Renewal of the Canadian Biotechnology Strategy

Resource Document

3

3.4 Ethics

3.4.1 Background Research Papers

Government of Canada Gouvernement du Canada

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Canadian Biotechnology Strategy Task Force
235 Queen Street, 7th Floor
Room 799B, East Tower
Ottawa ON K1A 0H5
Tel.: (613) 946-2848
Fax: (613) 946-2847
E-mail: cbsti@ic.gc.ca
Web site: **http://strategis.ic.gc.ca/cbs**

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Aussi disponible en français sous le titre : Renouvellement de la Stratégie canadienne en matière de biotechnologie, consultations en table ronde : documents de base.

Renewal of the Canadian Biotechnology Strategy Roundtable Consultation:

Background Documents

Ethics and Biotechnology:
The Role of the Government of Canada
by Derek J. Jones

Making Ethically Acceptable Policy Decisions:
Challenges Facing the Federal Government
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This document has been prepared by:

Derek J. Jones, JD

BioLex • Ethik
742 McEachran Avenue
Montreal QC H2V 3C7
Tel.: (514) 279-1016
Fax: (514) 279-7483

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Contents

Executive Summary

This report examines the role of the federal government in addressing ethical issues in biotechnology. Chapter 1 explores the ethical issues that are raised by biotechnology and models relied on to manage these issues. Chapter 2 focusses on governmental roles, accountability and existing federal structures and resources for addressing ethics issues. Chapter 3 offers recommendations for refining the role of the Government of Canada.

Ethical Issues in Biotechnology

A basic premise of this report is that questions and controversy on such biotechnological initiatives as patenting life, gene therapy, DNA banks, genetically engineered animals and food raise important issues of "public policy and regulatory ethics." As the biotechnological revolution continues, the associated ethical issues need to be identified, analyzed and imported into the policy-making responsibilities of government.

To illustrate important changes in the way ethical issues in biotechnology are addressed, the report examines three biotechnology case studies that implicate "public policy and regulatory ethics": cloning research in the 1970s, the human genome project, and a rDNA drug. Important lessons are drawn from the cases.

First, in public policy and regulatory debates on biotechnology, the trend is toward more explicit recognition of ethical issues and value contests.

Second, ethical issues arise across the entire life cycle of a biotechnological product or technique, from laboratory research, to broader testing, to product development, to general diffusion and use.

Third, one prominent structure that governments and society have increasingly relied on to identify and manage ethical issues is the independent, interdisciplinary advisory committee on ethics or biotechnology. When properly structured, such committees play significant roles in responding to and anticipating ethical problems. They:

- provide expert advisory opinions to government on ethical matters
- stimulate and channel public and governmental debate and reflection
- help build consensus toward a broad ethical framework and like norms that help define socially acceptable policy position
- inform public policy, regulation and law.

The case studies help identify four major models that have been used to develop substantive norms and to process ethical reflection:

- *professional standards model:* professional codes of ethics and conduct
- *case law model*: legal cases that raise ethical issues
- *public law model:* the public policy, legislative and regulatory process
- *advisory and ethics committee model:* independent and interdisciplinary.

Each model has strengths and limits in addressing ethical issues. Governments have often wed the public law model and the advisory and ethics committee model to create — at the international, national and ministerial level — publicly accountable ethics advisory committees.

Roles of the Federal Government

Largely through the public law process, the people of Canada have delegated to the federal government unique responsibilities and roles in the biotechnology ethics domain. Leading governmental roles include:

- advancing public process — debate, education and participation
- fairly distributing the benefits and burdens of biotechnology
- acting as a fiduciary of public monies and public trust
- fostering ethically acceptable conduct
- resolving disputes
- protecting public health, safety and those unable to protect themselves
- promoting research and development
- promoting and protecting human dignity.

Government Accountability: Norms and Process

The accountability of the federal government for "public policy and regulatory ethics" in biotechnology is largely a function of its paramount duties and roles, its substantive decisions and norms, and its processes for ensuring accountability.

The public law model aims to ensure that governments are answerable for the powers delegated and entrusted to them for the exercise of public duties. The important and sometimes exclusive nature of the roles of government requires that it be held to a high level of accountability.

