Regulating the Regulators

Science, Values and Decisions

October 1982

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October 1982

The Honourable Donald J. Johnston, PC, MP
Minister of State for Science and Technology
House of Commons
Ottawa, Ontario

Dear Mr. Johnston,
In accordance with Section 13 of the Science Council of Canada Act, I take pleasure in forwarding to you the Council's Report No. 35, *Regulating the Regulators: Science, Values and Decisions.*

Yours sincerely,

Stuart L. Smith
Chairman
Science Council of Canada

October 1982

Dr. Stuart L. Smith,
Chairman,
Science Council of Canada.

Dear Dr. Smith,

It is our pleasure to transmit this document to you. This report is different in many ways from previous Council reports, for although it does reach definite conclusions, its recommendations are not "final." The report is intended to stimulate further thought and experimentation in a much needed but difficult field. We see it as a challenge to think and act more broadly and with greater perception of the contemporary need for public participation in the regulatory process and in the steps which may, or may not, lead to regulation.

Since 1978 the Committee on Science and the Legal Process has investigated the capability of our governmental system to handle complex and divisive issues that arise from the interaction of science and human values. We have in no sense completed this work, as it would have been impossible to do so. But we have defined the scope of the problem and the limitations of our current system. No matter where we looked — in Parliament, in the judiciary, in government departments – no clear mandate was apparent, and each area was constrained by inadequate resources or by past traditions to deal effectively with the new questions which our society will have to resolve in the coming years.

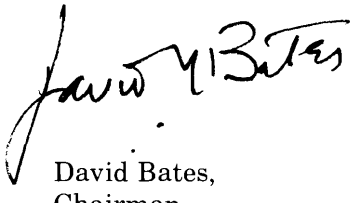
As a first step we have made recommendations, which, if acted upon, would improve the situation. But further work is essential. We recommend, for example, further research into the process by which boards of review are conducted, such as those mandated by the Hazardous Products Act and the Environmental Contaminants Act, and in addition a careful reconsideration of the process of standard setting. The public has to become aware of how the present system works, for the process must be made truly accountable if the public interest is to be protected.

When we began this study, matters of immediate economic concern to Canadians were much less pressing than they are today. Nevertheless, despite the present state of the economy, we emphasize the urgency of contending with value-scientific questions. Often it is too late to respond to the impact of advances in science and technology. As Dr. Léon Dion advised in our first committee meeting, the develop-

ment of a "proactive" system is vital. But this is a difficult task, requiring concerted and serious commitment, and therefore a long attention span, over a long period of time. A prospective view will be required to defend the public interest, and is essential to provide the foundation for well-based decision making. Canadians can no longer afford to address each issue in an *ad hoc* fashion, by piece-meal revisions of law and policy. We must define which institutions, organizations, and individuals should have the responsibility and assist in the resolution of these serious value-scientific questions, and who oversees and reviews any decisions which may be arrived at.

The Committee would like to express its profound appreciation of the invaluable work completed by science advisers Jack Basuk and Judith Miller. In this broadly ranging study, many people have helped to generate ideas. Legal consultant Howard Eddy, sociologist Liora Salter, psychologist Jill Morawski, and research staff worker Karen Fish, have provided many creative thrusts in addition to the task of developing background data absolutely essential to us to underpin our work.

Yours sincerely,



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Chapter I

Introduction

Science and technology have revolutionized the standard, quality, and style of living of most people. But many of the attendant costs were either hidden, ignored or not foreseen when a scientific advance was realized or a new technology was introduced. Along with benefits such as the virtual world wide elimination of small pox, we have seen environmental deterioration, depletion of non renewable resources and stresses on the moral and ethical fabric of our society. Traditionally, many of the resulting problems have been dealt with by the legal process.*

The differences between legal and scientific concepts of fact, knowledge, probability and proof present problems as science enters more and more into regulatory matters and as members of the public expect greater participation in technological decisions that affect their lives. Scientists discover what is. The law must adapt to these discoveries. But scientists are often frustrated by the inability of the legal process to act on what they consider clear and compelling evidence.[1]

The interaction between law and science at present is insufficient to allow anything other than a crisis-to-crisis response. In the 1980s, technological advance is happening too fast for the social and legal processes to adapt.

Reflecting on the growing gap between the scientific community, the legal community, and the wider public, professor Milton Wessel writes: "Many of the critically important modern problems which our society must today resolve – what I have called 'socio-scientific disputes' – are different in degree, and sometimes in kind, from those that our existing dispute resolution mechanisms were designed to handle."[2]

Wessel describes socio-scientific disputes (value-scientific disputes in this report) as having three principal characteristics: first, public interest in the problem and its resolution; second, the information needed to make a rational judgement is complex and difficult to evaluate; and third, "a sound final judgement requires the fine tuning and balancing of a number of 'quality-of-life' value concerns, about which different people may have widely varying attitudes and feelings."[3] When all three characteristics are present, they seem to

* Law has a strict meaning: the legislation, regulation and case law (judicial precedents) that form the legal system of a society. The law may be established by the legislature or by delegated legislative power (normally the Cabinet).

The legal process includes all measures taken by a government that could eventually result in legislation or regulation. For example, a commission of inquiry has some legal powers, although it does not make laws. Its work can be used to prepare legislation, or regulation and therefore is part of the "legal process." In this report, we use the term the "legal process" in the broadest sense, and include measures leading to guidelines on regulation prepared by public officers. Guidelines can have consequences as important as those of a law or regulation. Although Medical Research Council guidelines for researchers are not delegated legislation, researchers comply to avoid sanctions.

synergize and complicate resolution of the dispute, Wessel adds.

Bringing a jurist's view to the problem, Judge David Bazelon of the United States Court of Appeal has written:

> "The astounding explosion of scientific knowledge and the increasing sophistication of the public have radically transformed our attitude toward risk regulations. As governmental health and safety regulations become pervasive, there is a pressing need to re-define the relation between science and law. This is one of the greatest challenges now facing government and indeed society as a whole."[4]

Biologist Robert Sinsheimer brings yet another perspective.[5] He has challenged the scientific community to participate with non-scientists in considering policy questions. For example, he lauded scientists who first raised concerns about the implications of recombinant DNA research. Their efforts to deal with these concerns generated world wide attention.[6]

Value-scientific controversies consist of a mixture of facts and values, with varying weights given to each component. Sometimes values are explicit, but more often they are not. The complexity of the interaction of the two aspects contributes to the difficulty in resolving value-scientific disputes.* The nature of the controversy must be understood before any attempt is made to deal with it. Unfortunately

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* The following dialogue may clarify the difference between a disagreement over scientific facts, and the judgements made from them. Assume that Dr. A and Dr. B are giving evidence before a commission of inquiry looking into the possible hazard to children exposed to asbestos in primary schools. Both scientists are expert in the field, have reviewed all the scientific literature, and have agreed on the validity of the reported observations.

Chairperson: We now face the question of the extent of the hazard and the consequences to children exposed to asbestos in primary schools. What would be your view, Dr. A?

Dr. A: In view of the increased hazard which will result from asbestos exposure during childhood, and allowing a long time for the carcinogenic effect of asbestos to occur, my opinion is that a policy of no exposure is the only responsible one for us to adopt.

Dr. B: That is surely extreme. These children are going to walk about in cities and be exposed to airborne asbestos from brake linings of vehicles. Hence, they are unavoidably exposed to a certain amount of asbestos fibres.

Dr. A: That is surely an *additional* reason for tolerating no further exposure in the schools.

Dr. B: We have agreed that we have no evidence that a few fibres of asbestos in the lung are, in fact, carcinogenic. It does not seem reasonable to me to insist on a policy of total exclusion from one environment, knowing that some exposure is inevitable in another.

Dr. A: In my opinion, unless we take a position of removing exposure to known carcinogens whenever possible, we condone repetitive exposure that is bound to be harmful . . .

Such an exchange is not a scientific disagreement about the available data. Dr. A and Dr. B agree on what proportion of certain types of tumours may be attributable to asbestos. They differ on the reasonableness of a specific policy given the data. Their opinions may reflect differences in values or philosophy. The media often present this type of confrontation as a dispute over factual information. And the public perceives that scientists disagree about the conduct and results of experimentation.

the precise basis of a disagreement is rarely defined in sufficient detail for members of the public to understand the nature of the controversy. Thus an understanding of the role of values is needed.[7]

One must also distinguish between scientific and value-scientific controversy. Scientific controversy is dispute over the validity of scientific findings or the completeness of a data base. Value-scientific controversy is dispute over the social, ethical and political implications of scientific findings and their uses. Dispute over the *interpretation* of scientific findings bridges the two. Overlaps of these two categories are sometimes inevitable. In nearly every value-scientific controversy the science involved is also disputed, often because of its hypothetical and trans-scientific nature.* It must be emphasized that the resolution of a scientific controversy will probably not resolve the corresponding value-scientific dispute.

Further, questions centring on value judgements may have no single solution. In dealing with issues such as the treatment of congenital defects in newborns, the removal of life-support systems, or abortion, we do not expect and indeed may not wish to have a general rule, rigorously and uniformly enforced. Individual choice by different communities may be the basis of wisdom.

To a large degree Council interest in this area stems from its earlier study "Policies and Poisons."[8] That study dealt with occupational and environmental health problems arising from long-term, low-level exposures to known or suspected health-damaging agents. A need to resolve value-scientific and scientific controversies, especially around risk, was noted. While that study recommended the creation of a consensus-finding mechanism, it did not deal with the problem in depth. Partially on this basis, Council decided in 1978 to undertake a "Science and the Legal Process" study.

Council chose to focus the study on the impact of recent advances in the biological sciences for the following reasons:

- value-scientific questions in this area have received relatively little attention in Canada;
- the biological field, with its immediate impact on human life, brings into sharp focus the interaction between scientific fact and human values;
- regulation of recombinant DNA research in the United States, Canada and the United Kingdom, emphasized the inadequacies of our existing decision-making processes in dealing with questions of this kind.

The study committee commissioned a substantial body of research, in addition to organizing three workshops.[9] In preparing this

* Trans-scientific describes hypotheses that cannot be verified experimentally for ethical or practical reasons, e.g., human experimentation to test whether certain compounds are cancer-producing.

report, the committee also met with five experts in the field – authorities in risk assessment, commissions of inquiry, the judicial system, and regulatory decision making.

The committee also studied the inquiry process, for the public inquiry has been used in Canada as a major instrument for integrating scientific and technological information with value judgements. A commissioned background study by Liora Salter and Debra Slaco illustrates the ways that inquiries have been used in Canada to bring problems – such as the nonmedical use of drugs, the selection of nuclear power plant sites, and the safety of aluminum wiring – into public consciousness.[10] The study analyzed many aspects of the inquiry process, including the difficulty of defining roles taken by different participants, and the effect of the manner in which an inquiry was conducted upon its results.

The committee also examined decision making within three federal government departments to understand how scientific controversies are managed, and how complex scientific and technological factors are dealt with when policy decisions have to be made. A background study by G. Bruce Doern identified the diverse perceptions of scientific controversy held by public servants and the various ways that different kinds of scientific controversy are brought to their attention and handled.[11]

The following report addresses the substantial portion of the legal process in Canada related to regulation.* The process and mechanisms of regulation are analyzed against a background of concerns stemming from the impact of science and technology on contemporary society.

Council is publishing this report to stimulate discussion, thought, and action towards the improved meshing of science and the regulatory process. The report summarizes the study's findings and makes recommendations that are designed to help bridge the gap between science and the legal process, to encourage better utilization of science in regulation and to promote more accountability of the government process in decisions related to science and technology.

Chapter I introduces the scope of the problem and defines the terminology. Chapter II details recent advances in biology and the challenges they present. It considers, for example, recombinant DNA research and prenatal diagnosis. Chapter III reviews the governmental process, i.e., government departments, the judiciary and Parliament. Chapter IV describes the strengths and weaknesses of the inquiry process, and Chapter V considers methods of dispute resolution. The recommendations are set out in the final chapter.

* This report relies heavily on footnotes. This is due to the extensive, complex and sometimes subjective nature of the material. Much has been written and stated by a wide variety of people, covering a broad number of topics and reflecting various perspectives and opinions.

Council has concluded that there is an urgent need for new mechanisms and processes to resolve value-scientific controversies and to involve the public in the formulation of policy. Too few Canadians recognize the urgent need for experimentation in decision making. Consequently, this report draws attention to the need for a new strategy and for new methods of structuring dialogue about such matters within our society.

Chapter II

The Challenge of the New Biology

Each recent discovery in biology has uncovered a new layer of complexity. In 1953, for example, discovery of the structure of deoxyribonucleic acid (DNA) and the decoding of its genetic language were hailed as a biological revolution. Yet further analysis revealed long stretches of DNA that do not seem to code for any meaningful information, and sections of genetic material that jump from one segment of DNA to another. The straightforward, blueprint model of DNA no longer suffices.

The social implications of applying today's biological knowledge transcend biology. Recent advances in genetics, especially human genetics, are making the wise use of new techniques ever more difficult. For we are faced with ethical and legal choices hardly dreamed of a few years ago.* Some of these choices may be tragic.

The introduction of prenatal diagnosis has allowed early recognition of some types of genetic disease. And the birth of abnormal children may be prevented, although often only through therapeutic abortion. For example, fetuses with spina bifida can be diagnosed in this way. Spina bifida, however, varies in its severity. Surgery may treat it successfully, but many associated problems remain. The child may be retarded or physically disabled for life.

In some cases involving twin fetuses, one fetus may be normal and the other abnormal. Selective termination of an abnormal fetus carries many risks, and is not undertaken lightly. Few would welcome the difficult choices faced by the prospective parents.[1] Our ability to detect disorders prenatally or to identify those who will most likely develop a disorder in the future or transmit it to their children will increase significantly in the near future.

Recent advances make the question of relating scientific fact and experimentation to human values urgent. Emphasis on facts and values becomes sharply focussed as we gain more control over the evolution of life, with technical abilities such as recombinant DNA, tetraparental embryos,† heart transplants, the separation not only of procreation from sex but of sex from procreation, and the engineering of life forms to perform particular functions. Acclaim for the first

* We have, for example, new ethical and legal choices to make when people wish to sell body organs for transplants, to sell the service of bearing someone else's child, to screen for genetic susceptibility in the workplace, or to patent engineered life forms for commercial purposes. The US Supreme Court decision to allow patenting of General Electric's oil-eating microorganism is an example of the latter (Diamond, Commissioner of Patents and Trademarks v. Chakrabarty).

† A *tetraparental embryo* is one derived originally from two embryos from different parents. The embryo cells are disassembled early in development, before differentiation, and reassembled as one embryo which continues to develop, with some tissues developing from one type of cell and some from the other. This has been done with mice, resulting in mice with multicoloured fur.

heart transplant by Dr. Christiaan Barnard or of the first test tube baby by Drs. Edwards and Steptoe soon gave way to careful discussions about wise implementation. The criteria for determining death, possible stigmatization of test tube babies, liability for "failed experiments," the ethics of wombs for hire, legitimate embryo research, and indeed the fair allocation of expertise and resources required much searching.

Because of the nature and rapidity of these advances, we must examine not only our current response to the implications, but how we might best respond in the future. There is a tendency to operate on the technological imperative whereby whatever *can* be done, *must* be done. The argument can be taken one step further; if whatever can be done will be done by somebody, then why not by me. Yet, it is extremely important to take time to ask whether whatever can be done, *ought* to be done.

> In 1973, Dr. Louis Siminovitch wrote:
> "Recent advances in genetics again raise the spectre of the potential misuse of science. Progress in this field has been far reaching and certainly more rapid than most scientists anticipated; the prospects for genetic manipulation in man now, or in the near future, do not seem nearly as illusory as they did a few years ago. In fact, in genetics, what was once science fiction is now science. And what is now science fiction may be science a few years hence. Nevertheless, genetic manipulation in man is not yet practiced on a large scale. And this perhaps presents us with a unique situation: it may be possible to predict before – rather than after – the event how discovery in genetics will proceed, and how it will be exploited.
> "There is thus time to consider some of the probable scientific consequences, there is time to consider whether mechanisms should be developed to deal with these advances, and, most important, there is time to consider what mechanisms or social structures would best be suited to handle the scientific realities when they come to pass."[2]

Present Developments

Applications of new biological, particularly genetic, knowledge include a wide range of practical and theoretical developments that raise both traditional problems of ethics and some entirely new considerations.[3,4] Indeed, value choices and concerns vary with each development. The manipulation of human life through reproductive technologies and genetic surgery raises profound issues. But in-

dustrial applications, such as genetic engineering of microorganisms to produce desired chemicals, raise quite different concerns.

The following sections explore several facets of new biological knowledge. Prenatal diagnosis and genetic screening provide an opportunity to explore how policy is made and modified where scientific uncertainty has drastic results, where many value judgements are necessary and where the current resource crunch and constantly growing technological capability strain existing systems. Also the evolution of laws and guidelines for screening is of interest.

Recombinant DNA research is studied because it allows an estimation of:

1) the importance of the technique,
2) the scientific responsibility inherent in the self-imposed moratorium, and
3) the recent history of guidelines for control of research itself in Canada and elsewhere.

The further example of biotechnology extends the range of legal and ethical questions that challenge our policy system. The following four examples provide a concrete framework within which to examine policy options.

Prenatal Diagnosis

Nearly 5 per cent of the infants born each year have genetic disorders.* Furthermore, hereditary diseases account for at least 20 per cent of all infant deaths in Canada. Significant physical and mental disabilities characterize individuals with congenital malformations, chromosomal abnormalities or clearly defined, single gene disorders. It is not surprising that prospective parents who suspect their chances of bearing such a child are high seek prenatal diagnosis and genetic counselling.

By studying the genetic history and age of prospective parents, a genetic counsellor can often determine the probability of healthy children. Inheritance patterns enable the counsellor to make predictions.† Also the age of the mother affects the likelihood of aberrations in chromosome number, which account for disorders such as

* Five per cent is a low estimate of the effect of genetic disorders. A major proportion of miscarriages is associated with such conditions, and some hereditary diseases have a late age of onset. The onset of Huntington's chorea, a neurological disorder characterized by loss of physical movement and decrease in mental ability, occurs usually between the ages of 30 and 45.

† A genetic counsellor gives an individual genetic information about a disorder's heritable basis, treatment, prognosis and probability of transmission. The counsellor assesses risk, traditionally relying heavily on probability data.

Down's syndrome.* Such information can influence a couple's decision to conceive, to abort, to adopt, or even to marry.

In some cases, with certain diseases and where the risks are relatively high, a defective fetus can be identified by prenatal diagnostic techniques. Through amniocentesis (the process of removing and culturing fetal cells) many biochemical conditions, neural tube defects and chromosome abnormalities can be detected. But, the procedure is relatively costly and entails some health and accuracy risks, so it is used only for high-risk pregnancies. Other techniques, such as analyzing maternal serum, or visualizing the fetus with sound waves (ultrasonography) or fibre optics (fetoscopy) can detect structural deformities, sex, facial characteristics, and conditions such as a cleft palate.

Prenatal diagnosis can offer "clear" information but sometimes the information is of uncertain significance. A range of normal variations in chromosome structure have no apparent detrimental effects. But when unusual forms or slight variations occur, it may be impossible to judge what the effects will be.† Abnormalities such as an extra Y chromosome, determining maleness, pose special problems. It was once thought that an extra Y predisposed an individual to aggression and the likelihood of criminal behaviour. Further investigation has shown that aggressiveness can also be learned, the result of one's environment rather than simply the result of one's genetic make-up.

