible. Because of the first assumption (which is discussed in Chapter Four) the position of the Agency was that workers can be protected from carcinogens only by reducing exposure to zero. Yet, standards must be feasible, so OSHA believed that it was directed by science and law to reduce exposure to the lowest level feasible. RARG's regulatory philosophy, on the other hand, was based on the principle

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130 Ibid, pp. 35-7.

131 Ibid., p. 22.

that OSHA's regulations should be as little disruptive of the economy as possible. Therefore PEL's should vary from industry to industry.[132]

In spite of describing the Foster Snell economic analysis as having "major methodological problems. . . which make it impossible to place great confidence in its results"[133] the RARG report did cite the analysis in support of its contention that the cancer policy was likely to have "very high costs."[134] This is somewhat tenuous considering the admission that:

> We do not have, at this time, even an order of magnitude estimate of costs corresponding to a reasonable interpretation of regulatory coverage and stringency.[135]

Edward Strohbehn, the executive director of the Council on Environmental Quality, raised his eyebrows at several of the report's conclusions in a minority report which he sent to Eula Bingham. He disagreed with its principle that quantitative risk assessments and risk benefit analysis be performed. And he minimized the value of a cost-effectiveness criterion to evaluate regulations.[136]

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132 There is a tradeoff which was not addressed in the report between regulatory efficiency and economic efficiency of regulations. Designing individual PEL's, although perhaps more cost-effective (saving the most lives for the fewest dollars) is likely to be vastly more expensive for the regulator (in connection with this, see discussion of technology-based standards in Chapter Five). Anyone who advocates individualizing standards must also accept higher regulatory costs.

133 Ibid., p. 12. Moreover, the report devotes an appendix to discussing "Major Problems in the BAH Estimation Procedure" (Appendix A).

134 Ibid.

135 Ibid.

136 8 OSH Rptr. 797 (11/2/78).

By the time the hearing record closed (for the first time: itwould be reopened later) more than 180 posthearing comments had been submitted.[137] AIHC's brief, by far the lengthiest, was over four hundred pages.[138] But one of the most adventurous suggestions was made by the Manufacturing Chemists Association. Among other things, MCA advised that the policy be withheld until a uniform national cancer policy was adopted by all Federal Agencies, and until the economic impact of the policy was fully understood.[139]

On October 31, Judge Greene denied the petition to re-open the hearing to consider the HEW report and OSHA's regulatory analysis.[140] But she did permit the inclusion into the record of an industry rebuttal to the HEW report. On November 1, AIHC sent a letter to Bingham requesting that the record be opened for an additional sixty days to permit written comments to these documents.[141] This petition was

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137 Ibid., at 798.

138 Ibid.

139 8 OSH Rptr. 829 (11/9/78). This suggestion tempts sarcasm.

140 Ibid.

141 Ibid.

granted on November 15.[142] But Judge Greene's order allowed comments on the RARG report (and Strohbehn's dissent) as well as OSHA's regulatory analysis, without mentioning the HEW report.

In its comments on OSHA's regulatory analysis, AIHC accused the Agency of performing an inadequate analysis [the review was based on data from the standards on coke-oven emission, DBCP, acrylonitrile and benzene.][143]". . . OSHA has side-stepped completely an economic analysis of the proposal and its alternatives. Thus, the fear of OMB has come to pass - the proposed generic standards will never be evaluated economically. [144] The Council urged that OSHA perform a new analysis.

The Chamber of Commerce referred to the Fifth Circuit's decision to overturn the benzene standard (delivered on October 5) in its comments.[145] The Court had set it aside because OSHA had failed to show that it was "reasonably necessary or appropriate" as required by the OSH Act.[146] As will be discussed later, OSHA would amend the policy, but not for over two years, until it took a hint in a footnote to the Supreme Court's decision to uphold the ruling of the Circuit Court.

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142 8 OSH Rptr. 971 (11/23/78).

143 U.S. Occupational Safety and Health Administration, Regulatory Analysis of a Proposed Policy for the Identification, Classification and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk, Washington: Government Printing Office, 10/17/78, pp. 77 ff.

144 8 OQH Rptr. 1222 (12/08/79),

145 Ibid.

146 This case is discussed more fully below.

On December 15 the Chamber of Commerce made another appeal to the Executive Office regarding the policy, this time directly to President Carter.[147] (In the spring the Chamber had written to OMB, requesting that it apply pressure on OSHA to have it perform a regulatory analysis.) In its letter to Carter, the Chamber urged that in order to combat inflation the cancer policy as well as the proposed noise standards be "withdrawn, postponed or revised." The Chamber apparently favored the first of these alternatives since in another section of the letter it urged that "standards. . . may be established on a substance-by-substance basis" and that "standards. . . consider the many variables involving individual substances."[148] Clearly, the Chamber objected to the generic philosophy.

Judge Greene officially certified the hearing record on January 24, 1979.[149] The record included 291 exhibits and 106 post hearing comments.

On February 7 the Interagency Regulatory Liason Group (IRLG) issued its report, Scientific Bases for Identifying Potential Carcinogens and Estimating Their Risks.[150] The IRLG was composed of representatives from the four primary Federal Agencies with mandates to regulate toxic substances.[151] The report made a number of observations that bolstered OSHA's position. Among them:

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147 8 OSH Rptr. 1277-8 (1/4/79).

148 Ibid., p. 1278.

149 8 OSH Rptr. 1388 (2/1/79).

150 Published in the Federal Register on July 6 (44 Fed. Reg. 39858-79).

151 EPA, OSHA, FDA and CPSC. The Food Safety and Quality Service of the Department of Agriculture was included later.

(1) cancer studies involving mammals are valid for judging a substance's potential effect upon humans.

(2) it is appropriate to use doses that exceed the expected human exposure.[152]

(3) short-term tests, while not giving "definitive evidence as to whether a substance does (or does not) pose a carcinogenic hazard to humans," must be considered "suggestive evidence."[153]

(4) predictions of threshold to carcinogens are unreliable.[154]

Each of these is a conclusions reached by OSHA itself and contested to one degree or another by various parties in the hearing and in written comments. The report took a tentative view of quantitative risk assessment, pointing out its weaknesses and discussing how one should be performed, without asserting that it should always be done.[155]

AIHC would release a draft report on May 5 calling the study "a significant step toward the formulation of a national cancer policy" but roundly criticizing it for confusing "the scientific and regulatory function" by injecting "conservative assumptions" into the scientific process.[156] The importance of this argument cannot be stressed too strongly. Using it is a common tactic of the opponents of "mainstream

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152 For a discussion of this issue see pages 75-78.

153 For a discussion of this issue see pages 102-108.

154 For a discussion of this issue see pages 66-71.

155 But, as the report pointed out, some statutes require them.

156 9 OSH Rptr. 4 (6/7/79).

science," which "considers" these positions as beyond debate.[157] When faced with overwhelming evidence, these opponents are reduced to arguing that the mainstream illegitimately injects norms into what should be a "positive science." However, as is demonstrated in Chapters Four and Five, value assumptions must be injected into the science of carcinogen testing. It is only a question of whether or not they should be "conservative". By no means, however, is this meant to gloss over the question of how these assumptions should be chosen (which is given some attention in the sections mentioned above). Moreover, the importance of recognizing these assumptions and seeking to assess their influence on future decisions must be acknowledged. But it is false to suggest that the science can be done without the assumptions.

A bit of a scandal occurred that spring while OSHA was busy sifting through the hearing. The HEW report, released the preceding fall, had taken industry interests aback with its estimate that as many as 20 to 37 percent of all cancer cases are occupationally related.[158] So concerned was AIHC that it arranged with several researchers to perform critiques of the study. The Council released its official response to the HEW report, that not more than five percent are occupationally related, without releasing any of the critiques (but including summary sheets of each one). One of the reports, however, although questioning the details of the HEW study, itself estimated that as many as thirty-three percent of the cases are occupationally related.[159] Moreover, the University of Texas researchers who authored it, Reuel

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157 See Chapter Four.

158 According to Representative David Obey (D-Wis) industry representatives "screamed like stuck hogs." (8 OSH Rptr. 1625, 4/5/79).

159 Ibid.

Stallones and Thomas Downs, took a strong (and considering their estimate, justifiably realistic) view of the public health implications:

> We believe that any reasonable projection, whether higher or lower than the one presented is horrifying, and fully support the conclusion that this experience constitutes a public health catastrophe, and that the official response to it is fully justified.[160]

The report was revealed at an AFL-CIO conference in Washington on March 29. Needless to say, OSHA rode it for all it was worth. AIHC responded by noting that whereas the deadline for officially submitting its comments to OSHA was October 24, it only received the summary sheet of Stallones' study on the 23rd, and that it was because of time pressures, rather than because of any disagreement that it had not been included along with the other summary sheets.[161]

AIHC held a press conference the following week, at which Ronald Lang struck a strong pose, asserting that the Council's motives had been distorted and that in fact the report had not been deliberately withheld.[162] Lang made a two-pronged assault on the opposition. First, he asserted (somewhat self-righteously) that by discrediting AIHC the accusations undermine the entire regulatory initiative (and at the same time he offered OSHA a backhanded compliment):

> If these distortions go unchallenged they could destroy one of the most constructive efforts ever undertaken to identify potential chronic health hazards and to adopt these necessary controls to

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160 Ibid., p. 1626.

