CARCINOGENIC INDUSTRIAL CHEMICALS: DEALING WITH UNCERTAINTY AND RISK

BY
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This article examines the capacity of the law to regulate health in industry. It is argued that a comprehensive legal strategy must deal with the issues of uncertainty, risk and information. The author outlines and discusses the proposed occupational health policy of the Victorian Labor Government and makes an evaluation of its prospects for success against the experience of the Occupational Safety and Health Administration in the United States' of America. He concludes by making recommendations that may enable the regulatory authority to achieve its aims of implementing an effective health scheme.

I. INTRODUCTION

Recently, there has been much interest shown in what Lave describes as decision frameworks for regulatory policy.[1] In the light of scientific insight into carcinogenic chemical hazards, proposals have been made concerning the possibility of using a legal framework to control these hazards.

The Victorian Labor Government which took office in 1982, proposes a radical occupational health policy which envisages the establishment of a licensing system for

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1 L. Lave, *The Strategy of Social Regulation: Decision Frameworks for Policy* (1981).

industrial chemicals.[2] The toxic substances licensing scheme will require licences for all new chemicals or new uses of existing chemicals. Licences will be issued subject to the receipt of a satisfactory dossier compiled by the supplier, setting out such information as the chemical and physical characteristics of the material and the results of toxicity testing; including short, medium and long-term testing for cancer and reproductive effects. The dossier is to be open for public inspection for thirty days. The Occupational Health Division (of the Ministry of Employment and Training) will then, within sixty days, issue a licence or show cause why no licence should be granted. This decision will be appealable. The policy will implement a legally ordered decision framework which will deal with the overlapping issues of uncertainty, risk, and information.

II. UNCERTAINTY

Millions of chemicals are catalogued at centres such as the United Nations. The numbers in industrial use are estimated to be in the tens of thousands, with up to a thousand being introduced each year. In 1970, about 12,000 industrial chemicals were suspected of toxicity. By 1976, that number had risen to 22,000. Tests for carcinogenicity were carried out on about 6,000 chemicals, 1,000 of which were found to be hazardous in that they produced tumours in animals. At the most 500 chemicals are tested a year, with the results of about 150 tests reported.[3] It should be noted that many of those tested for carcinogenicity are intended for use in food and drugs, in which case the requirements of proof are stricter than for industrial use.

Uncertainty surrounds the hazardousness of chemicals as a result both of the shortcomings of the courses of evidence and of the economic and social pressures to press ahead with production. Wherever possible, it is important to distinguish the epistemological and methodological limitations of scientific proof from the economic and industrial constraints on inquiry. In considering the character of the scientific input, the types of evidence can be broadly catergorized as (a) animal tests (b) epidemiological data (c) bacteria tests and (d) comparison of structure-activity with other chemicals established as carcinogenic. The economic cost of testing varies between the types, and is due to the cost of administration of the test and any associated delay in the use of the chemical. Beyond a certain point, testing may even be regarded as technically impossible, on the basis that there are not sufficient professionals available to administer the tests (in 1980 Fishbein estimated that a maximum of 700 chemicals could be tested on animals each year given present

2 Australian Labor Party, Victorian Branch, *An Occupational Safety and Health Policy for Victoria,* (September 1981). The Policy is presently undergoing a twelve month study and discussion period, conducted by the Ministry for Employment and Training: see *Australian Financial Review,* (8 July 1982) 4.

3 L. Fishbein, *Potential Industrial Carcinogens and Mutagens* (1979). See also A. LeServe, C. Vose, C. Wigley and D. Bennett, *Chemicals, Work and Cancer* (1980). Locally, the Australian Council of Trade Unions, Victorian Trades Hall Council Occupational Health and Safety Unit has prepared an informative health and safety bulletin on chemical hazards: "Guidelines on Chemical Hazards" *Health and Safety Bulletin* No. 16 June 1982.

facilities[4]), or that there are not devices subtle enough to detect very low levels of substances in the workplace (a level suggested currently is around 1 ppb). In effect, these objections delay the economic decision to when scientists are trained and equipment developed. The costs of information requirements will be considered below but first the shortcomings in scientific evidence should be noted.

It is not surprising that the cheaper and quicker the test, the less informative it will be and the more uncertainty will remain. Any one experiment or survey has to be methodologically sound to withstand challenge, that is, valid and reliable within the competence of the technique. Futhermore, the informativeness or sensitivity of a test may be a matter of contention.

1. Animal tests

The utility of experiments on animals has been a matter of some debate. Parties dispute that the effects on animals or certain species of animal (especially species other than mammals) can be extrapolated to man, because of differences in metabolisms. The appropriateness of extrapolation from experiments on animals to real-life industrial conditions where the environmental factors are complicated and where the exposure is in low level doses over a long term, is consistently a matter of contention.[5] Administering the tests to rats and other animals, is, for the sake of speed, in high doses and in laboratory conditions. A particular source of concern here is the thoroughness or sensitivity of the test: to detect very low incidences of cancer in a population, a very large sample of animals would have to be tested over a long period of time. Millions of rats might be required; according to Weinberg, this is an example of when an issue becomes trans-science.[6] The demand for the demonstration of a causal mechanism rather than a correlation is a further strain on the methodology.

The lack of consensus about the informativeness of animal tests affects what may be said about safety in the absence of positive results as well as what can be said about hazardousness in the presence of positive results. For example, it may be said that due to the possibility of sampling errors, results which are not positive must be characterized beyond certain confidence limits as non-positive rather than negative.

2. Surveys of humans

Epidemiological data is collected from groups of workers exposed to the chemical. Comparisons are made between doses and incidences of cancer to try to establish some correlation and, more precisely, a dose-response relationship. The study is usually retrospective, undertaken as a result of some 'abnormal' incidence of the disease amongst the group. As various environmental factors can contribute to cancer, it is important to identify their presence among the study group in order to find a suitable control group with which to compare rates of incidence of the illness.

As most data is collected after the event, records may be incomplete or imprecise, especially in respect of the doses of exposure and the extent of environmental factors including lifestyle and particularly smoking rates. It may thus be difficult to isolate the contribution of the chemical, especially if the cancer appears only in old age, and

4 *Id.*, 3.
5 *Id.*, 47.
6 A. Weinberg, "Science and Trans-Science" (1972) 10 *Minerva* 209, 210.

transpires to be a common as opposed to a rare cancer, for example, lung rather than bladder cancer.[7] The logistics and expense of survey encourage sampling of the exposed group, which introduces the possibility of error. The choice of a suitable control group (an 'average' population) to serve as the comparison, can also be difficult. Furthermore, it must be remembered that the inquiry is as to whether the industrial chemical is making a contribution to the particular cancers — perhaps it cannot be assumed that the chemical is having no effect just because the industrial rate does not exceed the average rate for such a population.

3. The Ames test

Recently, a university biochemist developed a quick test to detect mutagenic chemicals, a property which has a significant correlation to carcinogenicity. He observed the effect of known or suspected carcinogenic chemicals on the genes of salmonella bacteria. Ames states that about ninety percent of these chemicals proved to be mutagenic; yet only a small percentage of all chemicals appear to be mutagens.[8] It is conceded that not all carcinogenic chemicals act on the DNA directly, so that some (especially those which act as promoters) will not be detected in this way. Difficulties in identifying mutagenic components in complex mixtures have been encountered.

4. Analogues

Slesin and Sandler contend that for some regulatory purposes, inferences about hazardousness should be made from similarities in physical and chemical properties, specifically structure-activity relationships, between new chemicals and those known or suspected to be carcinogenic, or at least mutagenic, teratogenic, or otherwise toxic chemicals.[9] This approach would form generic classes of chemicals. Stricter tests of similarity would involve small variations in structure, and structural or chemical similarities, rather than just structure-activity characteristics. Two particular aspects of uncertainty should be elaborated because of their role in the determination and allocation of responsibility for the contraction of cancer.

5. Multiple causes

If a number of environmental conditions carry the risk of cancer, the legal system might require proof of the actual contribution of the industrial chemical. It has been contended that cancer goes through stages of initiation and promotion, so that several factors — some carcinogenic in their own right and some in combination with other factors — may in the course of its development contribute to the onset of the illness.[10] The possibility of metabolic defences (and in particular elimination and remission), has also been suggested. If a worker develops a common cancer, it is difficult to show that the chemical was a contributor. The evidence is likely to be that the exposed group has

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7 L. Fishbein, note 3 *supra*, 43.

8 B. Ames, "Identifying Environmental Chemicals Causing Mutations and Cancer" (1980) 20 *Jurimetrics J.* 326, 333-34. See also D. MacPhee, "Mutagenicity Screening for Environmental Carcinogens" in D. Metcalfe (ed.), *Cancer, Causes and Control* (1980) 37.

9 L. Slesin and R. Sandler, "Categorization of Chemicals Under the Toxic Substances Control Act" (1978) 7 *Ecology L. Q.* 359.

10 T. Slaga, "Cancer: Etiology, Mechanisms and Prevention — A Summary" in T. Slaga (ed.), *Carcinogenesis — A Comprehensive Survey* (Volume 5 1979).

a higher than average incidence of the cancer. It has been argued that a time-to-occurrence distribution is a more precise measure; the question becomes whether exposure to the chemical has speeded the development of the cancer. This approach has given rise to the notion that a chemical which induces cancer is not hazardous if it is not the immediate cause of death. It must be noted, however, that the chemical may be a real contributor in a case where cancer only emerges as it does on average. Also the contribution of the environmental conditions is only probabilistic.

The question arises as to whether and if so, to what extent, any responsibility for the ill health can be attributed to the chemical. Lack of knowledge of the relative rates of contribution of the chemical and of the other environmental factors makes an apportionment of responsibilities difficult.

