Biotechnology, Ethics and Government

A Synthesis

Prepared for

The Canadian Biotechnology Advisory Committee
Project Steering Committee
On Incorporating Social and Ethical
Considerations into Biotechnology

By

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October 2000

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Michael McDonald, PhD

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Table of Contents

Executive Summary

The general aim of this report is to provide (a) a synthesis of six papers prepared for the government of Canada dealing with ethics and biotechnology and (b) an indication of gaps in information provided in those papers. CBAC's role as an advisor to the Government of Canada on all aspects of biotechnology including socio-ethical and legal aspects is taken as a starting point for this paper.

In Section I, consideration is given to the Government of Canada's involvement in biotechnology, especially in regard to areas where ethical issues are salient. This is described in terms of the evolution from the mainly economic development oriented National Biotechnology Strategy to the more inclusively oriented Canadian Biotechnology Strategy. Included here is a discussion of the roles and responsibilities of government and general expectations with regard to governance in the area of biotechnology policy.

In Section II, a broad overview is provided of ethics – outlining key concepts and approaches. Ethical judgements are described as integrative, holistic, or "all things considered" judgements requiring the intelligent integration of different types of knowledge and expertise. Ethics or moral philosophy involves the systematic study of norms and values in particular actions (right and wrong), consequences (good and bad), and character (virtue and vice). Ethics has three parts: descriptive ethics, theoretical ethics, and normative ethics, each of which has relevance to biotechnology policy as illustrated by the case of recombinant bovine somatrophin rBST. In policy areas, it is argued that ethical claims are based on appeals to general principles – principles that are often widely accepted but nonetheless open to argumentation and revision.

In Section III, the previous discussion of ethical concepts is used to show how ethics can illuminate public policy. Specifically, the use of ethics in public policy is described in terms of judiciously balancing or weighing relevant considerations – particularly principles in common use. In a liberal democratic society, public policy making appeals to liberal and democratic principles. Discussions of the ethics of public policy in the Canadian context are rooted in rich soil – equality before and under the law, democratic participation in government, accountability, the equal dignity of persons, pluralism, multiculturalism and the like. Some of the principles are substantive (equal dignity) and others are procedural (equal treatment before and under the law). Others have to do with standards of good governance in a democratic society – transparency (openness in decision-making) and the accountability of governors to the governed.

In Section IV, there is a general characterization of leading ethics themes in the biotechnology and alternative governmental approaches to them. Four major ethical questions are presented in the area of biotechnology. (1) How should public policy address uncertainties, whether real or perceived, about biotechnology? (2) Should there be social control over biotechnology? (3) Does biotechnological research and development show appropriate 'respect for life'? (4) How should government reconcile its role as a major promoter of biotechnology with its significant responsibilities as a regulator? Three examples of international experience with ethics advisory committees in biotechnology are also provided.

Finally in Section V, suggestions are made about future directions for research. Five topics or areas are suggested for further investigation: (1) the precautionary principle and other standards for dealing with complex benefits/harms tradeoffs under conditions of uncertainty; (2) so-called "fourth hurdle" restrictions on biotechnology; (3) concerns about

the dual roles of government as a promoter and regulator of biotechnology in the private and public spheres; (4) normative sources for Canadian governance of biotechnology including domestic, foreign, professional, industrial and other sources; and (5) current international work on ethics and biotechnology whether governmental, quasi-governmental, professional or from the NGO sector.

Foreword

This paper was commissioned by the CBAC. The paper has two primary aims. The first is to provide a synthesis of six papers on ethics and biotechnology written for the Canadian Government during the period 1996 to 1999. The second aim is to provide an assessment of where the papers take CBAC in terms of ethics and biotechnology and following from that an identification of areas for further development.

Three of the papers appeared as a 1998 Resource Document *Renewal of the Canadian Biotechnology Strategy* (RCBS) for the Canadian Biotechnology Strategy Task Force:

- "Ethics and Biotechnology: The Role of the Government of Canada" by Derek Jones (1997)
- "Making Ethically Acceptable Policy Decisions: Challenges Facing the Federal Government" by Ted Schrecker and Margaret A. Somerville
- "Biotechnology, Ethics and Government: Report to the Interdepartmental Working Group on Ethics" by Ted Schrecker, Barry Hoffmaster, Margaret A. Somerville and Alex Wellington

The other three appeared as separate documents:

- "Socioethical Implications of Biotechnology" by Jennifer Espey et al, Sponsored by the Department of Western Economic Diversification (1997)
- "Government & Biotechnology: Ethics Frameworks to Manage Moral Uncertainty & Policy Development", by Derek Jones, prepared for the Working Group on the Advisory Body, Ethics & Public Confidence of the Canadian Biotechnology Strategy Task Force (1998)
- "Towards a Coherent Ethics Framework for Biotechnology in Canada" by Derek Jones, prepared for the Government of Canada Interdepartmental Committee on Ethics in Biotechnology (1999)

In preparing this synthesis, attention has been given to the identification of possible gaps in the research. Nonetheless, this paper is not intended as an original research paper. Naturally in a synthesis of several hundred pages, detail has to be sacrificed for comprehensiveness and clarity. There is not enough room to offer the detailed survey of literature in ethics, law, government, science, risk, etc. covered in the six original papers.

I wish to express my appreciation to members of CBAC, in particular Dr. Arthur Hanson, Dr. Françoise Baylis, and Mr. Jonathan Syms, as well as Linda S. Williams, Senior Policy Advisor for CBAC for their comments on the outline for this report and the first draft.

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Introduction

As indicated in the Forward, the general aim of this report is to provide (a) a synthesis of the six papers dealing with ethics and biotechnology and (b) an indication of gaps in information provided in those papers. That is, given (a), it is worth asking (b) what do the six papers in question provide CBAC and what sorts of papers, studies, or other types of research might usefully advance the discussion beyond the areas covered by the six papers. CBAC's role as an advisor to the Government of Canada on all aspects of biotechnology is taken as a starting point for this paper.

This paper has five sections. In Section I, consideration is given to the Government of Canada's involvement in biotechnology, especially in regard to areas where ethical issues are salient. Included here is a discussion of the roles and responsibilities of government and general expectations with regard to governance. In Section II, a broad overview is provided of ethics – outlining key concepts and approaches. In Section III, the previous discussion of ethical concepts is used to show how ethics can illuminate public policy. In Section IV, consideration is given to leading ethical questions that have been posed about public policy for biotechnology. Finally in Section V, suggestions are made about future directions for research. Here, lessons are drawn from both Canadian and international practices in the area of ethics and public policy.

Section I: Government, ethics and good governance

A. The National Biotechnology Strategy

A useful starting point is the federal government's National Biotechnology Strategy (NBS) initiated in 1983.[1] NBS was designed to forward industrial development: it had four objectives:

1. Focussing biotechnology research and development on areas of strategic importance to Canada
2. Promoting the creation of human resources for biotechnology
3. Facilitating collaboration amongst sectors involved in biotechnology
4. Creating a positive investment climate for biotechnology

The mandate for the promotion of biotechnology lay with Industry Canada. Industry Canada worked with Health Canada, Agriculture and Agri-Food Canada, and Environment Canada. Health Canada was involved in the regulation of biotechnology; the other departments were involved in both the regulation and promotion of biotechnology. To facilitate public and private cooperation, several biotechnology networks were established. The National Research Council also devoted significant resources to biotechnological research and development.

[1] Espey 1997, p. 10. Barrett provides a good introduction to this strategy in her recent dissertation on canola. Katherine Barrett *Canadian Agricultural Biotechnology: Risk Assessment and the Precautionary Principle*, University of British Columbia, Department of Botany, PhD Dissertation 1999, pp. 79-80.

The NBS was instrumental in the creation of a substantial biotechnology industry in Canada. Thus, in 1995 there were five hundred biotechnology companies in Canada, employing twenty-three thousand people, and generating two billion dollars in annual revenue. At that time Canadian biotechnology companies were involved in developing applications in health care (44%), aquaculture and agriculture (28%), chemical products (17%), environment (10%) and mining, forestry and energy (1%).[2] Biotechnological products are in common use in Canada today. Medical products include insulin, human growth hormone, vaccines, and new cancer treatments. Genetically engineered herbicide resistant canola is the leading example in the agricultural area. [3] The bacterium B.T. is used to manage the spruce budworm and the gypsy moth in the forestry sector.

B. A growing concern for ethics

As the NBS was implemented, there were increasing public concerns about biotechnology and with that a growing awareness on the part of government and industry of those concerns. In particular, the mixed role of government as both the promoter and regulator of biotechnology drew criticism. In response to this and other public concerns, a number of federal interdepartmental groups were formed, including the Sub-Group on Public Awareness, the Sub-Group on Intellectual Property, and the Sub-Group on Communications. In the early 1990's various stakeholder workshops were held including workshops on proposed changes to the *Environmental Protection Act* (1992), public awareness of biotechnology (1993), the development of guidelines for labelling genetically modified foods (1994), and forest pest management applications (1995). In 1994, an Inter-departmental workshop was held on the ethical concerns raised by biotechnology. This workshop raised four highly relevant concerns:

1. Should departmental guidelines and regulations be developed or changed to reflect ethical considerations?
2. Should a new policy be developed, and, if so, at what level?
3. Should ethics committees be established at the departmental or interdepartmental level?
4. Should a multi-stakeholder committee be established?