161 Ibid.

162 8 OSH Rptr. 16562-3 (4/12/79).

> minimize any risks which exist. There is too much at stake for the nation to allow this to happen.[163]

Lang's second prong consisted of a rejection of all such studies (apparently forgetting the Council's own estimate): "We're not interested in entering into a numbers game."[164]

In the meantime, the Agency was seeking to put together a final rule. Deadlines were continually being set and then revised. On March 30, Eula Bingham stated that the policy was "in the final stages of being written."[165] In an interview on June 26 with the Bureau of National Affairs she said that she hoped to see the policy completed "by late summer, early fall."[166]

On August 9, 1979 the scientific portion of the preamble was distributed to the Agency staff for review.[167] One thousand pages long, the preamble was the result of six months of effort by members of the staff and Clement Associates. According to Jay Turim, Vice President of Clement, the consulting firm had identified thirty to forty key issues

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163 Ibid.

164 Ibid., p. 1653.

165 8 OSH Rptr. 1627 (4/5/79).

166 9 OSH Rptr. 101 (7/5/79). In that interview she also said that she saw no relation between the policy and the legal issues in the pending Supreme Court review of the Fifth Circuit's decision concerning the benzene standard.

167 9 OSH Rptr. 251 (8/16/79)

from the hearing record and outlined various positions on each.[168] Turim noted that the firm was careful not to draw a conclusion on any of the issues. According to an OSHA staff member, Anson Keller drew the conclusion from the evidence, as well as supervising the work of the firm's staff.[169]

An official memorandum signed by Eula Bingham targeted the approval of the final rule for early September.[170] In order to speed the review (and perhaps to minimize the amount of evidence available for later legal challenges) Bingham instructed the staff to bring comments directly to Keller, rather than author official memoranda.[171]

On September 13, Bingham stated that the policy would be issued "in a matter of weeks."[172] As an aside, two days earlier Susan Clark, an industrial hygienist at OSHA must have put a chill through the audience when she predicted at the national meeting of the American Chemical

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168 Ibid. This was the final part of the $600,000 contract that OSHA had awarded to Clement Associates in April 1977.

169 9 OSH Rptr. 251.

170 Ibid.

171 Ibid.

172 9 OSH Rptr. 355 (9/20/79).

Society that OSHA's policy "may well serve as a model for other regulatory agencies."[173]

But by the middle of October, the target was still a matter of weeks.[174] When disclosing that it would be issued by the end of November, Anson Keller also revealed that he was planning to leave OSHA on December 1. As a indication of the tenuousness of the new target date (as well as of Keller's importance) Keller announced that although he hoped to be able to leave on December 1, Bingham had asked that he wait until the policy was completed.

On November 1, Bailus Walker (who had replaced Grover Wrenn as Health Standards Director) stated that the policy would be issued in December.[175] The cancer policy may be out "mid-December or before." At the same time Walker took a positive view of the policy's impact, suggesting, once again that it would contribute to reducing the present regulatory backlog.[176] On December 11 however, Grover Wrenn (who was at that time the Director of Federal Compliance and State Programs) stated that the policy would be issued "within a month."[177]

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173 9 OSH Rptr. 340 (9/13/79.

174 9 OSH Rptr. 491 (10/25/79).

175 9 OSH Rptr. 539 (11/8/79).

176 At the time, OSHA was considering at least five other health standards.

177 9 OSH Rptr. 659 (12/13/79).

F. The Final Rule

Wrenn was very nearly correct. The cancer policy was released to the public on January 16, 1980.[178] Secretary of Labor Marshall himself announced it, terming it "the Nation's first comprehensive policy" for regulating cancer-causing chemicals in the workplace.[179] As expected, it drew both praise and scorn. President Carter's Domestic Policy Staff termed it "more flexible" than the proposal and observed that it reflects a "cost sensitivity."[180] It can be seen as being more flexible in two respects. First, the issuance of an emergency temporary standard is not automatic for Category I substances as it was in the proposal. Second, it did include risk assessment in a limited respect. Risk assessment would be employed to prioritize substances for regulation.

According to the policy, OSHA would first establish a "candidate list" of potential occupational carcinogens. Including or excluding a substance from the list would not be a reviewable action, for it would not be meant to reflect a final scientific determination that it is or is not a carcinogen.[181] OSHA would then draw two lists of ten substances as potential Category I and Category II carcinogens. The Agency would then follow section 6(b) guidelines to regulate individual

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178 9 OSH Rptr. 763-5 (1/17/80). It was published in the Federal Register on January 22 (45 Fed. Reg. 5002).

179 9 OSH Rptr. 787 (1/24/80).

180 9 OSH Rptr. 787 (1/24/80).

181 However, this is half-error, because substances would be drawn from this list, failing to regulate a substance logically could only be challenged at this point. So, precluding the legal review of the act of exclusion effectively bars a review of the Agency's failure to review that substance in toto. Moreover, when OSHA would publish the first candidate list in August, several firms would protest that in the public mind, inclusion constitutes guilt by implication, in essence complaining that the burden of uncertainty has shifted unfairly. (10 OSH Rptr. 715, 12/4/80).

substances. Although not wishing to be bound by any particular formula for prioritizing substances ["The setting of priorities is a complex matter which requires subjective and policy judgments."[182]], the policy does identify some of the factors that would be considered:[183]

(1) The estimated number of workers exposed;

(2) The estimated levels of human exposure;

(3) The levels of exposure to the substance which have been reported to cause an increased incidence of neoplasms in exposed humans, animals or both;

(4) The extent to which regulatory action could reduce not only risks of contracting cancer but also other occupational and environmental health hazards;

(5) Whether the molecular structure of the substance is similar to the molecular structure of another substance which meets the definition of a potential occupational carcinogen;

(6) Whether there are substitutes that pose a lower risk of cancer or other serious human health problems, or available evidence otherwise suggests that the social and economic costs of regulation would be small; and

(7) OSHA will also consider its responsibilities for dealing with other health and safety hazards and will consider the actions being taken or planned by other governmental agencies in dealing with the same or similar health and safety hazards.[184]

How can the significance of this cost-effectiveness be evaluated? In one sense, it is fairly significant, as an attempt to explicitly list those factors that had up until that time implicitly guided priority-setting and which, if a regulation were evaluated by its cost-effectiveness, would have to be components of the decision rule.

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182 9 OSH Rptr. 763 (1/17/80).

183 The guidance that the OSH Act itself offers is, if anything, slanted toward disregarding economic costs when setting priorities. "In determining the priority for establishing standards under this section, the Secretary shall give due regard to the urgency of the need for mandatory safety and health standards for particular industries. . . or work environments" (section 6(g)).

184 29 C.F.R. 1990.131, 45 Fed. Reg. 5002, 5285.

But, as will presently be argued, in another sense it had no real significance.

It seems reasonable to assume that including this degree of risk assessment was a political concession to the powerful forces urging "flexibility" and "rationality." Examining it, though, it seems obvious that it was a concession only on paper. OSHA's regulatory agenda (at least after its first two years issuing "national consensus standards") had always been set according to these principles. It had just been done implicitly. The real debate is not over whether or not to base the prioritization upon a risk assessment of some sort. Rather, it is over (1) whether it should be done according to an explicit formula or by a rule-of-thumb, and (2) the relative strengths of these factors.

(1) OSHA was careful to state that listing these elements does not create "legal rights." In other words, how the Agency uses them to set priorities would not be reviewable by the federal courts. So, in reality, the Agency was conceding very little. If it had its way, it would not be forced to defend its use or misuse of risk assessing.

(2) Fundamentally, the real disagreement over risk assessment lies over the relative importance given to the consideration of costs. One would expect that the Agency (under Bingham's administration) would place a much smaller coefficient in front of the "social and economic costs" factor in its implicit formula than would AIHC or API. But the Agency realized very shrewdly that what is not done (actually stating the relative weights) cannot be judged to be wrong (inconsistent with the OSH Act).

Although the policy received uniform condemnation from business interests, it received a mixed review from labor and consumer groups.

The United Auto Workers and the Oil, Chemical and Atomic Workers supported it strongly. Steve Wodka of OCAW termed it "a pioneering step."[185] But a number of groups expressed reservations. Its most conspicuous inadequacy from their point of view was its dropping the requirement that an ETS automatically be issued for Category I substances. Michael Wright of the United Steelworkers reported that the union was "surprised and dismayed" at the absence of any mandatory action.[186] Sidney Wolfe, Director of the Health Research Group, had the same complaint (as well as being concerned with the lack of a "use-permit system) although he termed the policy "a big step forward."[187] The AFL-CIO was so disturbed by the lack of an automatic remedy that it petitioned for review (more on this presently).