Sometimes the governmental roles in biotechnology will conflict. Such role conflicts may be addressed by ensuring that substantive norms, policies, and processes are in place to identify, manage or prevent them. When conflicts do arise, the integrity and credibility of government may depend on whether it has effective mechanisms to identify, mediate, arbitrate or resolve underlying value contests for coherent policy development.

Partnership with Non-governmental Players

The government must discharge its roles and responsibilities in concert with a range of stakeholders, for not all classes of ethical issues in biotechnology will fall completely within the domain of primary federal government responsibility. Examples of such issues are those of a largely private nature or those that may best be addressed by professional ethics norms. When the government delegates primary ethical responsibility to quasi-governmental or non-governmental entities, accountability concerns require that the relationship between the entity and the government be rigorously scrutinized in terms of the formal structure, mandate, independence, reporting duties and policy formulation responsibilities.

Federal Ethics Resources and Structures

An initial portrait of existing governmental ethics structures and resources has emerged from interviews with government analysts, a review of governmental reports and a questionnaire. The questionnaire was sent to the government departments represented on the Interdepartmental Working Committee on Ethics and Biotechnology. The results indicate that some federal ethics resources and structures are relatively well developed. However, in general, planned and coherent growth and development are required. The findings includethe following.

Ethics Issues: Particularly since the early 1990s, the number of biotechnological public policy and regulatory questions that present ethical issues before the government has increased. Many expect this trend to continue or to accelerate.

Ethics Committees: On a national level, Canada lacks an identified public entity with responsibilities for reflection and advice on the ethics of biotechnology. On an interdepartmental level, since 1994, the Working Group on Ethics and Biotechnology has provided a forum for interdepartmental dialogue. At the federal departmental level, a few departments have interdisciplinary standing committees on ethics. Other departments are considering their establishment. However, much of the ethics in science work across the government appears to be discharged by internal, *ad hoc* working committees or by other existing institutional committees that sometimes address ethics in biotechnology issues. Historically, the government has regularly relied on external advisory committees, whose membership sometimes includes ethics expertise, to advise some departments and recommend ethical norms (see Table A of this report).

Ethics Personnel: Few departments employ formally designated ethicists, ethics officers or ethics resource persons. Rather, part-time ethics responsibilities typically are overlaid onto or developed from general legal, policy, technical or regulatory responsibilities of

government personnel. This tendency suggests that the human resources investment in ethics is limited and has not been consistently a component of strategic planning.

Ethics Education and Documentation: Respondents to the questionnaire indicate that they have availed themselves primarily of the occasional governmental educational ethics fora, external conferences and self-education for ethical training. External coursework in ethics has seldom been pursued. Within the past few years, an increasing number of governmental workshops, retreats, roundtables and lectures on ethical issues relevant to biotechnology has been made available to individuals within departments. Access to printed ethics periodicals and documentation has grown in recent years in some departments. Access to electronic ethics literature is widely reported.

External Ethics Resources: Several departments have had recourse to external ethics analysts for research, reports and ethics education. External expertise is also channelled into government through the federal advisory committee structure.

Refining the Government Role: Recommendations

Four-point Ethics Covenant

The federal government, those involved in biotechnology and the public should affirm a four-point ethics covenant as follows.

Stewardship: In its stewardship and fiduciary roles, the federal government serves as the societal agent to whom Canadians entrust unique powers and responsibilities to act in the best interests of the public. The public monies, powers and responsibilities entrusted to the government should be used to harness the promise and minimize the perils of biotechnology for attaining the social, environmental and economic goals of Canada.

Toward an Ethical Framework: From Ethical Pluralism to Ethical Frontiers: The federal government should explicitly state, as a cornerstone of its National Biotechnology Strategy, that the research, development and diffusion of biotechnology should proceed "in a manner consistent with Canadian values and norms of ethical conduct." Ethical pluralism is a healthy reality in democratic societies, and this is a policy goal to which all can aspire. The challenge is to define ethical norms and an acceptable range of conduct for the scientific and biotechnological enterprise.