Uncertainty may also result because the line between normal and abnormal levels is somewhat arbitrary. For example, in fetuses with spina bifida the neural tube fails to close properly and alpha feto protein accumulates in the amniotic fluid. But slightly high alpha feto protein levels may or may not indicate spina bifida. Similarly, in testing for chromosome abnormalities, some cells from the amniotic fluid may appear abnormal and some normal. This may indicate contamination of the culture with maternal cells, changes in some of the cells during the culturing, or mosaicism in the fetus.‡ Fortunate-

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* Down's syndrome or trisomy 21 results from the presence of an extra chromosome number 21. The disorder occurs in approximately 1 in every 600 to 700 live births. This is a high incidence. The affected individual tends to be short, mentally retarded and more susceptible to infection than unaffected individuals. The likelihood of a mother bearing a Down's syndrome child increases with age, with a much higher rate in women over 35. The greatest number of prenatal diagnoses are performed for older women who may bear children with such chromosomal abnormalities. Older men are slightly more likely to produce progeny with Down's syndrome.

† It is sometimes possible to check whether the variations correlate with abnormalities by examining the chromosomes of the parents and other members of the family. Microscopic examination of stained chromosomes may reveal similar variations in apparently normal individuals.

‡ *Mosaicism* is a condition whereby some cells have one genetic constitution and other cells another. Severity depends on differences in the genetic makeup of the cells, as well as the percentage and location.

ly, such uncertainty is rare and additional testing sometimes clarifies the picture. More difficult is the fact that many disorders vary in severity, and tests frequently determine only the presence of a disorder and not its severity. Furthermore, many tests result in a certain percentage of false positives and false negatives, i.e., a small number of fetuses that test as abnormal will be normal and vice versa. This can create tragic situations when abortion is the major means of control.

Prenatal diagnosis obviously raises ethical issues. Its fundamental aim is to provide information on whether a fetus is normal or abnormal. An underlying assumption is that we know how to define a defective individual or a life not worth living. But in fact, such definition varies widely. We must ask to what extent attempts should be made to prevent the appearance of genetic defects through genetic counselling and prenatal diagnosis.* Individual rights and societal rights must be weighed when addressing issues such as the parents' freedom to choose. Some parents may choose to abort a fetus with a surgically correctable cleft palate, others a fetus that is not the desired sex. Fortunately, most see the latter as an abuse of prenatal diagnosis.[5] But establishing priorities and guidelines for prenatal diagnosis is difficult. Who should set limits? How do we set limits? On what grounds do we give access to limited services?

The report of a 1979 international conference on prenatal diagnosis in Val David, Québec, states:

> "The general and urgent impulse behind more public involvement in genetic decision-making is its unique potential both for individual and social *benefit* and for individual and social *harm*. Both potential results extend well beyond this generation alone. Here more than in many fields, there is an ongoing need to balance and resolve in a principled, reasoned manner the inevitable conflicts and competing claims between the common good and individual well-being, and between individual and institutional power. Such an exercise seems to us to call for broad public awareness and participation."[6]

The introduction of amniocentesis into Canadian clinical practice was well planned and based on national guidelines for safe standards and procedures, as a side benefit of a Medical Research Council (MRC) collaborative study designed to examine its hazards.

* Such approaches are unlikely to have a marked effect on the genetic burden of the population. In fact, the net result of genetic counselling and prenatal diagnosis may be to increase the number of genes in the population for a genetic disorder. Parents who might have decided not to risk bearing an affected child, are now able in many cases to eliminate the possibility by prenatal diagnosis. However, with conditions determined by recessive genes, in two of the three cases when the fetus is not affected, the fetus will be a carrier for the given condition and pass the recessive gene to future generations.

The working group of medical professionals, established in 1971, required the participants in the pilot project to adhere to Canadian guidelines for delivery of amniocentesis[7] and to follow all cases to birth. The group's report, released in 1977, has served as a planning guide for provincial health departments.[8] With minor variations, delivery criteria and services are now relatively uniform across the country.

The delivery of amniocentesis is an exception in the formulation and implementation of genetic policy in Canada, which, in general has been haphazard. Most genetic tests have been offered in scattered locations, and the nature of the tests has sometimes depended upon the particular interests of the research faculty. Public education, also, has varied widely. While more and more women are availing themselves of prenatal diagnosis, many high-risk pregnant women still do not know about nor receive genetic counselling and prenatal diagnosis. Important data are lacking, for example we often do not know why some high-risk women do not return for diagnosis with subsequent pregnancies.

An analysis of the prenatal genetic counselling services offered in every province was presented at a workshop sponsored by the Science Council in 1979. The participants included doctors, medical geneticists, lawyers, philosophers and social planners. They cited the need for a forum to discuss how to handle "grey" areas, to rectify inefficiencies, and to provide a structured way for non medical representatives to influence professional policy decisions. As a first step, they stressed the need for education in medical genetics for the public, as well as for medical professionals. Participants differed on whether a national policy group should be established, given the sensitivity of policy issues and the size and regional diversity of this country. But they agreed on the need for more information and communication among the personnel of the various genetic counselling centres.[9]

Genetic Screening

Genetic conditions in a given population can sometimes be detected by means of genetic screening. The tests, which may include biochemical studies and examinations for blood and chromosome abnormalities, are used to locate affected individuals who have not sought genetic counselling, or carriers who may transmit defective genes but are not themselves affected. Accumulating genetic data, at birth or later, will help in assessing genetic risk, counselling prospective parents, or treating certain diseases. A screening program works best for conditions that occur with high frequency in a well-defined, demographically concentrated population; can be treated or prevented; can be detected prenatally; or can be detected in carriers by means of a simple, accurate, low-cost diagnostic test.[10]

Although genetic screening has obvious merit as a preventive measure, there have been problems – many unanticipated and some unavoidable. A relatively successful mass screening program for a rare metabolic disease, phenylketonuria (PKU) reveals many of these difficulties. Individuals with PKU (it occurs in about 1 in 10 000 caucausians) are unable to digest phenylalanine, a common amino acid found in most proteins. The accumulation of undigested phenylalanine results in mental retardation. If detected early by means of a simple blood test on newborns, the effects of the disease can be prevented by a low phenylalanine diet.

Problems arose when PKU screening laws were put into practice. By 1967, PKU screening was mandatory in 44 states in the United States.[11] It was not until the program was well underway, however, that inadequacies of both the legislation and the scientific data upon which it was based became apparent. The legislation was insensitive to existing knowledge of the disease as well as to ramifications of across-the-board screening programs. Moreover, it is now known that the relationships between high levels of blood phenylalanine and retardation, diet and prevention, are not as clearcut as once believed. It was also learned that PKU can be detected earlier in males than in females. The screening programs were not set up to respond to these subtleties.

Furthermore, it was discovered that a child born with a high phenylalanine level may be normal, but mistakenly diagnosed as having PKU and given a special diet. This child could suffer more harm than an undetected PKU child. In addition, hearing false positive results might produce a psychological imprint on parents that any number of subsequent negative results could not erase. Controversy still rages over whether or when the diet of a PKU child should be discontinued.

As the PKU screening and treatment program developed, another problem surfaced. Treated PKU women give birth to retarded children. The inability to metabolize phenylalanine apparently creates an unfavourable uterine environment. Reinstitution of the special diet for the mother during pregnancy might, however, alleviate fetal retardation.

False negative and false positive results occur in any screening test. Indeed, a small percentage of abnormal reactions are to be expected with any wide-scale screening program and are extremely difficult to prevent. Even where benefits are very clear, a good screening program must be carefully planned to be sensitive to the complexity of genetic disorders, and to use sensible, reliable tests. Monitoring the effects of the program is essential, for subtle problems surface only after screening has begun.

Genetic screening has been extended to programs to identify clinically normal parents who may give birth to a child with a genetic

disorder. Such screening was implemented before an evaluation of psychological and social effects of finding that one carries a deleterious gene. In some cases, the gene occurs especially frequently in a particular ethnic group, such as the gene for sickle cell anemia in blacks or for the blood disease thalassemia in Mediterranean peoples. Screening in such cases has sometimes been misunderstood as eugenic attempts at genocide.*

Using extensive screening programs for identifying parents who may give birth to a child with a given disorder such as Tay-Sachs disease, Duchenne's muscular dystrophy, or sickle cell anemia is less

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* Reilly attributes many of the problems to poor understanding of the scientific facts by legislators.

"Ironically, just as the state laws were being written, there emerged sharp criticism of the value of sickle cell screening programs. At first these criticisms were made by scientists on technical grounds. Soon, however, they included broader, more political elements. A few articulate black physicians... began to argue that compulsory screening laws, ostensibly designed to help blacks, could boomerang into a novel source of discrimination. By the end of 1972 black community leaders in several states had begun major campaigns to repeal sickle cell legislation. Inevitably, as black citizens realized that sickle cell disease could only be reduced by influencing reproductive behaviour, there were cries of genocide. Given the content and working of the early laws, it is not surprising that they generated such criticism.

"The statutes contained glaring errors, including egregious drafting mistakes that hopelessly muddled the scientific facts about sickle cell anemia. They are a sad commentary on the abyss that separates lawmakers from technical experts. The most consistent scientific error was conferring disease status on sickle cell trait. For example, Louisiana law required that all students entering senior high school be tested for 'meniscocytosis, commonly known as sickle cell anemia.' It is extremely rare to 'discover' a person who is homozygous for sickle cell anemia through adolescent screening: multiple medical crises have usually made him painfully aware. The Louisiana law mistakenly equated homozygous sickle cell anemia with heterozygous carrier status. The Massachusetts law was even worse. It authorized tests on every child 'susceptible to the disease known as sickle cell trait or sickle cell anemia ... to determine whether or not he had such disease.' But unquestionably the most egregious provision is found in the opening paragraph of the National Sickle Cell Anemia Control Act. It states that 'sickle cell anemia is a debilitating, inheritable disease that affects approximately two million American citizens and has been largely neglected.' About 2 000 000 people in America (roughly 10 per cent of the American black population) carry the sickle cell gene, but fewer than 50 000 have sickle cell disease. That such sloppy language could be part of a federal law is most disturbing.

"At least two state laws showed a complete misunderstanding of the nature of sickle cell disease. The Georgia legislature amended its PKU statute in 1972 with a bill entitled Education-Immunization for Sickle Cell Anemia Required for Admission to Public Schools. Fortunately, this patently absurd title was not incorporated into the statutory code. In Louisiana the public health department was ordered 'to provide for the continued medical care, *dietary* and other related needs' [emphasis added] of children with sickle cell anemia. This law, also an amendment to a PKU statute, erroneously assumed that genetic diseases routinely follow the model of phenylketonuria."

Reilly concludes that: "Several of the early screening laws were written in a manner that greatly enhanced the possibility that carriers would be socially stigmatized." Philip Reilly, *op. cit.*, pp. 67-69.

For a brief discussion of some unintended, untoward consequences of screening programs, see also Ron Davidson, "Problems in Genetic Screening," *Social Issues in Human Genetics: Genetic Screening and Counselling, op. cit.,* pp. 48-51.

straightforward than PKU screening.[12] The only "treatment" available is a decision not to bear the child.

Tay-Sachs disease, highly prevalent among Ashkenazic Jews, provides a good example of the development and operation of a screening program. Before screening tests were available, high-risk parents were identified only when a child with Tay-Sachs was born. Counselling then consisted of telling the parents that their chances of having another such child in the next birth were one in four. Screening tests now can identify high-risk couples, giving prospective parents the information before pregnancy. Tay-Sachs also can be identified by amniocentesis; hence parents have clear knowledge upon which to base a decision.

Some screening programs offer less specific information. For example, Duchenne's muscular dystrophy occurs only in males, and prenatal diagnosis indicating a female fetus assures the parents of an unaffected child.* So far, however, no definitive test will distinguish affected from unaffected male fetuses. If parents elect to abort a male fetus, they do so knowing that 50 per cent of the time the aborted fetus will be normal. In the case of sickle cell anemia, prenatal diagnosis cannot as yet safely and reliably confirm the standard probability advice of a genetic counsellor, although a new method based on genetic engineering techniques is now ready for testing.[13]

Screening programs designed solely for gathering information are even more problematic. Although research may eventually allow for some treatment, it may not be helpful to know, for example, that you or your child may suffer from a slowly disabling disease that cannot be treated, such as Duchenne's muscular dystrophy. Some have claimed there is a right not to know as much as a right to know.

As we seek new genetic screening techniques, such as those that will enable us, for example, to identify individuals likely to die early of heart disease or cancer, we must consider the trade-offs. The information may not be worth the increased anxiety. And test results may prove wrong or identify only a high-risk population. Eventually we will be able to screen for those susceptible to a broad array of conditions. We must consider how to make a societal decision about whether such screening should be done and about the way we handle such information. Access to such data may endanger personal freedom. Consider the effect if the information was made available to life insurance companies, the electorate (in the case of political candidates), or employers.

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* Duchenne's muscular dystrophy is a devastating, sex-linked disease that occurs in 1 in 5000 male births and accounts for about 90 per cent of all muscular dystrophy cases. It is the most severe type, characterized by destruction and wasting of muscle tissue leading to death. It is generally evident by 10 years of age. About 75 per cent of affected individuals die by age 20. About 5 per cent live past 50. There is no treatment to date.

Screening has already been carried out in workplaces where employees are exposed to dust and smoke. Tests show that individuals with an alpha-antitrypsin deficiency may be prone to chronic lung disorders. Broader applications of such screening are a future possibility, and could result in practices that shift the burden of responsibility from the industry to the individual. If a certain group is identified as particularly vulnerable to a certain occupational health risk, abuse is possible. Women for example might not be considered for jobs that could threaten their fertility and the health of unborn children, rather than pressure being placed on the industry itself to create a safe work environment. Such questions require much thought.

Recombinant DNA Techniques

Recombinant DNA techniques allow us to select pieces of DNA, either extracted from an organism or synthesized in a laboratory, and join them to another piece of DNA that will introduce them into a host cell where they are reproduced and where the genetic information contained in the DNA may be expressed; thereby conferring new properties to the host cell. Recombinant DNA techniques make it possible to construct new and different genetic combinations from lifeforms normally genetically separate; thus the direction of evolution can be influenced. In many experiments, human genes are reproduced in bacteria.

Much recombinant DNA research has been performed in bacteria, especially the much studied *Escherichia coli* K-12. The techniques used make it relatively simple to study the structure and function of genes from higher organisms. Vast new areas for research have opened up, from initial steps to transfer nitrogen-fixing ability to non-leguminous plants to the production by bacterial cells of human hormones and many other molecules.

Shortly after the discovery of these techniques, scientists recognized that the ability to mix genetic lines, separate for millenia, might be hazardous. Other concerns were raised over the most common research tools – a bacterium derived from flora of the human gut that posed risks of propagating disease in human beings, and viral carriers known to cause tumours.

A favourite research procedure was to break DNA into random chunks, look for pieces with interesting properties and ultimately locate these genes on the DNA. The existence of "extra" information between the genes raised questions. Its function was not understood: some of it might be repressed genes, some might have sequences suspected to code for tumour-causing viruses. Could the random breaking and cloning of the DNA of higher organisms – particularly human DNA – accidentally liberate and express dangerous genetic material?

This risk caused sufficient worry among leading molecular geneticists that a world-wide conference of researchers was convened at Asilomar, California in 1973. The conference's recommendation for a moratorium on certain lines of research and for stringent safety precautions for others pending their evaluation made international news.

Anxiety by scientists over these risks peaked shortly after Asilomar, and has been declining ever since. Gradually evidence has been accumulating that many of the conjectured risks were insignificant. The bacterium, K-12, does not survive well in the normal human gut, and the frequency of K-12 recombining with non laboratory strains of *E. coli* or with other organisms has turned out to be too small to sustain the concern that altered genes might become permanent components of the human gut flora. In addition, from new understanding of the structural arrangement of non bacterial genes, it appears unlikely that a random piece of foreign DNA isolated from a higher organism will give rise to new and damaging proteins in the host, even if that host is a higher organism. Nevertheless, the recombinant DNA controversy showed how upsetting the new biology could be to the public, as well as the scientific community and those responsible for regulation.

While specific scientific concerns have been allayed for many, public anxiety continues. The public was and is concerned, not only with the specific risks named by the Asilomar conference, but with the general risk of creating *any* new lifeform.[14] More or less ignored in the whole concern over safety were larger, long-term questions about the morality of designing lifeforms and the wisdom of attempting to meddle with evolution. Some concerned members of the public were probably less willing to accept scientific assurances of safety when they saw these larger questions were treated by many scientists as outside the realm of science and therefore not their concern.

As recombinant DNA techniques are applied more extensively to human beings, the demand for public participation in the discussion of biological research and its applications is likely to grow. Current research into cataloguing every protein produced by individual human cells brings us closer to the ability to intervene actively in human genetics. Although such a comprehensive listing, plus nucleic acid data banking,[15] will not unravel all human mysteries, it will lead to a greater understanding of gene expression. This knowledge may allow the isolation of particular genes and their introduction into human beings, a technique already attempted to remedy a blood disorder. The fast pace of this research, the temptation to put new knowledge into practice quickly, and the value questions inherent in altering human beings makes examination of regulatory processes critical.

Biotechnology

Biotechnology – the exploitation of organisms, biological systems and processes to provide goods and services – promises to revolutionize many of our systems of production. It relies on recombinant DNA techniques, fermentation, cell fusion and enzyme technology. Biotechnologies have produced substances such as alcohol, single cell proteins, hormones and antibodies, and services such as waste recycling, pollution control, mineral extraction and enhanced food production.

Many, especially the media, greet biotechnology as the revolution of the 1980s, comparable in impact to the microchip. In fact, most marketable advances are still only promises. Cautions such as the following by Dr. Peter Senior of the British chemical giant International Chemical Industries (ICI) are rare and almost unheard amid the media "biohype." Senior notes:

> "All the easy things have been done. . . . Biotechnology is grossly overselling its potential and there is little likelihood on both scientific and economic grounds that we are staring a revolution in the face."[16]

Also unheard amid the commercial enthusiasm for biotechnology are the concerns it raises. First, there are possible health and safety hazards, particularly from the applications of recombinant DNA research. Future pollution control or bacterial mining, which require unleashing newly constructed organisms into the environment, may lead to unforeseen problems. We may disturb ecological balances, for example, by modifying soil bacteria genetically to make them more efficient pollution controllers. These biohazards, though uncertain, are potentially self-propagating, irreversible and large-scale. The possible escape and reproduction of harmful organisms that might cause disease or ecological damage means industrial safety and disposal practices will have to be adjusted. Health standards for workers will have to be changed to account for biologically active as well as inert materials. Second, the biotechnology industry draws extensively on the talents and work of university researchers, a practice that many see as threatening the independence and open communication of the universities.[17] Third, the Medical Research Council guidelines for recombinant DNA research were set up for MRC-funded university research projects. Applied to industry, they may prove inadequate for they depend on voluntary compliance and have no legal sanctions. University research differs substantially from large-scale industrial production which generally emphasizes secrecy and potential markets. As Professor Stuart Ryan of the MRC Biohazards Committee remarked:

> "Having taken part in the inspection of several labs during the past two years, I realize that inspection by itself does not really reveal what is being done. The inspectors must rely on the good

faith of the director and his staff. Where secret processes are in use, and even when processes are patented, concealment will be practised."[18]

In Canada, no forum exists to discuss concerns about this new technology along with the promises it holds. The Science Council, in collaboration with the Institute for Research on Public Policy, sponsored a workshop aimed at balanced consideration. But even at this gathering of scientists, government officials, labour representatives and academics, the call for industrial strategies far outweighed technology assessment. Faced with an industrial opportunity in need of highly-qualified people, venture capital, government support for research – the ingredients of a healthy entrepreneurial climate – the uncertain though potentially significant side effects of this new technology took second place.

Meeting the Challenge

Biological research advances are extensive and their implications serious. The time for concern is now. Scientists at Asilomar demonstrated concern with the impact of their work. Some geneticists demonstrate their concern by calling attention to the need for views in addition to the medical viewpoint when genetic counselling and screening policy is being formulated.