6. Levels of exposure

A second but related area of doubt is what, if any, is a safe level of exposure to a potentially carcinogenic chemical. Controversy surrounds the question whether there is any safe single dose or safe rate of intake. Can a 'no effect' or threshhold limit be established and translated into a maximum allowable concentration on any one occasion, or into a time-weighted average exposure, after the addition of an appropriate safety margin? It is argued from the perspective of theoretical science that there can be no complete certainty of a 'no effect' level. The need to sample means that findings are reliable within statistical levels of confidence: the negative or non-positive conclusions of a test or survey may be at least one to five percent in error. Over a large workforce, this may mean that several illnesses have not been predicted. In addition, exposure may produce a subtle effect which is sub-clinical.[11]

Opinion differs on several aspects of this issue, one of the most fundamental being whether a number of doses is required to initiate a cancer, in other words, whether a single dose may 'miss' or may be resisted. If single doses can contribute to cancer, the question becomes whether a certain minimum dose level is required before the chemical is considered hazardous. Here, the period of uninterrupted exposure to the chemical as well as the concentration of the chemical may be relevant. A further difference of opinion relates to whether the dose-response relationship is linear or logarithmic; whether the hazard increases evenly, or accelerates, with the dose level. The accumulation of doses remains significant for the course of the cancer; although maximum time-weighted averages may inappropriately allow excursions from a single dose level (for a limited period), they do monitor overall rates and so, perhaps, the rate of promotion of the cancer. The pattern of intake is also relevant. A series of small doses may have a more serious effect than a single large dose of the same total amount; lower doses may not reduce the risk of contracting cancer but they may increase the latency period. Notably, the critical feature of this field is the existence of uncertainty; the nature of dose-response relationships.

As unsatisfactory as it may seem, decisions about regulation have to be made on the strength of such incomplete and imperfect knowledge. The regulators need a policy about suitable responses to uncertainty and, in particular, about the standard and onus of proof which must be satisfied before a chemical is ruled safe or unsafe. In

11 A. Kolbye, "Decision-Making Issues Relevant to Cancer-Inducing Substances" in F. Coulston (ed.), *Regulatory Aspects of Carcinogenesis and Food Additives: The Delaney Clause* (1979) 93, 101.

determining the weight of different kinds of evidence *vis-à-vis* the use of the chemical, the social and professional backgrounds of the regulators' technical advisers is important. For instance, industrial medicine and biochemistry differ as to what is a respectable theory of carcinogenicity.[12]

III. RISK

1. Illness

The policy will represent how seriously the prevention of cancer is taken in contrast to the encouragement of innovative and profitable production. It will involve a comparison between the costs and benefits of inquiry: one question will be the extent to which, and at what expense, further investigation will provide greater insights into the properties of the chemical. The costs and benefits of being right and wrong about hazardousness will also be a major consideration. If, for example, the regulators require epidemiological evidence before they will control exposure to a chemical, some workers may be put at risk for the sake of such certainty. If, on the other hand, they require negative results from animal tests before they will release a chemical, use of the chemical may be delayed several years and a substantial cost testing added to the cost of development of the chemical.

While information about the costs and benefits of regulation is problematic, the policy-maker faces real difficulties in deciding whether the prospective harm justifies the burden of precautions, including the costs of futher inquiry. Hence it is necessary to analyse the various conceptualizations of the harm — or the risk of harm as it is usually characterised — and the burden of precautions, in order to determine whether the two can be projected and then compared.

The projection and comparison of the costs and benefits of the control of exposure are coloured by the fact that the costs and benefits are differently regarded by each of the interests affected. Thus, each group seeks to influence the legal decision to its advantage by emphasizing the impact of the decision upon it. If the costs and benefits could be assessed independently, the special pleading of the interests might be less critical. It appears, however, that not all the costs and benefits can be reduced to the terms of one objective unit, numerical or monetary, at least not without considerable distortion to the impacts projected and the values implicated.[13] Furthermore, a cost-benefit analysis of chemical use involves no judgement about the pattern of distribution of those costs and benefits; considerations of equity and morality may properly form part of a policy examination.[14]

2. Uncertainty and contingency

There are several aspects to risk which suggest that its estimation is subjective rather than objective. Consequently, it cannot be usefully quantified. Uncertainty might justify the view that there is a risk in proceeding with the use of the chemical; query,

12 B. Gillespie, D. Eva and R. Johnston, "Carcinogenic Risk Assessment in the United States and Great Britain: The Case of Aldrin/Dieldrin" 9 *Social Studies of Science* 265, 294.

13 C. Arup, "Soft Values, Policy Analysis and the Legal Process" (1982) 1 *Aust. J. of L. & Soc.* 10.

14 B. Whiting Jr., "Regulatory Reform and O.S.H.A.: Fads and Realities" (1979) 30 *Lab. L. J.* 514.

for example, whether the presence of uncontrolled extraneous variables in epidemiological surveys or the difference between the metabolisms of experimental animals and human workers, translates into an estimate of the extent of the risk of cancer. Thompson argues that the safety margins superimposed on threshold limit values, in order to cover for uncertainty about precise dose-response relationships, are necessarily arbitrary. He observes that the breadth of the margins are fixed as much according to the aesthetics of the numbers involved as a sense of the extent of the risk.[15] Uncertainty about the mechanism of cancer contraction will influence some to set the risk higher; people may be averse to working under conditions of uncertainty because of the lack of control over the processes which lead to illness. Risks are preferred if they can be managed. For others, the uncertainty may justify discounting the risk of harm and proceeding with the use of the chemical. This has been industry's argument, particularly when the onus of proof is on those who desire control.

Policy judgements will be more enlightened if it is determined whether occupational cancer is only regarded as a risk because of the uncertainty inherent in the evidence. The characterization of a hazard as a risk is an influential one: the idea of risk implies to many the chance of avoiding the illness altogether. As more evidence is collected, it becomes possible to identify cancer rates in various groups with greater precision and, to draw an analogy with the road toll, it approaches certainty in the sense that some individuals within the group will be struck down each year. Nevertheless, it is said that for any particular individual the hazard remains just a risk. This characterization may be the product of the lack of understanding of the mechanism — in this instance, the causes of cancer and the reaction within the body to carcinogens — so that it is not possible to say precisely which sub-groups and then which individuals will be afflicted. It may also acknowledge that there is an inherent chance element in the affliction of cancer: the affliction is dependent on the coincidence of a large number of contingent events.

In his consideration of nuclear power plants, Hafele distinguishes the two types of risk as (a) a risk of the type which is related to uncertainties in the knowledge of the employment of the laws of nature, and (b) a risk of the kind which refers to incomplete knowledge of initial and boundary conditions.[16] In the latter case, knowledge is likely to remain incomplete where the conditions are numerous, various, and somewhat random in occurrence. Despite extensive efforts to model all possible circumstances, predictions about nuclear power plant catastrophies remain in this latter category. In the case of cancer, however, it may be the mystery rather than the contingent nature of the cancer mechanism which leads to the risk characterization.

Sontag argues in her essay concerning the use of illness as metaphor that the mystery surrounding the cancer mechanism leads society to focus on the individual sufferers rather than the environmental sources, so as to allege that ultimately the contraction of cancer represents a characterological predisposition and a personal failing.[17] Illnesses

15 K. Thompson, "Margin of Safety as a Risk-Management Concept in Environmental Legislation" (1979) 6 *Columbia Journal of Environmental Legislation* 1, 19.

16 W. Hafele, "Hypotheticality and the New Challenge: The Pathfinder Role of Nuclear Energy" (1974) 12 *Minerva* 303, 313.

17 S. Sontag, "Illness as Metaphor" (1978). See also S. Epstein, "Regulatory Aspects of Occupational Carcinogens" in World Health Organisation, *Environmental Pollution and Carcinogenic Risks* (1976).

are accepted and resources are concentrated on finding ways of curing individuals. At the same time, when prevention is proposed, uncertainty about the mechanism, and hence about the exact target of carcinogens, is advanced as a reason to discount the environmental risks. In arguing against the regulation of genetic experimentation, Shapiro grades three types of risk: (a) direct and obvious risks, (b) statistically significant probabilities of occurrence in descendant generations, and (c) conjectural and long-range and indirect risks. In suggesting reasons for discounting risks, Shapiro links uncertainty with the lack of immediacy and directness of a harm.[18]

3. Disassociation

It would seem that risks are more likely to be tolerated if they are seen as the outcome of the system and thus as part of the exigencies of modern life. Society can enure itself to a quite predictable toll of life. For example, Swigert and Farrell argue that it was the personalization not only of the victims but also of the risk creators which led to the prosecution of the Ford corporation for homicide following deaths in its Pinto cars.[19] Similarly, it would seem that bizarre and graphic deaths attract more concern than the commonplace and insidious. So long as the deaths can be regarded largely as a statistical result, the risky activity may be tolerated. It is not easy to determine the appropriate response to risks that have been generalized and as a consequence assigned a low probability of occurring,[20] such as the estimate that a road user had a one in four thousand risk of death on Victorian roads in 1982.

There are a number of characteristics which interact to influence the subjective estimate of risk. The gravity of the harm itself is an influential consideration. Cancer is a debilitative and frequently fatal illness; its affliction is a grave and often catastrophic event. It seems that once the process has begun, development of the condition is irreversible and treatment involves painful surgery or medication, if treatment is effective at all. Page suggests that many people attach a high cost to a catastrophic or irreversible event.[21] As cancer is regarded as the dread modern 'disease', some professionals feel justified in withholding information about it in the belief that ordinary people may misunderstand or exaggerate that information. The preceding remarks suggest that attitudes to cancer are a mixture of fatalism and alarm. The key to this apparent contradiction may be disassociation; the hazard is discounted when it is diffused rather than targeted.