It is easy to understand the concern felt by labor unions for the absence of an automatic remedy. The fact that an ETS would automatically be issued was arguably the most effective component of the proposed rule. After all, it bypasses the regulatory mill almost entirely. And, as part of the proposal, it was probably the target most aimed at by business interests. It is possible that lawyers for OSHA believed an ETS automatically issued would be struck down in the courts unless the Agency could show that it was necessary to avert a "grave danger." The Agency would still possess the power to issue an ETS when it had sufficient evidence to show this. But why should it restrict its attention to substances that a Court would hold posed a grave danger? Moreover, it is possible that in many circumstances, issuing an

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185 9 OSH Rptr. 787 (1/24/80).

186 Ibid.

187 Ibid..

emergency temporary standard is not a cost-effective use of Agency resources.

G. Petitioning for Judicial Review

Section 6(f) of the OSH Act provides the right of judicial review of a standard. The litigant must file a petition within sixty days of the issuance of the standard in the U.S. Court of Appeals in which he resides or does business.

Environmental lawsuits are notorious for the utter confusion with which they often commence. But in the instance of the cancer policy this was carried to absurdity. At least eleven lawsuits were filed by various interested parties in four different courts. And one party (API) filed suit four separate times in the same court (the Fifth Circuit Court of Appeals). According to an informal count by the author, thirty-one distinct corporations, trade associations, and laborunions were dissatisfied enough to sue OSHA.[188]

The drama/comedy began on January 9 when after an "invitation only" briefing, the American Petroleum Institute petitioned the Court of Appeals for the Fifth Circuit to review the policy. The policy would not even be filed at the Office of the Federal Register until nine days later. But, no matter. A spokesperson for API indicated that the suit was filed as a "precautionary measure."[189]

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188 As will be discussed in the text, one party filed suit in the D.C. Circuit Court, one filed in the 3rd Circuit Court, twenty filed in the 5th Circuit and twenty-eight (many of them the same) filed in the District Court for the Eastern District of Texas.

189 9 OSH Rptr. 764 (1/17/80). OSHA had given the briefing to representatives of business and labor at which it revealed that filing was imminent.

The motivation behind API's haste was to win the "race to the courthouse." Ordinarily, a review of an OSHA regulation is heard in that court that has jurisdiction and in which the earliest timely petition is filed. Since this first suit was filed before the policy had been brought to the Federal Register, in all likelihood it would be considered "premature" (and was). The logic behind this restriction is obvious. It cannot be claimed that someone (or an Agency) is at fault before he has even done what he is accused of. Moreover, not imposing a restriction of some sort would make it impossible to logically determine which suit is actually primary. Furthermore, it is a question of fairness that all legal parties be accorded the same rights. A party should not be able to have a case heard in a court favorable to it simply because it has inside information. So, ordinarily a public action must occur to make a case justiciable.[190]

API's desire was to have the case heard in a court with a reputation of writing opinions favorable to business interests. It was the Fifth Circuit that had vacated the benzene standard, a very favorable case from API's perspective. Indeed, API had been the plaintiff also in that suit. But, unsure of themselves, the lawyers for API decided to file again on the 16th, premature by only two days. Perhaps getting a little nervous, lawyers for the AFL-CIO also filed on the 16th in the District of Columbia Circuit (the circuit with the

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190 However, in a very similar situation in which the litigants were made aware of the standard at an informal "invitation only" gathering the D.C. Circuit held (with one dissent) that "disclosure to the general public is not necessary to make Agency action ripe for judicial review." [Industrial Union Dep't v Bingham, 570 F.2d 965, 68 (D.C. Cir. 1977).] As the Court stated, an important part of the rationale behind the issue of ripeness is a question of fairness.

reputation of being most "liberal").[191] Perhaps to get the last word in, API filed once more on the 17th.

Both groups were in agreement in that neither felt that the policy was in the best interests of the workers. According to a lawyer for API, ". . . the rule will not provide the greatest benefit for workers" because of its apparent disregard for scientific principles.[192] And George Taylor of the AFL-CIO contended that the removal of the provision for automatic issuance of ETS's "would pose grave dangers for exposed workers."[193]

There were four suits filed on the eighteenth, apparently simultaneously. API and AFL-CIO each filed again, and AIHC ("with a host of industries and industry associations")[194] filed in the Fifth Circuit as well as in the U.S. District Court for the Southern District of Texas.[195]

AIHC's stated rationale in petitioning the District Court was that whereas the OSH Act specifies that standards be challenged in courts of appeal, the cancer policy was not a standard, but an administrative

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191 It seems a reasonable conjecture that a good part of the reason why the AFL filed in the first case was to enable the case to be consolidated and heard in the D.C. Circuit. An interesting instance of this strategy was in Hercules Inc. v EPA, 589 F.2d 91 (1978), a case concerning EPA's standards for endrin and toxaphene issued under section 307(a) of the Clean Water Act. The case was consolidated in the D.C. Circuit, where the Environmental Defense Fund had filed. And when EDF voluntarily removed itself, it remained in the D.C. Circuit, (one can imagine) much to the chagrin to Velsicol Chemical Co., which had petitioned the Sixth Circuit.

192 9 OSH Rptr. 788 (1/24/80).

193 Ibid.

194 Ibid.

195 Fourteen other organizations joined AIHC in these suits. One other petitioned the Fifth Circuit for permission to intervene in the suit. The district court suit was filed at 8:30 AM (EST). OSHA would seek its dismissal as being premature (9 OSH Rptr. 835). But Scurlock Oil Company filed its petition on time, at 1 PM.

statement of policy.[196] Beginning the suit at the district court level interposes another hurdle, and an additional delay for OSHA.

AIHC claimed that the policy violated due process in various ways. It also requested that the Fifth Circuit vacate the generic regulations until an economic and environmental impact statement was completed and circulated for comment. However, OSHA had in fact released an EIS on the 16th, at the same time that it announced the policy itself.[197] Depending on one's perspective, in claiming that the policy was not a regulation (in its district court suit) and at the same time seeking to have the regulation vacated (in the Fifth Circuit) AIHC was either covering all bases or trying to have its cake and eat it too.

On February 5, OSHA filed motions with all three courts to dismiss as premature all petitions for review which had been filed prior to 1 PM (EST) on Jaluary 18.[198] If these motions were successful, the only suits that would remain would be the AFL-CIO's in the D.C. Circuit, API's and AIHC's in the Fifth Circuit and Scurlock Oil Company's in the District Court in Texas. On February 4, OSHA had requested that the District Court stay all discovery in the case until the question of jurisdiction was answered.

A dark horse entered the running on February 15. The United Steelworkers filed a petition for review in the Third Circuit Court of Appeals.[199]

On March 3, OSHA filed a motion in the D.C. Circuit and sent a letter to the Fifth Circuit requesting that they decide quickly in which

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196 9 OSH Rptr. 788

197 Admittedly a little belated.

198 9 OSH Rptr. 835.

199 9 OSH Rptr. 924 (3/6/80).

court the case would be consolidated so that the Court could decide whether jurisdiction lies at the district or appeals court level.[200] In its motion, OSHA suggested that it be consolidated in the District of Columbia Circuit. It offered as reasons the fact that OSHA and hearing record are in Washington, and the council for API, AIHC and AFL-CIO are also in the area. Moreover, the fact that challenges to EPA regulations on carcinogens were limited to the D.C. Circuit argues for that Court to hear the cancer policy case as well.

As if it were not complicated enough, the American Iron and Steel Institute (and eleven major steel companies) petitioned the Fifth Circuit to review the policy on February 29, and the District Court for the Southern District of Texas on March 5.[201] AISI requested that its case be consolidated with other industry petitions in those courts. Again, it must be wondered what the motivation was for filing one and a half months after the fact. These plaintiffs would have little to add. One explanation, though, is that this additional suit would make it more difficult to have the case consolidated in the District of Columbia Circuit. As of that point in time, whereas only the AFL-CIO had filed in the D.C. Circuit, there were three timely suits in the Fifth Circuit comprising (a minimum of) twenty-nine parties.[202] Perhaps the strategy paid off. On April 2 the D.C. Circuit announced that it would leave the decision to the Fifth Circuit.[203]

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200 9 OSH Rptr. 923 (3/6/80)

201 9 OSH Rptr. 947 (3/13/80).

202 On March 14, there was yet another industry petition (9 OSH Rptr. 1051, 4/10/80).

203 Ibid.

On March 11, OSHA published an additional paragraph to the policyin the Federal Register allowing a procedure for administrative stays to be issued.[204] It stipulated that any party requesting a stay must submit a petition by March 31. On March 31 AIHC requested a stay, claiming that one was necessary to prevent irreparable harm to the affected industries and that there was "substantial likelihood" that it would prevail on the merits of the case.[205] On April 7 OSHA filed a memorandum with the Fifth Circuit informing the Court that its "preliminary assessment" was that the request would be denied.[206]

Little headway was made in the suits during the next four months. Although the policy officially took effect on April 21, OSHA did not use it, indeed it has not yet been used. On August 8 a judge from the U.S. District Court for the Southern District of Texas dismissed, for lack of jurisdiction, the pending cases in his Court.[207] AIHC and API immediately appealed the decision to the Court of Appeals for the Fifth

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204 Ibid.