Dr. Robert Sinsheimer summarizes:

"How shall we confront this very new human potential? Clearly we will need more than accepted custom, more than another law, more than technology assessment. We shall need a basically new vision and an adaptive philosophical stance. For all the ancient and unresolved human dilemmas arise again, to be seen in a new light which more fully exposes their true dimensions: the welfare of the individual against the welfare of the group, the welfare of the fetus and the sanctity of life; the issue of human primacy – the control of men over each other – and its reflection in human experimentation; the concept of normality and the tolerable range of human diversity; the tenuous balance between the power of knowledge and the knowledge of responsibility."[19]

Bioethics is a new discipline that deals with ethical issues arising from biology and medicine. It attempts to confront such questions and to clarify the value issues underlying a particular choice. Bioethics explores ways of making value judgements. Individual approaches differ widely. Some claim that this movement of philosophers from classroom theory to practical action is ill advised. They say there are *no* experts in evaluating values.[20] Nevertheless, bioethics institutes have played an active and sometimes effective

role in generating policy guidelines. The criteria for offering prenatal diagnosis, the protection of subjects of human experimentation, and the definition of death for transplant purposes reflect their involvement. Institutes such as the Hastings Institute for Society, Ethics and the Life Sciences (Hastings-on-Hudson, NY), the Kennedy Center for Bioethics (Washington, DC), the Westminster Institute for Ethics and Human Values (London, Ontario) and the Centre for Bioethics of the Clinical Research Institute (Montréal, Québec) have also been active in educating the public on value questions about applications of the new biology.

Public awareness is crucial. When value questions are interwoven with research, the decision and regulation process must include those beyond the scientific community. Rapid commercial development complicates problems of surveillance and regulation, demanding imagination in finding ways to broaden decision making.

Including lay individuals in bodies responsible for setting standards for scientific practice or experimentation is becoming more common. The US insistence on lay members on Institutional Review Boards to rule on the ethics of human experimentation, the inclusion of lay members in the US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and at home the Medical Research Council's decision to include several lay members when forming its Biohazards Committee exemplify this recognition of the need for a broader base for decision making that areas such as the new biology seem to require. The Cambridge Experimentation Review Board set up to consider whether recombinant DNA work would be allowed in Cambridge, Massachusetts, is an extreme in this regard. The board did *not* include scientific experts. In presenting its report, the board affirmed that "a predominantly lay citizen group can face a technical scientific matter of general and deep concern, educate itself appropriately to the task, and reach a 'fair' decision."[21]

To date Canada's legal system has not addressed the difficult legal and ethical questions posed by the new biology. As a country we have not assessed whether all that can be done must be done, or even should be done. As Professor Bernard M. Dickens of the Law Faculty, University of Toronto states, "It is distressing that so many of these questions are not simply unanswered in Canada, but unasked."[22]

The following chapters explore traditional Canadian approaches and ask if they suffice to handle the types of questions raised by the new biology.

Chapter III

The Government Process

Today, advances in science and technology raise questions that are not easily resolved. The example of recombinant DNA controls illustrates some of the complex issues faced by scientists, the government and the public. In this chapter, recombinant DNA research guidelines in the US, UK, and Canada are examined and analyzed in terms of availability of information held by government; degree of public participation in decisions; preference for negotiated or reasoned outcomes; and record keeping for accountability. The chapter moves from this case specific consideration to a discussion of the roles, in Canada, of government departments, the judiciary and Parliament with respect to regulatory decision making.

In the course of the DNA debate, scientists literally rubbed elbows over the table with government officials as well as concerned members of the public in efforts to reach agreement on a matter of fundamental significance to all. This case was unusual in two respects: it was carried on outside normal bureaucratic channels, and it involved the regulation of scientific research itself, rather than merely its technological application. National style and political tradition were important factors in determining how the issues were handled.

The Recombinant DNA Debate in the United States, the United Kingdom and Canada

Scientists themselves first drew attention to possible dangers from recombinant DNA research. In the United States, the 1973 Asilomar conference led to a book. *Biohazards in Biological Research,*[1] and in June of that year at the Gordon Conference on Nucleic Acids, a special session considered scientific responsibility for such hazards. Following the discussion, biologists Maxine Singer and Dieter Soll sent a letter, which was also published in *Science*, asking for creation of an ad hoc study group to consider potential hazards associated with recombinant DNA, to the presidents of the National Academy of Science and the National Institute of Medicine.[2] As a result, a study committee chaired by Paul Berg and under the auspices of those bodies was set up in 1974. The committee called for an international conference, a voluntary moratorium on certain research and for the National Institute of Health to establish a permanent advisory committee. The recommendation for worldwide control on aspects of scientific research was an unusual step, attracting extensive media attention.

In the United States, recombinant DNA research was regulated by guidelines set down by the National Institute of Health (NIH). The regulatory problem drew a great deal of public attention; indeed emphasis in the US was on full disclosure of all aspects of the problem and on open discussion of its potential effects. Scientists as well as the lay public took part. The resulting guidelines emphasized rules and

standards, contained lists and other operational definitions and were suited to routine enforcement. In practice, locally appointed biohazards committees assessed research and enforced guidelines, allowing adaptive and flexible responses. The US guidelines formed a basis for regulation in other countries.

In the United Kingdom, the Genetic Manipulation Advisory Group (GMAG) regulated research proposals through a case-by-case consideration. This advisory group was made up of representatives from the pharmaceutical industry, the universities, the unions involved in laboratory work, and the scientists. It functioned to ensure negotiation of the interests of both research and safety. Because GMAG was not making quasi-legislative rules in a formally structured procedure of public deliberation, it could be highly responsive to new findings about the scientific problems. Media attention was sparse, coming from the science press rather than the popular news outlets. The assessment research was administrative in approach, and general issues about controls were not publicly addressed.

In Canada, the recombinant DNA controversy was handled by the Medical Research Council (MRC). The issue attracted little public attention; controversy was limited mainly to the scientific community and government officials. Actually few recombinant DNA research projects were proposed, and public advocacy groups did not generate widespread concern. The ad hoc guidelines committee set up by the MRC maintained a low profile. All members of the committee but one, a lawyer, were scientists. Preparation of guidelines was a bureaucratic problem, rather than a political one.

Once the guidelines were in place, a permanent committee took over the task of assessing and monitoring recombinant DNA research. Most members of this Biohazards Committee were laypeople, including a lawyer and a clergyman; its chairman was also a layperson. Scientific membership came from a wide range of medical and life science disciplines. As a result, there were not enough recombinant DNA researchers on the committee for a scientific debate to take place, also the orientation of the group was bureaucratic. The Canadian regulatory process, in this instance, did not directly involve a government department or statutory regulation. Regulation was achieved through grant administration.*

* MRC has no regulatory authority in the strict sense, nor does it have the power or resources normally given to a monitoring agency. It set the guidelines for recombinant DNA research with which researchers seeking MRC funding were required to comply. These guidelines were adopted by other government granting agencies, as the standard for laboratory practice in government research. Subsequently, private sector researchers gave assurances of voluntary compliance. In all probability, the guidelines established a presumptive standard against which to determine negligence. Noncompliance, followed by proof of harm, would make a case for civil liability that would be very difficult to defend.

As can be seen, in each country constraints in the political system shaped responses to the controversy over recombinant DNA research. A parliamentary system depends largely on administrative action in setting guidelines and in regulation. By contrast, the American system requires political debate in most cases to set up or alter a regulatory system. During US consideration of recombinant DNA research, a wide range of issues and various approaches to assessment could be examined openly. Also the process encouraged direct public participation. But the American process was less flexible than its British counterpart, less responsive to new scientific information, and could be criticized for being administratively less "efficient." With broad scientific expertise and open discussion the American approach was successful in airing issues, but less so in resolving conflicts or revising official positions.

Which Way Works Best?

The choice of ways to regulate recombinant DNA research can be analyzed in terms of the following factors: the availability of information from government sources; the degree of public participation in decisions; the preference for either negotiated or reasoned outcome; and record keeping for accountability.

Getting Government Information

In the United States, the release of information by government is controlled by the *Freedom of Information Act*. In the recombinant DNA controversy, the only major problem arose with information that might affect the ability to patent the results of industrial research. Such information, sometimes required for research approval, was ultimately supplied to government under conditions that prevented public disclosure.

A more interesting feature of the American approach was the wide dissemination of both substantive data and information on the process itself. Although American law requires the official publication of environmental impact statements and of schedules and agendas for regulatory meetings, bureaucratic action went much further. NIH took an aggressive approach in spreading information. It funded research into risk, prepared inventories of laboratory containment facilities, and created a governmental source of information and a newsletter to spread it without having to publish formally in the *Federal Register*. NIH also published a multivolume record of its actions and decisions, with supporting documentation.

In the UK, no provision was made for freedom of information. In fact, members of GMAG were bound by the *Official Secrets Act* (a

Draconian prohibition on any disclosure), and they deliberated behind closed doors. GMAG had a serious crisis over patent information at one stage, aggravated by certain features of English patent law. However, GMAG also functioned as a source of information. It issued regulatory bulletins and engaged in many visits to research facilities. It actively, though quietly, spread information by means of its Secretariat.

In Canada, the ad hoc committee examined its proposed guidelines within the academic research community, although the Biohazards Committee meetings were open.* Its agenda was freely supplied to interested parties upon request, and the minutes show such parties attended committee meetings. Unlike the US, there was no formal announcement of meetings and the general public did not attend. The information-providing role of the Medical Research Council was low-key, but clearly important. Members of the ad hoc and Biohazards committees also coordinated personal efforts to raise public understanding, and to some extent acted with the tacit approval of MRC management.

Canada never promulgated regulations controlling recombinant DNA research. Regulations were prepared by Health and Welfare Canada, drawing on MRC guidelines. But because of questionable aspects and low estimates of the risks, the regulations were held in abeyance.

Nor was patentable research discussed to the degree it was in the other two countries. There was neither an apparent statutory problem (Canada does not yet have a "freedom of information" act†) nor a consultation problem resulting from members of the Biohazards Committee fulfilling the role of delegates.

For effective public participation in decisions about regulation, all potential participants must receive information about research and the regulatory process. In other words, if government is not to select the relevant interests in a controversy arbitrarily, information about where and when government decisions are being made should be readily available to the public. The American process did so. The British process assumed the participants had already been identified; relevant material was supplied within a closed process. The Canadian process assumed that interested unidentified parties would locate the seat of regulatory discussions on their own initiative, relying

* The Canadian process is characterized as *open* because there was no formal exclusion. Interested persons were allowed to participate on a regular basis. Because formal rights of participation did not exist, and the dates and agendas of meetings were not announced publicly, we do not characterize the process as *public*.

† On 28 June 1982, Bill B43 was enacted into law. The Science and the Legal Process study is not in a position to comment on the adequacy of the new legislation. Effectiveness may depend on interpretation.

on administrative policy to provide whatever openness existed. There were no guarantees that information would be supplied, that adequate notice could be obtained, or that attendance at the hearing would be allowed; although in practice all of these occurred.

Government often has, or can compel generation of, more information than is available to other participants in a controversy. Thus government's decision to withhold or release this information determines the usefulness of public participation.* The British experience demonstrates that a closed information process can work if major interests are correctly identified (identification was easier in the structured, geographically compact, and centrally governed British system). Yet heavy pressures for easier access to substantive information exist even there. In a more polarized atmosphere, it is unlikely that ad hoc administrative openness, such as occurs in Canada, would be adequate. Thus, a formal commitment to open access to both process and to substantive information is required.

Public Participation in Decisions

In all three countries, policy makers claimed that decisions were made with public involvement. In the United States, this meant that meetings were open, that information was readily available, that committee members were chosen from a broad professional spectrum, and that members of the public or interest groups who came forward were heard, as many were.

In the UK, the process was closed and certain GMAG members were selected as "representatives of the public interest." The policy was clearly representation by an elite, for members included a philosopher of science, a former editor of *Nature* (the prestigious English scientific journal), a social scientist and a barrister – two were women. The trade union representatives might have voiced public attitudes, insofar as two scientists, a former career civil servant, and an expatriate American labour organizer might be thought representative. In fact, the "public" was not present. GMAG was *not* a cross section of English society, although it was well designed to represent interests in the context of that society.

In Canada the same philosophy of public representation by an elite group was followed. The lay members of the Biohazards Committee were uniformly drawn from upper socioeconomic groups. While meetings were informal and well organized, the style was

* Withholding scientific data is sometimes explained on the grounds that it is incomplete or misleading. Such a judgement is seldom clear, often controversial, and a perfect cloak for a policy of arbitrary paternalism. It is better to disclose the data, indicating why it is judged incomplete or inconclusive. Virginia Held, "Freedom of Information and Government," *Westminster Institute Review*, vol. 1, no. 1, January 1981.

professional and technocratic. The Canadian effort to "represent the public" went only so far as to reach outside the research scientists' values and priorities for an outside critique. In this regard, members with medical backgrounds were often as helpful as "lay members" in that they did not wholly subscribe to a research-oriented ethic.

Canadian regulatory agencies, in general, have different traditions regarding the extent of public influence in decision making. Since its formation, the formal proceedings of the Canadian Radio and Television Commission (CRTC) have been structured to encourage public participation; whereas the Atomic Energy Control Board (AECB) has not adopted such an approach in relation to its regulatory responsibilities. The Environmental Contaminants Act specifies a mechanism for public participation, but this occurs very late in the decision process. The Environmental Assessment Review Process (EARP) has not fulfilled expectations of public participation or meaningful assessment. Finally, the recently adopted Socio-Economic Impact Analysis (SEIA)* process requires government departments to assess the social and economic impacts of some major regulations, but its public involvement occurs just before final regulatory action.

Unless rules specify clearly how an agency is to proceed, public participation may be overlooked or may be too late to have any significant effect. Statutory requirements for broader and better public participation are needed.† And, methods should be adopted to

* The Socio-Economic Impact Analysis (SEIA) Program for major proposed health, safety and fairness regulations (economic regulations are excluded) was jointly announced by the President of the Treasury Board and the Minister of Consumer and Corporate Affairs on 14 December 1977 and came into effect on 1 August 1978. Its main objectives are: to promote a more thorough and supportive analysis of the socioeconomic impact of proposed health, safety, and fairness regulations; to ensure uniformity in departments and agencies currently administering statutes that confer power to make such regulations; and to provide an opportunity for increased public participation in the regulation-making process. For a more complete discussion of SEIA, see G. Bruce Doern, *The Peripheral Nature of Scientific and Technological Controversy in Federal Policy Formation,* Science Council of Canada, pp. 34-38.

† Useful procedures include: adequate public notice of the proposed action, including a statement of the reason; public access to all written submissions; an opportunity to submit rebuttal in writing; the right to make oral submissions, and an opportunity for the deciding authority to question those submissions; time limits to the oral submissions; a public transcript of oral submissions; the use of cross-examination when facts are in dispute and resolution is necessary for the rule-making action; action be based on the record, and supported by substantial evidence; and action and the reasons for decision to go beyond a statement of the factual background and purpose of the action in general.

Many of these items would be disputed by some lawyers; the suggested scope of cross-examination is particularly contentious. In designing procedures for public participation, it should be remembered that each process places different demands on the public. R.C.B. Risk, "A Long, Sad Story: Siting Transmission Lines in Ontario (1981)," *University of Toronto Law Journal,* 27, pp. 62-70.

allow public participation in the *selection* of public representatives on bodies such as the Biohazards Committee.

Negotiated or Reasoned Outcomes?

An outcome is "negotiated" if a committee member can act as a delegate for an interest group and can "horsetrade" on its behalf. An outcome is "reasoned" if the committee member is asked to free his or her mind of bias and decide on the basis of the information available. In the three countries, this preference varied and often was not spelled out. Public discussion can severely inhibit negotiation; open, formalized procedures can interfere with efficient bargaining. While withholding essential data is an accepted negotiating technique; it negates reasoned decision. Negotiated and reasoned outcomes require different structures.

In the United Kingdom, GMAG was designed to allow negotiated outcomes, and the trade union members saw themselves as delegates. The Canadian Biohazards Committee members seem to have preferred reasoned outcomes. Members speaking to a point would declare a bias if it touched upon their research; it appeared that they were trying to clarify data for the others, not represent their own viewpoint.

The American committee was so large and members represented such diverse backgrounds that a generalization may be misleading. But American procedures were designed for utmost airing of the issues. Committee members were not delegates, and they probably sought reasoned outcomes. The procedures adopted encouraged open public discussion with informal questioning.

Many scientific controversies include issues that involve risk to human life or health. In these controversies, a reasoned articulation of the scientific aspects is essential before negotiation. Any other approach is morally irresponsible. The adoption of a genetic screening test for PKU, for example, requires careful unbiased consideration of the test's reliability, of the likely percentage of false positives and false negatives, and of possible additional follow-up tests to confirm diagnosis. Similarly, using amniocentesis for prenatal diagnosis programs requires a clear appraisal of hazards to both the fetus and the mother and of any scientific uncertainties that might exist. Regardless of individual opinions about the overall value-scientific question, no negotiation should be undertaken without this reasoned approach.

In a market economy, negotiation about economic issues without publicly accountable data is acceptable. However, even in economic matters, where questions about life and death are not at issue, persistent and inappropriate gains by private parties lead to legal curbs. In economic matters there is often a role for a reasoned approach based on reliable and acceptable data. While improving the reasoned

development of scientific data in such controversies may not be a moral imperative, it could still be useful.

We recommend that the choice between reasoned and negotiated outcomes in the functioning of policy advisory bodies be clearly and explicitly identified, and that both the public and the body be made aware of this choice at the outset.

Keeping Records

Records of decisions are kept in all three countries studied. In neither Canada nor the UK, however, are records normally a matter of public accountability. In the US, records are published, and accountability exists.

Our study examined the Canadian record in the recombinant DNA controversy, and found an adequate indication of what decisions were taken and why. But this is not full accountability, for the influences responsible for individual decisions are not explicit. The advice tendered by the Biohazards Committee can be understood as consensus on the body of data considered and the recorded reasons for consensus. However, such a record would not call to account members of the committee, unless they recorded formal dissents. The committee has always reached consensus.

If records of collective scientific advice are kept, decisions to deviate from this advice after other factors such as politics, economics or ethics have been taken into account will be identifiable. For example, in the US handling of recombinant DNA research, the ultimate decisions resided with the director of the National Institute of Health. His procedure was to give written reasons justifying any decision that deviated from advice received. Similarly in Canada, decisions reside with MRC. On occasion, the president of MRC has returned decisions to the committee for further deliberation.

If government is willing to publish the exact nature of its scientific advice, subsequent political and negotiating processes can be made more accountable. The essence of the scientific approach is to keep the "knowledge" process open to critical analysis, review, and revision. Unfortunately, Canadian traditions of ministerial responsibility and civil service anonymity make it difficult to hold anyone below the ministerial level accountable. If the responsibility and basis for a decision are not recorded or if background documents are not freed from the seal of cabinet secrecy, there is no way to separate scientific reasoning from political negotiation.

Accountable government decision making ensures that after the fact a regretted decision can be blamed on bad data, incompetent or narrow scientific advice, or spurious pleas of economic hardship from the regulatee. Accountability promotes better advice and a more adequate search for relevant data.

Government Departments and Regulatory Decisions

A government's policy-making process is not normally known to the public. Viewed from within government, numerous demands are placed upon a minister and a department when making any regulatory decision. These demands may reflect pressures from diverse constituencies such as ethnic or regional, or other special interest groups, from conflicting approaches or ideologies and from conflicting areas of governmental responsibility. Regulatory actions taken in other countries can also influence a department or regulatory agency. Besides responding to Parliament, departments must answer to pressures from central agencies (Treasury Board and the Privy Council Office, for example). New assessment procedures (program evaluation, environmental assessment, and socioeconomic impact assessment) may also have to be met in creating policies.