The contraction of cancer is not a wholly random or individually variable event. For their part in the workforce, workers in certain industries are more heavily exposed to hazardous chemicals than others; occupational mobility is by no means sufficient to spread the hazard from this source widely.[22] Furthermore, at a cost, the circumstances of exposure to a chemical can be contained and controlled much more than exposure

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18 M. Shapiro, "Introduction to the Issue: Some Dilemmas of Biotechnological Research" (1978) 51 *So. Calif. L. Rev.* 987.

19 V. Swigert and R. Farrell, "Corporate Homicide: Definitional Processes in the Creation of Deviance" (1980-1981) 15 *Law & Soc. Rev.* 161.

20 R. Kates, *Risk Assessment of Environmental Hazard* (1978).

21 T. Page, "A Generic View of Toxic Chemicals and Similar Risks" (1978) 7 *Ecology L. Q.* 207, 240.

22 N. Gunningham, "The Industrial Safety, Health and Welfare Act 1977 — A New Approach?" (1978) 6 *Uni. Tas. L. R.* 1.

to many of the general environmental conditions which, it appears, cause so many of the modern cancers. Occupational cases are man-made rather than natural occurrences. In addition, unlike cigarette smoking, it cannot be said that the hazard is freely assumed, if it is conceded that the industrial worker is traditionally the least well-informed and economically independent of the industrial parties to assess the hazard and to act to avoid it. Lowrance suggests that people attach a higher cost to risks which are assumed involuntarily and to those which they are unable to counteract.[23]

Accordingly, it may be obtuse to assimilate the risks of occupational cancer with the risks of cancer generally. However, methods of inquiry do encourage the particular risk to be submerged because they concentrate on departures from 'normal' rates of cancer in order to establish a correlation between illness and occupational exposure. It may be complacent to be satisfied that the group of workers does not experience rates that exceed the averages of the surrounding society, for the occupational exposure may be the actual cause in these cases. It appears though that the appearance of a rare cancer such as bladder cancer is regarded with more interest than the presence of common cancers such as lung cancer. Working from averages for more common cancers may be at the expense of the individual worker who has chosen to avoid some of the other environmental sources such as a bad diet.

To the extent that the contribution of occupational causes has been isolated, it seems they take a lesser toll than some other causes of cancer and some other illnesses. Accordingly, it is argued that where there is competition for resources, they should have either low priority or be disregarded.[24] It is regarded by some as unfair that the worker who chooses to smoke heavily should be protected. However, it may be simplistic to make comparisons according to numbers only; it cannot be assumed automatically that all the other risks have been accepted freely or that as much can be done to eliminate them.

Finally, discounting occurs because risk-making and risk-running are separated. Cancer has a long period of latency which induces complacency at the time when prevention would be effective. Given this latency, the benefits of precautions will invariably materialise in the future and so, psychologically, they will seem less substantial than the immediate costs of the precautions.[25] This attitude is represented in economic theory by the notion of discounting postponed gains. In the case of new industrial hazards, this attitude of discounting is compounded because there is no personal experience of the harm on which to build an estimate; yet it is in the nature of the illness that once it is contracted, it may be too late to reassess the attitude, to learn, as it were, by trial and error.

Though the hazard is long range, it may still be the same person who makes the risk as runs the risk; the same person so far as distinguishing between individuals, if not the 'same' person in terms of outlook and condition, for the victim may come to regret his choice.[26] In the case of industrial carcinogens, the persons who create the risk do not

23 W. Lowrance, *Of Acceptable Risk: Science and the Determination of Safety* (1976).
24 E. Blair, "Impact of the Delaney Clause Philosophy on the Chemical Industry" in F. Coulston (ed.), note 11 *supra*, 353, 356.
25 N. Ashford, *Crisis in the Workplace, Occupational Injury and Disease* (1976).
26 M. Kelman, "Choice and Utility" [1979] *Wis. L. Rev.* 769.

always share in the risk-running. While some of the technical staff may be exposed to the chemical along with the industrial workers, it is rare that exposure is extended to management. In some cases, the corporation which the management represents may run the risk of liability, but the risk of liability is quite different from the risk of illness.

Society might be more wary of a risk which is displaced and borne only sectionally; at the same time, it is quite human to discount a risk which will be run by others. Furthermore, the characterization of the way in which the risk is imposed affects how seriously the risk is regarded. The uncertainty about a hazard is relied on to distinguish deliberate decisions to harm from mere errors of judgement and uncontrollable actions. In this regard, some writers have recently argued the novel re-interpretation that exposure to industrial hazards fits the criteria of such intentional offences as homicide.[27]

4. Indicators

In sum, it appears that the factors which influence the estimation of risks are varied. It is necessary to consider what are legitimate sources of evidence of attitudes to particular risks. Discourse at a general level about varying perceptions and evaluations of risks cannot be avoided if decisions are to be taken by public bodies. As risk estimates are partly subjective, it is desirable to determine the views of those who will be exposed to it. However, there are serious obstacles: it may be difficult to reach all those implicated, their responses may not be true, and it may prove impossible to aggregate and operationalize their views where collective action is required. Moreover, there may be other, perhaps conflicting, interests to be taken into account in determining a policy response to the hazardous activity.

In the occupational sphere, there is the evidence of the contracts employees make individually or through their trade unions with their employers. It would be rare for the risk of a long range illness to be addressed specifically. Some economists have looked to premiums placed on wages in occupations with greater dangers of morbidity and mortality;[28] differentiations in liability insurance premiums for more hazardous industries is a less direct indicator. As an indicator of attitudes to risk, danger money should be treated with caution; lack of information and lack of bargaining power may lead to acquiescence in undesirable hazards. As the British Council for Science and Society suggests, apathy should not be equated with acceptance.[29] Acquiescence may be the result of quite limited practical options. Perhaps only long term social action can provide the real alternatives to running the risk. Sensing this, the common law has, for the purposes of compensation, progressively limited the notion of voluntary assumption of risk.

In addition, the harm will not be confined to those who are afflicted with the illness. The costs of ill-health fall not only on the worker but also on his family and the surrounding community. The easiest of these costs to calculate is the expenditure on such items as social security, health and medical benefits, and workers' compensation and common law damages insurance. Even so, this costing may meet complications

27 H. Glasbeek and S. Rowland, "Are Injuring and Killing at Work Crimes?" (1979) 17 *Osgoode Hall L. J.* 506, 523.

28 See *e.g.*, J. Sinden and A. Worrell, *Unpriced Values: Decisions Without Market Prices* (1979).

29 Council for Science and Society, *The Acceptability of Risk* (1977) 34.

because some of the costs are buried in general charges and public expenditure so that the cost attributable to the specific risk is not isolated. Some of the benefits of continued health are likewise economic, for instance the maintenance of productive capacity and the contribution of taxes from earnings; nevertheless, these benefits may be contingent on the general demands of the economy for labour of that kind.

On the other hand, some of the costs of ill-health and the benefits of health are intangible. Perhaps in the extreme, it could be argued, following a strict reduction of the issue to an economic account, that it was worthwhile killing old and incapacitated people. To avoid such conclusions, the intangible costs of ill-health such as pain and suffering might need to be taken into account, as is the case with the common law of compensation. The grief to people associated with those afflicted might also be recognised. There are corresponding intangible benefits stemming from continued good health. To note a distributional consideration at this stage, it might also be considered whether those at risk of ill-health are generally a group badly off, in particular a group worse off than the risk beneficiaries. Finally, returning to the manner of risk-making, it might be argued that deliberate decisions to sustain risks and to sacrifice some individuals for the sake of production, places others in danger of hardening society to the taking of life and limb.[30] It also offends the moral sensibilities of those who regard life and health as sacrosanct. Paradoxically, on this view, some people might develop an aversion to risk-benefit analysis.

IV. INFORMATION

It becomes clear from these observations that the problem is partly one of information. Information about the hazardousness of a chemical and an appreciation of the limits of that information are vital to a risk-benefit determination and to the determination of the steps to be required to safeguard against a hazard.

1. Placing the onus

Capacities to acquire and communicate information need not be considered in a vacuum. In a policy analysis conducted for the purpose of determining regulations, local patterns of manufacture, supply, and use can be considered to ascertain what information requirements are feasible. For example, it may be observed that the manufacture of new chemicals is quite highly concentrated in several transnational corporations.[31] These corporations make up and market most of the basic chemicals; they employ technical staff with the competence to comprehend scientific research on the qualities of the chemicals. Investigation requirements in the larger home markets of the corporations may mean that the manufacturer has already collected and documented the necessary information. The same information will often serve a large number of users. While a firm conclusion will depend upon empirical studies, it is arguable that the manufacturers, rather than the users, are more aware of the hazards

30 G. Schwarz, "Economics, Wealth Distribution and Justice" [1979] *Wis. L. Rev.* 799.

31 P. Alston, "International Regulation of Toxic Chemicals" (1978) 7 *Ecology L. Q.* 397, 400. See generally J. Backman, *The Economics of the Chemical Industry* (1970).

of the chemical.[32] Although users are more familiar than the manufacturers with their own processes, conditions of use may well be 'generalizable' across an industry and the manufacturer may have sufficient contact with the user to be made aware of the specific conditions of use. Also, employees will be more familiar with their own characteristics, but conditions such as pregnancy are sufficiently normal for the manufacturers to anticipate. Nonetheless, like common law liability, regulations can divide up the onus amongst the parties where each has a role to play in piecing together the necessary information.

Ultimately, the need for information leads back to the testing of the chemicals for carcinogenic effects. It would seem that the manufacturers are in the best position to do this. This remains so even when the regulatory authority is added; in the smaller states like Victoria, the authority faces the problem of scarcity of public resources for adequate technical staffing. However, requiring the manufacturers to test the chemicals makes the authority dependent upon the findings of an interested party. Regulations might need to specify the testing procedures to be observed in order that suppression or distortion of data does not occur; some monitoring of private testing might also be appropriate.