Preventive Ethics: Part of the governmental stewardship role should involve adopting preventive approaches to ethical issues raised by biotechnology. A preventive ethics approach involves a commitment to going beyond simply reacting to ethical issues, to anticipating them for policy analysis and development.

Ethics Resources and Structures for the Future: Part of the new ethics covenant should include a renewed and explicit understanding regarding the investiture of public monies; that is, that public monies shall be concurrently invested in both ethical and commercio-scientific resources of biotechnology. Preventive ethics entails new national and institutional initiatives, resources, committee structures and mechanisms.

Programmatic Initiatives

To bring to fruition the principles of the new covenant, the government should undertake a number of concrete initiatives.

Processes toward an Ethical Framework: The government should commit, through its National Biotechnology Strategy, to engaging stakeholders and the public in a process for defining an ethical framework that shall guide the research, development and diffusion of biotechnology.

A Preventive Ethics Strategy:

- The government should implement a preventive ethics strategy, in part, through its role as funder of biotechnology research and programs.
- Recent initiatives should be broadened to establish, as a cornerstone of the new National Biotechnology Strategy (NBS), a commitment to examining formal ethics, law and social implications (ELSI) of biotechnology. A reasonable proportion of the funding for NBS should be devoted to a formal ELSI program.
- Government departments should develop one- to three-year work plans for ELSI research and project agendas.
- Partnerships with centres of learning and expertise across Canada should be developed through ELSI strategic grant programs.

Ethics Advisory Committees:

- Serious and utmost consideration should be given to the establishment of a national advisory committee that includes in its mandate reflection, advice, the promotion of public participation in and the development of preventive strategies on ethical issues raised by biotechnology.
- The standing national ethics committees of France and Denmark, the standing Norwegian National Biotechnology Advisory Committee, and the time-limited U.S. National Bioethics Advisory Committee offer alternate government models for the committee.
- Interim responsibilities for ethics might be assigned to a duly constituted interim advisory committee or its functional equivalent.

Internal Government Working Committees:

- There should be an interdepartmental entity responsible for ethics in biotechnology that:
  - facilitates, harmonizes and orchestrates biotechnology and ethics initiatives across the departments
  - provides for the departments an interface with any national advisory committee with an ethics mandate
  - discharges ethics coordinating responsibilities under the National Biotechnology Strategy.

  The committee should have a clear written mandate, senior level operational and reporting duties, and the expertise and resources commensurate with the increasing importance of ethics on the government biotechnology agenda.
- The interdepartmental entity should oversee a larger and broader survey of ethical resources and structures within the government, with emphasis on departments not involved in the questionnaire in this report.
- Initiatives should be undertaken to minimize duplication of efforts and resources, and to harmonize ethics in biotechnology undertakings across the federal government.
- The membership, terms of reference/mandate, resources and work plans of interdepartmental and departmental committees with responsibility in ethics should be reviewed and revised where appropriate. The responsibilities of such committees should include both anticipating and responding to ethics issues.
- The interdepartmental entity should coordinate the development and implementation of the one- to three-year ethics and biotechnology work plans for government departments.

Governmental Ethics Policy Centres: The policy sectors of such ministries as Health Canada, Justice Canada and Industry Canada play important roles in the evaluation of ethical issues in biotechnology. If such policy sectors are provided with sufficient mandates, resources, expertise and reporting duties, then they may serve as models for centres of ethical reflection, analysis and policy development within departments across the government.

Ethics Resource Persons: The role of "ethics resource persons" within departments should be reviewed, refined and broadened to include responsibilities for ethics work agendas, education, coordination, committees and substantive ethics analysis.

Ethics Education and Training:

- An interdepartmental ethics education initiative should be developed.
- Education and training in ethics should be regular, planned and coherent.

- Ethics committees and ethics resource persons should have prime responsibilities for, and be among the prime beneficiaries of, ethics education and training.
- Mechanisms should be in place to ensure that government researchers are educated on, and complying with, ethics norms.

Ethics Documentation and WWW:

- Ethics literature and documentation should be readily available for government committees, policy analysts, regulators, the public, etc.
- A list of the relevant ethics literature should be maintained and updated regularly within a federal government ethics databank or intranet.
- To further public education and participation, the federal government should provide and promote public access to selected ethics and biotechnology documents, literature and developments via the Internet/World Wide Web.
- A selection of the background papers on ethics and biotechnology that have been written for the government should be published.