Proposals for a *new method* of assessing scientific and technical variables, or a rigorous approach to matters of scientific controversy are likely to be seen as impositions on an already overloaded policy process and as impossible demands on the scarce resources of a department. Doern's study of several federal departments indicated that senior government officials involved in regulation have a limited perspective on scientific controversy.[3] In light of day-to-day pressures, these officials can hardly be criticized if they have little appetite for resolving such controversy. They may be unable to obtain adequate information within their own departments, and may be unwilling to contract outside to secure such advice.

Thus, it is not surprising that a department, sensitive to the political nature of its regulatory function, may ignore important scientific aspects of a controversy unless external pressure forces it to take notice. Departments are reactive. Often only persistent media pressure will prompt consideration of an issue.

The number of issues classified as scientific controversies varies for each department. Energy, Mines and Resources officials have considered one issue a year to be scientifically "controversial". National Health and Welfare identified about 50 potential scientific disputes in one year, and Consumer and Corporate Affairs about eight in the same period. The number of scientific or value-scientific controversies determine, in part, whether there will be special inquiries to deal with them. A large number on the agenda may exceed the department's resources, and mechanisms to help establish priorities are lacking. (The ability of interested parties to call a special board of review under the Hazardous Products Act is a welcome exception.) Clearly the mechanisms for handling these controversies can be improved in both routine and special decision processes.

The inquiry into nuclear waste disposal, conducted by three individuals at the request of the Department of Energy, Mines and Resources illustrates one intradepartmental effort to resolve a scientific controversy.[4] This inquiry did not have the formal composition of a royal commission. Neither was it required to examine the question in detail nor given the resources to do so. It was not established to allow all segments of the public or of the body of scientists to consider the problem. Nor was it in a position to promote effective public education, although in retrospect it seems likely that those who established the inquiry hoped it would help the department to locate scientific information and educate the public. Insufficient resources and the procedures followed prevented this from happening.

One other means available to a department is an ad hoc advisory group that reports, usually confidentially, to the minister concerned. This type of investigation has the extreme disadvantage of being conducted entirely in private. If this process is evaluated in terms of the points already considered in the case of recombinant DNA regulation, several problems emerge:*

a) information is not available (the draft Access to Information Bill in committee stage at the time of writing, is weak in important areas);

b) no information on the process itself such as is published in the US, can be demanded legally;

c) in Canada, not even the rudiments of a statutory procedure, or requirement to publicize information on its use exist. Such public consultation as has occurred on an ad hoc basis is a tribute to progressive bureaucratic forces.

The failure of government to disseminate information and provide for its exchange aggravates the lack of scientific knowledge among senior officials and ministers. Background documents often do not benefit from outside scientific opinion or public comment. Both expert comment and factual submissions from the public are sacrificed. Judgements of public attitude are reduced to political guesswork. Values are not tested in open debate.

The Canadian departmental process appears to value consensus highly. It does not invite confrontation, rather advisory committees are oriented to advise the minister, or his or her surrogates. Consultation, when used, is often closed. Thus, an opportunity for a negotiated outcome is created, without all relevant interests being present. Too often the "clients" of a particular department will succeed in negotiating outcomes from which other, more diffuse interests are excluded. The result is insufficient exploration of relevant information and invalid inferences from data. Also, interested and possibly opposing groups are deprived of a hearing afforded to others, leading to a public view of unfairness.

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* See p. 32.

Finally, the formal procedures for recording cabinet decisions do not provide for separate treatment of scientific factors. While departmental records were not studied at length, it would seem that the absence of material is not so much a problem as is the identification of the scientific data supporting decisions. Procedures requiring a scientific record to support setting standards and regulations, such as the scientific record in support of the Environmental Protection Agency (EPA) standard in the United States, would allow accountability for the scientific basis of a decision, as well as political deviation from it. In this way, the quality of scientific advice received by government would be known as would the scope and responsibility for political deviation from such advice in response to social, economic or cultural factors.*

The Role of the Judiciary

Courts generally review fairness and procedures rather than pass judgement on scientific issues. In practice, though, this distinction may be hard to maintain, and courts may be required to make judgements based on conflicting expert opinion. However, when Parliament entrusts decision making to a tribunal with special competence, the role of the court in judicial review is not to substitute its judgement for that of the tribunal, but to ensure that the tribunal has stayed within the law in terms of its jurisdiction and procedures. Judicial intervention goes beyond these bounds only when a common law statute or the civil law clearly requires the court to review the merits of the case.

Judges in Canada have always respected the traditional roles of Parliament and the judiciary. The result has been what many today consider overly cautious and inadequate supervision of the bureaucracy. Only when Parliament has spelled out formal decision-making procedures or clearly delineated the jurisdiction of an official or agency do the courts accept a reviewing role. Parliament's tendency to pass statutes that give broad, discretionary powers to officials or agencies, unencumbered by jurisdictional or procedural constraints, has led to a separation of powers in Canada.

* Such reforms to the regulatory process have been suggested as well by the Parliamentary Committee on Regulatory Reforms. They recommended: early consultation with a wide range of interested and affected persons; greater use of public hearings and discussion papers; funding for public interest groups to participate in the regulatory process; access to information legislation; mandatory impact assessment for all proposed regulation; and explicit and comprehensive rules of practice and procedure for departments and agencies involved in regulation. This group also commented on needed parliamentary reforms. We support the thrust of their recommendations in these areas. Canada, Special Committee on Regulatory Reform, Chairman James S. Peterson, *Report,* House of Commons, December 1980.

Exceptions have occurred when the decision-making function of an official or agency is seen by the court as quasi-judicial. A decision is quasi-judicial if it affects individual rights according to prescribed standards. When that happens, common law permits the courts to require officials and agencies to stay within their statutory powers, to carry out their official duties, and to observe rules of natural justice in reaching decisions. But other bureaucratic action, not seen as quasi-judicial, remains virtually unsupervised and unchecked. By contrast in the US, the work of a regulatory agency and final promulgation of a standard is frequently challenged in the courts.[5]

Recent judicial decisions in Canada suggest that our courts may be expanding their supervisory role over the "executive" branch of government.[6] It has been held that, even when decision making cannot be classified as quasi-judicial, Parliament, by conferring decision-making power on an official or agency, has imposed a "duty of fairness." Under this ruling the courts could review virtually all cases of decision making by agencies and departments to ensure fair treatment.

It is too early to predict whether Canadian courts will extend "duty of fairness" into comprehensive requirements that bind government decision makers. They may confine the fairness requirements to form, with little regard for substance. Conservative tradition may tempt judges to draw back from the opportunity to forge new relationships between the courts and the bureaucracy. But there are portents of change. Certainly there is public feeling in Canada that the courts should ensure that the rights of society, in general, are more adequately protected.

Judicial review is a two-edged sword. Standardization of the process does not necessarily mean the public interest will be well served. Rights to review can be claimed by parties with varying interests in a controversy. Also, insistence on procedures of fairness may delay implementation of regulatory policies and may increase costs. Further, the courts offer little with regard to the substance of regulation, but a great deal with process. Despite these problems, we advocate judicial review as one way to help ensure fairness in procedures.

The Role of Parliament

Our study of the science resources available to Parliament revealed several important problems. Many Members of Parliament feel that the scientific information they receive does not meet their needs, the needs of their constituents, nor does it enable them to understand complex issues. The scientific information presented to MPs seldom addresses their concerns, namely:

- Where is the controversy?
- Who has studied the issue?
- What is their claim to authority?
- What are the consequences in political, economic and human terms?

MPs depend primarily on the bureaucracy as the source of information on scientific research and assessment of its significance. Among the non-bureaucratic resources available to them, only the Library of Parliament Research Branch, Science and Technology Division, was highly praised. But, because of its small research staff (eight), the branch has concentrated on support to Special Committees with scientific mandates. For example, the Special Committee on Alternative Energy and Oil Substitution alone received the almost full-time attention of seven researchers over a period of eight months. As a result of priorities and staff limitations, several MPs found that the branch could not respond to their requests quickly enough to be useful.

The caucus research offices, set up in 1968 to provide assistance to individual MPs, altogether employ 22 researchers. Most are hired directly from university; only one was identified as having a science background. For the most part these offices are now responsible to each caucus. The pace of the research is fast, and the results often influenced by party line. Demand for scientific information is minimal.

Each MP has a budget of $86 600 ('82/83) to operate an Ottawa and a constituency office. Parliamentary research assistants are occupied mainly with constituency work, and the salaries offered (maximum $24 300 ('82)) do not attract people skilled in scrutinizing technical and scientific documents.

Because the parliamentary agenda is already overcrowded with government legislation, and because legislative priorities are not established by the House, the Commons is not a feasible forum for substantive scientific discussion.

The Standing and Special Committees of the House are more amenable to a discussion of the scientific or technical basis of proposed policy. Even in Standing Committees, however, debate on science-related issues is generally superficial. The large membership (17-20), high turn over and much substitution weaken the committees' expertise. In addition, the partisan nature of committee debates, time limits on questioning witnesses, inadequate funds for hiring experts and researchers, and the rigidity of committee mandates, which are set by the House, reduce the quality of debate.

There is no Standing Committee for science. Annual budget estimates of bodies such as the MRC, the National Research Council and Science Council are reviewed by the Standing Committee for

Miscellaneous Estimates. It also deals with the expenditures of 18 other departments and agencies.

Many MPs favour Special Committees. These committees have a fixed membership of seven or eight, extensive research resources, a relatively short duration, and a narrow mandate within which a wide range of questions can be explored. Such committees avoid many of the pitfalls of the Standing Committees.

In the Senate, the only science mandate is held by the Standing Committee on Health, Welfare and Science. This committee's docket includes health and welfare, veteran's affairs, native people and Inuit, pensions, labour and social and cultural programs and the aged. Legislative activity in these areas alone has kept the committee occupied. While some members are interested in special studies on microelectronics or genetic engineering, approval by the Senate is required to address these areas.

MPs remain heavily dependent on the bureaucracy for scientific advice. Parliamentary challenges can be controlled by the lack of information, so for Parliament to function effectively ready access to sources of scientific information from outside the bureaucracy are needed. Also opposition parties and individual MPs must be given the resources to scrutinize goverment information, and to call government and the bureaucracy to account.

Reforms are needed in the decision-making process to give those outside Cabinet the power to trigger a review of a controversial issue, policy, or decision. Initiation of review should be politically accountable, but not under the control of Cabinet or the majority caucus.

Council recommends reforms to parliamentary procedures that would enable a specified number of MPs, either by petition or committee, to initiate inquiries into value-scientific controversies.* Council also recommends greater resources for MPs to enable them to investigate value-scientific controversies and access the scientific basis of proposed legislation.

* The Ontario Legislature provides for such action by Members of the Legislative Assembly (MLAs) under its Standing Order 33-B. Annual reports of each department are tabled in the legislature each year unless an exemption is allowed by the Speaker. Under 33-B, a petition of 20 members can forward the annual report of any department to its relevant committee. This standing order has been used by MLAs to investigate specific government decisions.

Chapter IV

The Inquiry Process

The inquiry can be a flexible policy instrument for dealing with value-scientific questions such as those posed by the new developments in biology. Inquiries are usually directed to conduct research and make recommendations, and often, although not always, are appointed on an ad hoc basis.* Inquiries stimulate much needed research, they involve new groups and individuals in the formation of policy, and they are highly visible to the public. Visibility ensures that established routines and relationships are made explicit and that assumptions or values are subject to scrutiny and debate. This is of particular importance in a parliamentary system, where departmental decisions are often shielded from public view and the Cabinet plays a critical policy-making role. In the absence of strong freedom of information legislation or with little judicial supervision of the procedures of regulatory agencies, inquiries are of additional significance.

Canada has many ways of conducting an investigative assessment. A commission of inquiry may be established under a federal or provincial inquiries act or an assessment may simply be convened, on an ad hoc basis, by a government department or legislative committee. It may be mandatory or discretionary. Some inquiries hold hearings; some do not.[1] Some conduct formal research; others simply review the scientific literature, hear testimony from those assumed to know the literature, or depend upon the intervening public to raise the necessary issues for consideration. Some inquiries attempt to function as a public opinion poll, seeking widespread public participation as a measure of public sentiment. Others seek mainly the participation of known interest groups and a mediation of those interests.

Conventional wisdom suggests that sometimes inquiries are commissioned to delay action or allow government inaction on problems. Little is known about why or how inquiries are actually commissioned for that information, like information about most Canadian decision-making processes, is often not made available to the public.

In Canada, inquiries have been tied to scientific assessments in recent years. The relatively new federal environmental assessment process and similar programs in most provinces allow inquiries into most major development projects. In most such assessment processes the environment is broadly defined, tying in consideration of technical, social, scientific and economic questions.[2] But the kinds of investigations conducted by an inquiry are diverse. Inquiries often

* Some permanent agencies (the Restrictive Trade Practices Commission for example) have the powers of an inquiry and submit recommendations, based on research and development, to their mandating government. Some legislative committees are mandated on a more or less permanent basis, but conduct several different assessments and prepare reports on a variety of issues.

are also used to investigate potential wrong-doing or a single event. Inquiries may be used to investigate a potentially dangerous drug, product or technology, even where resources exist within a governmental department to conduct the same investigation. Thus, the methods of research and investigation appropriate in one case are seldom fully applicable to another.

Science in Inquiries

Not everything investigated by an inquiry relates to scientific or technical assessment. Many of those who contribute are not scientists, and few would suggest that an inquiry limit participation to those with scientific credentials. Inquiries depend upon the perceptions and judgements of their commissioners and staff, who may have no scientific training.* Their job is to make recommendations for those whose commitment to a scientific assessment may be minimal. Thus, even an inquiry conducting a scientific assessment is not, strictly speaking, a scientific body, although it may conduct primary research.

In inquiries, rigorous scientific debate is minimal. Often what passes for scientific debate may simply reflect a difference of opinion about the steps to be taken in light of the data, about which factors to take into account, or simply reflect the different philosophies or values of the scientists themselves.

An inquiry airs scientific information and controversy in a context within which the public and policy makers can respond. Two problems result. First, individuals who present scientific information may be accorded little scientific credibility even when the information has been obtained by careful scrutiny of the literature.† Second, scientists not directly affiliated with government departments, proponents of projects, corporations or advocate (interest) groups, may be reluctant to participate in a scientific assessment conducted by means of an inquiry.‡

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* In the six inquiries studied by Salter and Slaco, less than half of the commissioners had any scientific training and only one had specific expertise in the subject under assessment.

† A number of those interviewed commented on the lack of credibility given witnesses for advocate groups, even when the intervenor had scientific training and expertise. The advocate interest was seen as colouring the scientific information presented.

‡ Reluctance to participate was discussed with the scientists interviewed. One noted, "Scientists hesitate to publish anything they cannot prove. . . writing a brief on the general effects would require a good deal of extra reading and would end up being largely opinion in any case." Another suggested that inquiries are verbal processes, centred on semantics and opinions. It is not important in science whether three scientists agree or disagree; truth is not to be found in consensus. An inquiry by its very nature seeks consensus. Salter and Slaco, *Public Inquiries in Canada, op. cit.*, p. 169; and *op. cit.*, pp. 72-73.

Salter and Slaco found that few unaffiliated scientists took part in the assessments. Scientists claim their reluctance to participate stems from an awareness of the limitations of their research, which is often narrow in scope. Participation in inquiries is sometimes viewed as going against good scientific practice. The often trial-like nature of public hearings, the pressure to reach consensus, and the sometimes strident advocacy of participants discourages members of the scientific community from making what may be critical contributions.

Those who conduct inquiries add to the scientists' reluctance when they misunderstand the nature of the scientific research process. Scientific work seldom produces the degree of unanimity necessary for simple policy recommendations. Nor are those involved always aware of the slow pace with which scientific work proceeds or how different conclusions might be reached from the same data.

As long as scientists are reluctant to participate, the burden for ensuring a "scientific" assessment falls upon the inquiry and its participants. Cross-examination may indicate where scientific assessment has been objective or has been affected by institutional affiliations; inquiries may conduct their own review or studies; lay persons may provide an evaluation of the scientific literature. But inquiries, even those oriented to scientific assessment, often lack scientific credibility. The value and quality of their assessment suffers as a result.

What is the Question?

Inquiries have been convened in Canada to explore a spectrum of questions, ranging from those that involve value judgements to those that do not. The former require an approach that ensures questions encompassing values are identified clearly and debated publicly. Such a commission may consist of individuals from various walks of life or may draw upon an advisory panel, as is common in the UK. Alternatively, a smaller commission may seek a comprehensive debate by ensuring that different perspectives are aired at the hearings. The hearings of the Berger inquiry were remarkably successful in generating a debate on conflicting values.

Facts and values are not always easy to separate, of course. Questions that arise when assessing a product or project are usually complex and an inquiry lacks the full capacity to isolate the issues involved. If an inquiry looks upon its work as an assessment of risk, it has already made a value judgement – it assumes that a project or product should be permitted *unless* significant problems can be identified that call for reconsideration. To those seeking a review of government policies, such an approach is often unsatisfactory be-

cause it may preclude a fair discussion of whether a particular project or other means would be appropriate or desirable. To others, who want a broad approach that takes social and cultural values into account, risk assessment alone appears to restrict the investigation's terms of reference and to weigh cultural factors against economic considerations as if they were comparable. Risk assessment often fails to meet the expectations of members of the public seeking the maximum *possible* protection from products or technologies that may prove dangerous – and about which much more needs to be known.* However, in choosing to conduct a risk assessment, inquiries seek to give the public the maximum protection that is practical given present scientific knowledge.[3]

Research and Arbitration in an Inquiry

Inquiries usually do not extend over a long period. Changes within communities, the long-term effects of technologies or products, or problems that may arise after design specifications or standards are changed are not easily measured by a one-time assessment. Thus, although the goal is prediction, an inquiry's ability to forecast and monitor the impacts of a project or product is limited. An inquiry may sensitize policy makers to the range of questions affecting the application and success of a policy. Without adequate continual assessment and monitoring of the project or product, a predictive assessment is wasted effort.

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* The inquiries oriented to risk assessment met significant public dissatisfaction in each case. Their public participants and inquiry staff disagreed about the criteria that should be used to measure risk. The Aluminum Wiring Inquiry provides a good example. As Salter and Slaco note: "However fair and comprehensive the assessment process may have been, the use of two different measuring sticks in the evaluation of risk was bound to create some problems. The inquiry could be seen by some of its public participants as falling short of its goals in part because in their view, the wrong criteria for assessment had been used. The inquiry could be seen, as it was by some, as politically motivated, as serving only the vested interests of institutional intervenors, because it was working within a balance of interests in determining the extent and seriousness of the problem. It could be seen as inadequate because copper and aluminum were never fully compared by the inquiry itself. All of these perceptions were based on the *nature of the criteria* used to measure risk, *not* on the measurement or assessment itself." Salter and Slaco, "Inquiries into the Use of Potentially Dangerous Products," Manuscript Report, Science Council of Canada, January 1982, p. 73.

The decision to focus the assessment on risk is not given in the commissioning of a scientific inquiry. As Salter and Slaco noted, "Of course one might decide not to centre an inquiry on the measurement of acceptable risk. The question might be put quite differently. Dr. Ham, for example, has suggested that the question of an inquiry (or development) is not what risk but *whose* risks. He raises a critical point. Dr. Ursula Franklin puts the question another way. "All electrical or other technologies will fail," she noted. "The important task of an inquiry is to locate the means by which they can 'fail safely', with minimum danger to the public." Had the Aluminum Wiring Inquiry chosen to address either Dr. Ham's or Dr. Franklin's questions, it would have been a very different inquiry indeed." *Ibid.*, p. 68.

Many areas of science that fall within the work of an inquiry, particularly the social sciences, are relatively underdeveloped in Canada.* Data are seldom available about how susceptible a particular population may be to different risks, about alternatives for economic development, about the economic and social consequences of a particular regulation, or even about the willingness of segments of the population to accept a risk.