205 Ibid. The grounds for a Court's issuing a temporary injunction are quite similar.

206 Ibid.

207 10 OSH Rptr. 285 (8/14/80).

Circuit (of which Texas is a part).[208] AISI waited until August 27 to join their appeal.[209]

On September 15, the Fifth Circuit decided to hear the case, although it had not yet ruled on the appeal of the District Court ruling concerning jurisdiction.[210] This is just where the case has remained. The entire effort and the intricate strategies that were employed to have the Judiciary overturn the policy were wasted. It had derailed by itself. The following section chronicles how this came about.

H. Later Developments

The denouement of OSHA's generic cancer policy has been brought about through two causes. The first was the Supreme Court's decision affirming the Circuit Court's vacating of the benzene regulation. The second was the change in regulatory philosophy that occurred with the change of Presidential administrations in the winter of 1981.

On July 2, 1980 the Supreme Court delivered its opinion in Industrial Union Department v. American Petroleum Institute, 448 U.S. 607. A close majority of five to four decided to affirm the Circuit Court's decision. Although this is not the place to closely analyze the decision, a few words of observation are in order. Of the majority of five, only four ruled on the substantive issue of how OSHA should regulate. Justice Rehnquist wrote a concurring opinion in which he argued that section 6(b)(5) was an unconstitutional delegation of legislative authority to the executive (at 687). A plurality of four

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208 10 OSH Rptr. 286 (8/14/80).

209 10 OSH Rptr. 358 (9/4/80).

210 (No. 80-3018).

ruled that the evidence for a risk quantification had to be used to set standards that are "reasonably necessary or appropriate" (at 639).[211] However, this threshold determination can only be made after the risk of exposure is quantified. OSHA had not even attempted to construct a dose/response curve for occupational exposure to benzene, thinking that it was unnecessary since section 6(b)(5) directs that toxic substances be controlled to the extent feasible.[212]

Since the same line of reasoning had been followed in the cancer policy, it was clear that OSHA might have to amend it. Moreover, in a footnote (at 645) the Court strongly intimated that it did not favor the feasibility construction of the cancer policy. But since only a plurality had ruled against OSHA on these issues, this part of the ruling did not have the force of law. The minority opinion, written by Justice Marshall, strongly supported the benzene standard that OSHA had issued (688-724). Nevertheless, in November 1980 Bailus Walker revealed that the Agency was considering amending the policy in light of the Supreme Court's decision.[213]

By December 16, OSHA had decided that changes were needed. On that date the Agency asked the Fifth Circuit to stay its proceedings until the changes were made.[214] The Court granted the request on the 23rd. The letter that the Agency sent stated that republishing the provisions and their accompanying preamble "is among the Agency's highest

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211 Section 3(8) defines "health and safety hazard" as a standard that is "reasonably necessary or appropriate to provide safe and healthful employment."

212 According to Grover Wrenn this was done as a test case: Personal interview with author (1/11/81).

213 10 OSH Rptr. 629 (11/20/80).

214 10 OSH Rptr. 795 (1/8/81).

priorities, and we are confident that it will be accomplished with all due speed."[215] This should not be surprising. By this time, the OSHA of Eula Bingham was a lame duck. On the second Tuesday in November the American electorate had voted in a new Administration, and one that was not very likely to continue along the same regulatory path. In cold hindsight, the feverish contortions that OSHA would go through to breathe new life into the policy after the blow given it in the Supreme Court's decision seems like wasted effort considering what was to become of the policy. But this is an unfair appraisal. Although many of its early sponsors were no longer employed by OSHA (Grover Wrenn having left that summer, and Anson Keller the preceding winter) there must have been a strong feeling of kinship among those remaining (among whom, Chuck Gordon had attended virtually the entire hearing 2-1/2 years earlier) for the policy itself, and a desire to "see it through."

In the very last days of the Carter Administration in January, OSHA published revisions to the policy to bring it into conformity with the benzene decision.[216] These changes removed all references to "feasible levels,"[217] substituting the requirement that standards eliminate "significant risk."[218]

At the beginning of this section it was suggested that the policy's denouement stemmed from two causes. Certainly the benzene decision was one. It undercut OSHA's attempt to streamline the standard-setting process by requiring that risk be quantified (and implicitly assessed) so that standards be set that are "reasonably necessary or appropriate."

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215 Ibid.

216 46 Fed. Reg. 4889 (1/19/81) and 46 Fed. Reg. 7402 (1/23/81).

217 46 Fed. Reg. 4890-92.

218 46 Fed. Reg. 7403-5.

A whole set of scientific issues would need to be considered in individual rule-makings and would be contestable in the courts.[219] If this alone had occurrred, the cancer policy would have limped along. It is impossible to determine what impact such a policy would have had on decision-making.[220] But the final nail was driven into its coffin with a set of decisions by the OSHA of the Reagan Administration.

Whereas the change in regulatory philosophy at OSHA had been slight when Carter became President, the change was absolute in 1981. Carter was as concerned with regulatory reform as is Reagan. But, in the sphere of toxic substances, Carter meant to reform regulation through coordinating the responses of the various federal agencies and by making them justify seemingly non-cost-effective and inefficient standards. Witness the explosion of interagency committees and task forces during the Carter Administration.[221] These committees sought to influence OSHA to greater standards of cost-effectiveness. But because the Agency had a strong labor "bias" it was able to resist. And Executive Order 12044, for all its bluster, in itself had little impact on standard-setting. As evidence for this, see how relatively easy it was for OSHA to fulfill the Order's procedural mandate by filing a regulatory analysis which was simply an exposition of the reasoning that had gone into the cancer

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219 Notably, all of the assumptions that go into the construction of a dose/response curve.

220 Moreover, the conclusion of Part III presents an argument that its potential impact was limited from the outset.

221 Those that had, or were meant to have, an influence on the development of the cancer policy included the Interagency Regulatory Liason Group, the Regulatory Council, the Toxic Substances Strategy Committee and the Regulatory Analysis Review Group.

policy proposal in the first place.[222] The goal of the Reagan Administration has been perceived to be the discontinuation of federal activities that protect workers' health.

The first step that the new Administration took (on January 29, 1981) was to postpone, in accordance with a memorandum from the President, until March 30, all federal regulations that were to take effect in the interim.[223] There had been a great deal of grumbling concerning the "midnight regulations" of the Carter Administration. Reagan's memorandum was seen as a way of preventing the new administration from being saddled with new responsibilities that had not been carefully thought out. But, as it turned out, it was also used to scuttle regulations that the new Administration did not approve of. The memorandum began: "Among my priorities as President is the establishment of a new regulatory oversight process that will lead to less burdensome and more rational federal regulation."[224] The action was applauded by spokespersons for the Chamber of Commerce and the National Association of Manufacturers.[225] Among several OSHA regulations that were affected were the revisions to the cancer policy which were to have taken effect on February 18.

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222 A problem in designing any procedural requirement is how to make it potent while preventing it from being unduly constricting. Perhaps the best example of this is the largely formal requirement of the National Environmental Policy Act that an agency perform an impact statement on any action that is likely to have a significant effect on the environment. An adequately prepared and filed statement that details in exquisite detail massive environmental impact of the action fulfills the mandate of the Act. The action itself will be legal. courts have grappled with this, but have in general been reluctant to place any substantive meaning on the Act's provisions.

223 10 OSH Rptr. 1225 (2/5/81).

224 Ibid., p. 1226.

225 Ibid.

On March 9, the American Petroleum Institute sent a brief to Secretary of Labor Raymond Donovan urging that after a period of notice and comment, the policy be more extensively amended so that (1) consideration of scientific issues in individual rule-makings not be foreclosed[226] and (2) it specify that benefits bear a reasonable relationship to costs.[227] But, it is difficult to understand the brief's later comment that these changes would "preserve the ample benefits of generic rulemaking."[228]

On March 25, the policy was listed as one of the twenty-seven regulations that would be reviewed as part of the Administration's plan for "economic recovery."[229] And two days later OSHA formally withdrew the amendments, to permit the Agency to "address the alternatives that had not been fully considered and then later, if appropriate to repropose the amendments."[230] The tables had turned. Ronald Lang, now apparently on the inside, predicted that, "The withdrawal of the

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226 American Petroleum Insititute, In re Proposed Amendments to the OSHA Policy for the Identification, Classification and Regulation of Potential Occupational Carcinogens, OSHA Docket No. H-090A, 3/9/81, p. 22.

227 Ibid., p. 29. On this point it cited President Reagan's Executive Order 12291 which specified that Federal acts not be adopted "unless the potential benefits to society. . . outweigh the potential costs to society." (46 Fed. Reg. 13193).