2. Costs

Gascoine and Carruthers list the sorts of costs which a screening requirement can create.[33] These costs are barriers to international trade (given the import and export of chemicals), the cost of additional information collection including the testing of chemicals, dampening of innovation in chemicals, delay in the introduction of chemicals, the disclosure of trade secrets, the costs of administering the screening system, and the costs of meeting the disparate information requirements — of labelling, for instance — of different jurisdictions.

If the release and use of the chemical are made conditional upon testing, the innovation and the application of the chemical will be inhibited; the requirement of the testing and the uncertainty of a licence may prove prohibitive where the chemical is barely profitable or where it can be rapidly superseded by another.[34] Requiring licences only for new chemicals favours existing chemicals and creates barriers to entry into the market of chemicals which may in fact be less hazardous than the old.[35] In the initial stages, considerable effort will be made to have chemicals classified as existing rather than new chemicals.[36]

There are now independent scientific centres originating and evaluating evidence, such as the United Nations International Agency for the Research of Cancer and the United States National Institute of Occupational Safety and Health. If these centres

32 S. Galitsky, "Manufacturers' Liability: An Examination of the Policy and Social Cost of a New Regime" (1979) 3 *U.N.S.W.L.J.* 145.

33 D. Gascoine and I. Carruthers, "Economic Aspects of the Control of Hazardous Chemicals" in Commonwealth of Australia, Department of Home Affairs and the Environment, *The Cost and Benefits of Environment Protection* (1981).

34 P. Alston, note 31 *supra*, 438.

35 M. Maloney and R. McCormick, "A Positive Theory of Environmental Quality Regulation" (1982) 15 *J. L. & Econ.* 99.

36 This is presently occurring in Europe as the European Inventory of Existing Commercial Chemical Substances is compiled, prior to the implementation of the European Council Directive requiring the notification of all new chemicals together with their test results.

can keep pace with the flow of new chemicals, they may relieve some of the burden on the manufacturers and the regulatory authority. Given the risk of undue influence on the regulatory authority by the industry, it may be desirable as well as convenient for testing to be done other than by the authority. As differences of opinion stem not only from differences in patronage but also from differences in professional experience, it will be difficult to find a centre that is disinterested and dispassionate.

3. The industry

The possible problems facing the design and enforcement of a licensing scheme can be considered in the context of the nature of the chemical industry in Australia. The 'chemical industry' forms a mosaic.[37] Its products range from basic chemicals, including heavy and bulk chemicals, to intermediaries, and all sorts of end products containing chemicals; in their development and application, chemicals are processed, combined, and fabricated into other products. The Victorian Government policy proposes to place the onus of obtaining a licence upon the suppliers of new chemicals and of chemicals for new uses. Such a licensing scheme must include a definition of 'chemical' and in particular, a 'new' chemical. The inclusion of 'new uses' may be intended to detect hazards which arise from the refinement and combination of chemicals.

Participation in the industry is also richly textured. With changes in materials and in uses, companies with other product bases, most notably the oil companies, have entered into chemical manufacture. Large chemical companies have diversified into intermediaries and, to some extent, into consumer products. Companies have been joined together into conglomerates which are among the largest in the world. In such circumstances, the licensing scheme must determine what it means by the supplier, and when some chemicals may be manufactured for internal, industrial use. The neat common law distinctions between manufacturers and users, between risk-creators and risk-takers, are, in practice, blurred.

Despite this lack of definition and the lack of distinction between the parts, the industry can in many ways be pinpointed. Production is highly concentrated where large scale technology is required. There are small and middle sized producers, but the problem of regulating them is not very significant as the total number of establishments remains small.[38] The small companies, amongst which there might be some 'backyard operators', do not invent or manufacture new chemicals but rather do they specialize in custom building fine chemicals as intermediaries and end products.

The number of companies involved in real manufacture may thus be well under one hundred. Furthermore, even if the number of chemicals is great and the rate of innovation rapid, there is high concentration within product lines. It seems that there is only one supplier for well over half the chemicals.[39] This is a result of patenting, the need for expertise, the size of the initial investment, the pressure for rapid exploitation, and other restrictions on competition.

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37 A. Hunter and L. Webb, "The Chemical Industry" in A. Hunter (ed.), *The Economics of Australian Industry* (1965).

38 Australian Bureau of Statistics, *Manufacturing Establishments: Summary of Operations by Industry Class in Australia 1980-1981* (1981).

39 A. Hunter and L. Webb, note 37 *supra,* 310.

It is not difficult then for the supplier to be pinpointed. In the case of many new chemicals, the supplier will be a large corporation and one of a very small number of corporations, even if it is divided into separate companies and establishments. That same corporation may have imported the chemical. Importation is the source of a sizeable share of the total Australian supply and much of the discovery of new chemicals is done overseas at the headquarters of transnational corporations.[40] Although the local branches of these transnationals do not enjoy the same advantages of economy of scale, they would have access to the results of any toxicity tests that the corporation was required to do at home.

4. Responses

The concentration of the industry may facilitate regulation in some ways. A small number of large suppliers can be easily identified; they are more likely to have the resources to absorb the costs of regulation; their bureaucratic character and prominence in the market may make them adverse to law-breaking.

At the same time, the interest at stake for each is sufficiently high to justify fighting regulation.[41] Their place in the economy of the state is sufficiently important for it to be argued that any serious burden will have adverse consequences across the state. Most immediate will be the threat to jobs, in that the licensing scheme may not only add to the costs of the industry but also stimulate it to introduce more automated processes. Although the chemical industry is capital intensive and is not a large employer of labour,[42] in a time of high unemployment the loss of any jobs may be considered serious, particularly if they are in sensitive geographical areas.

The industry may suggest that the costs of regulation will be expressed in higher prices for their products. Given the pervasive use of chemicals in industry, the large industrial users may form a significant opposition group.

The local chemical industry might argue that the regulation will place them at a competitive disadvantage. It would seem though that the restrictions would apply to all suppliers, including imports from interstate and overseas. It would be more efficient if the requirements were applied in all states and the costs of proving safety thus spread out across the country. It would also make compliance easier if the requirements could match those of the home markets such as those of the United States and the European Economic Community. It is possible that a unilateral requirement will discourage suppliers from offering chemicals for use in Victoria. More importantly, restrictions placed by the licensing authority on the handling of the chemical in its manufacture or use, might shift the emphasis of the corporations to plants in other places.

A broad social account of the costs and benefits of hazardous chemicals might indicate that such effects are not undesirable. The restrictions might encourage the industry to search for safe substitute chemicals. There are alternative substances to which some users could turn. Quite apart from the problem of externalities, the local industry is not particularly efficient and has required considerable protection.[43] The

40 Commonwealth Department of Trade and Industry, *A Study of the Rate of Diffusion of New Technology within Australian Industry* (1972) para. 10.1.

41 G. Stigler, "The Theory of Economic Regulation" (1971) 2 *Bell J. Econ. & Man. Sci.* 3.

42 Commonwealth Department of Trade and Industry, note 40 *supra,* para. 10.3.

43 *Id.,* para. 10.1.

production of many of the basic chemicals requires considerable investment in plant and this makes the corporations less mobile. Epstein's account of controversies in the United States over the regulation of several chemicals, suggests that the industry is not always agreed on the difficulties of compliance.[44] One or more of the competitors may modernise their technologies sufficiently for compliance to be comparatively easy.

Nevertheless, the choice between costs and benefits will be made in a constricted, short term circumstance. In a recession, where existing capacity is not fully utilised, extra costs in one state may lead to greater use of plants in other states; the extra costs may be enough to deter investment in any new plants within the state. In an inflationary environment any costs passed on to the users of the chemical will also be critical. These immediate effects will weigh heavily in a state that has concentrated on manufacturing industry, and conditions such as inefficiency which ought to be arguments for cleaning up or winding down the industries become arguments for protection. Direct dealings with the industry may have made the bureaucrats sensitive to its problems. In an electorate preoccupied with economic matters, at least some members of a new Labor government may not wish to have a destabilising effect upon a local industry. It is important then that in the passage of the scheme, the policy analysts obtain some accurate predictions of the effects on profitability, use of capital, prices, employment, and support industries. It seems though in difficult economic times that, any threat to the prospects of large corporations and plants is treated as a symbol of the declining fortunes of the economy overall.

V. THE UNITED STATES EXPERIENCE: THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

The Victorian licensing scheme would endeavour to structure the way in which decision-making on uncertainty, risks, and information requirements would occur. This will be a considerable departure from the traditional approach in Australia[45] and the experience of the United States Occupational Safety and Health Administration will prove most instructive when considering its prospects.

1. The Occupational Safety and Health Act

In contrast to the British model which has been followed in Australia and which is characterized by administrative discretions, private deliberations, and domestic, consensus-oriented bodies, the American scheme is marked by a statutory framework

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44 S. Epstein, *The Politics of Cancer* (1978) chapter 5.