Some inquiries conduct original research to reduce uncertainties. A few have allocated resources for the systematic analysis of evidence presented, and thus for the proper arbitration of scientific issues. However, because inquiries usually have limited time and finances, original research is often limited and not extensive. More often, the inquiry will depend on studies conducted elsewhere, even though such studies may not be completely applicable.

To some extent, inquiries choose between a research and arbitration approach. A research-based inquiry, like Le Dain, needs the resources and time to permit adequate research. The Le Dain Commission took five years; the Berger inquiry three. The research model may be more responsive to the dictates of science than the arbitration approach, but often does not produce recommendations that can be easily implemented. Research and policy-making often exert conflicting pressures on an inquiry.

The arbitration model, on the other hand, is more easily oriented to producing policy recommendations. When competing claims are based on different bodies of knowledge, as happened in the Berger inquiry, arbitration can be centred directly on the scientific questions being addressed. When two or more competing applications for the same or similar projects exist, again as in the Berger inquiry, the inquiry can adjudicate the decision involved.

When, however, scientific uncertainties are significant and the literature sparse, effective arbitration becomes much more difficult. The inquiry, for example, can concentrate on the proposed design of the project, but in doing so simply emphasizes the engineering aspects of the project and provides a useful sounding board for the proponent.

Alternatively, the inquiry can widen the range of questions by including related problems. This occurred in the Cluff Lake Board of Inquiry in Saskatchewan, which considered the problems of nuclear

* Perhaps the best example is the Cluff Lake Board of Inquiry which was highly dependent upon research done in other jurisidictions. Little field work had been done before the inquiry in the specific areas to be affected by the mine. As well, few socio economic studies or community studies had been conducted in the northern communities involved. As one expert intervenor interviewed put it: "There was no information on the native economy. There was no information about animal movements. There was no information about the movement of people in Northern Saskatchewan, no base-line environmental data, no base-line hydrological data." Salter and Slaco, "Nuclear-Related Development," *op. cit.*, p. 97.

proliferation.[4] Here again arbitration will be confounded if scientific uncertainties are high, if qualified scientists are unable to participate, or if the issue is too diffuse to allow useful scientific debate. When an inquiry chooses such an approach but has little to arbitrate, value judgements rather than scientific assessment mould the debate. Occasionally, polemics result, not scientific assessment.

Because inquiries are under pressure to produce clear choices for government they find quantitive data attractive. They want data that are easily sifted and measured. Risks are compared, alternative sites gauged, costs are measured in monetary or comparative terms. Social questions often are treated as technical problems and assessed by referring to simple demographic information. Ethical questions may be reduced to a cost/benefit analysis.* The quality of life in a community may be measured through its employment or alcoholism statistics.

Although such measures are useful in determining what might be done to alleviate the impact of a new project, they disguise more salient features of technological development and community life. Those who oppose a project may be seen as "anti-progress," when their intent may be simply to suggest alternative means of development. Some things are not easily measured, such as the cost of the loss of wildlife from stripmining or acid rain. Costs, not easily remedied by increasing the number of hospital beds or setting up a detoxification centre, likewise are difficult to predict. Such costs are often ignored.

When an issue falls within the jurisdiction of various agencies – such as nuclear development – one might assume it would receive a comprehensive assessment. But often, in fact, such an issue is examined merely in terms of the variables deemed important by each agency. The dynamic effects of a technological development on human and natural environments are masked when separate agencies conduct their own assessments. The Environmental Assessment Review Process (EARP) attempts to coordinate research efforts, but even these assessment panels find their efforts blocked by jurisdictional and departmental conflicts. The existence of interdepartmental or interprovincial committees may mask a lack of research in specific areas. Furthermore, committee representatives may be more inclined to protect the interests of their jurisdiction than to contribute fully to the assessment. Unfortunately, comprehensive inquiry does not always solve the problem. Departmental representatives may be constrained when testifying. The inquiry itself may prove unwieldy, the investigation too diffuse.

* Although many inquiries cast their assessment as a cost/benefit analysis, the Cluff Lake Board of Inquiry went furthest with this approach.

Public Participation

Salter and Slaco write:

> ". . . an inquiry cannot provide a means of assessing public opinion. It is not a public poll, nor does it provide systematic information on a specific range of questions. It may be less costly than a referendum, but it cannot fulfill the same function. For those who believe that political decisions should reflect, nay mirror, the attitudes of the public at any one time, an inquiry is a poor tool."[5]

The role of the public in an inquiry is not well understood, certainly not by inquiries and often not by the public representatives themselves.* Theoretically, the public can contribute in four ways. People may act as advocates of a particular interest or as the clients of a proposed project, service or product. They may offer knowledge based upon their own experience. They may act as a sounding board in appraising particular risks, an early warning system of public opinion in general or the opinions of those directly affected. Finally, they may act as "lay scientists," drawing upon scientific literature to call attention to inconsistencies in data, inadequacies in research or in the value judgements being made.

Public advocates may or may not represent the public. In any case, the question is largely irrelevant, in that the strength of a point of view seldom depends upon the number of people who hold it. Many advocates have experience as clients of projects or services similar to those under consideration. Information based on a person's experience can supplement inadequate scientific data, but only if resources are provided for its systematic analysis. Again, the question of representativeness is unimportant, for specific information is being sought.

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* Commonly, public participation is linked to public interest, but defining the public interest is difficult. Salter and Slaco note that little agreement exists about what constitutes the public interest and how it should be derived. They argue, "It may make sense to draw a distinction between public and consumer interest. Consumer interest may be that which can be seen as in the interest of each consumer, considered separately but in aggregation. Consumers have an interest in the availability of service and certainly in the cost of services. Public interest, on the other hand, is often most easily equated with the 'general good,' (Dewey, 1927) the good of the society seen as a collective unit.

"If the public interest is considered as consumer interest, the role of public intervenors is clear: the public can identify problems in service and indicate what the public will accept. But if the public interest is considered in terms of the general good, then the 'public interest' is a matter for debate in which the public has a part to play." Salter and Slaco, "The Use of a Regulatory Tribunal as an Inquiry," Manuscript Report, Science Council of Canada, January 1982, p. 66.

To argue that the public has a critical role in an inquiry, then, is not to suggest that public advocates are always representative of the public at large or even significant segments of the population. For example, local residents may prefer no change to that imposed from outside or little understood in the community. This conservative bias often reflects a fear not so much of change, but of loss of control over the direction and impact of change. As a study conducted by the Organization for Economic Cooperation and Development (OECD) noted:

> "Touched by anxiety over the future, by a sense of powerlessness over the present, citizens are seeking more direct ways of influencing the outcome of decisions on matters which they perceive as affecting their lives. In some cases, their motives are altruistic – they purport to seek a more equitable distribution of economic and social costs and benefits. For others, public participation is seen as a means of making governmental agencies more accountable to the people. For most people, however, it is far more personal. They wish to regain a measure of control over their lives – a control they feel has been abrogated by bureaucratic processes which appear to them to be, more often than not, directed to the resolution of technical problems, rather than to meeting human needs."[6]

The public alone cannot define what is in the best interest of society at large. What is in the public interest is a matter for debate, not only among public advocates but also among scientists, members of the inquiry and the mandating government. Seldom is consensus reached easily. Nor should an inquiry draw its conclusions solely from the evidence presented by those who have intervened. A comprehensive scientific assessment process demands an open investigation and a search for adequate answers to complex problems. Adequate answers seldom result from a compromise of interests, from a resolution of views offered at a hearing, or from the evidence of those who, for whatever reason, have chosen to intervene. The negotiation of interests and perspectives, the debate over values, is only one element in developing adequate recommendations, albeit a critical element.

Generally, inquiries make few distinctions between participants, even though the contributions sought may differ and participants are affected by very different constraints. Nevertheless, an inquiry seeking the benefit of public experience must tailor its hearing schedule, agenda, and resources to ensure such participation. Often participants will have to be actively sought.

People are often intimidated by the formality or public visibility of an inquiry and may not respond, even to a well-conducted advertis-

ing or information campaign.* When confronted by intervenors from government departments or corporations or those with impressive scientific credentials, private citizens may doubt the significance of their contribution. Salter and Slaco found that those who conducted the inquiries thought few members of the public had participated. Whether this was due to apathy, as some claimed, or simply an imbalance of interests represented, the presence of experts, the formality or court-like demeanor of the hearings, or the multiplicity of issues and hearings calling for public participation was not entirely clear. Advocate group members apparently found little apathy among the public. If factors other than apathy are a cause, then measures can be taken to increase public involvement.

Cross-examination and courtlike procedures may discourage participation. Placing a member of the public, say from a fishing community, in a court-like setting is inappropriate; placing the corporate representative of a major development project in an informal setting, without requiring disclosure or permitting cross-examination, is equally so.†

The contributions scientists or the public can make to a scientific or technical assessment depends on a conscious effort to facilitate their participation. Sufficient funding to allow groups to bring expert witnesses, follow the hearings, educate their constituencies or con-

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* Intervenors gave several reasons for the lack of public response. Salter and Slaco note: "Opposition to the Point Lepreau project never took the dimensions of a mass movement. It would not surprise members of advocate groups that AECB only received one letter from the public on the nuclear plant proposal. In part, the advocate groups' job of reaching the public with information was considered difficult and demanding of resources that were out of the hands of any advocate group. In part, members of groups were convinced their numbers were limited by the amount and kind of information that had already been made available to the public". "Nuclear-Related Development," *op. cit.*, p. 86.

† Under some conditions, cross-examination is valuable. Public advocates may draw attention to connections between various issues or to relevant scientific literature that may have escaped the attention of the inquiry. Cross-examination can clarify the point at which strict scientific or statistical interpretation ends and value judgement begins. On occasion, cross-examination is necessary to sensitize an inquiry, policy makers, and scientists to a range of social, value and cultural considerations.

Cross-examination and other court-like procedures are appropriate when facts are disputed or when the data need to be probed. Also technical questions may be clarified. If, for example, a scientist is describing an epidemiological study, questions about the interpretation of data may be exacting and rigorous. Finally, cross-examination lends the appearance of an adjudication to an inquiry, increasing the probability that its recommendations will be seen as based on a complete and fair assessment.

Cross-examination may discourage the public, as well as scientists. Rules of evidence and codified procedures are seldom applicable in inquiries. Inquiries and courts are different. The assumption that all relevant data will be revealed in the clash of interests, is inappropriate in a scientific assessment. A clash of interests may be needed to gather information, but it is seldom sufficient. The inquiry's efforts are directed to determining fact, and not simply attributing blame.

duct original research for example, is only a first step. Poorly-funded groups cannot represent their interests fully. The amount of funding depends upon whether the advocates are expected to contribute mainly to the policy debate or to the assessment. When groups must collect and analyze experiential data (on the level of tides in coastal waters and the relationship to fishing, for example) or gather original research, as in the Berger inquiry, the amount of funding needed is significant. On the other hand, when the aim is simply the informed and consistent participation of various groups in a debate, funding can be geared to the costs of maintaining an educational program and encouraging participation in the hearings.

Limitations of an Inquiry

However significant and useful the Canadian inquiry process is, certain limitations exist. Inquiries cannot resolve *all* conflicts, despite the demands and expectations placed on them by governments and the public. No matter what procedures or approaches are used or how many commissioners with whatever qualifications are involved, an effective inquiry cannot be guaranteed. The ad hoc inquiry is a temporary forum and involves institutions and individuals whose loyalties and responsibilities lie elsewhere. Even though greater concentration on the assessment at hand might produce a more satisfactory solution or even a compromise, interest groups *use* an inquiry to educate their members and followers, to lobby governments, to gain support for new programs, or to protect their jurisdictions.

Any inquiry into corporate or government activity may identify areas of apparent negligence or even wrongdoing. Walking the line between full disclosure of all relevant information and turning an inquiry into a court, with its limited flexibility, is difficult. When an inquiry becomes courtlike, lawyers may enter the picture to protect the interests involved. Then, the frank exchange of information, difficult under the best conditions, may become virtually impossible.*

* The impact of lawyers and legal issues on an assessment is significant. As Salter and Slaco note: "For the public intervenors, the inquiry setting provided either protection or licence, depending on the perspective. It would be unprecedented and contrary to all assumptions about inquiries if *individuals* who spoke were to find themselves charged as a result of some statements made before an inquiry. For the institutional intervenors, however, the problems were more complicated. Whatever legal actions might be taken would occur outside of and separate from the process of an inquiry. Nonetheless, any statement of responsibility or any admission of negligence in the inquiry could later be used in a court setting." "Inquiries into the Use of Potentially Dangerous Products," pp. 86-87.

See Salter and Slaco, *Public Inquiries in Canada,* pp. 196-203 for further discussion of the use of court like procedures in inquiries.

Many inquiries have generated innovative recommendations only to see them neglected. However much the inquiry, or its intervenors seek a broad discussion of issues, the mandating government usually wants a simple statement on how to proceed – should a product be taken off the shelf, for example, or should a mine permit be granted? The government also needs a number of non controversial measures to deal with any problems that might result from the decision. Inquiries that produce sophisticated reports, reflecting a genuine understanding of the issues often find their analysis passed over in favour of a simple decision taken out of context.*

Inquiries are often launched because of political pressure, yet the questions they investigate usually demand a dispassionate view and a long-term perspective. Inquiries that function in an atmosphere of public controversy may produce a credible report, but sometimes only by sacrificing effective policy recommendations. In some cases, the controversy produces a confrontation that obscures the issues. Those intervening have little interest in any investigation, but seek only the value debate and an effective arbitration in their favour. Thus, although an inquiry on abortion might have little chance of success today, one on genetic counselling, involving some of the same issues, might produce a comprehensive assessment and clear policy recommendations.

In addition to seeking recommendations, a mandating government may view an inquiry as a planning body and the involvement of the public as conducive to good planning principles. In the inquiries studied, the planning function often failed.[7] Those who acted as continuing participants did not reflect the range of public interests required for successful comprehensive planning. Many participants sought to resolve a value debate. Disclosure of interests in an adversary proceeding or even a scientific assessment drew participants into debate and deflected them from the task of planning. Those who questioned the necessity for a project (for example, the intervenors in the Point Lepreau hearing in New Brunswick) felt compromised by efforts to involve them in designing measures to decrease the negative impact of the project as it was being built.

A planning inquiry may require a different kind of mandate, procedures, and participants than would inquiries oriented to scientific assessment or policy debate and possibly should follow after the assessment and policy questions have been debated fully in public.

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* The final report of the Cluff Lake Board of Inquiry, for example, contained one "ultimate" recommendation, which was accepted, and a number of conditional recommendations, demanding signficant changes in the orientation of the government and which were accepted only in part. Some staff from that inquiry expressed disappointment that "the spirit of the recommendations" was "lost," while the ultimate recommendation was accepted. *Public Inquiries in Canada,* p. 77.

Finally, establishing an inquiry or conducting an assessment is rapidly becoming an automatic response of government to controversy surrounding major development projects.* Inquiries are often used to determine the regulatory standards as the project is being built. Yet the link between inquiries and regulation is tenuous. Inquiries operate without any guarantee that assessment will be continuing or proposed regulations will be enforced. Unrealistic expectations of the Canadian regulatory process, and its capacity to follow up on the recommendations made by inquiries, are common.

* As noted with reference to Saskatchewan: "Under Saskatchewan's assessment process, it is likely there will be either multiple inquiries at any one time or a diminishing number of public considerations of applications. The year of the Bayda inquiry, for example, three boards of inquiry were established. For each new application for a project, another inquiry is possible.

"There is a real danger that the province may drown in its own inquiry process, particularly when the number of inquiries commissioned under other jurisdictions and kinds of legislation are taken into account. Either the province will develop inquiry fatigue or it will move to withdraw more and more questions from the inquiry-based assessment, assuming that the issues have been adequately assessed in earlier inquiries. In either case, the public demand for public debate is unlikely to be satisfied.

"Inquiry fatigue may not reduce participation; it may preclude intelligent participation by wearing down the participants and demanding that government departments create a special staff whose sole job is appearing in inquiries (as has happened in Ontario). Once the participants are weary or have become professional, their ability to bring the unique or the particular to light with reference to specific applications is diminished; their ability to respond with depth and consideration to the challenge of questioning is also diminished. Inquiries can become set pieces, staging grounds for a continual replay of the same debate." Salter and Slaco, "Nuclear-Related Development," *op. cit.*, p. 172.

Chapter V

Dispute Resolution

The complexity and highly public nature of contemporary value-scientific issues such as applications of prenatal diagnosis, genetic screening and recombinant DNA, are challenging our social system, government institutions, and the educational, legal and scientific communities. The scientific uncertainty and implications for society that surround such disputes have forced once technical questions into both the political arena and the public domain.* Although the role of scientists is important, they often cannot, or choose not to predict the environmental and health effects of a particular technology. If they do make predictions, their scientific credibility may be jeopardized.†

Political implications, public anxiety and distrust, and scientific uncertainty influence the appropriate method for resolving a value-scientific dispute. When choosing, the following questions must be addressed:

What is the source of conflict? The disputing parties must agree about what the problems and uncertainties are.‡ Is it a scientific *or* a value-scientific controversy? Any issue can have elements of both types of controversies.

What are the political traditions and institutions of the government decision-making process? These influence its degree of openness, its

* "Until recently, the risks of technology have mainly been perceived as a technical problem, not a political issue; a problem to be relegated to expertise, not to public debate. But controversies have politicized the issue of risk, called attention to the interests and the question of power that are involved. Several features of the disputes over risk have contributed to this politicization and to the difficulties of conflict resolution." D. Nelkin and M. Pollak, "Consensus and Conflict Resolution: the Politics of Assessing Risk," *Science and Public Policy*, October 1979, vol. 6, no. 5, p. 307.

† "The chief difficulty in attempting to study big controversies is that of their uncertainty. One experiences difficulty in finding point, centre, grounding, shape, and indeed content. The task of examining such matters is vague, because they pose questions without number which can be answered in as many ways as they can be rephrased, in which there are further questions concealed, all of them made imponderable because of a lack of agreement on what is at issue, and what one should do if one should come to know." Milton R. Wessel, *Science and Conscience*, Columbia University Press, New York, 1980, p. 120. M.R. Brett-Crowther, "Uncertain Decision Making on Environmental Problems," *Science and Public Policy*, vol. 7, no. 5, October 1980, p. 391.

‡ It should be noted that achieving agreement on the issues in dispute is often impossible. It is only possible if parties recognize a common interest or are subject to common legal compulsions in an authoritative statement of the issues to be addressed. Lord Ashby found three kinds of uncertainty in policy making related to protection of the environment: about facts, about people's opinions about facts and about the future consequences of present decisions. "Protection of the Environment: the human dimension," *Proceedings, Royal Society of Medicine*, vol. 69, October 1976, p. 175. See also Chapter 1 of this report, pp. 4-5. Also D. Nelkin and M. Pollak, *op. cit.*, p. 313.

methods of seeking consensus, and willingness to make information available to the public.*

What are the objectives? Are they to defuse political controversy, find an expedient solution, achieve a degree of social consensus, or reduce scientific uncertainty for the purpose of making policy?

So far, several models of dispute resolution have been discussed implicitly, but this chapter summarizes the theoretical choices. The four common models are: adversary, mediation, closed consultative, and open consultative. Actual cases of dispute resolution probably involve more than one mode in that they do not appear to be mutually exclusive. Largely theoretical, the relationship of these modes to dispute resolution is open to conjecture. Therefore, this report does not favour any of them. More experimentation and research is needed to decide which mode or mixed mode is appropriate under a given set of circumstances.