Further evidence of the public's and the government's concerns with ethical issues in respect to biotechnology can be found in several reports issued by federally supported agencies and commissions. These include:

- The ethical implications of genetic testing[4]
- The ownership of human tissue[5]

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[2] Espey 1997, p. 10. The figures are from 1992 and should be updated and illustrated in graph form to show the rapid growth of the area.

[3] See Barrett

[4] Science Council of Canada, *Report 42: Genetics in Health Care*, Ottawa 1991 and Law Reform Commission of Canada, *Genetic Heritage* (study paper by B.M. Knoppers) Ottawa, 1991. See also the *Tri-Council Policy Statement on the Ethical Conduct of Research Involving Humans*, Ottawa 1998.

[5] Law Reform Commission of Canada, *Procurement and Transfer of Human Tissues and Organs*, Ottawa 1992. See also the *Tri-Council Policy Statement on the Ethical Conduct of Research Involving Humans*, Ottawa 1998.

- Gene therapy[6]
- DNA Banks and privacy[7]
- New reproductive technologies involving biotechnological research and applications[8]
- Labelling of genetically engineered food[9]

The subjects of these documents provide an illustrative sample of some leading ethical issues in biotechnology. Each of these might be seen as presenting good news/bad news possibilities raising in many cases ethically problematic choices. Thus, on the one hand, genetic testing may provide individuals with important health information and may ultimately lead to efficacious treatments for some. On the other hand, genetic testing may lead to discrimination with respect to employment and insurance against those carrying particular genetic markers; it may even lead to groups being (further) stigmatized and marginalized. On the non-medical side, genetically modified foods (and organisms) have the promise of creating a more secure, economical and enhanced food supply. At the same time, many have concerns about "Franken-foods" and the potential breeding of super-weeds and other adverse effects (e.g., the loss of biodiversity through the escape of genetically modified seeds and fish). Each of the areas represented in these reports raises difficult questions about complex choices. These include questions about risks and safety (e.g., who has the burden of proof?), fairness (e.g., will a new technology impose unfair burdens on some?), human dignity (e.g., genetically engineering super- or sub-humans), and human control over nature (e.g., does biotechnology represent an improvement on or an assault against the natural order?). Linking many of these issues are concerns about the role of government in the promotion and regulation of biotechnology.

In 1998, the Canadian Biotechnology Strategy (CBS) replaced the NBS. The CBS was intended to balance industrial development with social and ethical concerns. The 1998 Canadian Biotechnology Strategy proposed the establishment of an independent advisory committee on biotechnology. This committee was created in 1999 as the Canadian Biotechnology Advisory Committee (CBAC). CBAC provides advice to government on socio-ethical issues of biotechnology and their implications for public policy as well as on many other related areas – social, ethical, legal, environmental, health, regulatory, economic and scientific. Previously under the NBS, the national advisory body (which was called the National Biotechnology Advisory Committee) was composed of CEOs of biotechnology companies and university biotechnology researchers and reported to Industry Canada. Under the CBS, CBAC is composed of individuals drawn from the scientific, business, general public, ethics and environmental communities and reports to the ministers of the seven federal departments concerned with biotechnology.[10] Part of CBAC's mandate is "to raise public awareness and engage Canadians in a dialogue

[6] Medical Research Council of Canada, *Guidelines for Research on Somatic Cell Therapy in Humans*, Ottawa, 1992. See also the *Tri-Council Policy Statement on the Ethical Conduct of Research Involving Humans*, Ottawa 1998.

[7] *Privacy Commissioner of Canada, Genetic Testing and Privacy*, Ottawa 1992.

[8] Royal Commission on New Reproductive Technologies, *Proceed With Care*, Ottawa 1993.

[9] Agriculture Canada, Food Inspection Directorate, *Communiqué: Labelling of Novel Foods Derived Through Genetic Engineering*, Ottawa, Dec. 1995

[10] These are Health Canada, Industry Canada, Department of Fisheries and Oceans, Agriculture and Agri-Food Canada, Natural Resources Canada, Environment Canada, Department of Foreign Affairs and International Trade.

concerning issues raised by the development and application of biotechnology."[11] To this end, it has standing committees devoted to stewardship ("social, ethical, legal, environmental and regulatory dimensions"), economic and social development ("scientific developments leading to biotechnological innovations and their applications to health, the environment and the economy") and citizen engagement.

C. Governmental roles and responsibilities

With respect to biotechnology, the Government of Canada has appeared in a variety of roles, including the following:

- Investing public monies in research and development either through public sector agencies (e.g., Agriculture Canada) or through grants or other types of financial assistance to university-based researchers or private sector researchers;
- Establishing cost-sharing programmes for industry to develop collaborative relationships with universities and provincial research groups;
- Encouraging and funding the exchange of personnel amongst federal, provincial, university and industry research units;
- Working to harmonize domestic and international regulations with biotechnological development in Canada;
- And, most recently, through CBAC explicitly seeking expert advice and citizen engagement on multiple aspects of biotechnology including ethical, legal, social, economic, and scientific issues.

These should be seen as related to central governance responsibilities for the federal government (some of which are shared with provincial governments). These include first of all the general responsibilities of the government as a fiduciary of public duties, trust and monies. Second, the federal government has significant responsibilities in the area of public health and safety. Third, the federal government has responsibilities arising from its direct (e.g., through research grants and in-house research) and indirect (e.g., through taxation policies and leadership) roles in research and development. Fourth, government has responsibilities as a standard-setter and regulator in such areas as patents, licenses and regulations. In some cases, the standard setting is direct and in others it works indirectly though the use of spending powers.[12] Fifth, most prominently through the courts, but also through administrative tribunals, the government has formal responsibilities for resolving disputes and, through precedent, the framing of legal claims. Sixth, the federal government acquires responsibilities as a result of agreements with other nations in areas important to biotechnology, such as health, scientific and biomedical research, agricultural regulations, international trade and related areas (e.g., intellectual property). Seventh, democratically elected governments have a general duty to be responsive and accountable to their citizens.

D. Expectations with regard to good governance

Governments at all levels have a responsibility to meet standards of good governance. The University of Ottawa's Centre for Governance says that at the organizational level governance is "about the processes by which human organizations,

[11] CBAC web-site: http://cbac.gc.ca

[12] Research involving human subjects and research involving animal subjects are two examples of the latter.

whether private, public or civic, steer themselves."[13] Governance is also relevant at the inter-organizational level. The Ottawa Centre for Governance notes that at this level governance pertains to:

- the complex ways in which private, public and social organizations interact and learn from one another;
- the manner in which citizens contribute to the governance system, directly and indirectly, through their collective participation in civil, public and corporate institutions; and
- the instruments, regulations and processes that define the "rules of the game."[14]

So good governance for an organization, like a government, university or business, would include such common features as "a clear mission; responsibility; accountability; transparency; stewardship; flexibility; succession; representation; and simplicity". [15] The fulfillment of the organization's mission is a paramount concern – be it to make profits, do good works, or act as a government. For complex bureaucratic organizations, the management of agency-risks is a salient concern, i.e., "the risks that are imposed on principals due to the fact that agents have interests that may conflict with those of the principals whom they are supposed to serve".[16] In large part, good governance consists in keeping an organization on track and more specifically addressing the forces that would push it off track. To control agency-risks, organizations need to develop accountability relationships, establish an appropriate mix of incentives and disincentives, and develop the feedback loops that provide quality assurance and quality improvement. At an inter-organizational level, good governance centres on the moral quality of the relationships organizations have with each other and with their own stakeholders – so trustworthiness, responsibility, and fairness are also central. Framing an organization's pursuit of its objectives are general moral standards, e.g., limiting the use of force, providing protection for the vulnerable, and respecting human rights.

It is worth noting that many of the elements of governance are contestable, particularly in regard to "political" as opposed to "managerial" accountability. Managerial accountability centres on "agreed tasks according to agreed criteria of performance"; whereas, political accountability moves into areas where there are debates about the appropriate degrees of openness and directions of accountability. Disputes about political accountability are reflected in arguments about the public's role in policy making. Thus, for example, on the traditional model public consultation has consisted of closed-door meetings with professional experts, while on a more contemporary model it involves open door meetings with all interested parties.[17]

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[13] <http://www.governance.uottawa.ca/english/overview/o_defi.htm>
[14] Ibid.
[15] See the 1999 Canadian Institutes for Health Research (CIHR), *Public Report on Governance*, at p. 7.
[16] See Allen Buchanan, "Toward a Theory of the Ethics of Bureaucratic Organizations", *Business Ethics Quarterly* 1996.
[17] See Patricia Day and Rudolph Klein (1987), *Accountabilities: Five Public Services*, London UK, Tavistock Publications, pp. 26-27. Schrecker, Hoffmaster, Somerville, and Wellington, p. 243 on professionally open versus democratically open decision-making.

Section II: What is ethics, and what does it offer to public policy?

As indicated, the Government of Canada has taken a number of initiatives in the ethics and biotechnology area. Ethical issues also arise for the federal government in relation to its governance responsibilities both internally within government and externally in relation to outside organizations, be they foreign governments, provincial governments, industry, NGOs, or the general public. Most importantly, through the NBS and now the CBS, the federal government has been a major initiator and agent of change in Canadian biotechnology. Indeed, in the adoption of the CBS, the government recognises the importance of ethics and other social considerations in respect to biotechnology policy. But to understand the government's responsibilities and the responsibilities of other actors in the area, it is necessary to offer a capsule description of ethical judgements and ethics.