45 In Victoria, the regulation of occupational exposure to chemical hazards has been *ad hoc*; the onus has fallen on those who seek regulation and as the decision to regulate is discretionary and private, the standard of proof required to persuade the Health Commission of the need to put regulations to the Executive Council has been unclear. While a few substances were specially regulated in the late 1970's, the only instrument resembling a general regulation — the Harmful Gases, Vapours, Fumes, Mists, Smokes and Dusts Regulations — was formulated in 1945 and last reviewed in 1965. Its schedule prescribes threshold limit values for some 300 substances, a few of them carcinogenic. Approaches in other states have been similarly *ad hoc*, for instance, the adoption by the New South Wales Government of the National Health and Medical Research Council's model carcinogenic substances regulations: Carcinogenic Substances Regulation 1982 (N.S.W.).

providing a clear statement of purpose, obligations to act, definite criteria, open and adversary proceedings, and standing to seek judicial review.[46]

In 1970, during the Nixon Republican Administration, the United States Congress enacted the Occupational Safety and Health Act.[47] In the body of the Act, Congress declared its purpose to be "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".[48] To further this purpose, the Act required the Secretary of Labor to promulgate standards and in dealing with toxic materials or harmful physical agents, to set "the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even in such employee has regular exposure to the hazard . . . for the period of his working life".[49]

Given the large number of chemicals in use, the Occupational Safety and Health Administration (O.S.H.A.) was required to promulgate as occupational safety and health standards any national consensus standards or established federal standards in existence at the time, unless their promulgation would not result in the improved safety or health. A national consensus standard was one produced by a nationally recognised standards-producing organisation. Furthermore, if the Secretary determined that employees were "exposed to grave danger from exposure to substances or actions determined to be toxic or physically harmful or from new hazards" he was to provide for an emergency temporary standard if that standard was necessary to protect employees from such danger.[50]

2. Process

The Act elaborated a procedure for the Secretary of Labor to follow if he were to promulgate any occupational safety or health standard. Kelman describes the process as "byzantine in its complexity".[51] Following representation from interested parties, O.S.H.A., acting on behalf of the Secretary, is empowered to appoint a committee to advise on the issue. O.S.H.A. may act on its own motion to initiate the process but, normally, the process begins with a 'criteria document' from the National Institute for Occupational Safety and Health, containing a summary of existing literature and recommendations for a standard.

The advisory committee consists of equal numbers of representatives of labour and business as well as a number of public representatives. Its proceedings are informal and conducted in public; the committee may take testimony from interested outside parties. A technical officer within O.S.H.A. then evaluates the advice and proposes a standard; this is considered by senior officials and then the final proposal is published in the Federal Register. Interested persons are afforded a period of 30 days after publication in which to submit written data or comments. If an interested person objects to the proposed standard and requests a public hearing, the Secretary must fix a time and

46 B. Gillespie, D. Eva and R. Johnston, note 12 *supra,* 282.
47 29 U.S.C. §651 (1970).
48 *Ibid.*
49 §655(b)(5).
50 §655(c)(1).
51 S. Kelman, "Occupational Safety and Health Administration" in J. Wilson (ed.), *The Politics of Regulation* (1980) 236, 244. P. Weiner, "O.S.H.A.'s Standard-Setting Process" (1981) 32 *Lab. L. J.* 23.

place for such a hearing. The hearing is conducted by an administrative law judge. After the hearing, additional time is made available for submitting comments, and lawyers frequently submit detailed legal briefs.

Then O.S.H.A., usually one of its technical officers or project managers, must work through the entire record in order to formulate a ruling for the final standard. The Act requires the Secretary to issue a rule within sixty days of the hearing. The final standard is published in the Federal Register, accompanied by a statement of reasons explaining why the particular standard was selected. The Act then provides that any person who may be adversely affected by the standard has sixty days after promulgation of the standard to file a petition challenging the validity of the standard with the United States Court of Appeals for the Circuit, requesting a judicial review of the standard.

In its first year of operation, O.S.H.A. established national consensus standards for some 400 toxic substances, based on the levels recommended by the American Conference of Government Industrial Hygienists. Five years after its establishment, O.S.H.A. had established permanent new standards for only 15 carcinogenic substances, while its assistant secretary conceded that 1,500 to 2,000 substances were suspected of carcinogenicity.[52] By 1980, permanent standards had been created for 24 substances. Kelman recounts that in 1972 one standard was promulgated for asbestos. In 1974, standards for fourteen carcinogens and for vinyl chloride were set. In 1976, a standard for coke oven emissions was formulated, while in 1978, standards for arsenic, benzene, cotton dust, lead, acrylonitrile and the pesticide DBCP were set. No standards were set in 1973, 1975 or 1977. From the detailed accounts of their passages, it would appear that all the standards for the carcinogens, asbestos, vinyl chloride,[53] the 14 carcinogenic chemicals grouped together,[54] coke oven emissions, and benzene, have been disputed by industry, both within the standard setting process and on review in the federal courts. Most of the other standards have been similarly disputed. On the other hand, while the labour unions have generally participated in proceedings to support O.S.H.A.'s standards, they have also petitioned and otherwise applied pressure on O.S.H.A. to promulgate more standards. Indeed, the unions have sought judicial review of O.S.H.A.'s failure to act to set in train the promulgation procedure.

3. Review

Most of O.S.H.A.'s standards have been reviewed by the courts. The challenges have been as much concerned with the feasibility of O.S.H.A.'s standards as with O.S.H.A.'s evidence that a chemical was hazardous. The Act requires that O.S.H.A. set standards to the extent feasible, and employers have objected that compliance would have a serious economic impact on the industry in question. In the earliest cases, the federal courts recognised that imperfect understanding and incomplete information were unavoidable features of this field and that consequently a standard would be a mixture of the varying degrees of fact and policy. Whether there is sufficient evidence

52 E. Bingham, "O.S.H.A.: Only Beginning" (1978) 29 *Lab L. J.* 131.

53 D. Doniger, "Federal Regulation of Vinyl Chloride: A Short Course in Law and Policy of Toxic Substances Control" (1978) 7 *Ecology L. Q.* 500.

54 J. Page and P. Munsing, "Occupational Health and the Federal Government: The Wages Are Still Bitter" (1974) 38 *Law & Contemp. Prob.* 651.

that a chemical was carcinogenic is ultimately a legal question and not a factual one; whether, in conditions of uncertainty, the attitude is to be precautionary or adventurous, and in favour of health protection or production.[55]

According to Doniger, the legislative history of the Act indicates a precautionary and protective thrust. He recounts the statement of the House of Representatives Committee Report that it was not intended that O.S.H.A. be paralysed by debate surrounding diverse medical opinions. Uncertainties about the existence of danger were to be resolved in favour of the employees. The courts accepted this interpretation of the Act and, in part, allowed for O.S.H.A. to base standards upon conclusions drawn not only from established data but also from uncertain information on the frontiers of scientific knowledge, where the existing methodology or research was deficient.[56]

O.S.H.A. began to settle on the type and quantity of positive evidence it would treat as sufficient to set the standard. It should be noted that, while the emphasis of the scheme was on health, the burden was on O.S.H.A. to prove that a chemical was hazardous. It was necessary for O.S.H.A. to consider the strength of positive evidence, standing both on its own and in contrast to unsupporting evidence.

In several of the cases in which standards were established, O.S.H.A. had clear epidemiological evidence of the hazard. In other cases, it seems that O.S.H.A. was prepared to set a standard on the basis of one positive animal test, at least where it was backed by other, less informative or more suggestive, evidence. Furthermore, O.S.H.A. was prepared to regulate in the face of negative or non-positive results. It accepted the theoretical point that sampling errors and the other limitations in laboratory tests and epidemiological surveys meant there could not be complete assurance about low no-effect levels of exposure. In such instances, it was prepared to require lower levels of exposure at a time when there was positive evidence of hazardousness only for higher levels.

It has been noted that O.S.H.A. was guided in its judgements by the pro-health, precautionary thrust of the scheme — 'false negatives' were considered to more costly than 'false positives'. However, even with this statutory direction, O.S.H.A. was constrained so long as it took a chemical by chemical approach to standard setting. In 1977, O.S.H.A. adopted a generic approach to the regulation of new chemicals, proposing to initiate standard setting according to whether the new chemicals fell into the same category as known or suspected carcinogens.[57] Three categories of carcinogen were recognised in the approach:

(a) those confirmed by cases of human disease, or positive results in tests on two mammal species, or tests on one mammal species which were independently replicated, or in tests on one which were confirmed by the results of such short terms tests as the Ames bacterial test;
(b) those found carcinogenic in a single animal test or in suggestive epidemiological studies; and
(c) those for which there was suspicion but insufficient evidence of carcinogenicity.

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55 P. Kraus, "Environmental Carcinogenesis: Regulation on the Frontiers of Science" (1976) 7 *Environment Law* 84, 108.
56 Note 53 *supra*, 558.
57 29 C.F.R. 1910 — 10000 (1977).

If chemicals fell into the first category, a temporary emergency standard would be issued so that exposure would be allowed only at the lowest levels technically feasible, and then only under controlled conditions with sensitive monitoring procedures and with warnings to those affected; meanwhile, proceedings would be initiated to set a permanent standard. If a chemical fell into the second category, proceedings would be initiated to fix a permanent standard. The public would be advised of those which fell into the third category, but standards would not be set for these chemicals.

The generic approach was necessary to order priorities for the investigation of chemicals; it could not, however, relieve O.S.H.A. of the burden of fixing the ultimate standards individually.

4. Minimum proof

In 1980, the United States Supreme Court struck down the standard O.S.H.A. had set for exposure to benzene and settled the minimum proof required of O.S.H.A. to justify its standard.[58] The Court ruled that as the Act required a standard to be feasible, O.S.H.A. was obliged to demonstrate that the benefits of regulation at the proposed limit of exposure, bore a reasonable relation to its costs. Costs of regulation might be high; it was claimed in the benzene case that compliance would cost US$500 million. O.S.H.A. was obliged to provide some evidence that reduction to the low level proposed would reduce illness and death amongst those exposed; there had to be 'substantial evidence' in the record of O.S.H.A.'s deliberations for the level proposed. This was translated into a requirement that it be more probable than not that exposure at the levels to be prohibited presented a 'significant risk' to health. Recognising that the evidence in its nature might be inconclusive, the Supreme Court allowed that, given the policy of the Act, O.S.H.A. would be within its powers if it chose to take a conservative view of the evidence. Nevertheless, its assumptions and estimates had to be scientifically supportable and not mere conjecture. At the same time, O.S.H.A. did not have to show that the benefits matched up to the costs.