Adversary Proceedings

The adversary process is the central feature of the judicial system. It is based on long-established rules of procedure aimed at seeking justice, fairness and the settlement of disputes. The process brings together identified opponents in a dispute to present evidence and witnesses to support each case. Some form of examination is used to bring out all relevant information. A third party determines, on the basis of the evidence, a clear winner and loser in the debate.†

The adversary procedure, conducted in public with the power to subpeona information and witnesses, can be a powerful way to increase accountability.[1] Cross-examination can effectively probe the

* See G. Bruce Doern, *The Peripheral Nature of Scientific and Technological Controversy in Federal Policy Formation*, Background Study 46, Science Council of Canada, Ottawa, 1981, p. 29. Also see Howard Eddy's discussion of how three countries dealt with the concern over recombinant DNA research in "Regulation of Recombinant DNA Research: A Trinational Study," forthcoming.

† "The adversary process is the central feature of the system of legal institutions and procedures set up by our society to resolve controversies that arise between contending interests, values and ideologies. The adversity – to use the word in its old dictionary meaning – is supplied not by the process but by the parties to the conflict; the adversary process is merely the decisional mechanisms for resolving their conflict. Decisions must be reached even in the absence of any source of perfect information or wisdom. We therefore arrange an orderly contest of the parties in the courtroom, in which adversary roles are assigned to reflect the reality of the underlying dispute. Those of us who are engaged in conducting these proceedings have an awed awareness of the risk of arriving at an imperfect decision often with enormous consequences for the individual and for our society." David L. Bazelon, "Psychiatrists and the Adversary Process," *Scientific American*, vol. 230, no. 6, June 1974, p. 18.

limits of confidence in the scientific data. When the question addressed has no clear-cut answer, however, the debate takes on a philosophical flavour, and a rigorous battle over scientific evidence becomes irrelevant.

Effective adversary proceedings require:

- a precise definition of the issues clearly showing the areas of scientific uncertainty;
- formal and fair proceedings;
- money to cover the cost of intervention for groups who might not otherwise have access to the information and technical expertise accessible to their opponents; and
- a written record of all material submitted.

One adversary approach to scientific controversy is the Science Court. As described by its popularizer Arthur Kantrowitz, the Science Court consists of a "panel of judges who . . . adjudicate factual statements that remain controversial following an adversarial procedure." The goal is to identify and reduce uncertainty in science used for policy purposes. Each disputing body submits the "facts" of its case to cross-examination and contrary evidence, and finally to an opinion of judges, established scientists in areas related to the dispute. An advantage of a Science Court is that it would be conducted in public, and all sides of an issues would be part of the public record.

On the other hand, the Science Court model is hindered by several factors.[2] First, the "court" deals only with questions related exclusively to scientific facts. In many value-scientific disputes, agreement on factual evidence will not dispel the more difficult value conflict. Second, because the procedure is costly, social benefits must be evident. Third, in Canada a Science Court would be obstructed by the lack of effective freedom of information legislation, resulting in an inequitable distribution of expertise. Finally, usually only government bodies have the money and resources to force a "court" proceeding.

The Science Court model seems to have failed because the process was not freed from policy imperatives. It has been used in situations where public controversy was so intense that the scientific facts were not at issue. In a heated situation, adversary examination of scientists becomes an arena in which parties seek other policy ends. Unless all contesting parties have a significant commitment to fair resolution of an issue, it is unlikely that sufficient interest will be generated to initiate and successfully conduct a Science Court.[3]

In complex public-interest disputes, which many value-scientific controversies are, the adversary mode is often inappropriate. First, the procedure, usually a battle between a large corporation, public interest group and a government, seldom serves the public interest. Second, the adversary approach, which seeks to resolve a dispute by a

single solution, is suspect to participants who believe that quality-of-life or value questions can have many solutions. Third, adversary tactics of disputing parties can often influence the decision more than the merits of the controversy.[4] For instance, cross-examination, an integral part of many adversary proceedings, may shift the emphasis of the debate from issues to the credibility of witnesses. In these circumstances, cross-examination can intimidate witnesses and even discourage their participation.

Mediation Proceedings

Mediation is an alternative to adversary proceedings. It differs not so much in the techniques used, which may be adversary in nature, but in its goals. It seeks to achieve a compromise between contesting parties who participate voluntarily, and to reduce differences rather than declare one side the winner. It is a negotiating or bargaining process with the mediator encouraging discussion rather than acting as a judge. Mediation operates without time constraints, but it may end in enforced arbitration, as in labour-management disputes. But both sides must agree on the arbiter and to abide by the arbitrated decision.

Professor Dorothy Nelkin points out that mediation works best when two major protagonists share sufficient common interest so that they can reach a mutually satisfactory compromise. Mediation has been used successfully in the United States to settle disputes over highway routes and strip mining policies. In more complex issues, however, antagonist groups are often ill-defined and seldom share values that will allow compromise.[5] The Genetic Manipulation Advisory Group in the UK and the US National Commission on Protection of Human Subjects for Experimentation use the mediation mode.

One danger of the mode is that parties may consciously or unconsciously side with each other to their mutual benefit, leading to public distrust of the process as a whole. As a negotiation of limited interests, the mediation model may lack an overall perspective and result in "horse-trading" which does little to illuminate the basic problem involved.

Effective mediation requires that;

- all identifiable interests are represented;
- those present understand the issues, their common ground, and their areas of disagreement;
- the mediator has the confidence of all parties;
- all materials presented be made available on request; and
- mediation be followed by a public forum so that parties can be held accountable.

Closed Consultation

This model is based on private deliberations among carefully selected individuals who are technically competent in areas relevant to the issue. The Hare Commission initiated by Energy, Mines and Resources to study the effects of nuclear-related development exemplifies this mode.

Many government departments and agencies have convened special advisory panels to clarify uncertainties in scientific data and opinion and to reach a professional consensus. This is an information-seeking process, generally convened for urgent political ends. The composition of the advisory committee may not be public knowledge and sometimes the committee reports confidentially to the initiating minister. Nevertheless, it has a valuable if limited role.

It is limited because only a few of the relevant actors are included. The process of choosing scientists to participate is often discretionary, shaped by the conscious or unconscious bias of the initiator.* Also, the public is excluded. Even if a report is made public, as was the Hare Report, the elitist approach to collecting evidence may undermine public confidence in the findings.

The closed consultative mode is often defended as an expeditious, and low cost means of "legitimizing" policy decisions. It is often chosen when a quick decision is needed or in matters of emergency or national security. In general it works best with an apathetic public and an unaccountable government.

Open Consultation

This model differs from the previous one in that it actively seeks the participation of a broad range of individuals. Recent reforms to the

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* "Perhaps most significant, there is a perception on the part of some scientists that there is inherent, insidious bias in the panel-selection process and, as a result, in the panel's studies. This view argues that the person appointing the panel, subconsciously (or perhaps consciously) chooses people whom he believes will be partial to the result he favors; others are characterized as 'less well qualified,' 'unreasonable,' 'extremists,' or 'flakey,' and excluded. The National Academy of Sciences and its membership are seen as strictly 'establishment' controlled and composed very largely of scientists who have 'achieved' in major ways within the present 'repressive' economic and social system, dependent upon government and industry for funding and other support, and certainly not reflective of the views of other less 'well-fixed' opinion in the scientific world. Whether or not any of this is true is really almost irrelevant. The perception itself means that the general community does not always accord the status of true scientific 'consensus' to the conclusion of a scientific panel studying a controversial issue. For all these reasons, the 'scientific advisory committee' approach – valuable as it clearly is – is not enough."

The use of expert advisory groups has been virtually outlawed in the US. See M. Cardozo, "The Federal Advisory Committee Act in Operation" (1981) 33, *Administrative Law Review*, 1. M. Wessel, *op. cit.*, pp. 146-147.

environmental assessment process in Canada (Socio-Economic Impact Analysis (SEIA) and the Environmental Assessment Review Process (EARP)) have resulted in consultations or hearings with the public on issues such as nuclear power plant sites[6] or spent nuclear fuel refining. Although these bodies do not have the power to halt or even delay a development (such decisions rest with Cabinet or Parliament) they have helped to generate public participation.

A variation of this mode is the Cambridge Experimentation Review Board in Cambridge, Massachusetts. The board, composed solely of non scientists, studied the situation and made recommendations.* Success in this instance can be attributed largely to the unique characteristics of the community. This mode is likely only effective in the resolution of local or regional disputes.

In the UK, a similar process is commonly used by advisory bodies composed of experts, bureaucrats and members of the unaffiliated public. These bodies may evaluate a succession of problems or, more commonly, may resolve a single question such as the location of a new airport.

Milton Wessel has explored extending this mode.[7] Wessel's proposed scientific "consensus-finding" conference would limit itself as strictly as possible to scientific issues. It would not claim expertise in determining quality-of-life. The aim would be consensus not negotiation. Ideally, a nonscientist would chair it and the conference would encourage broad scientific involvement through invitations, publicity and voluntary participation. The presence of lay people and the media would prompt socially aware scientists to attend, thus encouraging public acceptance of the results. Such a conference would be effective in influencing administrators, legislators, courts, executives and the public.

Wessel's "consensus-finding" conference is one stage in a formal and publicly visible regulatory process that exists in the US. For such conferences to be used effectively in Canada, formal and open procedures for regulatory decision making must be made mandatory. The conference should be part of a process that encourages public participation in the identification of controversial issues, provides affected parties with ample notification of pending decisions, and hears evidence from a broad range of interests.

For the open consultative mode to work, all groups and individuals must have access to information and expertise to ensure effective participation. To be successful participants must be committed to reaching a viable consensus.

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* A more detailed description of this body can be found in Chapter II.

Chapter VI

Strategies

The need to cope effectively with value-laden scientific disputes is urgent. One of the major difficulties in dealing with contentious issues is that *how* to deal with them is itself contentious. The task will be made easier, however, if we recognize a need for activities directed towards the formation of scientific consensus, particularly when uncertainty masks or distorts an issue.

The public must become more aware of the issues – the scientific aspects as well as questions of social values. The public should have more say in social and policy decisions, and in turn those who make regulatory decisions should be more accountable to the public. And there is a need for experimentation with new strategies for resolving value-scientific disputes* as well as detailed examination of review mechanisms. Our recommendations are intended to contribute to these goals.

Obstacles to New Strategies in Canada

In order to set our recommendations in context, we first list characteristics of the Canadian scene that hinder the development of new strategies. While some of these are unique to Canada, some are shared by other countries.

1. The difficulty of communication and diversity of interests due to the size and regional differences of this country.

2. The powerful economic incentive for industrialized nations to seek and exploit technological innovation, even in the face of recognized scientific uncertainties and ethical dilemmas.

3. Many governments, which results in overlapping responsibility in some areas and neglect in others.

4. The attitudinal and communication gap between the disciplines of law and science. The orientation of traditional science education towards facts divorced from social context and the narrow scope of most undergraduate and graduate programs have produced an overspecialized approach to problem solving.

5. The apathy of the general public about scientific matters.

* Value-scientific controversy is dispute over the social, ethical and political implications of scientific findings and their uses. In many value-scientific controversies the science involved is also disputed. For a further exploration, see pp. 10-11.

6. Inadequate research or experimentation into ways to resolve value-scientific disputes. The Canadian government has not done enough to support or encourage consensus-finding conferences. Groups that might support such activities are scarce, and those that do exist have been less active than their American counterparts. In joint conferences with the US, Canadian concerns are often submerged.

7. The lack of an agreed-upon theory and methodology even to determine what the value choices are, and to establish norms, and to do so in a fair and consistent manner. Attempts to clarify many of the implications of biological research illustrate this deficiency.

8. The low priority given to early warning and preventive mechanisms in the decision-making process.* Future-oriented assessments require constant monitoring, not just case-by-case consideration. Monitoring of the environmental and social impacts of technological development is seldom conducted in a rigorous fashion. Even when monitoring is comprehensive and a problem is detected, an effective mechanism for intervention may not exist.

9. The short-term nature of political attitudes which hinders our ability to deal with long-term scientific and ethical problems. Time and resource limitations constrain government departments to dealing with immediate problems. Commissions of inquiry, one of the more innovative government aids to decision making, are seldom able to address the changing implications of contemporary issues, for they are short-term undertakings. They provide a "snapshot" at a particular point in time.

10. A judicial system oriented to private property rights, negligence and compensation for loss or damage. This orientation is counterproductive to resolving many contemporary disputes where negligence may only be proven over time if at all although the effects may be irreversible and far reaching. The system is also restricted by formal rules of admissible evidence and by the imposition of severe constraints on who may bring action.

* Several innovations have been tested in this regard. The project entitled "Mini-Assessment for Selected Future Environmental Problems" in the Office of Strategic Assessment and Special Studies of the US Environment Protection Agency is an interesting case in point.

11. Inadequate accountability processes. It is common in Canada for regulatory decisions to be reviewed in Cabinet. Government secrecy, particularly at the Cabinet and ministerial levels, conceals the process behind regulatory decisions.[1] Accountability of such decisions is compromised by informal consultations with selected interests.

12. The frequent absence of formal procedures specifying required steps, including public participation, in the preparation of regulations.

13. The lack of strong freedom of information legislation.* Citizen access to the information upon which regulatory decisions are based is severely restricted in the absence of such legislation.

14. Insufficient encouragement or funding of public interest groups to allow for fair representation of diverse interests. Also procedures to administer such funding are lacking.

15. The lack of protection for "whistle blowers" – scientific or technical employees in industry or government who sound warnings about processes or products or call attention to critical research findings. Without a clear policy guaranteeing a fair hearing, many such people remain silent rather than risk their jobs and reputations.†

16. No requirement for cabinet documents to include the scientific and technological factors associated with a proposed policy or action.[2]

17. Limited discussion of value-scientific issues and ways to handle them in Canadian scientific journals.‡

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* On 28 June 1982, Bill B43 was enacted into law. The study is not in a position to comment on the adequacy of the new legislation. Effectiveness may depend on interpretation.

† "Our complex society needs increasing input from those who perceive otherwise unnoted risks or opportunities and bring messages that may be unwelcome to established authorities. To use criticism and dissent constructively in dealing with both risks and opportunities, clear policies are needed, with definitions of procedures for due process in controversial cases and, if necessary, formal hearings and a possibility of appeal." John T. Edsall, "Two Aspects of Scientific Responsibility," *Science 212*, 3 April 1981, p. 14.

‡ *Québec Science* partly serves this function for French-speaking Canada through its letters to the editor and paid inserts.

Areas for Reform and Experimentation

We recommend reforms in the following areas: Parliament, the judiciary, government departments, regulatory agencies, and inquiries.

A More Effective Role for Parliamentarians

Members of Parliament demonstrate little interest in science. Only a small percentage of MPs have a scientific or technological background, in part because a term in political office is not likely to benefit the career of someone committed to a scientific field.[3]

The Ad Hoc Committee of Parliamentarians, Scientists and Engineers (COPSE), which originated from a committee formed in 1976,* is an effort to bridge the gap between parliamentarians and the scientific, engineering and technological communities. Meetings have been organized to discuss a variety of policy issues pertaining to science and technology. This initiative, limited though it may be, may raise the consciousness of MPs, and would familiarize scientists with the constraints inherent in the political process.

More effective participation by parliamentarians would be aided by implementation of the following recommendations:

1. A Standing Committee on Science and Technology should be established jointly by the Senate and the House of Commons. This committee would advise on science- and technology-related issues, including value-scientific questions. The Australian initiative in this area could provide a useful model in determining the mandate and operation of such a committee.† At the same time parliamentary reforms are needed to give such a body the power to *initiate* inquiries into issues within their mandate. The findings of such inquiries should be tabled and debated in the House of Commons.[4]

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* In November 1976 the Association of the Scientific Engineering and Technological Community of Canada (SCITEC) formed a committee of parliamentarians and members of the scientific and technical community in an attempt to bridge the gap between the two camps. Between 1976 and 1978, it met several times to discuss various policy questions with strong scientific and technological components. After a two-year hiatus, the committee has just been reorganized and renamed the Committee of Parliamentarians, Scientists and Engineers (COPSE). It is hoped that the revised meeting format will attract wider participation from both groups.

† One successful innovation in parliamentary involvement in science and technology comes from Australia. Their Standing Committee on Science and the Environment of the Senate was established in March 1976. Members of this non partisan committee scrutinize scientific and environmental matters. Through briefings, background papers, attendance at conferences and visits of inspection, they attempt to assess relative priorities in these areas and conduct public hearings into the most pressing. In addition, the annual reports of various government authorities are referred for examination.

2. Senate appointments should include larger numbers of senior scientists in order to improve attention paid to value-scientific issues, as well as to guarantee an informed membership for the recommended committee.*

3. A parliamentary internship program for scientists should be established. By working in conjunction with the recommended Standing Committee on Science and Technology, such scientists could make a worthwhile contribution, both to government decision making and to the scientific community.†

4. All endeavours to inform Members of Parliament about scientific and related value-scientific matters should be encouraged. The Committee of Parliamentarians, Scientists and Engineers (COPSE) is an important initiative. Many OECD countries have active committees of this type.‡

5. Mechanisms are needed by which concerned Members of Parliament can trigger parliamentary or extraparliamentary assessments of specific issues.

6. The research capabilities of the Library of Parliament Research Branch, Science and Technology Division, should be expanded. This body provides expert non partisan advice to committees and individual MPs and Senators. It is unable to handle many of the requests it now receives.

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* In 1980, no more than ten Canadian senators had worked in a scientific or medical field, and six members were doctors or dentists. These figures were drawn from biographical sketches of Senators in the *Canadian Parliamentary Guide*, ed., Pierre G. Normandin, Ottawa, 1980. There is thus room for slight error, considering the mixed occupational and educational background of Senators. The figures do, however, reveal the preponderance of lawyers and administrators (approximately 57 per cent) in the Canadian Senate, and the dearth of members trained in a scientific field.

† In the US, the Congressional Science and Engineering Fellows Program and the more recent Science, Engineering and Diplomacy Fellows program, coordinated by the American Association for the Advancement of Science in conjunction with sponsoring societies, have been well received. Since 1973, the number of fellows has grown from 6 to 41 per year. Members of Congress are enthusiastic about the program, no doubt because of the high-quality services they receive at no cost. Conversely, sponsoring societies have benefited from better public relations, greater understanding of government operations, and the infusion of scientific and engineering talent into the congressional staff structure. SCITEC (The Association of the Scientific Engineering and Technological Community of Canada) and the Royal Society of Canada should continue their efforts to find money and support for a Canadian counterpart. Further information on US programs, AAAS, 1776 Massachusetts Avenue N.W., Washington, DC.

‡ In Sweden the Royal Swedish Academy of Engineering Sciences established a committee of Engineers, Scientists and Parliamentarians (RIFO). The committee arranges regular discussions about pertinent science-engineering topics, meets with other European parliamentarians, and organizes study trips to industries and institutions in various parts of Sweden. Approximately two-thirds of Sweden's parliamentarians are members.

An Increased Role for the Judiciary

Canada has little tradition of a judicial role in rule making. There are limited grounds for judicial review of a regulatory decision. Our recommendations are aimed at facilitating an increased role for Canadian courts to oversee the proper functioning of government. If a regulatory agency knows that it must follow its mandate and that its procedures can be critically reviewed by a court, it is more likely to consider all aspects of a value-scientific controversy, to review the scientific literature thoroughly, to obtain opinions from independent scientists, and to solicit opinions from interested public groups.

Such an expanded role would be facilitated by implementation of the following recommendations:

1. When exercising statutory powers to make rules with general applicability, departments and agencies should be required by legislation to adopt formal procedures such as: advance notification to affected parties, funding of accredited intervenors, public hearings, advance release of materials relevant to those hearings, publication of documents and oral presentations received by the agency, and boards of review. Such legislation would help ensure that facts and issues are fully disclosed, and that all relevant and necessary scientific information and opinion are brought before the tribunal, and that all interested parties and members of the public have an opportunity to take part. Practices to regularize rule-making procedures are overdue in Canada.*

2. For decision making related to specific cases, procedures to be followed by government departments and agencies should be carefully prescribed in legislation. Such legislation would be similar to that recommended in 1.