228 Ibid., p. 33.

229 10 OSH Rptr. 1387 (4/2/81).

230 46 Fed. Reg. 19000. At the same time, OSHA was administratively withdrawing several other last minute regulations as well as informational materials which it felt provided a biased, and therefore inappropriate, view of the occupational health situation.

amendments is only part of the effort to review the whole standard."[231] Steve Wodka had a somewhat more dour view: "It seems that this Administration is taking a meat-ax approach to worker health regulation."[232]

It was clear that opposition to the policy was broadly based. On June 13 the Office of Management and Budget announced that it was reviewing the policy, and that it expected the review to be completed by December.[233]

The one positive event for the policy occurred on June 17, 1981 with the Supreme Court's ruling in the appeal of the D.C. Circuit's decision to uphold the cotton dust standard.[234] This was a widely anticipated decision because it was expected that the Court would rule on whether the OSH Act mandated that cost-benefit analyses be performed. The Court had avoided this question in the benzene case, overturning the standard on more limited grounds (that OSHA had not fulfilled its burden of showing that the standard was "reasonably necessary or appropriate"). But because OSHA had offered sufficient evidence that the standard for cotton dust would offer benefits, the Court was forced to rule on the issue of whether benefits must bear some reasonable relationship to costs.

The majority consisted of the four dissenters from the benzene case plus Justice Stevens (who had written the plurality opinion in I.U.D. v

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231 10 OSH Rptr. 1387.

232 Ibid.

233 11 OSH Rptr. 51 (6/18/81)

234 American Textile Mfrs. v Donovan, 452 U.S. 490 (1981). Earlier that spring OSHA had sought to withdraw the regulation after oral arguments had already been heard in the winter. But the Court refused to vacate the Circuit Court's decision (10 OSH Rptr. 1385 4/2/81).

A.P.I.). In no uncertain terms it rejected the contention that "reasonably necessary or appropriate" standards can only be gotten by weighing the benefits against the costs (at 513). Moreover, through an examination of the legislative history of the Act, the majority came to the conclusion that Congress had understood that it would involve substantial costs and that in using the construction "to the extent feasible" Congress intended that standards not be based on a cost-benefit analysis (at 519-20).[235]

But the Court's decision had no impact on the deliberations within OSHA of the fate of the cancer policy. In July the Department of Commerce released the results of a survey on which the policy was ranked as the sixth most burdensome federal regulation (even though it was yet to be implemented).[236] In September OSHA revealed that it was evaluating the cancer policy (along with nine other health standards). The study, whose purpose was to evaluate "new scientific and technological developments" and cost-effectiveness questions was expected to take from two to three years.[237]

In a speech before a conference of the Rubber Manufacturers Association, Mark Cowan (a Deputy Secretary of Labor for OSH) revealed that the Agency was about to formally amend the policy.[238] In a very

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235 On this last point the Court may be less clear. In the Advance Notice of Proposed Rulemaking to amend the policy, published the following January, the Agency stated that in its decision the Supreme Court "permits OSHA to utilize cost-benefit analysis in setting priorities" (emphasis added); (47 Fed. Reg. 187, 89, 1/5/82). In fact, however, the Court was not even ruling on priority setting. Whether this can be construed as "permission" I am unable to judge however.

236 11 OSH Rptr. 113 (7/9/81).

237 11 OSH Rptr. 276 (9/3/81).

238 11 OSH Rptr. 310 (9/17/81).

revealing comment Cowan explained the new rationale for genericrule-making:

> We don't want to look at each substance differently. We want some kind of generic policy so that those out there producing the substances will know how we're going to deal with them.[239]

The value of a cancer policy lay in its benefits to business, not workers.[240] In an interview with the Bureau of National Affairs on September 24 Cowan questioned the publication of priority lists prior to regulation. It "could do a lot of damage to the psyche of the public and damage to the industry." And he predicted that the Agency would publish the Advance Notice of Proposed Rulemaking by the end of the year, and hoped that the evaluation would be completed by late 1983.[241]

The ANPR was published on January 5, 1982.[242] Its aim was to seek public comment in order to determine whether the policy needed to be revised. It pinpointed six questions:

(1) How OSHA should consider cost-effectiveness in standard-setting.

(2) Whether it is appropriate to retain the "no exposure level" provision for those substances that have suitable substitutes

(3) Whether negative data should be considered.

(4) Whether the priority-setting process should be changed.

(5) "How" cost-benefit analysis should be incorporated in the priority-setting process.

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239 Ibid.

240 Perhaps a criticism of Bingham's handling of the policy is the failure to stress this aspect of generic rule-making more strongly.

241 11 OSH Rptr. 343 (10/1/81).

242 47 Fed. Reg. 187 (1/5/82).

(6) Whether the policy should specify techniques of quantitative risk assessment and significant risk determinations.

The focus of each of these questions is on how to shift the burden of uncertainty back onto the shoulders of the workers. It appears self-evident that should the policy be re-proposed by the Reagan Administration it will be a a vastly different document than the one inherited from the Carter Administration. Politically it has the ability, and legally it has the right to reconsider regulations. Although it will be shown presently that at its best the policy would have had limited benefits to regulation, in spite of this it does seem a shame that the policy is scuttled so easily after so involved and dynamic a regulatory battle.

TABLE 15.

PRINCIPAL ISSUES RAISED DURING THE PROCEEDINGS

OSHA's Proposal	The Response	How Dealt With in the Final Rule	Textual Reference
—proposal in general	occupational exposure is insignificant in national cancer rate	considered untrue and irrelevant	pages 34-44
—no explicit provision for updating of policy	science will be "frozen"	provision added for automatic review by Directors of NCI, NIOSH and NIEHS every three years and petitions from public	
-limitations on issues in each rule-making	science will be "frozen"	retained as in proposal	
-ETS automatically issued for Category I substances	unfair; violates due process	provision eliminated	
—no provision for regulating greatest risks first	not cost-effective	provision for priority-setting added	
-classification by evidence from animal tests	unreliable	retained, and strengthened	pages 62-65
-there is no threshold	an incorrect assumption	retained as in proposal	pages 66-71
-finding of beign tumors to be considered as significant or malignant	unscientific	considered only under certain circumstances	pages 78-81
-short-term tests will be used	unreliable	retained as in proposal	pages 102-108
-structural similarity was not included	a valuable form of evidence	will be used when appropriate	pages 108-110
-positive data supersedes non-positive data	unscientific	modified to permit use of non-positive data when appropriat	pages 99-102
-risk will not be quantified	throws away information, is wasteful of society's resources	retained as in proposal[243]	pages 133-15
-exposure to equal zero when there is a suitable substitute	unfair and wasteful	retained as in proposal	
-PEL to "lowest feasible level"	wasteful, should use risk/ benefit analysis	retained as in proposal[1]	pages 124-126
-PEL to "lowest feasible level"	producers should have to obtain permits	retained as in proposal	
-control primarily through engineering changes	wasteful; should be through "work practices"	retained as in proposal	

243 These provisions were changed when the policy as amended on 1/19/81 and 1/23/81.

TABLE 16.

PRINCIPAL ASPECTS OF THE VARIOUS SCHEMES

Category	Manner of Classification	Consequences of Classification	Permitted Exposure Level	Issues Permitted in Hearing
		OSHA'S PROPOSED RULE[244]		
I "Confirmed Carcinogens"	(1) humans or (2) 2 mammalian species of (3) single m.s. if replic. or (4) single m.s. if supported by short-term tests or other evidence	-immediate issuance of ETS -proposal within sixty days	-lowest feasible level immediately -as low as feasible through engineering controls, except when "suitable	(1) whether substance is correctly classified (2) determination of l.f.l. or existence of substitute (3) whether substance has "unique properties or uses" (4) the environmental impact
II "Suspect Carcinogens"	(1) 1 unreplicated bioassay (2) other "suggestive evidence"	-proposal within sixty days	"an appropriate level based upon acute of chronic effects"	Same as for "I" except determination of "appropriate rather than "lowest feasible" level
		AIHC'S ALTERNATIVE		
I "Known Human Carcinogens"	epidemiological or "other human data"	-ETS only when life-threatening hazard is known to exist -follow normal 6(b) guidelines	dose/response to quantify risk; then risk-benefit analysis; emphasis on control through "work practices"; no substitution	No Restrictions
II "Confirmed Animal Oncogens	"well documented results of adequate mammalian bioassays in at least two different species"	Same as for "I"	Same as for "I"	No Restrictions
		OSHA'S FINAL RULE		
I	(1) humans (2) single mammalian bioassay with concordant evidence, e.g. short-term tests	-no automatic ETS -issuance of proposal -sixty days for comments -one hundred days until hearing	as low as feasible except when "suitable substitute" exists: then exposure to equal zero	(1) where there exists "substantial new evidence" (2) whether it is correctly classified (3) environmental impact (4) determination of lowest feasible level (5) existence of suitable substitutes
II	(1) if evidence meets "I" but is only suggestive (2) single bioassay without concordant evidence	Same as for "I"	"As appropriate and consistent with the statutory requirements on a case-by-case basis"	Same as for "I" except determination of "appropriate employee exposure level" rather than "lowest feasible level"
		AFTER AMENDMENTS		
I	Same as for Final Rule	Same as for Final Rule	"the lowest feasible level which is reasonably necessary or appropriate to eliminate significant risks; no exposure if there is a suitable substitute and if substitution is reasonably necessary or appropriate to reduce significant risk	Same as for Final Rule except: (a) determination of significance or risk (b) other valid and relevant arguments will be considered
II	Same as for Final Rule	Same as for Final Rule	Same as for Final Rule	Same as for Final Rule