In contrast to the previous cases, O.S.H.A. had not had clear positive results from animal tests or epidemiological surveys to indicate a hazard at the level it was setting for exposure to benzene. The ruling in the benzene case might therefore be restricted to the weakest case. In 1981, the Supreme Court upheld O.S.H.A.'s standard for exposure to cotton dust.[59] It reiterated its opinion that O.S.H.A. was not required to strike a fine balance between the costs and benefits of regulation; its standard would be upheld provided it was not frivolous and it addressed a significant risk of harm, not necessarily to society as a whole but to a specific group of employees. On the other hand, the standard should not threaten the industry as a whole and amount to a *de facto* prohibition of a certain occupation. It was estimated the cotton dust standard would lead to a 1.68 per cent contraction in consumption for cotton yarn.

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58 P. Stone, "Case Comments: The Significant Risk Requirement in O.S.H.A. Regulation of Carcinogens: Industrial Union Department, AFL-CIO v. American Petroleum Institute" (1981) 33 *Stan. L. Rev.* 551.

59 *American Textile Manufacturers Institute, Inc.* v. *Donovan (Cotton Dust)* 101 S. Ct. 2478 (1981) discussed in "The Supreme Court, 1980 Term, B. Labor" (1981) 95 *Harv. L. Rev.* 319.

5. Political pressure

Recent events support the generally made observation that the legal structure of a regulatory scheme is not the sole determinant of its direction and force. From its establishment, industry interests have been critical of interventions and impositions by O.S.H.A., and these criticisms have been taken up by media and politicians with free enterprise sympathies. These criticisms were levelled as much at the Administration's safety specifications and enforcement practices as its chemical exposure standards.

Kelman recounts some of the proposals made to reduce O.S.H.A.'s autonomy.[60] Bills designed to exempt small employers from O.S.H.A.'s requirements have been introduced into the Congress; one to exempt farms with less than ten employees was successful. Another prohibited the imposition of fines for mild violations if there were fewer than ten such violations in a citation. Within one year of its commencement, members of Congress had introduced as many as one hundred bills to amend or repeal the Act; O.S.H.A. officials were regularly called before Congressional committees.

The most effective pressure to reorient the scheme has come from the Executive.[61] White House economists in all four administrations (those of Nixon, Ford, Carter and Reagan) have intervened to oppose what they see as over-regulation by O.S.H.A. With increasing concern about inflation, intervention increased during the Carter administration, when efforts were made to have O.S.H.A. relax its cotton dust standard, and a proposal made to the President that he acquire the power to veto O.S.H.A.'s regulations. These proposals were rejected, but a regulatory analysis review group was established to examine major O.S.H.A. proposals, and, by Executive Order, O.S.H.A. was required to prepare inflationary impact statements to accompany its proposals. From outside the scheme, cost-benefit analysis again became relevant to the evaluation of O.S.H.A.'s proposals.

With the advent of the Reagan administration, O.S.H.A.'s long serving director, a toxicologist who had worked with labour unions, was replaced by a young lawyer. As Smith reports, the new director ordered a reconsideration within O.S.H.A. of the exposure limits for cotton dust and lead, and a postponement of a tighter limit on noise.[62] New standards on asbestos, formaldehyde, ethylene oxide, and cadmium, which were in partial stages of preparation, have been put aside. The generic carcinogen policy is likely to be revised. Safety requirements will be given more emphasis than health standards. It would appear that a major objective for O.S.H.A. will be to reduce work time lost to employers through employee injury, a loss which ninety-seven percent of the time is safety rather than disease related. Moreover, staff in the health standards office will be reduced by ten percent. The agency will no longer act where the evidence is merely suggestive, as the courts have sometimes permitted it to do.

This new approach within O.S.H.A. is allied to the overall deregulation strategy of the White House, which is coordinated by the Office of Management and Budget.[63]

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60 Note 51 *supra*, 256.

61 K. Newcomer and G. Kamber, "Changing the Rules of Rulemaking" (1982) 11 *Bureaucrat* 12.

62 R. Smith, "O.S.H.A. Shifts Direction on Health Hazards" (1981) 212 *Science* 1482. See also F. Perera and C. Petito, "Formaldehyde: A Question of Cancer Policy?" (1982) 216 *Science* 1285.

63 F. Thompson, "Deregulation by the Bureaucracy: O.S.H.A. and the Augean Quest for Error Correction" (1982) 42 *Public Administration Review* 202.

First given force by a 1981 Executive Order, it has received support with the passing by Congress of the Regulatory Reform Act of 1982.[64] The Order gives the Office power to delay and review important new regulations proposed by most executive agencies including O.S.H.A. The new Act gives the Congress a veto. Cost-benefit analysis will be required to justify the adoption of major rules. The Order states that regulatory action is not to be undertaken unless the potential benefits to society for the regulation outweigh the potential costs to society. The costs to society include the costs of industry's compliance. In their survey of the new approach to regulation, Newcomer and Kamber characterise it as an economising approach.[65] They conclude that, except where legislation explicitly forbids cost-benefit analysis, all rules are to be justified in economic terms. The burden of proof is upon the agency to demonstrate the need to issue a rule. They suggest that the shift in regulation approval away from the middle level managers of the agencies to the heads and cabinet officials, has now extended to the executive office of the President. This centralised regulatory process will require bureaucrats to sell their cases for regulation to "more distant and hostile juries for approval".

VI. EVALUATION

The occupational health question represents a struggle to reconcile complex powerful forces, namely industrial growth and human welfare. It is not possible to represent all the components and dynamics of such a field here. Hence, the focus is on the role that the law plays in articulating and assessing health questions, particularly their scientific or technical aspects. More precisely, the interest of the paper becomes the extent to which the role of the law varies with its form. In examining the influence of legal features on the character of occupational health schemes, several distinctions may be discerned. In the discussion of approaches to regulation, distinctions have been made between technical and policy matters, between legal and industrial modes of dealing with such matters and, within legal modes, between rights and discretions models.

1. Legal Regulation

Some pro-health commentators are sceptical about the use of a legal strategy to control hazards. Following Pashukanis, Livock suggests that the law works against greater health promotion by re-casting the issue in a misleading way.[66] He argues that the law characterises health as a matter for relations between the individual employer and employee. Instead of recognising that occupational health is a function of the broad conflict in interest between capital and labour with very real limits imposed on health promotion by the pattern of control of sources of knowledge and work processes, the law atomises the issue and removes it from its proper context. Health becomes a matter of contract between employer and employee, and the law

64 N. Ashford, "The Regulatory Reform Act of 1982" (1982) 16 *Environ. Sci. Technol.* 365A.
65 Note 61 *supra,* 15.
66 R. Livock, "Science, Law and Safety Standards: A Case Study of Industrial Disease" (1979) 6 *Brit. J. L. & Soc.* 172.

superimposes arbitrary obligations on the employer and the employee to respect health generally or in prescribed ways. Health becomes a matter of the observation of these legal requirements which appear to have been determined objectively and disinterestedly. The law does not reveal the premises on which the scheme is formulated, such as how and at what prices the goods should be produced, nor does it demand realistic methods of prevention.

On the other hand, Hirst argues that this is often a rather strained characterization of the workings of the law.[67] It applies best to the traditional statutory approach whereby worker safety and health have been regarded as welfare rather than industrial concerns. The significance of the industrial and other structural characteristics of the health issue is being increasingly recognized. The most notable development is the requirement that firms have safety representatives, safety committees and safety policies. In formulating general policies, informal consultations have developed between government, employers and unions, culminating in the establishment of official advisory councils and commissions in Victoria.[68] These changes have been given impetus by the growing interest of unions and employers in health matters. Furthermore, as regulation becomes more extensive, increasing delegation of legislative power to the executive and administrative agencies of government has occurred.[69] With the connections between these agencies and industry established, industrial and legal approaches to health regulation begin to merge.

It is said that delegation is necessitated by the complexity and rapid rate of change of the technology. Technical expertise is required to help formulate effective standards. At the same time, because health policies involve value judgements, for instance about acceptable risks of illness and acceptable information costs, it is appropriate for those affected to take part in standard-setting and that their perceptions and interests should influence its outcomes.

2. Technical advice

The placing of representatives of the industrial parties on the decision-making bodies does not mean that the policy questions will be properly resolved. It may not be realistic to expect such representatives to grasp fully the implications of characterizing health questions initially as technical questions. The presentation of health questions as technical questions may act to remove a critical part of the issue from the industrial or political decision-making body's competence. Characterizing the determination of hazardousness as a purely technical matter may preclude debate over the conflicts which are bound up in the health issue. In contrast to situations where the consequences of greater or lesser regulation are clear, collaborative decision-making bodies may not think they are making compromises between health and production;

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67 P. Hirst, Introduction to B. Edelman, *Ownership of the Image* (1979).

68 The Industrial Safety Health and Welfare Act 1981 (Vic.) established an advisory council made up of nominees of employer associations, the Trades Hall Council, government departments and safety associations. The new government is establishing a Commission comprising a Chairman, equal numbers of nominees from the Trades Hall Council and employer associations, together with three health and safety experts jointly nominated by the Council and employers.

69 *Cf.* J. Winkler, "Law, State and Economy: The Industry Act 1975 in Context" (1975) 2 *Brit. J. L. & Soc.* 103.

they may in fact feel they have not had to reach this uncomfortable stage of the decision-making.

It is arguable that each stage of deliberation over regulation requires a determination of policy regarding the balance between health and production.[70] Reactions to incomplete and imperfect scientific knowledge of hazards involve decisions about the costs and benefits of inquiry and of the prospects of false negatives and false positives. In regulating hazardous chemicals, policies are to be formulated regarding the tolerable degree of uncertainty and the location of the burden of that uncertainty.