3. Legislation also should liberalize standing rules of the courts. Standing rules impose technical constraints. They prevent individuals or groups whose property rights have not been demonstrably affected from seeking judicial review of government decisions in cases in which substantial public interests are at stake. Toxic waste disposal is one such case.

4. The judiciary should conduct more widespread judicial review of government decision making. This could lead to higher standards for inquiry, disclosure and fairness in value-scientific issues.

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* The Law Reform Commission of Canada has recently indicated that an increased role for the judiciary would be appropriate. We look forward to the publication of its detailed comments on administrative procedures, particularly in the area of regulation.

Government Departments and Regulatory Agencies

Government departments can trigger investigations of scientific, technological or value-scientific questions. Differences of opinion within and between departments can prompt a ministerial decision to establish a personal advisory committee or to launch a limited inquiry. Where differences of opinion exist between Cabinet ministers, a commission of inquiry is commonly used to resolve or at least postpone the issue.

Clearly, however, the finer points of resolution of scientific, technological or value-scientific controversies cannot be a major part of the agenda of senior government officials. It is unrealistic to expect any government department to allocate funds from its budget for a special examination of such a controversy because of the inevitable competition for funds within and between departments. The anonymity and secrecy of the public service, coupled with the lack of effective freedom of information legislation, gives the bureaucracy powers that are difficult to check. Also, the departmental process does not have a broad enough base or a sufficiently rigid statutory procedural requirement to ensure its accountability to the public. Further, departmental ministers are responsible only to Parliament and are protected by caucus and Cabinet secrecy. Government departments, in general, have not yet established formal channels for inviting informed comment and for acting on persistently controversial issues. Therefore, we recommend that:

1. Government departments involved in value-scientific disputes should make explicit their consideration of alternative policies, the likely areas of future concern, the range of scientific uncertainty and the probabilities of anticipated risk. Evaluation of a technology should include feasibility, safety, economic factors, psychological aspects and societal impacts. A continuous and comprehensive assessment of field studies and scientific data should follow. The Socio-Economic Impact Analysis (SEIA) and the Environmental Assessment Review Process (EARP) require strengthening to help fulfill these functions.

2. In addition to such anticipatory approaches as SEIA and EARP, government departments and agencies should consider setting up an accountable appeal mechanism, such as a board of review. In many cases, such a board might eliminate the need for judicial review. In contrast to judicial review, a board of review might be in a position to consider the substance of the regulation, as for example in the boards of review mandated under the Hazardous Products Act and the Environmental Contaminants Act.[5]

3. A granting fund to encourage the development of new strategies for handling value-scientific problems should be established. Such a fund would be administered by a granting council such as the Social Sciences and Humanities Research Council (SSHRC) or the Natural Sciences and Engineering Research Council (NSERC). SSHRC's strategic grants program on the Human Context of Science and Technology provides one promising avenue for such research.[6] Bodies such as the Science Council of Canada, the Law Reform Commission, the Secretary of State, the Ministry of State for Science and Technology (MOSST) and the Ministry of State for Social Development should conduct inhouse research, or contract out research in this area as it relates to their own mandates. These activities should be considered as new programs, and priorities and funds allocated on that basis. Among these programs should be research into specific dispute-resolution models.*

4. Scientific and technical advisers within government departments and agencies should act as catalysts for the consideration of science in policy issues. Scientific advisers should be involved in all stages of policy development and should be given sufficient staff and departmental authority to monitor controversial issues and introduce items to the policy agenda. Moreover, senior scientists should be appointed to central agencies such as the Privy Council Office, the Prime Minister's Office and Treasury Board.

5. The federal and provincial governments should use "green papers" to reach the interested public. This approach has been used with some success in the past.†

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* Four basic models for dispute resolution (adversarial, mediational, closed consultative and open consultative) are discussed in Chapter V.

† Traditionally, a government green paper describes the issues, outlines government thinking, and makes tentative policy recommendations. Then public comment is invited. This is followed by a white paper which usually presents a revised government position. The current Québec government has used "green" and "white" papers with some success in areas such as education, energy and cultural development. In 1979, it issued a green paper on scientific research entitled "Pour une politique québeçoise de la recherche scientifique." This was followed by a series of open meetings to which interested members of the public were invited to submit briefs and make verbal comment. A white paper, published in 1980, "Un projet collectif," certainly reflected that input. While many can quarrel with the results of the process it is fair to say that the process itself was above reproach in that it appeared to be an honest attempt to get meaningful input from industrial, academic and government scientists as well as from other interested parties.

This approach was also used by Indian and Northern Affairs with an oil drilling proposal for Lancaster Sound. A preliminary report, incorporating citizen and expert response, has been drafted. See Lancaster Sound Regional Study, "All about the Green Paper" and "The Lancaster Sound Region 1980-2000: Draft Green Paper," DINA, Ottawa, December 1980.

Effective Use of Commissions of Inquiry

As discussed in Chapter IV, an inquiry is one of the most visible and flexible tools used by governments to explore science-related policy issues, to assist decision making, and to bring issues to the attention of the public, policy makers and politicians. An inquiry is a temporary forum, bringing together institutions, advocate groups and members of the public, to address a specific public issue.

Inquiries are not new, but in recent years they have been used more extensively and for a wider range of purposes. Almost every application for a pipeline, oil port, uranium mine or power plant is now subject to an inquiry. Inquiries are used as forums to involve the public in the planning process and are also called in response to the outcries of advocate groups. To those setting up science-related inquiries, at either the federal or provincial levels, we recommend that:

1. The procedures adopted by an inquiry should reflect the kind of information sought. Depending on the question addressed, a successful assessment can take the form of a formally mandated inquiry, an ad hoc assessment panel, or a committee of the legislature. Any inquiry should be given the flexibility and resources to choose among various approaches and techniques. In some cases an adversary process, with provisions for cross-examination, is essential for full disclosure of information. In soliciting information regarding values or social impacts or in delimiting scientific uncertainty, more informal procedures such as community hearings, scientific seminars, commissioned research or consultation are appropriate.

2. Inquiries should take an arbitration approach only when scientific uncertainty is minimal and several sources of research are available. Resources should be devoted to obtaining adequate expertise so that discussion is based on sound scientific advice.

3. An inquiry should address narrow specific questions, but provision should be made for a wide-ranging discussion of relevant scientific issues. Opportunity should be provided for the full discussion of scientific information.

4. Adequate resources must be allocated, including funding to assist and encourage the participation of public interest groups and those directly affected by the proposed development; funding for independent research if necessary; and funding for systematic analysis of the relevant scientific literature and data submitted at the hearings.

5. An inquiry must provide easy access to the written record with detailed justification of its recommendations, taking into account testimony submitted by intervenors. This will contribute to fairness and due process.

General Policy

Our ability to deal with value-scientific disputes would be improved by considering the following:

1. An urgent need exists for a public forum to air value-scientific disputes and discuss methods of handling them. In Québec, *Québec Science*, a successful, provincially subsidized magazine, partially serves this function. A national scientific journal directed towards the widest possible audience should be established to improve dialogue and promote consensus on value-scientific questions. Government funding is essential and ample precedent exists.[7]

2. Scientific associations and societies can make a greater contribution in uncovering value-scientific issues. Such associations, through their journals and membership meetings could promote dialogue on the value and social implications arising from scientific research. They should also participate actively in the parliamentary and bureaucratic arenas. Means such as presenting solicited or unsolicited briefs to parliamentary committees,* departmental advisory groups, inquiries and task forces should also be explored.

3. Scientists have an active role in the resolution of value-scientific disputes. Scientific responsibility requires awareness and communication of the likely impacts of research. Educational institutions, scientific associations, governmental and corporate bodies should foster this attitude.

4. When risk assessment is part of a policy process, the social, political and value assumptions underlying the evaluation of risk, and the trade-offs involved in making a decision must be stated and justified in light of the final decision. This information should be contained in a public record of the decision-making process.

* Although all standing committees will allow unsolicited presentations, and some even advertise for briefs, approval to be heard must be granted by the committee. Also, briefs and presentations must fall within the committee's mandate, which is set by a resolution in the House.

5. Effective freedom of information legislation is essential to allow non-governmental scientists and the general public to scrutinize government research and its applications, to review scientific data used to support specific developments, and to assess the impacts of these developments on society and the environment.

Appendices

Appendix A – Environmental Assessment Review Process

In December 1973, the Canadian Cabinet decided that a process for evaluating the environmental consequences of federal programs and policies was needed. As a result the Environmental Assessment Review Process (EARP) was created on 1 April 1974, and slightly modified in February 1977. The Cabinet memoranda directed the Minister of the Environment, in cooperation with other ministries, to use the process to ensure that the federal government departments and agencies: 1) consider environmental matters throughout the planning and implementation of projects, programs, and activities initiated by the department or agency, or for which federal funds are solicited or for which federal property is required; 2) undertake or obtain an assessment of potential environmental effects before commitments or irrevocable decisions are made for projects which may have an adverse effect on the environment; 3) submit assessments of all projects that will have a significant effect on the environment to the Department of the Environment for review; 4) incorporate the results of environmental assessments and reviews in the design, construction, implementation, and operation of projects, giving environmental problems the same degree of consideration as that given to economic, social, engineering, and other concerns.

EARP currently functions in two independent phases: 1) initial environmental screening by line departments and agencies to determine whether individual proposals are likely to have significant environmental effects; and, 2) formal review of major projects. This phase is administered by the Federal Environmental Assessment Review Office (FEARO). Projects are referred to FEARO by initiating departments when the latter's internal screening processes reveal potentially significant impacts. A panel of experts, appointed by FEARO and the Department of the Environment, undertakes a public review of a detailed impact assessment (EIA). This document is prepared by the proponent/initiating agency, but is supposed to satisfy guidelines prepared by the review panel.

Dr. William E. Rees of the School of Community and Regional Planning, and the Institute of Animal Resource Ecology, University of British Columbia, has written extensively on EARP. He claims that:

> "EARP suffers from the absence of any formal (legal) basis for the process, and total reliance on the concept of self-assessment by proponent/initiating agencies. EARP's success in meeting basic environmental objectives is totally dependent on the extent of cooperative volunteerism within and between individual operating agencies and departments.

"Whether one views this inherent "flexibility" as a fatal flaw or essential strength, EARP has become the principal means by which the federal government evaluates the ecological, and increasingly the socio-economic and technical, impacts of development projects. EARP, or at least the formal review phase, has also emerged as virtually the only organized form for a direct public input into many resource-related decisions that will affect the pattern of Canada's growth and development for decades.

"Why, from an environmental perspective, has the implementation of EARP at both the initial screening and formal review phases, so failed to inspire? Perhaps the most compelling answer lies in the federal government's unswerving devotion to unfettered self-assessment combined with EARP's complete lack of legal force. By consequence, overall responsibility is not clearly assigned to any one department, and none is legally required to do anything. Instead, the matter is left as a question of proponent discretion . . . It appears, then, that the notion of accountability has long since disappeared as an operating principle.

"Through a combination of cooperative will, institutional evolution, and legislation, Canada might conceivably establish ideal procedures for environmental impact assessment. The record suggests, however, that without parallel development of national policy guidelines or even regional/scale planning concepts, even this born again EARP would not work satisfactorily. In the absence of any interpretive policy framework, what precisely does it mean to take 'environmental matters into account'? By what or by whose criteria does an initiator or ultimately a review panel decide whether the anticipated impacts of a project are 'significant'?

"Many of the adjustments required for EARP to rise to full potential could be implemented administratively by FEARO with no change of mandate and without legislation. However, the FEARO requires a stronger mandate, if only to ensure that the government actually does what it claims it is already doing through EARP. Measures can be taken that will create a more rigorous and systematic framework for EARP. In particular it would have to ensure that available information and expertise are brought to bear on major federal development decisions, and that effective interests are adequately represented. Certainly they would reduce present discretion of initiating agencies, mainly by limiting the temptation merely to go through the motions. Until such requirements are in place, the whole elaborate trappings of EARP will continue to function as little more than the ecological conscience of federal agencies, a nagging irritation whose authority is based more on moral suasion than on legal clout.

"Finally, EARP on a project-by-project basis requires a broader, coherent decision framework. The most important contribution of EARP to date has been to display in stark relief the sorry state of senior government policy development. There is increasing awareness that what had earlier been perceived as a problem with EARP is not a problem with EARP at all. While there is a risk of being prematurely optimistic I believe this already has begun to produce positive results, at least at the federal level. It is within an integrating framework that a legislative EARP might find a positively constructive niche."

Source: Dr. William Rees, "EARP at the Crossroads: Environmental Assessment in Canada," accepted for future publication in *Environmental Assessment Review*, Plenum Press, New York.

Appendix B – Study Documentation

Background Studies

The Peripheral Nature of Scientific and Technological Controversy in Federal Policy Formation
Background Study 46, by G. Bruce Doern

Public Inquiries in Canada
Background Study 47, by Liora Salter and Debra Slaco,

Occasional Publications

Social Issues in Human Genetics: Genetic Screening and Counselling,
Proceedings

Biotechnology in Canada: Promises and Concerns,
Proceedings of a workshop sponsored with the Institute for Research on Public Policy

Regulation of Recombinant DNA Research: A Trinational Study
by Howard Eddy, forthcoming

Parliamentarians and Science
by Karen Fish, forthcoming

The Misuse of Psychological Knowledge in Policy Formulation: Three Case Studies
by Jill Morawski, forthcoming

Other Papers

Inquiries into the Use of Potentially Dangerous Products
Manuscript Report
by Liora Salter and Debra Slaco

The Use of a Regulatory Tribunal as an Inquiry
Manuscript Report
by Liora Salter and Debra Slaco

Nuclear-Related Development in Three Provinces
Manuscript Report
by Liora Salter and Debra Slaco

Computers and Privacy: A Preliminary Study
by Paul J. Davidson

Science and the Judicial Process
by Howard Eddy

Proposals for the Resolution of Scientific Controversy the Science Court and Others
by F. Knelman

Bioethics and Public Policy
by Judith Miller

Technological Development and Institutional Response: Historical Dynamics and Contemporary Issues
by Saul N. Silverman and Deanna F. Silverman

Workshops

Social Issues in Human Genetics: Genetic Screening and Counselling
September 1979, Ottawa.

The Peripheral Nature of Scientific and Technological Controversy: A Case Study of Three Federal Departments
5 May 1980, Ottawa.

Biotechnology in Canada: Promises and Concerns
September 1980, Aylmer, Québec.

Issues in Science and the Legal Process
A Workshop Discussion with Prof. J. Ravetz, University of Leeds, England; Dr. S. Jasanoff, Cornell University; Justice G. Le Dain, Federal Court of Appeal, Ottawa; Judge D. Bazelon, US Circuit Court of Appeals, Washington; Dr. R. Sinsheimer, Chancellor, University of California, Santa Cruz
15 and 16 December 1981

Notes

I. Defining the Difficulties

1. For a comparison of legal and scientific methods and the differing perceptions of "truth" in law and in science, see James A. Martin, "Proposed Science Court," *Michigan Law Review*, vol. 75, April/May 1977, p. 1058. A series of essays in *Scientists in the Legal System: Meddlers or Essential Contributers?* ed. William A. Thomas, Ann Arbor Science Publishers Inc., examines the relationships between scientists and lawyers in a number of different contexts.

2. Milton R. Wessel, *Science and Conscience*, Columbia University Press, 1980, p. 4. Wessel is a professor of law with specialized experience in the resolution of complex public interest disputes.

3. *Ibid.*, p. 5.

4. At a meeting with the Science Council in December 1980, Judge Bazelon noted: "In 1946, a judge reviewing agency actions – in rate regulation, labour law, or security law – could be expected to have some understanding of the subjects reviewed. The principal areas of governmental regulation fell more or less within the general experience of most lawyers. Today, new knowledge is fundamentally altering the way we look at ourselves and the world. Society is learning that many so called accidents of fate – cancer, mental retardation, even crime – may be subject to some control. But individuals can neither control nor defend against these forces. The result is a new era of government regulation. When reviewing regulatory action in the many arcane areas of science and technology, a court can have very little real knowledge of substantive questions. And, as the old warning goes, a little knowledge is a dangerous thing." David Bazelon, *Science*, vol. 205, no. 4402, 13 July 1979, p. 277.

5. Robert L. Sinsheimer, "The Presumptions of Science," *Daedalus*, Spring 1978, pp. 23-25.

6. See Howard Eddy, "Regulation of Recombinant DNA Research: A Trinational Study," Science Council of Canada, forthcoming.

7. An extensive discussion of the interrelationship between science and human values is beyond the scope of this report. In *Modern Science and Human Values*, Dell Publishing Co., New York, 1956, Professor Everett Hall, formerly a professor of philosophy at the University of Chicago, pointed out that the *perception* of a dichotomy between scientific facts and human values is a *recent* development. He notes, "It is to the point, to indicate that both positivists and objectors are committed to the admission of a fundamental distinction between facts and values, and that this is something peculiarly modern." Professor Karl Popper in *Unended Quest*, Fontana Press, 1976, notes that a world devoid of life would be a world without values. The discussion is continued in greater depth in Popper's addendum, "Facts, Standards, and Truth," in *Open Society and Its Enemies*, 4th ed., vol. II, Princeton 1966. In a recent British television series, "Men of Ideas," (1978) Professor Brian Magee, in conversation with Dr. Hare, professor of moral philosophy at Oxford, noted, "This notion that facts and values are independent of each other is fundamental to our science-based, perhaps one might even say science-dominated, culture."

8. Science Council of Canada, *Policies and Poisons: The Containment of Long-term Hazards to Human Health in the Environment and in the Workplace*, Report 28, Supply and Services Canada, Ottawa, 1977.

9 See list of research conducted for the study, pp. 85-86.

10. See Liora Salter and Debra Slaco, *Public Inquiries in Canada*, Background Study 47, Science Council of Canada, Ottawa, 1981.

11. G. Bruce Doern, *The Peripheral Nature of Scientific and Technological Controversy in Federal Policy Formation*, Background Study 46, Science Council of Canada, Ottawa, 1981.

II. The Challenge of the New Biology

1. A recent report of a successful selective termination of an abnormal fetus in a twin pregnancy illustrates the choices and risks:

"Presented with the diagnosis of carrying one normal and one affected fetus, the parents were confronted with the difficult task of making one of two decisions: to

induce abortion and lose both fetuses, or to continue the pregnancy. The mother desperately wanted to have the normal child, but could not face the burden of caring for an abnormal child for the rest of her life. Having been made aware of the case report from Sweden in which selective termination of an abnormal twin had been successfully performed even though the unaffected twin was delivered prematurely, she asked if a similar procedure could be offered to her. If it had been refused, she would have chosen to abort both fetuses. At that point, she was referred to us.

"Extensive medical and legal counselling and an explanation of the many risks were provided. These risks included abortion of both fetuses, premature delivery of the surviving fetus, performing the procedure on the wrong twin since markers for sac A or B were lacking, and the development of disseminated intravascular coagulation in the mother as a result of fetal death *in utero*. In view of the fact that the procedure had never been performed in this country, we decided, out of an abundance of caution, to obtain confirmation from a court of law of the parents' right to consent on behalf of the normal fetus."

Thomas D. Kerenyi and Usha Chitkara, "Selective Birth in Twin Pregnancy with Discordancy for Down's Syndrome," *New England Journal of Medicine*, 304, 18 June 1981, pp. 1525-27.

2. Louis Siminovitch, "Genetic Manipulation: Now is the Time to Consider Controls," *Science Forum 33*, vol. 6, no. 3, June 1973, pp. 7-11.