244 OSHA's draft proposal was almost identical to the proposed rule.

TABLE 17.
CHRONOLOGY

Principal Agency Actions			Significant Related Events	
		1976		
Winter	"CBS incident"			
		1977		
			Morton Corn resigns	01/13
01/24	draft proposal issued and sent to NACOSH			
			Eula Bingham takes office	03/23
			NACOSH presents recommendations	05/05
10/04	proposal issued			
10/07	draft environmental impaat qtatement iqqued			
			formation of AIHC announced	11/22
		1978		
			AIHC's alternative released	01/10
			Foster Snell study released	03/27
05/16	hearing begins			
07/14	list of 269 Category I substances released			
07/25	hearing ends			
			HEW report released	09/15
10/24	regulatory analysis released			
			RARG study released	10/25
		1979		
01/24	hearing record certified			
			IRLG report released	02/07
		1980		
01/16	final rule issued EIS released			
			suits filed	01/09-03/14
02/05	OSHA requests that suits filed prior to 01/16 be dismissed			
			Supreme Court's benzene decision	07/02
			Fifth Circuit decides to hear the case	09/15
12/16	OSHA asks that Court stay the case pending amendment			
		1981		
01/19, 01/23	amendments isqued			
03/27	OSHA withdraws amendments			
			OMB announces it is reviewing policy	06/13
			Supreme Cout cotton dust decision	06/17
		1982		
01/05	ANPR to reconsider policy released			

CONCLUSION TO PART III
Natural Limitations of "Generic" Rule-making for Regulating Potential Occupational Carcinogens

On the preceding pages a generic policy was presented as offering a short-cut to standard setting by deciding through regulatory fiat evidentiary issues that had been a source of legal challenge of many of OSHA's regulations. Its authors hoped that, thus streamlined, the standard-setting process would be more productive; more hazards would be eliminated from the workplace with a consequent greater savings of lives. But there is reason to suspect purported gains to effectiveness of any but the most radially general generic policy.

Under the formulation contained within OSHA's proposal and the final rule, standard-setting would be reduced to a relatively simply two-stage recipe:[1]

(1) classification,
(2) determination of the lowest feasible exposure level.[2]

In "stage one" a substance is classified as a human carcinogen if it caused cancer in any one of a certain pre-specified set of ways. "Stage two" determines a permissible exposure level by means of a feasibility analysis of technological as well as economic parameters.[3]

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1 See Table 16 ("Principal Aspects of the Various Schemes")

2 Under the amendments to the policy, a risk assessment would also be performed.

3 Moreover, Category I carcinogens can be effectively banned if they possess a "suitable substitute."

The standard-setting process as a whole can be simplified into three steps:

(1) developing and issuing a standard;
(2) presenting the standard to the public and allowing comments;
(3) defending that standard in a court of law.

Certainly, at first blush, OSHA's generic policy would seem to dispense with many of the administratively and judicially crippling issues that, according to the prevailing view (discussed in these last two Chapters) had prevented OSHA from truly confronting the occupational cancer problem. But this is an instance when one would be misled by his initial perception. The cancer policy did not address most of the puzzling evidentiary and legal issues, and those that it did address were done partially.

To begin to see this, one needs only reflect on how substances would actually be classified according to the policy; on what it means to say that, "'X' caused the excess tumors in experiment 'A'." There are no markers delineating positive from non-positive results. Rather, the researcher must mark them. This involves an intuitive, yet intricate act of inference that is sometimes too casually termed "scientific judgment." This act has many parameters. In any experimental situation, each paramter lends an additional dimension of uncertainty to the significance of the results. Several of these parameters are discussed, and the uncertainty that accompanies each is gauged, in Chapter Four.

OSHA skirted the truly important and difficult questions bearing on the degree of significance that should properly be attached to

experimental results. Two indicative examples, significant in themselves, were the Agency's failure to pre-specify protocols that experiments would be held to, and its failure to enumerate standards of "statistical significance."

If there was a consensus on any issue raised during the hearing it was that carcinogen identification is simply too complicated to restrict permissible evidence by stipulating that it conform to pre-stated standards:[4]

> OSHA's avoidance of particular minimal or desirable testing and/or interpretation protocols accords with scientific opinions of most experts appearing at the public hearing.[5]

There will be no simple way for OSHA to evaluate the evidence presented. The Director of the National Cancer Institute explained that:

> Many experiments raise specific problems of interpretation; the resolution of these problems requires evaluation by experienced professionals in several disciplines, and cannot be reduced to a formula.[6]

But the virtue of formulae is in their eliminating frictions in the decision process. So, by this concession to scientific rigor the Agency decided to refrain from reducing a certain amount of friction from each of the three steps in the standard-setting process.

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4 There were exceptions, from the Environmental Defense Fund, as well as from witnesses for industry (see Hearings at Fed. Reg. 5140-41).

5 Hearings, Fed. Reg. 5139.

6 Arthur Upton, Ibid., p. 5149..

OSHA also avoided completely the tricky issues involved in setting standards for statistical significance.[7] The final regulation makes only the barest mention of these issues:

> Statistical evaluation will be used in the determination of whether results in human, animal or short-term studies provide positive evidence for carcinogenicity, but will not be the exclusive means for such evaluation.[8]

Once again, whether the results of a study are statistically significant is a decision that will need to be made in individual rule-makings.

The fewer decisions made within the cancer policy itself, the more would need to be made thereafter, and the smaller would be the benefit in terms of regulatory effectiveness. These questions, and others, that OSHA failed to conclusively address, would inevitably plague the Agency in future rule-makings. One of the issues that would be permitted in hearings and legal challenges in rule-makings under the policy is whether the substance in question was correctly classified. There are many ways of contesting the reliability of experimental findings. And there is no reason to believe that an interested party who felt damaged by an OSHA standard would voluntarily refrain from exercising its legal rights. In light of these considerations, the actual gain to effectiveness stemming from OSHA's attempt to pre-specify criteria of classification must be doubted.

The second stage of the regulatory recipe delineated in the cancer policy is determining the lowest feasible exposure level of a substance

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7 For a discussion, see pages 91-99.

8 29 C.F.R. 1990.1439(j).

already identified as a Category I carcinogen.[9] But determining feasibility is a difficult task.[10] It is one thing to mandate that an analysis be performed, but another to perform it. Moreover, any decision will likely be contested administratively and judicially. "Labor" will challenge a standard it believes to be too high to adequately protect workers. "Business" will challenge one it believes to be onerous. So, how much of a saving is had by merely stipulating that permissible exposure levels be at the lowest feasible level, something that courts had recognized from the start?[11]

The issues that the policy foreclosed, such as the validity of animal testing at high dose levels, were rarely in dispute. Indeed, at times courts have been more accepting of uncertain evidence than OSHA itself was in the proposed policy.[12]

As a member of the Solicitor's Office of the Department of Labor pointed out, legal challenges to OSHA health standards (prior to the benzene case) have focused on three principle issues:[13]

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9 Category II substances would undergo a different type of assessment.

10 For a fuller discussion see pages 124-126.

11 Of course, until the benzene case, in which the Courts held that standards also had to be "reasonably necessary and appropriate."

12 The best illustration of this was the acceptance by the District of Columbia Circuit Court of a conclusion of the carcinogenicity of certain PCB's by EPA under section 307(a) of the Clean Water Act based on evidence of structural similarity [Environmental Defense Fund v EPA, 598 F.2d 62 (D.C. Cir. 1978)]. OSHA, on the other hand, did not even include this type of evidence in the proposed rule, but did change its position in the final rule to permit it when appropriate.

13 Richard Voigt, "What are the Federal Laws that Govern Hazardous and Toxic Substances?: The Workplace," Proceedings of the Conference on Environmental Law - Toxic Substances, Williamsburg, Virginia: College of William and Mary, 1979, p. 85.

(1) the technological feasibility of the standards' requirements,

(2) the economic feasibility of the standards' requirements,

(3) the scientific basis for the standards' exposure level.