The lay conception, at least until recently, has been that scientific knowledge represents facts in an objective, detached and unified manner. Scientists are seen as transmitters of information rather than participants in social debates. Consequently, it is expected that the advice of the expert at hand, whatever his speciality, will be the same as any other qualified and experienced person in the field would give.[71] The sociology of science recognizes however that both social and professional situation affect the scientist's opinions as to what constitutes good evidence, his reception of theoretical suppositions and his estimation of the strength of available data.[72] Studies indicate how both external and cognitive factors affect scientific judgements. In the realm of chemical hazards, the studies suggest that there will be differences between, on the one hand, the occupational toxicologists, industrial doctors and hygienists and, on the other, the research chemists, physicists and biologists. The differences are significant because traditionally the toxicologists have had the greater access to the rule-recommending and rule-making bodies, while much of the pathfinding work has been done by the chemists.

It is the case that the toxicologists are employed mainly in industry by the major corporations and in government by the health authorities. As applied scientists, their efforts are channelled towards the needs of their organization. Nonetheless, it would be erroneous to contend that the toxicologist's occupational situation causes him to support only that evidence which serves his organization's interests — or, for that matter, to contend that the academic scientist is always disinterested. Rather does the toxicologist's type of training and his professional experiences in an industrial setting, often as a medical adviser, lead him to prefer clinically manifested signs of illness, proof of casual relationships between industrial conditions and ill-health, and empirically developed therapy techniques. His situation does not prove that he will ignore or distort evidence which is unfavourable when it emerges in the industrial setting; rather is it likely to influence his view of the sort of evidence which is advanced by other

70 See Section I *supra*.

71 D. Robbins and R. Johnston, "The Role of Cognitive and Occupational Differentiation in Scientific Controversies" (1976) 6 *Social Studies of Sciences* 349.

72 S. Blume (ed.), *Perspectives in the Sociology of Science* (1977).

classes of expert evidence that may be easier to collect, predictive rather than retrospective, and more analytical and theoretical than sensory and particularistic.[73]

This injunction is particularly apt when related to the formation of opinions about carcinogenic chemicals for, as Barnes points out, scepticism and criticism are more frequently directed to work anomalous to an entrenched paradigm, to results that are produced by a recently developed technique and by experiments unavoidably unreliable because, for example, they are dependent on measurements near a technical threshold.[74] In the case of carcinogens, this attitude is likely to militate against the acceptance of the evidence of tests on animals, and on bacteria, and the comparisons of structure — activity, and in particular the theory that there is no safe threshold level of exposure to a carcinogen.

The nature of the regulatory process can determine that the lay decision-makers are presented with only one of the relevant schools of scientific thought. Furthermore, if the process reveals the differences in expert opinion and offers no guidance about how to respond, the decision-makers may become excessively hesitant about taking action, and so the allocation of the onus of proof may be critical to whether health or production is favoured by this behaviour. Reiser recounts that the Congressional committee investigating the hazards of smoking was surprised and disappointed by the uncertainty and disagreements in the ranks of the scientists.[75] It heard that the evidence was only of correlations between tobacco and cancer and not causation, that the connections were only probabilistic, and that counter-hypotheses could therefore not be refuted absolutely, at least not in the absence of further research and experimentation. The result was a strong recommendation for further research and a tentative recommendation for weak regulation. When an issue is thrown open in such a way, the lay panel may also be inclined to seize on such extraneous features as the status and demeanour of the various experts in an effort to choose between the conflicting opinions.

The way in which scientific dissensus is managed becomes more problematic if the goals of regulation are ambiguous or conflicting. In an analysis of the political context of scientific advice, Ezrahi identifies the four possible situations to be agreement on goals with scientific consensus, agreement on objectives without scientific consensus, scientific consensus and disagreement about objectives, and disagreement about

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73 A local example of such differences was the clash reported in the *Age*, (24 May 1982) 3. In giving evidence to the enquiry into hazardous chemicals being conducted by the Federal House of Representatives Standing Committee Environment and Conservation, Doctor Donald McPhee a university lecturer in microbiology, described the relationship between industry and the standard-recommending committees of the National Health and Medical Research Council as 'a cozy relationship'. Doctor McPhee had been appointed adviser to the parliamentary committee. According to the newspaper report, the response of the medical services adviser in toxicology to the Commonwealth Health Department, Doctor Black, was to state that the allegation was unfounded. He said that while some of the members of the Council's committees were industry employees, they were not on the committees as representatives of industry. They were appointed as experts in the field and they included some of the leading academics in pharmacology, toxicology and related fields. Doctor Black added that while the Department recognised Doctor McPhee's expertise in the field of bacterial genetics and mutagenesis, when he attempted to speak as an authority in such recognised fields as epidemiology, occupational health and toxicology, his conclusions had to be regarded as suspect.

74 B. Barnes, "On the Reception of Scientific Beliefs" in B. Barnes (ed.), *Sociology of Science* (1972) 279.

75 S. Reiser, "Smoking and Health: The Congress and Causality" in S. Lakoff (ed.), *Knowledge and Power: Essays on Science and Government* (1966).

objectives coupled with scientific dissensus.[76] Clearly the last situation, which fits the case of occupational carcinogens, is the most problematic. Ezrahi cites examples such as the controversies over the use of intelligence tests in the educational system and over the production and deployment of anti-ballistic missiles.[77] Under these conditions, matters of fact and value are blurred, and scientific and political disagreements tend to interpenetrate and to aggravate the controversy. Scientific uncertainty and dissensus may be exploited by interest groups to further their preferred objectives.

The impact of technical advice will not end with the question of hazardousness. Expert advice will be tendered about the content of the risk-benefit account and in particular the cost of precautions. It is safe to say that the lay person is sceptical about the scientific character of the discipline of economics but the extent of his appreciation of the limits of the descriptive and evaluative powers of this discipline and particularly the price measure is also important, for it will quite naturally appeal to some parties to stress the economic and quantifiable above the non-market and intangible costs and benefits of competing policies. Treasury-type agencies of government will also be tempted to give emphasis to these features, particularly the costs of administration of a scheme.

3. Policy determination

Even if they do appreciate the context in which technical opinions are formed and can assess them accordingly, union and employer representatives may not possess the authority exclusively to determine occupational health policies. These officials may not be able to represent all the interests implicated by occupational health decisions and especially those who are affected only indirectly or in the long term. For instance, in any association of workers, there will be queries about the legitimacy of its consent to a hazard to bind individuals, particularly those workers who have voted against the position adopted and those workers who have not joined the association. In most situations, the union will also comprise members who will not be exposed to the risk. In addition, the costs of illnesses are not limited to the workers who are afflicted.

Arguably, society, through the law, is entitled to take the broader view of the appropriate mix of health and production. The question arises as to who is to represent the public interest. It would be naive to think that the public officials in the relevant agency do not have values of their own. Similarity in social background or professional experience may mean that these values align with those of the regulated. In any case, studies of regulatory behaviour indicate that through the repeated formal and informal contacts, exchanges of information and personnel, and collaborative decision-making, the officials are prone to identify with the interests of the regulated.[78]

This is most likely where the costs of regulation fall on a more informed, concentrated and powerful group than do the benefits, in particular where the projected costs to the producers are more material and immediate than the benefits to the consumers, and the regulators must rely on the producers for information about the impact of the technology and the implications of regulation. This is true to some

76 Y. Ezrahi, "Utopian and Pragmatic Rationalism: The Political Context of Scientific Advice" (1980) 18 *Minerva* 111.

77 *Id.*, 120.

78 W. Carson, *The Other Price of Britain's Oil: Safety and Control in the North Sea* (1981).

extent of the regulation of industrial chemicals but the unionization of workers and the growing interest of union personnel in health matters (subject to the difficulties of appreciating cancer risks fully)[79] also afford the consumers influence,[80] particularly when they are affiliated with the political party which provides the government and take part in the formulation of its policies.

In any case, it would be simplistic to attribute too much significance to the characters of the public officials and to their contacts with those regulated. Rather, whatever the dedication of the officials, the agency is obliged to operate within a given economic and political system. There is flexibility within that system but as resources become scarce and conflict heightens, the agency may find that its options are reduced and its terms of reference altered, and the demands for proof of hazardousness as well as feasibility of precautions changed accordingly.

4. Legal framework

Law reformers are inclined to argue that a strong statutory framework and a formalised procedure for standard-setting will give an agency more authority and autonomy. After comparing the paths of standard-setting in Britain and the United States, the aldrin/dieldrin study concluded favourably along these lines for the American model.[81] It observed, *inter alia,* that the adversary model permitted the introduction of opinions of hazardousness from standpoints other than those of the agency and the industry and required the 'insiders' to articulate their methodologies and assumptions.

The experience of O.S.H.A. indicates that the statutory framework helped to identify the issue of uncertainty and to formulate a response to it, so that the setting of standards was not held up at the initial point of policy formulation. Nevertheless, it is true that a clear value judgment by the Parliament in favour of health and precaution does not guarantee that a scheme is effective or cost effective in preventing illness. Where the officials of the scheme are strongly committed to health protection, they are likely to be more averse to false negatives than to false positives and they may consequently be resilient to suggestions that they have erred or to demands that they economize in their choice of regulations.[82] It would seem prudent to monitor the impact of standards after they have been instituted. However, in the case of standards designed to prevent long term illnesses, the analysis is brought back to the necessary shortcomings of the evidence. The surest test is delayed twenty or thirty years and even then, the contribution of the content of the standard can be obscured by other such variables as observance and enforcement practices.[83]

In identifying an effective scheme, the indicators must therefore be somewhat more impressionistic and theoretical. For instance, it appears that the United States scheme has not extended controls to many more chemicals than the traditionally *ad hoc* Australian approach but the standards set have been more strict. While O.S.H.A. did

79 See Section III *supra.*
80 B. Dabscheck, "Theories of Regulation and Australian Industrial Relations" (1981) 23 *Journal of Industrial Relations* 430, 437.
81 B. Eva, D. Gillespie and R. Johnston, note 12 *supra,* 289.
82 F. Thompson, note 63 *supra,* 207.
83 *Cf.* W. Vicusi, "The Impact of Occupational Safety and Health Regulation" (1979) 10 *Bell J. Econ.* 117.

adopt as national consensus standards the threshold limit values recommended by A.C.G.I.H. for some 400 toxic substances[84] which did not include carcinogens, this adoption did not have to meet the same statutory criteria or formal procedure as did its subsequent promulgation of new standards.