3. "The advent of new understanding and new technologies in genetics and in the control of behaviour raises important ethical issues ... The new knowledge produces new problems on which much new thinking is needed in ethics by theologians, ethicists and scientists meeting together. When such a group was recently brought together by the World Council of Churches..., they formulated an important principle for such discussions. They said, 'Churchmen cannot expect precedents from the past to provide answers to questions never asked in the past. On the other hand, new scientific advances do not determine what are worthy human goals. Ethical decisions in uncharted areas require that scientific capabilities be understood and used by persons and communities sensitive to their own deepest convictions about human nature and destiny. There is no sound ethical judgement on these matters independent of scientific knowledge, but science does not itself prescribe the goal'."

C. Bird and P. Albrecht, eds., *Genetics and the Quality of Life*, Ecumenical Consultation on Genetics and the Quality of Life, Pergamon Press, 1976, p. 203.

A consideration of ethics and technology in LeRoy Walters, "Technology Assessment and Genetics" is also of interest. He argues that technology assessment incorporating ethical considerations can serve as a useful, flexible policy tool in applications of new biological knowledge. See *Ethics and Health Policy*, eds., Robert W. Veatch and Roy Branson, eds., Ballinger Publishing Co, Cambridge, Mass., 1976.

4. Judith Miller, "Bioethics and Public Policy," forthcoming.

5. In its "Guidelines for the Ethical, Social and Legal Issues in Prenatal Diagnosis," (*New England Journal of Medicine*, vol. 300, 1979, pp. 168-72), the Genetics Research Group of the Hastings Center discouraged use of prenatal diagnosis for sex choice. Marc Lappé in "Choosing the Sex of Our Children," (*Hastings Center Report*, vol. 4 February 1974, pp. 1-3) states: "A society which would choose male offspring in preference to females (or vice versa) is probably not one which is ready for the responsibility of assuming regulation of the balance between men and women. Certainly, one which would preferentially deny rights and opportunities to women would appear to disqualify itself as having the necessary fairness and wisdom to proffer to its citizenry the option of sex selection."

The Winnipeg centre for prenatal diagnosis has a policy not to tell parents the sex of the fetus until after the second trimester, except in cases of sex-linked disorders. In general, participants at the Science Council workshop argued that sex choice not be the motivation or result of prenatal diagnosis. The opposite view and its implications are discussed in: "Prenatal Diagnosis for Sex Choice," *Hastings Center Report*, vol. 10, February 1980, pp. 15-20.

6. "Prenatal Diagnosis, Past, Present, and Future: Report of an International Workshop," John L. Hamerton and Nancy E. Simpson, eds., Hotel Sapinière, Val David, Québec, 4-8 November 1979.

7. "Canadian Guidelines for Antenatal Diagnosis of Genetic Disease: a Joint Statement," *Canadian Medical Association Journal III*, 1974, p. 180.

8. Medical Research Council, *Diagnosis of Genetic Disease by Amniocentesis During the Second Trimester Pregnancy*, Report No. 5, Ottawa, 1977.

9. See *Social Issues in Human Genetics: Genetic Screening and Counselling*, proceedings of a workshop, Science Council of Canada, September 1980. A national policy group is discussed on pp. 88-95.

10. The Ontario Council of Health recommends that mass screening programs for detecting genetic disease be instituted only when:

- quick follow-up methods of definitive diagnosis are available;
- prompt treatment is available with facilities for its careful control;
- genetic counselling services and access to amniocentesis programs are available; and
- all the psychological, social, legal and other implications of such programs have been examined.

See Ontario, Task Force on Genetic Services, *Genetic Services: A Report of the Ontario Council of Health*, Ontario Council of Health, Toronto, 1976, p. 7.

See also Philip Reilly, *Genetics: Law and Social Policy*, Harvard University Press, Cambridge, Mass., 1977.

11. For a further discussion of the effects of mandatory screening laws, see Philip Reilly, *op. cit.*; and Samuel P. Bessman and Judith P. Swazey, "Phenylketonuria: A Study of Biomedical Legislation," *Human Aspects of Biomedical Innovation*, E. Mendelson, J.P. Swazey and Irene Tavies, eds., Harvard University Press, Cambridge, Mass., 1971.

12. For further discussion see Philip Reilly, *op. cit.* Also discussion of the psychological aspects of genetic counselling can be found in *Genetic Counselling: Psychological Dimensions*, Seymour Kessler, ed., Academic Press, NY, 1979.

13. See Thomas H. Maugh, "Sickle Cell (II): Many Agents Near Trials," *Science*, vol. 211, no. 4481, 30 January 1981, pp. 468-70; and also "Method Detects Sickle Cell Anemia in Fetuses," *Chemical and Engineering News*, vol. 59, no. 18, 4 May 1981, p. 5.

14. For further discussion of the Asilomar conference and the events leading up to it, as well as of public anxiety concerning recombinant DNA research, see Howard Eddy, "Regulation of Recombinant DNA Research: A Trinational Study," forthcoming; and Clifford Grobstein, *A Double Image of the Double Helix: The Recombinant DNA Debate*, W.H. Freeman, San Francisco, 1979.

15. See, John Abelson, "A Revolution in Biology," *Science*, vol. 219, 19 September 1980, pp. 1319-21; "Gene Transfer Moves Ahead," *Science*, vol. 210, 19 December 1980, pp. 1334-36; "The Complete Index to Man," *Science*, vol. 211, 2 January 1981, pp. 33-35.

16. Robert Walgate, "Single Cell Protein Organism Improved," *Nature*, vol. 284, no. 5756, 10 April 1980, p. 503.

17. Judith Miller, "Biotechnology and University Ethics," *Westminster Institute Review*, October 1981, pp. 6-8.

18. H.R.S. Ryan, "A Statement of Concern for Biotechnology," *Biotechnology in Canada: Promises and Concerns*, proceedings of a workshop, Science Council of Canada, September 1980, pp. 60-61.

19. "Genetic Manipulation: Now is the Time to Consider Controls," *Science Forum 33*, vol. 6, no. 3, June 1973, pp. 7-11.

20. See Arthur L. Caplan, "Ethical Engineers Need not Apply: the State of Applied Ethics Today," *Science, Technology, and Human Values*, vol. 6, no. 33, Fall 1980, pp. 24-32; and Dorothy Nelkin "Wisdom, Expertise, and the Application of Ethics," *Science, Technology, and Human Values*, vol. 6, no. 34, Winter 1981, pp. 16-17.

21. Grobstein, "Guidelines for the Use of Recombinant DNA Molecule Technology in the City of Cambridge, January 1977," Appendix IV, *op. cit.*, p. 154.

22. Bernard M. Dickens, "New Laws for New Knowledge?" *Canadian Family Physician*, vol. 25, August 1979, p. 891.

III. The Government Process

1. A. Hellman, M.N. Axman, R. Pollack, eds., *Biohazards in Biological Research*, Cold Spring Habour, NY, 1973.

2. Letter published in *Science*, vol. 181, 1973, p. 1114.

3. The discussion of decision making within government draws heavily upon G. Bruce Doern, *The Peripheral Nature of Scientific and Technological Controversy in*

Federal Policy Formation, Background Study 46, Science Council of Canada, Ottawa, 1981, pp. 67-86.

4. This committee, known as the Hare committee, is described in: Canada, Energy, Mines & Resources, *The Management of Canada's Nuclear Wastes,* Supply and Services, Canada, Ottawa, 1977. See also Salter and Slaco, "Nuclear-Related Development in Three Provinces," Manuscript Report, Science Council of Canada, January 1982, pp. 227-231.

5. Judge David Bazelon of the US Circuit Court of Appeals described the US Court's role in his address to the Science Council: see "Science and the Legal Process: A U.S. Judicial View," *Issues in Science and the Legal Process: A Workshop Discussion,* forthcoming.

"Whether *such procedures* can be judicially *imposed* has been the subject of much controversy in the US. Current American efforts to reform the administrative process concede the necessity of further structure in rule making. Debate focusses on whether Congress, the agencies themselves, or the courts will impose the added procedures.

"Judicial review is a device to control the administrative process. It can also defeat some administrative action. The court guarantees the fairness and obedience to the law of the administrative procedure. The court cannot possibly "second guess" the administrator on the scientific merits of a case; to do so would frustrate the legislative policy which created the administrative body in the first place. Administrative bodies have the technical expertise to deal with the scientific aspects of a case, unlike judges who usually have no particular scientific expertise."

6. *Nicholson vs Haldimand, Norfolk Regional Board of Commissioners of Police* (1978) 88 D.L.R. (3d) 671 (S.C.C.); *Islands Protection Society vs Regina.* (1979) 4 W.W.R. 1 (B.C.).

IV. The Inquiry Process

1. Some useful discussion on inquiries in Canada can be found in: George F. Henderson, ed., *Federal Royal Commissions in Canada 1867-1966, A Checklist,* University of Toronto Press, Toronto, 1967; Gerald Le Dain, "The Role of the Public Inquiry in Our Constitutional System," *Law and Social Change,* ed., J.S. Zeigel, Osgoode Hall Law School, Toronto, 1973; J.D. Maxwell, "Royal Commissions and Social Change in Canada," unpublished PhD dissertation, University Microfilms, Ann Arbor, Michigan, 1966; and V. Seymour Wilson, "The Role of Royal Commissions and Task Forces," *The Structures of Policy Making in Canada,* eds. G.B. Doern and Peter Aucoin, MacMillan, Toronto, 1971.

2. For a discussion of the environmental assessment process in Ontario, Saskatchewan and for federal projects, see Liora Salter and Debra Slaco, *Public Inquiries in Canada, op. cit.,* pp. 51-62; for more detailed discussion, see Liora Salter and Debra Slaco, "Nuclear-Related Development in Three Provinces," Manuscript Report, Science Council of Canada, January 1982, pp. 45, 119, 125 and 211. (Hereafter cited as "Nuclear-Related Development")

3. For a full discussion of the implications of using risk methodologies in an assessment, see Salter and Slaco, *Public Inquiries in Canada, op. cit.,* pp. 156-159.

4. "Nuclear-Related Development," *op. cit.,* p. 167.

5. Salter and Slaco, *Public Inquiries, op. cit.,* p. 73.

6. Organisation for Economic Cooperation and Development, *Technology on Trial: Public Participation in Decision-Making Related to Science and Technology,* Paris, 5 September 1978, SPT 78 (18) Scale 2, pp. 11-12.

7. For a full discussion of inquiries and planning see "Nuclear-Related Development," *op. cit.,* pp. 285, 288 and 303-305.

V. Modes of Dispute Resolution

1. Salter and Slaco, *Public Inquiries in Canada, op. cit.,* pp. 107-108

2. F. Knelman, "Proposals for the Resolution of Scientific Controversy: The Science Court and Others," forthcoming.

3. See, for example, the presentation by Ms. Ronny Brooks on the unsuccessful effort to hold a science court on power lines in the state of Minnesota, presented in the panel on "Resolution of science and technology controversies" at the Edison Convention, 3 April 1979, San Francisco, California. Tapes of the session available from Adams Convention Reporting, 11 Galway, San Rafael, CA.

4. M. Wessel, *op. cit.*, p. 35.
5. D. Nelkin and M. Pollak, *op. cit.*, pp. 312, 315.
6. Salter and Slaco, *op. cit.*, pp. 47-62.
7. M. Wessel, *op. cit.*, pp. 173-183.

VI. Strategies

1. Canada, Royal Commission on Financial Management and Accounting, *Final Report,* March 1979, pp. 21-30.
2. Doern, *op. cit.*, pp. 52-54.
3. Karen Fish, "Science Resources for Parliamentarians," unpublished paper.
4. For further discussion of committee reform see Roman March, *The Myth of Parliament,* Prentice-Hall, 1974, pp. 120-134.
5. For a discussion of boards of review, see Environmental Contaminants Board of Review, *Report on Outside Review and Public Participation,* Part 2, Environment Canada and Health and Welfare Canada, July 1980.
6. See "The Strategic Grants Program Guidelines" and the extensive background papers (3 volumes) prepared on "The Human Context of Science and Technology," Strategic Grants Division, Social Sciences and Humanities Research Council, Ottawa, Ontario.
7. See *Government of Canada Publications,* Department of Supply and Services.

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Regulating the Regulators

Science, Values and ıs

Summary of Report 35

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The bulk of legislative and regulatory decision making, in Canada and throughout the world, is devoted to coping with the effects of scientific and technological developments. As a result, most policy issues today contain a scientific or technological element.

In some cases, the scientific component of a policy issue is not controversial — the vaccination of children for smallpox is an example. In many others, the science is uncertain, perhaps even unknown — nuclear power development, the freon-ozone interaction in the stratosphere, and the environmental effect of pesticides. Most common of all, and inclusive of the previous two categories, are value-scientific disputes that pivot not only on laboratory findings but also on the values involved in interpreting that information for public policy purposes — human exposure to asbestos, the control of acid rain, and the criteria and techniques for offering genetic screening and prenatal diagnosis fall into this category. In these cases, the facts and values involved are not easily separated and the objectivity of the science itself can be called into question.

The search for ways to involve the public in issues of scientific origin and to mesh science and value elements to arrive at sound public policy choices highlights anew some of the weaknesses of our governing system and demands a rethinking of our decision-making process. The Science Council's latest report, **Regulating the Regulators: Science, Values and Decisions,** addresses this challenge.

Developments emerging from the biological sciences in particular are challenging for our system of laws and regulations. Today scientists are able not only to describe life but also to manipulate, reshape and ultimately create it. With this new power come ethical dilemmas that many now say are not the exclusive preserve of those making the discoveries.

The recent discovery of biological techniques such as recombinant DNA (a genetic technique used to give new characteristics to a host cell), the combining of embryo

cells of two species to create a hybrid organism, and the engineering of life forms to perform special functions have given today's scientists more control over the evolution of life than they had ever previously imagined. The 1973 conference held in Asilomar, California was inspired by concern over the potential hazards posed by recombinant DNA experimentation. Pending further evaluation, a moratorium was called on certain lines of research; and although recent research has indicated that the risks involved in the technique are insignificant, the conference paradoxically revealed how value-scientific issues can remain unquestioned by the scientific community. No attempt was made to allay public concern over the morality of designing lifeforms or the wisdom of endeavouring to meddle with evolution. Such issues were considered to be beyond the realm of scientific concern.

As scientists search for new means to identify potential diseases through genetic screening, more attention should be placed on the possible repercussions of such information. How will it be used? And by whom? Will individuals, marked as potential illness victims, be excluded from workplaces considered dangerous to their health? Or life insurance policies? Will the onus for occupational health risks be shifted from industry to the individual? Women, in particular, might not be considered for jobs potentially threatening to their fertility or the health of their unborn children rather than industry taking the initiative and providing a safe work environment. Such questions require careful and urgent consideration.

In **Regulating the Regulators,** the Science Council argues that Canada's legal system has not addressed the difficult legal and ethical questions posed by the new biology. In the words of Professor Bernard M. Dickens of the Law Faculty, University of Toronto, "It is distressing that so many of these questions are not simply unanswered in Canada, but unasked."

This Science Council report, the result of a three year

research study, describes some of the most potentially beneficial and also disruptive developments in the new biology. It explores traditional Canadian approaches to resolving value-scientific disputes in search of new ways to handle the types of questions raised by this powerful area of science.

The report's discussion of the development of recombinant DNA controls in the United States, Britain and Canada reveals how different styles of governing affect the regulatory process. Whereas in the US all aspects of the potential effects of this technique were disclosed and the controversy drew a great deal of public attention, in Canada, the regulatory problem was dealt with mainly by the scientific community and government officials. The Canadian approach was bureaucratic rather than political.

The report uses this case to emphasize the need for more transparent and accountable decision making in Canada. The current relatively closed process of departmental deliberations works against the incorporation of a wide range of scientific and public evidence. The multitude of demands placed on a federal department by other agencies, political ideologies, and diverse regional and special interest groups, make it easy for scientific aspects of a controversy to be ignored unless external pressures, such as the media, force departmental officials to take notice. The common failure of departments to disseminate information and provide an avenue for feedback often aggravates the lack of scientific knowledge among senior officials. In addition, the Canadian traditions of ministerial responsibility and civil service anonymity make it difficult to hold anyone accountable for a decision made below the ministerial level. Greater accountability will only be achieved if the responsibility and basis for government decisions are put on public record, if the background documents on which these decisions were based are freed from the seal of Cabinet secrecy, if information about where and when government decisions are being made is easily accessible

and if statutory requirements for broader and better public participation are enforced.

Judicial review of the fairness and procedures of departmental and regulatory decision making is one way of protecting the interests of citizens and knowledgeable outsiders. Many consider the Canadian judiciary to be overly cautious and therefore an inadequate supervisor of the bureaucracy. Recent judicial decisions in Canada suggest that our courts may be expanding their supervisory role over the "executive" branch of government, a direction that the Science Council supports — the greater accountability and due process that result from this development are seen to outweigh the possible concomitant delays and occasional inequities.

Parliamentarians are also heavily dependent on the bureaucracy for scientific information and lack the resources to scrutinize the validity of data on which policies are based. Because of the heavy administrative and constituency workload carried by MPs and the powerlessness of most members to effect change in legislation put before them, neither the House of Commons nor its Standing Committees currently provide an adequate forum to assess the scientific aspects of an issue.

In Canada, inquiries have often been commissioned to conduct scientific assessments.* In six inquiries studied by the Science Council (including the Royal Commission on the Non-Medical Use of Drugs, the Cluff Lake Board of Inquiry in Saskatchewan and the Aluminum Wiring Inquiry in Ontario) scientific debate was found to be minimal. The often trial-like nature of public hearings, the pressure to reach consensus and the sometimes strident advocacy of participants discouraged the participation of all but a few scientists who were not affiliated

* Because most inquiries of this type air scientific information in response to public policy needs, the subjects discussed generally have a prominent value component.

with a government department, proponent company or advocate group. The value and quality of the scientific assessment suffered as a result. The value-scientific assessment conducted by these inquiries also suffered **from a lack of reliable data in several pertinent areas. Data are seldom available about how susceptible a particular population may be to different risks, alternatives for economic development, the economic and social consequences of a particular regulation or even about** the willingness of segments of the population to accept a risk. The final frustration for people involved in an inquiry is that the innovative recommendations they produce are often neglected. Governments want noncontroversial solutions to a problem and an inquiry that produces a sophisticated assessment of the issues often finds its analysis passed over in favour of a simple recommendation taken out of context.

In **Regulating the Regulators,** the Science Council argues that the speed of technological change is now too fast for our social and legal processes to adapt, resulting in a crisis-to-crisis response on the part of government. The report challenges the economic imperative that drives industrialized nations to exploit technological innovations even in the face of scientific uncertainty and ethical dilemmas and calls for scientists, the public and decision makers to seek new ways to deal with existing and surfacing value-scientific controversies.

The Science Council recognizes that this challenge is not an easy one. Two recent attempts to create a model policy process (the Environmental Assessment Review Process and the Socio-Economic Impact Analysis) demonstrate that innovative and refreshing approaches do not always produce better or more publicly acceptable decisions or attract previously silent sectors of the public. Therefore, Council's recommendations are aimed at sensitizing policy makers and the public to the **role and limitations of science in the decision-making process.**

In **Regulating the Regulators,** the Science Council recommends:

- that a Standing Committee on Science and Technology be established jointly by the Senate and the House of Commons to advise on scientific matters, including value-scientific questions and to initiate inquiries into issues within their mandate;
- that formal procedures be required by legislation of departments and regulatory agencies to ensure that facts and issues are fully disclosed, that all relevant scientific information and opinion are brought forward, and that all interested parties and members of the public have an opportunity to take part;
- that the judiciary conduct more widespread judicial review of government decision making to ensure higher standards for inquiry, disclosure and fairness in value-scientific issues;
- that a federal government granting fund be established to encourage the development of new strategies for handling value-scientific problems;
- that Commissions of Inquiry be provided with sufficient resources for a comprehensive assessment of the issues, including funds to assist and encourage the participation of public interest groups and those directly affected by the proposed development, for independent research, and for a systematic analysis of the relevant scientific literature and data submitted at the hearings.

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