The first two of these most-litigated issues would not be foreclosed in Agency hearings or judicial review on individual standards in OSHA's cancer policy (as set forth in the final rule). And owing to the Supreme Court's interpretation of the OSH Act in the benzene decision, OSHA amended the final rule to include the admissibility of challenges to individual standards based on the third issue. Bearing all of this in mind, it is apparent that Grover Wrenn's early statement that the policy was "not intended to be a cookie-cutter approach to turning out regulations in a large number"[14] was a serious underestimate. To use an analogy employed in a very different context elsewhere in this paper, the policy suggests itself as being a vast expenditure spent shoring up the walls of an old house to keep out the elements when the house has no roof.

Moreover, if the argument contained in Chapter Six is correct, that courts exercise most of their power reviewing procedural components of rule-making rather than the substantive provisions of the standards themselves, then the cancer policy does little to disarm the judiciary of its most potent weapon of review. Courts will always exercise a careful scrutiny of the manner in which Agencies fulfill their procedural responsibilities, the Supreme Court's decision in Vermont Yankee notwithstanding. What this means is that, if a party wishes, it

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14 7 OSH Rptr. 53 (6/9/77). See page 223.

will have little difficulty getting into court to challenge a health standard promulgated by OSHA.

OSHA's cancer policy was the most ambitious attempt by any Federal Agency to change the way in which suspected carcinogens are regulated. If used, it would permit standards to be based on a less meticulous review procedure than had been necessary. Its advocates had thought that by setting out criteria ahead of time and foreclosing certain issues from administrative and judicial review, data could almost be "plugged in." The policy was an attempt to shift some of the burden of evidentiary uncertainty onto the shoulders of those who benefit through the use of these candidates for regulation. And in principle one would expect it to work. The immediate reason why it has not yet worked is political: the change in Presidential Administrations in 1980 ushered in an entirely different attitude on the part of OSHA toward issuing health standards.

But if the argument of the preceding pages is accurate, there is another, more, fundamental reason why OSHA's policy would not succeed in allowing the Agency to begin to consider a significant portion of the hundreds of substances for which there is evidence that they are human carcinogens. If this argument is correct, then the policy was doomed from the start. To understand why, one needs to appreciate the relationship between evidentiary uncertainty and the structures in American law that are designed to guarantee individuals' rights of due process. The cancer problem cannot be truly met until a way is found around these legal structures. These concerns will be sketched more fully in the following, final, Chapter.

CHAPTER EIGHT
Summary, Conclusions and Recommendations for Future Research

Summary

Even the most casual glance at federal efforts to control carcinogens conveys an impression of ineffectiveness. Few substances have been regulated in the more than ten years since Congress began to direct sustained attention toward the risks posed by cancer-causing substances. One possible explanation for this is that the agencies of the government to which Congress has delegated its power have been unable to reach a consensus among expert opinion regarding the principles of science upon which the evidence for rational and legally defensible regulation must be based.

This paper explores this hypothesis by examining three questions. The first question concerns the general structure of the evidence underlying standards controlling exposure to carcinogens. This structure is described and alternative approaches that might be taken within this structure are discussed with a particular emphasis toward identifying and assessing the significance of the sources of uncertainty within each. It is concluded from this examination that any rational scheme of regulating suspected carcinogens must be based upon conspicuous and radical uncertainty.

The second question of the paper is what implications this uncertainty has for effective standard-setting. This question is explored by analyzing the constraints upon standard-setting imposed through the legal system as well as those imposed by the uncertain

character of the evidence. The legal system requires that government actions be based upon enough evidence to ensure that individuals' rights not be violated unfairly. It is argued that by itself, evidentiary uncertainty is not a constraint upon regulatory effectiveness. Rather, it is the relationship between this uncertainty and the requirement of due process that limits the ability of agencies to effectively control suspected carcinogens. The rights of parties who have legal standing to question standards in federal courts has imposed an excessive strain upon every stage of standard-setting. Thus, the constraint on rule-making is not simply scientific, but also social, political, and legal.

The third question of the paper concerns the degree of power of agencies to employ less strict standards of proof than is presently necessary. A case study is presented of what has been the most ambitious attempt by any federal agency to make it easier to regulate suspected carcinogens: OSHA's generic cancer policy. The attempt by the Occupational Safety and Health Administration to issue an effective "generic cancer policy" failed because the Agency was unable to resolve the tension between its dual constraints of radical evidentiary uncertainty and the obligation to respect rights of due process in a way that would make it significantly easier to set standards. Thus we conclude that OSHA effectively did not have the power to shift the "burden of uncertainty."

It is inferred from this, as well as the general inability of federal agencies, that regulators do not possess the effective power to shift the burden of uncertainty sufficiently to permit a concerted and long-term program that would identify, assess and control the risks from

carcinogens. If this is to be done it can only be by the public confronting the political issue of how much protection it wishes the government to offer and by Congress designing administrative mechanisms that will enable this ideal to be realized.

Conclusions

> . . . as a Probability is that which happens usually but not always, Enthymemes founded upon Probabilities can, it is clear, always be refuted by raising some objection. The refutation is not always genuine: it may be spurious: for it consists in showing not that your opponent's premise is not probable, but only in showing that it is not inevitably true. . . But the judges think, if the refutation takes this form, either that the accuser's case is not probable or that they must not decide it; which as we said, is a false piece of reasoning.
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> Aristotle, De Rhetorica, Book II, Chapter 25, 1402b

> . . . the crucial question in public health and safety debates today is the manner in which uncertainties in the evidence will be resolved.
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> Jeff Masten, "Epistemic Ambiguity and the Calculus of Risk: Ethyl Corporation v Environmental Protection Agency," 21 South Dakota Law Review 425, 50 (1976).

Cancer is largely a disease of the environment; controllable by controlling that environment. As a disease it knows few peers in the magnitude of its destructiveness and the tragic manner in which this destruction is wrought. Because it stems so intrinsically from the way in which American society is structured, individuals are unable to determine for themselves whether they will fall victim.[1] So, if there is to be prevention it must be by limiting exposure to those substances that cause or contribute to the disease. And because it is a "social

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[1] However, as individuals, they do have influence over this. For example, a person who does not smoke has a much lower probability of getting most cancers than one who does.

disease" there can be prevention only with the active participation and leadership of the Federal government.

> Cancer in the last quarter of the nineteenth century can be considered as a "social disease," rooted in the technology and economy of our society. The prevention of cancer is largely an attainable goal, but it requires the coordinated effort of our society in it many components: government, the scientific community, industry, labor and qualified public opinion.[2]

Yet, the Federal government appears to be largely helpless to curtail this continuing tragedy. There are political forces within American society that are able to use legal institutions to hinder efforts by the government to regulate suspected health hazards. Certainly it is not wrong that there exist the opportunity to appeal government actions. But this opportunity comes at the cost of regulatory effectiveness, and in this instance "effectiveness" is measured in "lives." This is the dilemma that government regulators face, and whose horns OSHA sought to squeeze through by means of its generic carcinogen policy. The fact that it was unable to speaks loudly for the formidability of the predicament.

There is nothing more certain in the fields of carcinogen identification and assessment than that nothing is certain. The concerned disciplines exhibit radical uncertainties that stem from a fundamental ignorance of the truth of the assumptions that underlie them. If society is to seriously enter the cancer debate, these uncertainties must be recognized by those who are responsible for making political decisions, and a conscious and public strategy should be taken

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2 Umberto Saffiotti, quoted in Ronald L. Morley, "Filing Overlooked Claims for Occupational Diseases," 13 Trial 36, 39 (February 1977).

to render explicit the implications of these assumptions for the government's efforts to control cancer.

Two current properties of cancer have been mentioned that hold great significance for the way in which the science of carcinogen identification should be performed. The first is that at present cancer is a social disease. Thus, the researchers who seek to identify properties in the environment that contribute to the disease are doing science that might have an immediate and profound impact on society as well as on individuals. Although not studying institutional and individual behavior, their research may profoundly affect this behavior. In a potentially non-trivial sense, they are doing social science. By itself, this behavior has no implication for the way in which this research should be performed. For their immediate objects of study will still be within the natural sciences. But the second property of cancer at the present time makes this potential be realized, transforming "carcinogen identification" into a social science.

There are radical uncertainties connected with identifying and quantifying the risk from human carcinogens. Chapters Four and Five contained a discussion of these uncertainties. Their importance to all concerned parties to the regulatory process cannot be stressed too strongly.

Certainly all science involves descriptive uncertainty in varying degrees. But few sciences possess the degree of uncertainty that carcinogen identification and quantification do, coupled with their social and political impact. What this means is that there will often be better reason for aspects of the purportedly scientific paradigm to be determined for social than for strictly scientific reasons. This is

most evident in the discussion surrounding the various models for quantifying risk. As is demonstrated in pages 133-151, models are chosen for the type of conclusion sought. A linear, no-threshold model is often chosen because it is usually most "conservative," although there is no evidence that it offers the more exact representation of actual response at low doses.[3] This is really counter to the way in which Science normally operates. This does not make it "bad" science; merely "different" science.