A. Ethical judgements as "all things considered" judgements

Ethical judgements are not stand-alone judgements, rather they are integrative, holistic, or "all things considered" judgements. The Canadian moral theorist Thomas Hurka put this point well in a book on the ethics of global warming:

> An ethical judgement about climate policy is not just one judgement among many, to be weighed against economic, political, and other judgements in deciding how, all things considered, to act. It is itself an all-things-considered judgement, which takes account of economic and other factors. If a climate policy is right, it is simply right; if it is ethically wrong, it is wrong period.[18]

That is, in making an ethical judgement about global warming or biotechnology, "ethics" is not one factor to be considered alongside other factors, like legal, scientific, or economic factors. Rather a sound ethical judgement involves an integration of all the relevant factors. Since expert judgement is relevant in the recognition and understanding of relevant factors and their interplay, combined expertise is essential. In this joint endeavour, what ethicists can contribute on the basis of ethical theory and work in applied ethics is help in understanding the complex ways in which such integrative judgements can be made, criticized and justified.

[18] Thomas Hurka 1993, "Ethical Principles" in *Ethics and Climate Change*, Harold Coward and Thomas Hurka, Wilfrid Laurier University Press, Waterloo, Ont. p. 23.

B. Ethics as an area of systematic study

Ethics or moral philosophy involves the systematic study of norms and values in particular actions (right and wrong), consequences (good and bad), and character (virtue and vice). It is generally divided into three parts: descriptive ethics, theoretical ethics, and normative ethics.[19]

1. Descriptive ethics

Descriptive ethics is aimed at providing systematic explanatory accounts of the values that people actually have.[20] Consider, for example, trying to understand why a specific population appears to be more upset about the remote chance of illness from genetically modified food than about the much more statistically significant chance of food poisoning from unrefrigerated meat? Is it just because of the unfamiliarity of the former compared to the latter, or is there something else at issue – such as the relative lack of control people feel they have of eating an unlabelled genetically modified food compared to that eating contaminated meat? From a policy perspective, the former situation might be dealt with through a program of public education, while the latter might be best addressed by labelling products to give consumers choices. In other words, it can become important for practical decision-making to understand the concerns that motivate people.

The term “ethos” from Greek and the term “mores” from Latin mean the same thing – “customs” or “habits”. They are the roots from which the words “ethical” and “moral” are derived. They reflect a major main concern in descriptive ethics – describing what people think is right, morally appropriate, laudable and the opposite. In descriptive ethics, the main aim of moral philosophers is to reconstruct the deeper structure or structures, that is to say, to identify the underlying principles and perspectives of specific ethical views. Since ethical judgements are “all things considered” judgements the principles and perspectives thus identified must also be integrative.

2. Theoretical ethics

The second department of ethics is theoretical ethics (more technically known as “meta-ethics”). Theoretical ethics involves the examination of various concepts central to ethics. One example relevant to biotechnology would be an examination of whether safety is a normative or a scientific concept. Another is consideration of how the precautionary principle is similar to or differs from an ethics that takes into account the interests or rights

[19] The terms “moral” and “ethical” are generally used interchangeably in this document as roughly equivalent in meaning. The distinction between "ethics," on the one hand, and "morals" and "values," on the other, is useful because sometimes a person's sense of morals (e.g., sense of right and wrong) or sense of values (e.g., what is thought to make for a good life) is expressed mainly in action and feeling, rather than in explicit judgments that are rationalized and justified by a logical structure of stated principles that are a principal concern of the moral philosopher.

[20] In their 1992 Report for the Aboriginal Research Coalition of Ontario “Finding a Balance of Values” filed with the Ontario Environmental Assessment Board, McDonald, Stevenson and Cragg define descriptive ethics as “the part of ethics that describes the morals and values of individuals or groups, as these morals and values are shown in customs, practices, traditions and ideologies. Based on the work of anthropologists, sociologists and other social scientists, as well as the direct study of texts and the testimony of informants, it attempts to interpret and structure practices and the ways in which one might attempt to ground or justify them.”

of future generations.[21] Theoretical ethics moves beyond descriptive ethics in its concern with explaining and particularly justifying moral opinions or practices. The explanations offered in theoretical ethics may be about the meaning, nature and purpose of moral discourse in human life and its development over human history. The justifications may be in the form of a rational reconstruction, i.e., the articulation of basic principles, the derivation of subsidiary principles and their application to particular problems, and/or defence or rationale for the form of justification offered, for example, by way of models of rationality and moral behaviour.[22] This paragraph is itself an example of theoretical ethics – because it defines or analyses the central aspects of ethics.

There is substantial agreement among theoretical ethicists that moral standards differ from other kinds of standards of behaviour (such as self-interest or prudence, law, art, various crafts or skills, manners, etc.) in the following five basic ways.[23] They help explain the ways in which sound moral judgements are "all things considered" judgements.

1. Moral standards are associated with special emotions and standards including guilt, shame, remorse, self-esteem, and indignation.
2. Moral standards are based on impartial considerations. It cannot be the case that a given action, say stealing, is right for me but wrong for you simply because you are you and I am me.[24]
3. Moral standards are concerned with matters thought to be important to human well-being.[25]
4. Moral standards cannot be changed by authoritative rulings. An action is not right or wrong simply because someone says it is. There is neither a moral parliament nor a supreme court of morality. Moral judgements are based on an appeal to reasons – reasons that are, as indicated in (2), impartial.
5. Moral standards are supposed to override consideration of self-interest; the moral point of view is then superior to the self-interested or prudential point of view. Morality is concerned with the "best interests" of everyone living together as part of a community. Indeed, one of the primary functions and tests of a morality is how well it adjudicates conflicts amongst diverse individuals and resolves them in a mutually satisfactory manner that allows them to live together with tolerance and respect.[26]

3. Normative ethics

By contrast, normative ethics involves an enquiry into the values that people ought to have. For example, in assessing new types of biotechnology, a question will arise as to whether the interests of future generations count equally, at some discounted rate, or not at all with the interests of those now alive?[27] Rather than providing explanatory

[21] Barrett (p. 50) describes the precautionary principle as primarily a legal concept stating "better safe than sorry" or she says, "More accurately, if less clearly, …as 'better to be roughly right in due time, bearing in mind the consequences of being very wrong, than to be precisely right, too late'."

[22] This characterization of theoretical ethics is from McDonald, Stevenson, and Cragg 1992

[23] This list is based on Manuel Velasquez (1991), *Business Ethics: Concepts and Cases*. Third Edition. Prentice-Hall, Englewood Cliffs, N.J., p. 13.

[24] Hare, R.M (1963), *Freedom and Reason.* Oxford University Press, Oxford

[25] Kurt Baier (1957) *The Moral Point of View.* Cornell University Press

[26] Kurt Baier

[27] The English philosopher Derek Parfit's 1984 book Reasons and Persons prompted a revival of interest in this question. The UBC economists David Davidson and Charles Blackorby in a variety of publications explore the issues associated with this question with considerable subtlety and mathematical sophistication.

frameworks for the moral beliefs people have as is done in descriptive ethics, normative ethics involves the study of whether these beliefs are sound or appropriate.[28] For example, there are considerable differences of opinion about the moral appropriateness of patenting a higher life forms like Harvard's genetically-modified onco-mouse, or Myriad's patenting a gene sequence like BRCA 1 and 2 that indicate hereditary forms of cancer.[29] Is patenting a fair reward for ingenuity and investment, or is it instead privatizing what is properly in the public domain or in the case of the gene sequence in the intimately personal domain?

Thus, normative ethics involves the making of moral judgements – judgements about right and wrong action, about what is fair and unfair, about who is virtuous and vicious, about what is conducive to welfare and illfare – where these moral judgements are informed by a descriptive ethics that gives a broad perspective on human affairs and from theoretical ethics a knowledge of the various explanatory and justificatory theories that have been advanced. So in normative ethics, moral philosophers look for standards of considerable importance, namely, impartial standards vital to human welfare, which override harmful conflicts of self-interest. These are standards that enable members of different communities to assess their legal and social customs, practices and institutions from a common perspective – the moral point of view. The identification of such standards is crucial to the public policy process.

4. Ethics in public policy: the example of rBST

Each of the three areas of ethics is relevant to public policy discussions. A good example is provided by the debates around the licensing of synthetic bovine somatrophin (rBST).[30] In regard to descriptive ethics, it was important for government to understand the principal stakeholders' values – the manufacturers of rBST, the dairy industry, farmers, and the general public – and not just what each stakeholder valued but also why they valued it – in particular how concerns about rBST were linked to each of the stakeholders' core values. But to make choices with respect to public policy, e.g. regulatory policy, government would be moving beyond descriptive ethics characterization of value-conflicts and value-similarities. Explicitly or implicitly, decision-makers would be entering the area of normative ethics by making choices with respect to relevant standards for regulation, e.g. effects on human health, animal welfare, industry stability, environment, and a host of other relevant considerations. In making such choices, questions in theoretical ethics would also arise, e.g., are "health" and "safety" value neutral scientific concepts or are they value laden?

C. Justifying moral choices

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[28] Normative ethics may be described as "the branch of ethics concerned, not so much with studying or theorizing about, but with actually making normative judgments in morals and values, that is, making judgments about actions, persons and their character, using a moral and value vocabulary. As ethics (contrasted with naive morality) it makes use of, or is informed by reflection on, descriptive and theoretical ethics." Ibid.