It can be argued that the legal ordering of the scheme has been used to complicate and delay, if not obstruct, O.S.H.A.'s progress in setting standards for hazardous chemicals. This is particularly so where there are many parties involved and those parties tend to see the issues on which they differ as fundamental. The conflict becomes, in Thompson's view, "an ongoing morality play".[85] The adversary system, especially to the extent it allows oral testimony and cross examination, draws out differences rather than encourages consensus. Their personal experiences may cause concern in some scientists that the system comprises proper modes of inquiry and professional conduct and may lead them to refuse to take part in standard-setting. Labour unions may be tempted to divert resources into the legal processes: in the United States, first pressuring O.S.H.A. to establish standards and then defending those standards, and O.S.H.A. itself, from attack. Industry goes to considerable expense to negotiate or oppose the standards. The agency is channeled into a search for standards that satisfy the substantive and procedural legal requirements rather then meet the pressing health problems or comprise a comprehensive approach to the issue.[86]

Under the pressure caused by the breadth of the field, the scientific dissensus, and the conflict over objectives, the agency may respond with such strategies as 'oversight', 'flight', and 'remedialism'. It may downgrade or deny hard issues, delay, and concentrate on regulating areas that are the least controversial or that are at a critical point because illnesses have developed on a large scale.[87] The agency may experience tension and turnover in staff as the recommendations of professional officers are filtered by management sensitive to the political responses to regulation.

It should also be noted that standards almost invariably comprise a compromise between health and production, because of the deficiencies in knowledge and the constraints of feasibility. A scheme that involves due process and participatory decision-making may diffuse responsibility and afford such compromises more legitimacy than other approaches. Legal standards not only limit but also permit

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84 The Conference has also prepared documentation of the evidence on which the recommended limits are based. Epstein describes the Conference (rather flamboyantly) as an industry oriented, quasi-consensus body whose standards are proprietary in nature, reflecting their narrowly focused trade origin: Epstein, note 44 *supra*, 391. The Conference's limits have been adopted (with a few exceptions) by the National Health and Medical Research Council; see occupational health guide, Threshold Limit Values, available from the Council in Canberra. The guide includes limits for forty known or suspected carcinogens. The Council has also prepared model carcinogenic substances regulations, scheduling sixteen substances for which it thinks there is strong evidence of carcinogenity: see National Health and Medical Research Council, *Report of the 85th Session* (1978) appendices XVII and XIX. The Council's committees, which formulate the recommendations, comprise in varying degrees, government health officials, university academics, corporation medical officers and union representatives.

85 Note 63 *supra*, 205.

86 S. Breyer, "Analysing Regulatory Failure: Mismatches, Less Restrictive Alternatives, and Reform" (1979) 92 *Harv. L. Rev.* 549.

87 M. Cohen, J. March and J. Olsen, "People, Problems and Solutions and the Ambiguity of Relevance" in J. March and J. Olsen (eds.), *Ambiguity and Choice in Organizations* (1976) 32. K. Keiser, "The New Regulation of Health and Safety" (1980) 95 *Poli. Sci. Q.* 479.

exposure to the hazards: in a sense, they 'licence' harm. Indeed, they may freeze exposure at a given state of knowledge, technique and economy.[88] Amendments to lower or raise existing standards may be as slow as the promulgation of new standards. A uniform specification may not allow sufficiently for variation in the circumstances of application of a chemical.[89]

5. Responses

If a health scheme with both stability and purpose is to be provided, then the appropriate legal strategy may be to take more care with the design of a scheme. On the one hand, it may be well advised to consider structuring some aspects of the scheme most precisely. A clear statement of purpose would help to resolve ambiguities when they arose in the operation of the scheme. In order to ensure that some headway is made with the volume of chemicals requiring deliberation, it may be necessary to cast the government authority's functions in terms of obligations rather than powers, and reinforce these with deadlines for action, and with criteria by which priorities between chemicals can be established. The short term tests are useful for establishing priorities, and consideration may also be given to the seriousness of the hazard alleged and the circumstances of use such as the number of workers who will be exposed to the chemical. Consideration might also be given to the advantages of deeming a certain type of evidence to be, under specified conditions, sufficient proof that a chemical was hazardous or was not hazardous, depending on where the scheme placed the onus of proof.

Nonetheless, as it is in the nature of the type of evidence available that determinations that a chemical is safe will be inconclusive, it is possible that fresh positive evidence could emerge after a chemical is licensed. It is desirable for the policy makers to determine how the authority will respond to fresh evidence. Periodic reviews of licences, or the power to re-examine licences in the light of new evidence, might be considered. It is also desirable to consider the correct response to fresh, non-positive evidence, where a licence had been refused. This feature of the licensing system has implications for the subsequent common law liability of the manufacturers and the regulatory authority itself.

On the other hand, it may be advisable to retain some discretion and flexibility in the way in which the scheme achieves its designated tasks. In particular, the deliberations about hazardousness might be separated from the negotiations over feasibility,[90] and these deliberations confined to 'paper hearings' so as to encourage reasoned and dispassionate debate over evidence. In order to establish priorities and interim standards, the authority might be empowered to adopt the recommendations of a recognised research institute such as one of the international bodies or perhaps the National Health and Medical Research Council.

Finally, the importance of a tight legal structure cannot be over emphasised. Regard must also be given to the background and calibre of the persons appointed to the authority, the range of their expertise, and their political and administrative acumen.

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88 R. Livock, note 66 *supra*, 199.

89 J. Braithwaite, "The Limits of Economism in Controlling Harmful Corporate Conduct" (1982) 16 *Law & Soc. Rev.* 481.

90 See *e.g.*, A. Mazur, "Science Courts" (1977) 15 *Minerva* 1.

The size of the budget allowed the authority in the pursuance of its objectives is critical; the appropriation for staff may well be the effective policy decision about the extent to which occupational health will be pursued. The political interest shown in the decisions of the authority by such bodies as the Premier's department, other departments through the Cabinet, members of Parliament, and of course industry and union organisations will be significant. To provide some balance, the authority may need the support of other government and industrial bodies; an occupational health programme might also provide means by which industries could formulate standards which improve on those of the authority or which operate in the absence of standards by the authority, as well as suitable incentives to do so.

6. The proposed Victorian licensing scheme

In terms of the legal structure, several aspects are unclear. Perhaps the biggest gap is the lack of specification of the approach to existing uses of existing chemicals, including the criteria by which to distinguish new from existing chemicals and uses.

Regarding new chemicals and new uses for existing chemicals, the policy specifies that licences will be issued only on receipt of a satisfactory dossier. This dossier is to set out the result of toxicity testing of the material, but the requirement does not establish whether it will be sufficient for the supplier to provide results of tests that have been done, or whether the supplier is to ensure that some sort of testing is performed. Once the dossier has been provided, the occupational health division is to issue a licence or show cause why no licence should be granted. The policy does not indicate what will constitute good cause to refuse a licence. In these ways, the policy does not fix the type of evidence which will be sufficient to comprise a satisfactory dossier or which will be sufficient to establish cause to deny a licence.[91] In addition, the policy does not detail the procedure by which the dossier will be presented and accepted or by which the authority will show cause why no licence should be granted. While providing that the dossier be open to public inspection, the policy does not indicate what rights such other parties as the users and the unions will have to support or oppose the granting of a licence. The nature of the appeals process also requires definition. Procedures for periodic review of licences and licence conditions must also be considered. Partly for these reasons, the policy does not reveal where, effectively, the burden of proof will lie. It is acknowledged that many of these matters could only be expected to be revealed in the implementation of the scheme, following the Victorian Employment Committee's consultations and deliberations within the Ministry for Employment and Training and the Occupational Safety and Health Commission.

The relationship of the administering authority with the other arms of government also awaits definition. It appears now that the scheme will be administered by a health and safety division within the Ministry of Employment and Training rather than the Department of Labour and Industry. Previously, the Ministry has been a more junior portfolio than the Department. The extent to which other departments will give over their responsibilities for occupational health is yet to be determined; similarly, the relative roles in policy formation of the Division and the new tripartite Occupational

91 Compare the elaboration of such matters in Australian Council of Trade Unions, *Submission to the House of Representatives Standing Committee on Environment and Conservation Hazardous Chemicals Inquiry* Melbourne, July 1981.

Safety and Health Commission. Of significance also will be the interest shown in the design and operation of the scheme by the Department of the Premier and Cabinet, by those Departments traditionally concerned with either occupational or environmental exposure such as the Departments of Health, Industrial Affairs, Minerals and Energy, Conservation and Agriculture and by the Departments charged with the promotion of industry such as the Ministry of Economic Development, and by the new Department of Management and Budget. The new Government has embarked upon a restructure of state administration in order to strengthen the overseeing and coordination of departments and authorities by the executive in Victoria. This may have the welcome effect of reducing duplication and waste; it may also provide an added focus for political anxieties at an economically sensitive time.