It is not difficult to sense, as a non-scientist, the equivocation felt by researchers as a result of their being placed into this impossible situation. They are forced to do that which all through their training and careers they had been warned not to do, and for good reason. The history of science is littered with theories that were more descriptive of conclusions desired than the world as it existed. So one feels sympathy for scientists who are asked by society to violate the canons of their discipline.

Is it more scientific, however, for a scientist to withhold judgment? The normal response in this instance is for a scientist to defer judgment until he is reasonably certain of its truth. Whether this is an appropriate response in this instance, when the political impact of the nature of the assumptions made may be profound, is a question of ethics as well as of the philosophy of science. A traditional position on this question is that it is when the political implications of scientific decisions are profound (and consequently it is in the

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3 Not all linear extrapolations presume the absence of a threshold.

interest of non-scientists to influence the decisions) that Science must be most wary of normative entanglements.

It is sometimes suggested that making the assumptions explicit will suffice to prevent the conclusions from being misused. Thus, bias is removed by labeling the linear dose/response curve "conservative." But if this is the only estimate made, then it would be natural for a person to forget that it is conservative, and tend to take it as something like the truth. So there may be little utility in merely labeling it.

The only way to get around this is for there to be a public forum of sorts to decide how protective society should be with respect to potentially toxic substances, and to let this degree of caution determine scientific methodologies of identifying and quantifying risks. It is foolish to pretend that science is able to provide answers to questions that it has trouble even formulating (when scientists are making judgments based upon personal preferences rather than educated intuition) and when the answers can have significant social implications.

Paradoxically, because carcinogenesis is so little understood it needs to be de-mystified. Because so many of the questions that bear upon the significance of experimental results transcend science experts may have little of value to say about them. Imagine the following hypothetical situation:

A federal agency is charged with determining whether or not God exists. It goes about answering this (unanswerable) question by asking if of a randomly selected group of fifty sane lay individuals. It gets some "No's", some "Yes's" and some "Maybe's." Many of these people enclose their answers in long elaborately reasoned apologetics.

Howshould the Agency evaluate the evidence and make its decision? It could select a level of significance and test the null hypothesis. It could exhaustively sift through the written comments and try to tease out of it the better choice. Or it could flip a coin. Of these three options, which is the most valid?

Repeat the experiment with fifty theologians of the major faiths. Would the evidence be different? Would it be better? Should our agency evaluate the evidence of experts differently; give it more credence?

These questions are meaningful because of the insufficiency of the evidence to reach conclusions to the questions to which they are addressed. There is an analagous insufficiency in the evidence for the carcinogenicity of most suspected carcinogens. Going back to the question of God's existence, in what sense can it be asserted that a critical reading of the apologetics would disclose the truth? A great deal of effopt is expended critically reading the evidence for the assumptions on which different models of risk assessment are based. Yet, after all is said and done, many of the same questions remain.

It follows from all that has been said that rarely can there by anything approaching certainty when identifying carcinogens and quantifying their risks. It is either naive or disingenuous to expect it. The preceding Chapters referred to the favorite rhetorical tactic taken by opponents of OSHA's regulatory campaigns as making use of the fundamental uncertainties in the fields to charge the Agency with ignoring conceptions of due process by acing in the absence of certain knowledge. Perhaps the best published instance of this was an abstract

of a speech made by H.B. Morley, the Chairman and President of Stauffer Chemical which Chemical Week included in its "Other Views" page.[4] Entitled "No room for McCarthyism in toxicology," it compared the indicting of substances as toxic on less than absolute certainty to the specious denunciations made by the Senator from Wisconsin. "Thorough research must be conducted before mechanisms are fully understood to permit confident preventive action. . . The scientific community should judge facts that come from high-quality science - painstakingly performed, emphasizing mechanisms critically reviewed. . . There is no room for McCarthyism in such a national problem." Although compelling at first sight, this is a false analogy. Whereas McCarthy rarely had any evidence at all for his accusations - and then it was only hearsay - there is fair evidence for the toxicity of many of these substances. It is just that Morley considers the evidence inconclusive, largely because of the character of the assumptions incorporated. The relevant question is how much evidence is sufficient, keeping in mind that there can be no absolute certainty. If there is any single conclusion of this dissertation, it is that this can only be confronted as a political question. Its answer has two parts. The first is political and normative. The second is scientific and empirical. If a consensus is not reached on the first before the second is attempted, it will be impossible to satisfactorily answer the second.

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4 Chemical Week, vol. 122, (5/3/78), p. 5.

But little attention is paid to the first by scholars. It is both more intractable and also may be viewed as being less scholarly.[5] A good portion of this work has been devoted to examining the logical constraints of the evidence. Another portion has examined the actual effectiveness of standard-setting. It seems patently clear from all of this that although the uncertainty in the evidence is immense, it is not the chief constraint to effective rule-making. There is no lack of data. What is lacking is a genuine consensus on what these data mean. And, of course, that is the problem. Because of their ambiguity the data mean whatever a person wants them to mean. This is apparent from this very paper. For example, discussion nominally of the relevance of animal data for the testing of human carcinogens (pages 62-65) is in fact only partly that. It is mostly the argument, "If substances are to be identified as human carcinogens, then animal data must be used." But this is a very different question. Ultimately it is a political (and legal[6]) one. It is similar to the question of statistics, "What is the correct ratio of 'false positives' to 'false negatives' in regulating potential hazards?" So, it is very difficult to separate the empirical from the normative considerations in these questions.

In the absence of a consensus, individuals are able to use the mechanisms of administrative and judicial review to disrupt the government's attempts to set standards. And many people mistakenly

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5 Perhaps this is an unfair inference from the fact that so little time is spent determining social preferences and designing political mechanisms that permit their expression in an efficient and fair manner, and so much is devoted to examining the logical constraints on the evidence.

6 Legal, because of the demands of statutory law that "unreasonable risks" be reduced expressed in so many words or through similar constructions.

attribute this inability by government as due to an intrinsic uncertainty in the evidence. Rather, it is a reflection of the determination that the burden of evidentiary uncertainty is to be borne largely by those who seek to restrict the presence of suspected risks. There is no legal imperative that this be so.[7] It occurs because agencies have not yet designed policies that re-allocate this burden.

There are two crucial missing components of the federal regulatory campaign against cancer. The first is making the political determination of an acceptable level of risk; deciding how protective we wish to be. The second component is designing administrative mechanisms which will enable this level to be realized. By focusing upon questions of evidence the real stumbling blocks to effective control of cancer are passed over. The problems at this point in time are political and legal, not scientific.

Recommendations for Future Research

In this section are traced three areas of additional research which would contribute to addressing the concerns expressed above.

1. Part II presents a preliminary assessment of the degree of uncertainty that inheres in the risk and benefit estimation that underlies most carcinogen regulation. There is a pressing need for this uncertainty to be more closely examined in specific instances. for there is a common lack of appreciation by researchers of the magnitude

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7 For example, see Environmental Defense Fund v. E.P.A., 598 F.2d 62, 85 (D.C. Cir. 1978).

of this uncertainty which further investigation would diminish. One fruitful direction of study is to intensively examine the evidentiary sources that form the bases for carcinogen regulations issued by the federal government to determine the degree of reliability of their estimates. For the justification of a regulation rests on the expected value of its net benefits, which takes into account probability of outcome. A highly uncertain estimation is a fortiori one that is not likely to occur. Certainly this type of research is extraordinarily difficult to perform. For it falls prey to the same weaknesses that it addresses. It is likely that only "hand-waving" estimates of uncertainty and reliability are possible. But in the absence of more sophisticated analytical techniques hand-waving is to be preferred over silence.

2. It is particularly intriguing to ponder the roots of this vast variability in risk estimation. Ignoring that due to experimental error, it stems from the presence of differing assumptions at various stages of the research project. As was discussed in Part II, there is often no obvious reason why one type of assumption should be preferred over another. It appears, then, that assumptions are chosen on the basis of (and conclusions thereby depend upon) dictates other than those of normal science.

Perhaps this is a trivial observation. But it needs to be borne in mind when assessing the significance of purportedly objective research. How do experts make assumptions when their training provides inadequate guidance?

3. Yet, these do not go to the root of the problem of theinability of agencies to catch up to all the hundreds or thousands of suspected carcinogens in circulation. If the conclusions expressed in this Chapter are correct, then the primary causes of this inability are not insufficient evidence per se, but the failure to design regulatory procedures that enable agencies to consider likely carcinogens. A generic cancer policy is one option around this constraint. But, if OSHA's experience with its cancer policy can be considered typical, then federal agencies possess little power to design strategies that markedly increase the speed at which they consider substances. The implication of this is that Congress alone has the means to do this by permiting agencies to circumvent the time-consuming procedures that they must presently follow in order to comply with the indeterminate specifications of present law.

Research needs to be performed to determine the options that are available to Congress, and the likely benefit of each to regulatory effectiveness. For it is not apparent, at first blush, that there exists a simple legislative solution. One must wonder whether even a Congressional "generic cancer policy" could avoid the Scylla and Charybdis of inflexibility on the one hand, and directionness on the other that OSHA's regulation was unable to.

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