[29] Harvard has applied to patent its onco-mouse in Canada. See *President and Fellows of Harvard College v. (Canada) Commissioner of Patents* (2000) A-334-98. Appeal granted to Supreme Court of Canada, October 2000.

[30] Espey (pp. 4-5) argues that government handling of rBST shows how the lack of explicit concern with the public implications of biotechnology leads to problems. By contrast, the case of rBST is being used here to illustrate the value of ethical thought in identifying central aspects of the debate around biotechnology.

In public policy debates, governments will make choices – even the decision to postpone and put off making a definitive choice is itself a choice. Making choices raises a central ethical issue: whether and how choices can be justified? That is, when people or institutions are faced with choices they want to make reasonable choices – choices supported by good reasons. But there are many different kinds of reasons for making particular choices, for example, whether or not to license rBST for use on Canadian farms. The decision could be made on the basis of current policy, interest group lobbying, public opinion polls, administrative precedent, the personal feelings of senior bureaucrats or politicians, etc. But it is to be hoped that the decision will be made on the basis of good moral reasons which as indicated above are motivating reasons that are impartial, promote human well-being, non-arbitrary and overriding considerations of self-interest.

But to justify the choice of one of these requires moral argumentation. That is, it is fair to ask whether a particular choice can be justified from the moral point of view. The moral point of view should be one that all the affected parties can reasonably endorse. It should not just reflect the interests of some of the parties, but all of them. That is, the choice should be justifiable interpersonally.

At this point, it is fair to say that there is debate amongst ethicists about the best normative theory to use for moral justification. While it is not possible in this document to cover the full range of ethical debate, it is worth marking out some areas of the debate that often appear in public policy discussions. One area concerns the appropriate relationship between means and ends. This will lead into a discussion of whether moral claims can be proven or supported and if so how.

1. Making ends paramount – consequentialist perspectives

There is a major difference between taking ends to be basic in moral reasoning and taking means to be basic. If ends are taken as basic, then ends literally justify the means used to achieve them. On one interpretation of this view, ends are just givens – whatever people happen to want – their revealed preferences in contemporary welfare economics. On an alternative interpretation, only morally worthy ends, like human happiness, justify the means used to achieve them. Both these interpretations are essentially consequentialist in saying that only the consequences really matter.

A very influential theory of this general type (consequentialism or ends justifying means) is utilitarianism. Utilitarians take happiness or pleasure to be the one end worth pursuing for its own sake.[31] But they mean more than that each person should pursue his or her own happiness or self-interest. Rather utilitarians believe that each person or moral agent has an obligation to pursue the happiness of everyone they affect (not only humans, but any other being whose happiness is affected, including animals). That is, happiness should be viewed impartially as valuable – regardless of distributional effects. There are many versions of utilitarianism each depending on how strongly the obligation to advance happiness overall is stated. In its strongest classical form, utilitarianism is the view that in making a choice one has the obligation to select an option that maximizes overall happiness. So in the rBST case, a utilitarian might well claim that the decision to not license rBST was justified on the grounds that the negative effects of rBST on animal welfare outweigh any compensating gains in economic efficiency.

[31] Early utilitarians like Jeremy Bentham saw utility or welfare as a kind of feeling state – viz., pleasure. Later utilitarians including contemporary welfare economists take welfare as the satisfaction of expressed preferences.

Utilitarianism has been very influential in modern thought especially in economics. The normative branch of economics known as welfare economics is based on strong utilitarian principles. Welfare economics is the basis for very important managerial and regulatory methodologies, such as cost-benefit analysis. Many of these methodologies rely on the idea of surrogate markets in which an attempt is made to determine a price when there is no actual market. For example, surveys may be used to determine what some person or group is willing to pay to achieve a benefit or to avoid a bad consequence. Such an artificial price is sometimes called a "shadow price."

2. Making means paramount – deontological perspectives

In contrast to the consequentialist view that ends justify means is the view that from the moral point of view there are inherent ethical constraints on the choice of means, particularly that there are certain types of actions that ought not to be done even though they would otherwise produce good results and types of actions that ought to be done even though they do not produce good results. This is very much reflected in common sense morality in the view that there is something inherently wrong with breaking promises, telling lies, or doing violence to others regardless of the amount of good achieved or evil avoided. This concern with the character of actions rather than their results is also to be found in virtue ethics according to which there are appropriate and inappropriate ways of being and acting in special roles (e.g., the courageous soldier and the impartial judge) or simply as a person (e.g., being a decent and caring person).

This general concern with the character of actions or in the case of virtue ethics the character of persons rather than ends is classified by moral philosophers as "deontological" from the Greek word for "duty" or "obligation". In the large family of theories that can be classified as deontological or duty-centred, the basic idea is that ethical standards function as limits or "side-constraints" on human actions and in particular limit the use of particular means (e.g., force or fraud) for the pursuit of even worthy goals (like general prosperity.[32]

The clash between consequentialists and deontologists is sometimes seen in debates about biotechnology. For example, there are those who argue that decisions about whether to pursue or allow a particular form of biotechnology, such as genetic therapies or the creation of transgenic animals, should be decided on the basis of "the greatest social good" as measured in actual economic benefits to Canada or using an avoided cost methodology (shadow markets) to determine net social gains or losses. Critics may vehemently object to such a consequentialist approach because they see it as improperly treating core and symbolic values[33] as purely replaceable and priceable commodities. That is, it gives rise to commodification, in particular treating what is priceless, sacred, or irreplaceable as if it were a mere commodity.[34]

3. Justice

[32] Robert Nozick (1974), *Anarchy, State, and Utopia.* New York, Basic Books, p.29.

[33] Cragg 1999 has argued that terms like "core" and "symbolic values" better capture actual usage than the philosopher's tradition term "intrinsic value."

[34] In an unpublished 1999 paper, Cragg persuasively argues that treating core or symbolic values as simple economic values is the kind of misunderstanding that sabotages meaningful discussions. Cragg bases his argument on an analysis of several Canadian environmental disputes. Wesley Cragg (1999), "Mapping Values, Descriptive Axiology and Applied Ethics: Lessons from Four Environmental Ethics Case Studies", Canadian Philosophical Association.

A primary concern of deontologists is with the distribution of benefits and burdens. Viewed from a strictly consequentialist perspective, only the total net amount of good produced matters regardless of its distribution. Deontologists and most ordinary people have a non-consequentialist perspective on matters of distribution. The questions of who gets what and why are important to most people and important not just because they serve certain ends, e.g., increasing GNP, but because it is felt that fairness and justice are inherently morally important. However, there are many different principles to which people commonly appeal in regard to the just or fair distribution of benefits and burdens: merit, effort, ownership, luck (e.g., the flip of a coin), promises, desert (e.g., guilt or innocence), and special relationships (parent-child). Justice issues also arise in regard to fair procedures (procedural justice), e.g., what are fair procedures for determining if a GMO is safe, and rectification of wrongs (corrective justice), e.g., what forms of compensation should be available to those who are damaged by an experimental gene therapy. Developing plausible theories of justice has been a central preoccupation of contemporary moral and political philosophers.

4. Is there a foundation for ethics?

Given the variety of ethical theories and theories of justice, it is fair to ask if one of them has been proven right. In surveying a wide range of contemporary theories of justice, the Canadian philosopher Will Kymlicka expresses the consensus view amongst ethicists that "moral philosophers have not yet discovered a knockout argument for or against these different theories."[35] Indeed, many moral philosophers reject the idea that there could be such "a knockout argument". Rather in philosophy generally, the notion of indisputable foundations, has been generally rejected as a model of both scientific and normative knowledge. Instead, the move has been to coherentist theories, which stress bringing the diverse parts of a scientific or normative theory into "reflective equilibrium." In his enormously influential 1971 book, *A Theory of Justice*, the philosopher John Rawls says:

> Therefore, we do better, I think, to regard a moral theory just as any other theory.... There is no reason to suppose that its first principles or assumption need to be self-evident, or that its concepts and criteria can be replaced by any other notion, which can be certified as non-moral.... I have not proceeded then as if first principles ... have special features that permit them a peculiar place in justifying a moral doctrine. They are central elements and devices of theory, but justification rests upon the entire conception and how it fits in with and organizes our considered judgements in reflective equilibrium. As we have noted before, justification is a matter of the mutual support of many considerations, of everything fitting together into one coherent view.[36]

Here it is important to understand that Rawls is talking not only about the testing of ethical theories but also about the testing or validation of scientific theories. Testing either type of theory is very much like trying to repair a boat at sea. Starting from scratch is a non-option. One starts with what one has at hand and repairs the boat as one goes along.

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[35] Will Kymlicka (1993), "Approaches to the Ethical Issues Raised by the Royal Commission's Mandate" in *New Reproductive Technologies" Ethical* Aspects, Royal Commission on New Reproductive Technologies Research Studies, vol. 1, Ottawa, Supply and Services Canada, p. 13

[36] Rawls, John. *A Theory of Justice.* Harvard University Press, Cambridge, Mass. 1971. pp. 578-9

Taking a non-foundationalist perspective means that it is important to see how various considerations fit together – do they cohere with each other – hence, the term "coherentism". The test of a good ethical theory then will, in large part, be pragmatic – is it illuminating or helpful and does it make sense in terms of other things that we know? On such a view, it will be important to hold particular theoretical perspectives as open to revision. The appropriate intellectual attitude will be to treat theoretical judgements, whether scientific or ethical, as "fallible" rather than taking them as infallible and never to be challenged dogmas.

D. Putting ethics into practice: rules and principles

In ordinary life, including making public policy, ethical judgements are generally made without any explicit appeals to normative ethical theories, e.g., to a particular theory of justice. Rather when ethical justifications are offered, they are usually offered in terms of general principles, like "treat people fairly" or "do no harm". Here it is useful to contrast principles with rules.

The philosopher and lawyer Ronald Dworkin says both principles and rules set standards of behaviour. "Rules," he says, "are applicable in an all-or-nothing fashion. If the facts a rule stipulates are given, then either the rule is valid, in which case the answer it supplies must be accepted, or it is not, in which case it contributes nothing to the decision."[37] A principle, by contrast, "states a reason that argues in one direction, but does not necessitate a particular decision." Hence, "principles have a dimension that rules do not – the dimension of weight or importance."[38] So when two principles point in opposite directions, one must ask which principle is the weightier or more important. However, when two rules conflict, the issue is not that of relative importance but of which rule is valid in the particular circumstances. If the rule is valid, then it applies; hence, it is binding. If it is not valid, then it is irrelevant. One might see rules as like light switches that are either off or on; principles are like rheostats that can be brighter or dimmer. Rules, then, can be mechanically applied; principles require judgement and, in the case of a conflict of principles, a judicious balancing of competing considerations.

One reason that principles are important in policy making is that they provide a platform for rule making. That is, appeal is made to principles to justify general regulatory or administrative objectives and processes, which are then translated into substantive and procedural rules. Appeal is also made to principles when policies are up for revision or in cases in which different policies appear to be at cross-purposes.

Section III: Ethics in public policy – judiciously weighing relevant ethical considerations

A. Appeal to widely shared principles

The ethical perspective urged here is to treat the use of ethics in public policy as a way of judiciously balancing or weighing relevant considerations – considerations usually identified by principles in common use. The objective, of course, is to make good "all things considered" moral judgements that can be used to ground and formulate public policy. On the view of moral and scientific theory presented in the discussion of theoretical

[37] Dworkin, Ronald. *Taking Rights Seriously*, London, Duckworth Press, 1977, p. 24
[38] Dworkin p. 28

ethics, it is appropriate to treat both moral and scientific claims as always in principle revisable, i.e., to regard such claims as fallible. In the sometimes messy and often times complex world of public policy-making the aim is not ideal or perfect justification but something more moderate and achievable – as it were "good enough" policy-making, that is decisions reasonably supported by common moral principles (including principles of good governance).[39]

While appeal in ethical reasoning is made to principles in common use, there must be openness to the idea that at least some commonly accepted principles are improperly used, restrictively applied, or otherwise inadequate. Otherwise, there would be no possibility of moral change or moral progress. For instance, in regard to the equality of men and women or in treating animals as important in their own right and not just as property, a major shift in moral perceptions took place that could be described as either the development of new ideas of moral equality (in the case of women) or moral importance (in the case of animals) or as the radical extension of old ideas of equality and importance.

B. Principles grounding Canadian society

In a liberal democratic society, public policy making appeals to liberal and democratic principles, particularly of the sort that motivate various human rights documents including the *Canadian Charter of Rights and Freedoms*. So in talking about the ethics of public policy, there is no beginning completely from scratch or from some moral ground zero. Rather discussions about the ethics of public policy in a Canadian context are rooted in rich soil – equality before and under the law[40], democratic participation in government, accountability, the equal dignity of persons, pluralism, multiculturalism, and the like. Some of the principles are substantive (equal dignity) and others are procedural (equal treatment before and under the law). Others have to do with standards of good governance in a democratic society – transparency (openness in decision-making) and the accountability of governors to the governed. Principles that will be adequate for policy making in the Canadian context need also to be open to – or perhaps, even embody – central features of the Canadian experience – e.g., multiculturalism and the recognition of key collective rights. As already noted, there can be disagreement about principles – what they are and how they apply. But presumably in a functioning society, there will be some that command significant assent even though there will be others that are now in dispute although once generally accepted and others that are not yet, but soon will, be part of a substantial social consensus.

There is a further consideration of some importance regarding the interpretation and use of principles. Principles are often stated in quite general terms, e.g., "polluter pays" or "those who bear the burdens should reap the benefits". The generality of such statements may leave them open to rival interpretations or applications when it comes to specific cases. Thus, for example, with respect to new reproductive technologies (NRTs) involving biotechnology, both supporters and opponents of such NRTs may appeal to human dignity. But what human dignity means in this context will vary crucially, for example, depending on whether one takes human dignity to be a moral property attaching to all products of conception from the moment of conception or takes the view that it only applies later on in the developmental process. In public discourse, it is important to try to

[39] See McDonald's ethical decision-making framework at www.ethics.ubc.ca.
[40] The *Charter* s. 15 also includes "the right to the equal protection and equal benefit of the law".

anchor generally accepted principles in the concrete context of cases, practices and policies on which there is substantial agreement and then seek to extend that agreement to controversial issues.

Ideally, the hope is that a set of fundamental principles (interpreted against a background of commonly accepted cases) will command a consensus amongst all rational members of society.[41] That is, each member would on reflection endorse the principles as right and appropriate for policymaking – though they might well disagree about their applications to particular cases.[42] Nonetheless, sometimes the best one can hope for is compromise – a much more provisional and temporary acceptance of a substantive or procedural principle as a way of getting through particular controversies that at least gives to the various parties to the dispute something that they each wanted but not everything that they regard as their due.

C. Relevant ethical considerations for policy-making

The argument thus far is that public policy making should take into account a number of important ethical considerations. These include:

- General moral principles and processes
- Governance requirements: democratic accountability, transparency and public participation
- Constitutional, legal, and historical shared understandings about institutional powers, responsibilities, and structures

Policy-making is generally interstitial or situational in having to take into account not only the general context, but also commitments made in other policies. In biotechnology as in other areas of policy, Canada has made specific domestic and international commitments on a wide-range of subjects, including health, public safety, trade, and human rights. Sometimes these commitments are revisited in order to be revised or renewed, at other times they form an essential context for making policy. Policy-making should draw on a wide range of expertise, including, where appropriate, legal, political, economic, scientific, and ethical expertise.

Section IV: Leading Ethical Issues for Public Policy and Biotechnology

A number of important ethical issues in the area of public policy for biotechnology have already been offered by way of example. In this section, the aim is to offer a broad-brush characterization of leading ethics themes in the area and sample governmental approaches to them. As Espey notes many of the issues in this area are not unique to biotechnology though her claim that "the debate is only tangentially about biotechnology"

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[41] Jonathan D. Moreno 1995, *Deciding Together: Bioethics and Moral Consensus*, New York, Oxford University Press, p. 45. Moreno also notes (p. 39) that "consensus is an inescapable feature of moral decision making, but one that causes anxiety amongst moral theorists. As Jennings notes, it reinforces patterns of power, channels and neutralizes conflict, and diffuses responsibility, thereby supporting established patterns of domination. Yet appeals for and to consensus are ubiquitous. And without consensus how could any view, including that which is right, prevail in human affairs except by coercion?"

[42] Espey (p. 3) remarks, "The critical question for government is how to justify policy to the public which it serves. In a society where consensus on policy is rarely, if ever, attainable, it is the process which legitimates the policy." The account given here of principles includes both procedural and substantive principles.

may well understate public concerns directed to biotechnology itself.[43] It might be more accurate to think of biotechnology as a hot button for a series of broader public hopes and fears.

In considering these issues, it is important to understand the general context for public concerns. These include:

- A quickly expanding knowledge base: rapid scientific / technological change in biotechnology and areas relevant to further research and development
- Decreased governmental resources in a time of decentralisation and privatization
- An international context marked by globalization and competition
- Growing public scepticism about and even mistrust of governments and business, as well as of professional experts
- Continuing public demands for fair treatment (especially of vulnerable groups) and for accountability on the part of decision-makers
- Concerns for health and the environment especially about areas of uncertainty

The above list is intended as indicative and not exhaustive of current factors that are relevant to public policy making in biotechnology.

A list of leading issues is bound to be selective. But based on the research represented in the six papers that are the basis of this synthesis, the following general themes are salient:

A. How should public policy address uncertainties, whether real or perceived, about biotechnology?
B. Should there be social control over biotechnology? In particular, do various forms of biotechnology impose significant adverse effects on vulnerable groups, e.g., the third world, women, research subjects, and indigenous peoples?
C. Does biotechnological research and development show appropriate 'respect for life'? For example, will it lead to the commodification of human life or disrespect for nature?
D. How should government reconcile its role as a major promoter of biotechnology with its significant responsibilities as a regulator?

Underlying these three general concerns are two major crosscutting concerns that are central to the perceived legitimacy of public policy making in this and other areas:

- What is the appropriate range of knowledge and expertise in setting public policy for biotechnology? In particular, how, if at all, should ethical concerns be taken into account?
- Is it possible to have public policy discussions that are informed, allow meaningful participation on the part of all stakeholders, and build trust?

A. Addressing uncertainties

Many technologies, not just biotechnology, have made people, especially in economically advanced industrialised countries like Canada, sensitive to the creation and management of new uncertainties. To a significant degree, this sensitivity is due to technology itself in allowing the tracking, measurement, and often increased control of events affecting humans. This sensitivity can also be seen as a by-product of increased

[43] Espey, p. 3

prosperity (due also in part to technological development). As people move beyond survival needs, they have the luxury of contemplating the quality of their lives in increasing detail. A further factor here is that of modern communications. There is now literally a global awareness of new risks, whether imagined or real.

A major part of the debates around modern technologies concerns the range of considerations that are relevant to public policy. This is linked to questions about whose expertise is relevant and which disciplinary language shall be predominant in policy discussions. That is, setting the language of public policy debate frames issues in crucial ways. Hence, a continuing theme in discussions of new technologies is whether the language of debate should be purely scientific – empirical, objective and value-free – or whether the debate should also take into account commitments and choices that have to be justified on moral grounds.

1. Risk-analysis and risk-perception: scientific perspectives

Standard risk analysis has had a profound effect on the framing of public policy. On this view, there are two main variables: (i) benefits-harms and (ii) probabilities. Both can be quantified – (i) in terms of a positive or negative magnitude of benefit/harm, and (ii) as the likelihood of an event's occurrence (ranging from zero to one). "Risk" in a technical sense that is neutral between benefit and harm is defined as a product of (i) and (ii).[44] Judgements about risk in this technical sense can be evidence-based. For (i), the study is generally made of revealed preferences in actual, hypothetical or in some combination of the two. For (ii), data is gathered on the frequency of events (e.g., the number of fatal rear end collisions per year) over a statistically significant period of time. Mathematically sophisticated tools of analysis (e.g., fault-tree analysis) can be used to establish comparisons between complex sets of options. This leaves room for disputes amongst experts about the probabilities – disputes about the adequacy and accuracy of observations of people's preferences or event probabilities and also about methods of analysis. But these seem in principle to be resolvable disagreements and resolvable without any appeal to values.

However, advocates of value-free risk analysis do try to take account of values in another way, namely, as perceptions that may or may not be in accord with the underlying realities revealed by risk-analysis. Thus, one groundbreaking study of risk showed that even experts in risk-assessment held contradictory views about risk depending on how choices were framed, e.g., over whether choices were posed in terms of either the loss of an opportunity or its gain.[45] While the study showed that most participants made literally irrational (in the sense of self-contradictory) choices, it also showed that some irrationalities were very deeply rooted and perhaps not eradicable.

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[44] In ordinary language, the term "risk" connotes the possibility of a harmful, negative, or unwanted state of affairs.

[45] A. Tversky and D. Kahneman (1982), "Belief in the Law of Small Numbers" in *Judgement Under Uncertainty" Heuristic and Biases*, D. Kahneman, P. Slovic, and A. Tversky, Cambridge, Cambridge University Press, pp. 23-31. Also see K.S. Schrader-Frechette (1991), *Risk and Rationality: Philosophical Foundations for Populist Reforms*, Berkeley CA, University of California Press, pp. 77-88.

2. Arguments for more holistic perspectives

Many critics of biotechnology and other forms of new technologies have argued that framing policy debates in terms of risk-analysis and risk-perception misses central ethical issues. In an important Canadian case study of scientific risk-analysis, Brunk, Haworth, and Lee convincingly point to a number of elements that are missed through standard scientific methodologies.[46] These include whether or not risk is imposed on people or whether it is voluntarily selected – a matter that is central to the debate about the labelling of genetically modified foods and an issue that divides the US and Canada from the EEC and many other countries. Another issue is the distribution of risk and the unfair imposition of burdens on the vulnerable.

A crucial issue has been that of onus or the burden of proof. The Brunk study identified a major issue as that of the conditions under which safety testing for the herbicide in question (alachlor) was done. Farmers who wore protective clothing including expensive gloves and masks and who carefully followed the manufacturer's instructions for handling and application had only marginal exposures to toxic chemicals. But the reality of application in most farming settings – high heat, little protective equipment, and lack of time – meant that in the field toxic exposures were likely to be greater.[47] Where does the onus lie – on the company to produce a product that is 'safe' under normal conditions for use or on users to meet the conditions specified by the manufacturer for safe use? However, this question is not one that can be handled by standard risk-perception or risk-analysis methodologies.

That is, in addition to questions about the appropriate standard of proof (how much evidence is enough?), there are also questions about the burden of proof (who should have to produce the evidence?) And beyond this lies the question of the locus of decision-making (who makes the final decision?) These three are central ethical issues in setting governmental policy for biotechnology. Behind them lies a range of other ethical issues. For example in the alachlor case, there is a major question about the fair distribution of benefits and burdens: are farmers or pesticide manufacturers unfairly burdened under current regulatory arrangements?

Another criticism levelled against standard risk-assessment methodologies is that they don't map well unto psychometric studies of risk perception.[48] Such studies account for risk perception on the basis of two main factors: "dread" and "unfamiliarity." And the results of these psychometric studies do not correlate with standard risk perception studies, which are based on fear of death. So faced with exactly the same probability of death, subjects were much more fearful of an event like a nuclear accident – where they feel they have little control or familiarity – than being in fatal automobile crash – where subjects feel the opposite.

Debates about the appropriate methodology for assessing uncertainties resemble debates between consequentialists and deontologists. There can be a good deal of speaking past rather than to each other. One side is convinced that all the relevant factors can be expressed in terms of a few simple variables (e.g., utility, and probabilities), and the other side is equally convinced that such reductionism eliminates the issues that morally matter most. The likely result is that each side will write the other side off.

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[46] Conrad G. Brunk, Lawrence Haworth, and Brenda Lee (1991), *Value Assumptions in Risk Assessment: A Case Study of the Alachlor Controversy*, Waterloo Ont. Wilfrid Laurier University Press.
[47] Brunk, pp. 93-95
[48] Schrecker, Hoffmaster, Somerville and Wellington, p. 140.

Reductionists come to regard their opponents as irrationally clinging to antiquated, obscure and irrelevant notions. Anti-reductionists think their reductionist opponents are dangerously simple-minded and oblivious to central moral values.

B. Fourth hurdles: social control over biotechnology

The issue of social control over biotechnology has been raised in terms of creating so-called "fourth hurdles"[49] in public policy. The first three "hurdles" are safety, quality, and efficacy. The term "fourth hurdles" can be used to generically describe policy interventions designed to take specifically into account concerns for distribution, equity and community interests. This is not, of course, to say that communities have no interest in the first three hurdles, but the interest in these is one they have as individuals rather than as members of the community. For example, a consumer may ask if genetically modified foods (including food derived from transgenically modified livestock) will provide nourishment and taste good without adversely affecting her health? From a fourth hurdle perspective other issues would be salient, such as the effects of the introduction of genetically modified crops on such social factors as impact on family farming or on the general environment. Some countries have moved to adopt fourth hurdle provisions. Thus Norwegian legislation on the release of genetically modified organisms requires special attention to sustainability and community benefits.

In the medical area, the patenting of the gene for BRCA1, a gene that been implicated in some forms of hereditary breast cancer, provides another example. Critics suggest the gene's patenting by Myriad Genetics has adverse implications for research and clinical practice particularly for those who do not have access to this technology. Now the arguments for and against paying regulatory attention to such distributional effects raise difficult trade-off questions. Perhaps, patenting such genes will lead to better treatments for at least some people with breast cancer. Is that worth increasing the inequities between those, individuals and populations, who have the resources to access such treatments and those who do not? That is, questions arise about distribution and equity as well as about cost-effectiveness in the maximization of health benefits. Should, as the Royal Commission on New Reproductive Technologies proposed, there be special concern in public policy making for vulnerable persons?

Concern for the vulnerable also arises at the international level. As Canada and other economically advanced countries enter agreements about patenting, labelling, and trade in biotechnological products, many worry about the effects on poorer countries. Will they fall further behind economically because, for example, of the 'brain drain' of their best scientists in biotechnology to wealthier countries? Moreover, will their populations be testing grounds for new and possibly hazardous biotechnological products?

C. Respect for nature and commodification

At a profound level there are two radically different views of nature and humanity's place within the natural order. Each of these views has religious and secular forms. The views are expressed in art and literature as well, e.g., in the romantic poets view of nature as sublime as opposed to the classical view of nature as something to be subdued. On, the dominant industrial view, nature is to be used for human purposes. This may be phrased in religious terms as divinely ordained or in a secular perspective as embodying progress. On the opposing view, nature has a mysterious "sacred" quality that deserves

[49] Ibid, p. 148.

respect and sets limits to human intervention. Margaret Somerville describes[50] the contrasting positions in terms of "pure science" perspective and "science-spirit" perspective.

An analogous type of concern has been raised about potential for various forms of biotechnology leading to the commodification of life, e.g., through the genetic manipulation of human genes for eugenic reasons. As a term "commodification" carries the negative implication of treating something that is valuable in its own right (e.g., a person) as if it only has economic value. Sometimes the concern is that a given form of a new technology (e.g., new reproductive technologies) will lead to literal commodification (e.g., women selling their ova for implantation). Often though the concern is that a new form of technology will embody or encourage a commodifying or instrumentalist perspective with respect to humans, nature or the environment. For example, the fear might be that even if literal trading of human reproductive materials is illegal, new reproductive technologies may have the net effect of valuing women primarily for their reproductive capacities rather than as persons in their own right. It might be argued that the limitations Health Canada has set on gene therapy by blocking research in germ cell therapy and a number of other reproductive and genetic technologies reflect, at least in part, concerns with the dangers of commodification.[51]

D. Regulating while promoting: dealing with conflicts of interest

As indicated in Section I, the federal government through the National Biotechnology Strategy and now through the Canadian Biotechnology Strategy has played a major role in the development of Canadian biotechnology. Yet the government has at the same time significant responsibilities in terms of regulation. As illustrated above in the discussion of "fourth hurdles", there are very important issues around the nature and extent of regulation, in particular whether any factors should be taken into account beyond safety, quality and efficacy. However, there is a major question about the dual role of the federal government as a promoter and regulator of biotechnology. Does this raise actual, potential or perceived conflicts of interest?[52]

One way of morally managing such conflicts is through openness. This raises the question of whether there is sufficient openness with regard to the government's roles in promoting and regulating biotechnology, especially where the two roles overlap. There are many thorny issues here. For example, with research and development important property rights are generated. Thus, there are legitimate interests in trade secrets. At the same time, there are important issues about the adequacy of regulatory standards and the fairness of their applications that demand openness. Barrett, for example, criticizes Agriculture Canada's role on the following grounds:

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[50] Maragaret A. Somerville (1996), "Are We Just 'Gene Machines' or Also 'Secular Sacred'? from New Science to a New Societal Paradigm," *Policy Options* 16 (March) : 5. Quoted in Schrecker, Hoffmaster, Somerville and Wellington, p. 251.

[51] See Health Canada, "New Reproductive and Genetic Therapies: Setting Boundaries, Enhancing Health" June 1996.

[52] See McDonald, website article on conflicts of interest: www.ethics.ubc.ca. Also see McDonald et al *The Governance of Health Research Involving Human Subjects*, Law Commission of Canada (forthcoming) on institutional conflicts of interest Section F-1. The general principles for dealing with conflicts of interest are discussed in Hands: Clean and Tied, Dirty and Bloody" *Dirty Hands*, David Shugarman and Paul Rynard, Eds. Broadview Press, Peterborough Ont., 2000, pp. 187-198.

> By the late 1980's, pressures from government, industry and (to a lesser extent) the environmental community prompted Agriculture Canada to develop regulations for agricultural biotechnology that would simultaneously provide assurance of environmental safety while encouraging continued development of the industry. The resulting policy framework – "science-based risk assessment" – has been subsequently used to demonstrate that rDNA crops are "safe". However, data used in risk assessment are generated by crop developers and not publicly available. Detailed evaluation of the risk assessment or herbicide tolerant canola (obtained through the Access to Information Act) revealed significant shortcomings in the depth and breadth of questions, methods of inquiry, analysis of data, and plausibility of conclusions. I contend that closed policy-making procedures among like interests, and long-term prior commitments to agricultural biotechnology by government and industry has fostered a risk assessment framework based primarily on economic and technical considerations.[53]

Barrett goes on to argue for including the precautionary principle in regulatory policy and adopting a "broader decision-making framework (including definitions of 'sound science') and wider (public) participation."

The second way of managing conflict of interest situations is through avoiding dual role situations, that is, by vacating one of the conflicting roles. In terms of governance, this requires separate and not co-mingled accountability relationships so that regulation and promotion are clearly kept at arm's length from each other. But independence is not enough if the range of issues being regulated is kept so narrow that major value issues are kept off the table through restrictively delimiting "risk assessment", as Barrett suggests. That is, conflicts of interests can be exacerbated by narrowly defining the issues that are allowed on the regulatory table.

E. Offering ethical advice on biotechnological policy

From the six papers synthesised for this report, a strong case has been made for integrating ethics into biotechnological policy-making. With the CBS and the establishment of CBAC, the Government of Canada has provided a means for seeking advice in this area. It was argued in Section II that ethical judgements are "all things considered" judgements. Hence, the advice that CBAC offers on ethical issues should be holistic in the sense of taking account of the full range of relevant factors, be they scientific, economic, social, legal or political (as discussed in Section III). The advice offered should be agent-specific in recognizing the agent's – in this case the Government of Canada – rights and responsibilities (as discussed in Section I). Thus, as a major actor in the biotechnology area, the Government of Canada faces the challenge of making good holistic decisions that serve the interests of all Canadians (including future generations) and fulfill the Government's many responsibilities both nationally and internationally. Given its mandate, CBAC has an important advice-giving role in this area. In this regard, it is worth looking at both domestic and foreign experience in this area.

In some cases, Canada or its agencies have explicitly addressed ethical issues in public policy. The establishment of the Royal Commission on Reproductive Technologies

[53] Katherine Barrett *Canadian Agricultural Biotechnology: Risk Assessment and the Precautionary Principle*, University of British Columbia, Department of Botany, PhD Dissertation 1999, pp. ii-iii.

provides an example of the federal government seeking advice on contentious ethical issues. Similarly, the establishment of the Tri-Council Working Group on Ethics in 1994 to propose a new policy on the ethics of research involving humans to MRC, NSERC, and SSHRC represents another initiative in seeking advice on ethical policy. The Canadian Council on Animal Care provides an example of a standing group that provides oversight and guidance on ethical issues regarding research involving animals.[54] Other Canadian initiatives specific to ethics and biotechnology were provided at the start of Section I.

1. Three examples of international experience with ethics advisory committees in biotechnology

First, France has developed a formal ethics advisory framework and process for dealing with ethical issues in the biological, health and medical sciences. The National Advisory Committee on Ethics in Health Sciences is a standing, independent, interdisciplinary committee. The committee has forty members – from a wide range of areas including government, university, philosophy, theology, and science. Parliament and other public bodies may seek ethics opinions from the Committee. The Committee also has a public education mandate and convenes an annual public conference on ethical issues. Jones suggests that the French model provides an exemplar for the process of developing ethics opinions in a pluralistic society.[55] He identifies the following stages as central:

1. Formal procedures for requesting ethics opinions
2. Interdisciplinary expertise in identifying ethical issues
3. Inclusive consultations and debate
4. Evolving deliberations to define guiding ethical principles in an ethics opinion
5. Drafting processes that accommodate differing ethical perspectives and that harmonize value conflicts
6. Processes to disseminate the ethics opinion and advance public education and discussion

The Committee's work has played an important role in shaping national discussion of issues and has resulted in legislation concerning biotechnology patents, genetic testing, and medically assisted procreation.

Second, Norway has an ethics advisory framework that centres on biotechnology. The process by which central ethical principles has emerged in Norway is different than in France. In Norway, many of the principles originated in *ad hoc* parliamentary and governmental committees on ethics and were codified into law, including the law that created the Norwegian Biotechnology Advisory Board. By contrast, the French National Advisory Committee generated its own guiding principles. Since the early 1990's the Norwegian Biotechnology Advisory Board has issued many opinions on a wide range of matters – including sustainable development, protection of human health, privacy and confidentiality. The Norwegian Board also plays a more regulatory role than the French Advisory Committee, e.g., in reviewing specific applications for genetically modified organisms. In this respect, there may be a tension between its advisory and regulatory functions. Finally, like the French Committee, the Norwegian Board is involved in fostering

[54] As indicated in McDonald et al,*The Governance of Health Research Involving Human Subjects*, Law Commission of Canada (forthcoming), CCAC's ostensible counterpart on the human research side – the National Council on the Ethics of Human Research or NCEHR – has a very restricted mandate and is not in a position to make or even advise on national policy for research involving humans. See Section F-1.

[55] Derek Jones, p. 14, 1999.

public education through national workshops and international conferences and through its many reports.

Third, the European Union has had two successive committees to deal with issues of ethics in biotechnology. The first committee, which lasted from 1991 to 1998, was a small (seven to nine person) group called the Group of Advisors on the Ethical Implications of Biotechnology of the European Union. It followed a process like that of the French Advisory Committee with initial background and technical reports, expert consultation, public hearings and frequent meetings to facilitate consensus. While the Group of Advisors began with fairly narrow terms of references, it has over time broadened its concerns culminating in its final opinion on the 1998-2002 research and technological program of the EU. This opinion laid the basis for a broad EU framework for biotechnology. Central issues in the framework include:

- Considering biotechnology on the basis of respecting national difference and shared common values
- The need to reconcile value conflicts in scientific research
- Concerns for animal welfare
- Respect for central values in research involving humans
- Grounding ethics assessments on basic ethics research

The EU acted on this report and in 1998 created a new body, the European Group on Ethics in Science and the New Technologies, a twelve-person group with a broader mandate. The evolution of this larger and widened mandate says something important about ethics and biotechnology – the interconnectedness of ethical issues – and about the needs of contemporary governments – for a full spectrum examination of the ethical issues raised by modern biotechnology.

2. Apparent international agreement on ethical norms

In his 1998 and 1999 papers, Derek Jones provides a very useful table of sample international ethical norms derived from canvassing leading documents on ethics and biotechnology and then identifying important ethical principles that are explicitly cited.[56] The list might be interpreted in two different ways. On Jones' interpretation, a significant finding is the high degree of overlap and agreement on basic principles. This can be seen as representing growing international consensus on basic norms in many areas, e.g., in the ethics of human research.[57] A different interpretation is that nominal agreement on general principles masks serious and substantive disagreements.

Similarly, one might ask whether the apparent recent international consensus on banning human cloning is really a matter of deeply and widely shared values or only a somewhat superficial temporary agreement regarding the development of a particular technology at a particular time. In 1997, there was the announcement of the cloning of Dolly the sheep. This raised the question of the extension of this technology to human cloning and to the use of cloning generally. Within a short period of time, the French National Bioethics Committee described cloning as a "grievous assault on human dignity", the EU ethics advisory group asked for strict regulation of animal cloning and a prohibition of human cloning, the US National Bioethics Advisory Committee proposed a five-year ban on federal funding for human cloning, UNESCO declared human cloning "contrary to

[56] Jones 1999, Table A, p. 12

[57] Baruch Brody (1998), The Ethics of Biomedical Research: An International Perspective, Oxford, Oxford University Press p. 36

human dignity" and the Council of Europe created a protocol banning human cloning. Again, it is fair to ask if the apparent agreement is superficial or substantial.

V. Gaps and potential areas for future research

As indicated in the forward, the main purpose of this paper is to provide a synthesis of six background research papers that were part of the renewal of the Canadian biotechnology strategy – a renewal that led to the adoption of CBS and the establishment of CBAC. In this part of the paper, the author has been asked to point out "gaps" in the information provided in the six papers. To do that, it is essential to clearly state what in the opinion of the author the papers have done.

1. They have provided an account of ethics and its relevance to policy making for biotechnology.
2. They have identified significant responsibilities of the Government of Canada in this area.
3. They have provided some suggestions about the way in which the Government of Canada might address these responsibilities.

The synthesis provided in this current paper has focussed on items (1) and (2). The third item (3), which is particularly articulated in the three closely related papers by Derek Jones, seems to me to have been addressed through the establishment of CBAC. So the extent to which CBAC wishes to take up specific recommendations in the Jones' paper, e.g., regarding providing educational services for government agencies and the like, are a matter for CBAC and not for this paper.

Five gaps are discussed below. CBAC might take on useful work in any of these areas.

A. The precautionary principle and other standards for dealing with complex benefits/harms tradeoffs under conditions of uncertainty

While many of the issues in this area are discussed in the papers by Espey and by Schrecker, Hoffmaster, Somerville, and Wellington, CBAC and the bodies it serves could use a good reference paper on standards for dealing with the tradeoffs between benefits and harms in situations under conditions of uncertainty. While these matters have been touched upon in Section IV of this paper, a good reference piece would have a glossary of standard terms and concepts, a fair-minded characterization of the main lines of debate between different perspectives, and a useful guide to parts of the extensive literature that are relevant to policy contexts. The literature that would be canvassed is rich and complex. Having a guide to it would be helpful for CBAC itself and the agencies it serves. Given the centrality of such issues to debates about biotechnology, such a reference piece would also provide a platform for current and future research projects and prevent needless repetition.

B. "Fourth hurdle" restrictions on biotechnology

Schrecker, Hoffmaster, Somerville and Wellington provide an interesting but brief discussion of fourth hurdle restrictions on biotechnology.[58] This is a topic worth developing in its own right, particularly in regard to the potential tradeoffs that may be

[58] p. 148

forced by fourth hurdle restrictions. Thus, arguments urged on behalf of "fourth hurdle" restrictions on biotechnology and other forms of technology often have a double-edged aspect. While fourth hurdles may serve important social concerns of the sort described above in this paper, they also can at the same time be ways of restricting trade and nullifying hard-won competitive advantages or negating natural advantages. Though many would argue otherwise, I also believe that such fourth hurdles can and have been used to disadvantage poorer countries, e.g., by developed countries setting restrictions on imports from the developing countries.

Yet adopting a strategy that *a priori* rejects the legitimacy of any fourth hurdle impediments is myopic in two distinct ways. First, it may be morally myopic in rejecting out of hand legitimate concerns. Second, even if one has doubts about the legitimacy of the concerns themselves, it may be politically myopic in that the concerns are unlikely to disappear if ignored. They may simply re-emerge in the form of a first, second or third hurdle argument.

C. Promoting while regulating – avoiding conflicts of interest and managing conflicting obligations

As noted earlier, concerns have been expressed about the dual roles of government as both a promoter and regulator of biotechnology in the private and public spheres. This gives rise to two issues. One is about conflicts of interest – real or apparent – and their avoidance. The other issue concerns the management of conflicting obligations. Conceptually the two issues are distinct. Conflicts of interest are morally suspect *per se* and thus to be avoided. Whereas, conflicting obligations (in the form of obligations to support interests that happen to be in conflict) are not *per se* morally suspect but have to be dealt with in a morally responsible manner.

An illustration may help explain the difference. A judge would have a conflict of interest if she rules on a case in which she has a direct financial or other personal interest, e.g., her partner is a party to the case. Here, it would be clearly wrong for her to sit in judgement on the case. On the other hand, a judge would face conflicting obligations if she were faced with a situation in which the plaintiff had a good case for a substantial delay in proceedings to assess newly discovered evidence and at the same time the defendant had a good case for a speedy resolution of a long-standing dispute. That is, there is both a good reason for delaying the case and a good reason for proceeding quickly with the case. Here the judge has to choose between two apparently right courses of action. Now while there may not be an obviously right choice in a conflicting obligations case, there will likely be better or worse choices. So the issue is not, as in the case of conflict of interest, a matter of avoidance; rather it is a matter of morally balancing and managing conflicting obligations. That is, the issues raised in the two are different, but both give rise to significant ethical choice situations.

In trying to promote and regulate biotechnology, the Government of Canada and its agencies face both types of situation. In terms of conflict of interest, the main concern should be with institutional as opposed to individual or personal conflicts of interest. Institutional conflicts of interest occur when institutions take on or are assigned roles in which a reasonably objective observer would say that the institution cannot fairly manage the roles in question. For example, it would be an institutional conflict of interest for a company to have its own chief financial officer provide an external or public audit of its

own books.[59] An independent auditor is necessary for this purpose. Similarly, institutions face conflicting obligations when, for example, they have to balance financial against environmental considerations.

As was the case for the first of the gaps identified – standards for dealing with benefit/harm and uncertainty, this topic strikes me as a fairly fundamental gap in the research. There is useful material in law, ethics, and policy to draw upon that would illuminate both types of situation for the government itself and its agencies for dealing with such matters. These are also issues that are quite relevant to private and not-for-profit sector organizations involved in Canadian biotechnology. For example, universities have partnered with government in biotechnological research and development. This sometimes gives rise to conflict of interest situations, e.g., researchers involved in peer review activities for areas in which they have commercial interests. It also can create situations in which universities are torn between conflicting obligations – e.g., between the production of publicly available knowledge and respect for the trade secrets of industrial partners.

D. Normative sources for Canadian governance of biotechnology

In the recent work that my colleagues and I did for the Law Commission of Canada on the governance of health research involving human subjects, we identified and examined various normative sources for governance of the area. Some of these were represented in laws and legal decisions at both provincial and federal levels. Others were more a matter of policy or else represented established institutional practices for public, private, and not-for-profit sector organizations. There were also professional standards and international agreements and declarations. From this, we drew a picture of governance that was in many cases inadvertent, confusing, and even contradictory. While this may not be the case for Canadian governance of biotechnology, it seems important to map the area.

In this regard, I would call special attention to the area of international agreements and understandings because these strike me as being much more important than may be widely understood especially in a period of global investment and trading.

E. International work on biotechnology and ethics

Closely related to the preceding suggestion is a further suggestion for research and information-gathering on international work in ethics and biotechnology. For example, the six papers synthesized have some information on the efforts of some countries that have bodies with a somewhat similar role to CBAC. But the material struck me as illustrative at best and rather unsystematic. There are significant gaps in terms of coverage with, for example, very little information on either the UK, or the US, our foremost trading partner.

Similarly, there is insufficient information about international efforts from a variety of sources (governmental, quasi-governmental, professional or from the NGO sector). It would seem highly relevant to CBAC's activities to identify the ethical standards adopted by scientists in such key areas as forestry, agriculture, and fisheries. For instance, the International Plant Genetic Resource Institute has recently revisited its code of ethics. The

[59] Internal audits are for a company's own use. External audits are produced to assure others, e.g., investors or creditors, of the accuracy and reliability of the financial report.

Institute's primary concern is with the preservation of genetic diversity especially in developing countries.[60] This concern for genetic diversity is relevant to Canadian biotechnology policies. An important question is whether biotechnology helps developing countries through increasing the total amount of food supplies or harms them through centralizing economic control in the hands of trans-national corporations and reducing local control.[61]

While CBAC has individuals with expertise in many of these areas, it would undoubtedly help the departments and agencies it serves and the Canadian public to survey from time to time the relevant standards in these areas. One area of special interest is around the development of internationally accepted ethical benchmarks in various biotechnology areas, e.g., gene therapy, food safety standards, or the humane treatment of transgenically modified animals. This is a moving target in that standards will evolve, however, the matters under consideration are central for CBAC and the agencies and interest groups it serves.

F. Conclusion

The six papers synthesized in this report show the relevance of ethical – all things considered – judgements to Canadian policy for biotechnology. With the adoption of the CBS and the establishment of CBAC, there is a policy umbrella and agency available to facilitate governmental consideration of ethical issues in biotechnology. The five gaps identified above represent significant areas for ethics research sponsored or conducted by CBAC. They represent areas that are fundamental to CBAC's mandate and are likely to be of considerable interest to CBAC's stakeholders.

[60] The International Plant Genetic Resource Institute is part of the Consultative Group on International Agricultural Research, which is well known for its work on the Green Revolution through the International Rice Research Institute and similar bodies for maize, wheat, potatoes, etc. I owe this information to Dr. Gene Namkoong (Forestry, UBC) an internationally renowned researcher and pioneer in forest genetics.

[61] The same concerns arose in regard to the Green Revolution of the 1960's.