Introduction

In the pluralistic societies . . . a complete consensus on moral and philosophical issues is not likely. . . . On the map of these new technologies, the ethical pathways are not yet clearly marked. . . .

— Group of Advisers on Ethical Implications of Biotechnology of the European Commission, 1996

Like all revolutions, the biotechnology revolution has begun to change the way we live and think. Over the past decade, it has particularly emerged from the research laboratory into the market and before the consuming public and governments. Like all technologies, it imparts benefits and burdens. Sometimes it prompts debate, contests of values and ethical uncertainty or controversy.

In this context, the report examines:

- the role and responsibilities of the Government of Canada in addressing ethical issues raised by biotechnology
- the processes and resources of government for discharging its evolving roles and responsibilities.

To address these issues, Chapter 1 of this report explores government roles through selected biotechnological case studies at the interface of law, ethics and public policy. The interface is defined in and referred to in this report as the "public policy and regulatory ethics" of biotechnology. The case studies help to identify four models of processing ethical reflection. The analysis reveals that numerous governments have turned to independent, interdisciplinary advisory committees on ethics/biotechnology as a leading process mechanism for channelling public debate and ethical reflection into regulatory and public policy on biotechnology. Chapter 2 focusses on a range of leading government roles and duties and government accountability in ethics. It also examines some of the resources and structures within the government for addressing ethics issues. Chapter 3 offers recommendations for refining the government role with a four-point ethics covenant.

1. Ethical Issues in Biotechnology

1.1. Identifying and Addressing "Ethical" Issues

1.1.1. Leading Public Policy Questions

A central and threshold question in determining the role(s) the federal government plays in responding to ethical issues of biotechnology is what is meant by "ethics." The literature indicates that a range of public policy issues have come before society and governments over the years, including the following sampling:

- *Conflict of Roles/Interest:* How does government effectively manage the promotion and regulation of biotechnology?
- *Research Limits:* Is some biotechnological research or product development so objectionable as to warrant temporary moratoria or permanent prohibitions?[1]
- *Tissue Disputes:* What norms will best regulate the procurement, storage, access and use of human tissue, cell lines and like human biological materials for research or cultivation into biotechnological agents?[2]
- *Labelling:* Should genetically engineered food products be labelled as such, to promote consumer sovereignty, individual and cultural autonomy and the informed assumption of even minimal risk?[3]
- *Transgenics:* Is it wrong to create transgenic animals or plants that do not ordinarily occur in nature?
- *Duties to Animals:* If the creation of genetically engineered animals is sometimes justified for furthering human health, what duties are nonetheless owed these creatures?[4]
- *Patenting Life:* Is it ethical to patent microbial, animal or human life forms?[5] Does the patenting of human cell lines commodify[6] the human person?

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1. U.S. National Bioethics Advisory Commission, *Cloning Human Beings* (Rockville MD: 1997).

2. See *Moore v. University of California,* discussed in subsection 1.3.3 below.

3. P. B. Thompson, "Food Biotechnology's Challenge to Cultural Integrity and Individual Consent," Hastings Center Report 27 (1997): 34–38.

4. Netherlands, *Animal Health and Welfare Act 1992*, art 66 (licence for biotechnological initiatives involving transgenic animals may issue if, *inter alia*, "there are no ethical objections . . .").

5. U.S .Congress, Office of Technology Assessment, *New Developments in Biotechnology: Patenting Life* (Washington, DC: GPO, 1989).

6. M. J. Radin, "Reflections on Objectification," *S. Cal. L. Rev.* 65 (1991): 341–54.

- *DNA Banks:* If criminal justice will be enhanced by compulsory DNA testing of criminals for inclusion in a national DNA data bank,[7] should we also apply the technology to military recruits,[8] job applicants, newborns?[9]
- *Personhood, Privacy and Human Dignity:* Does the scientific reductionism of biotechnology, when applied to humans, reconstruct or recast our vision and valuing of the human person? How, for instance, do we define and implement notions of genetic privacy, genetic ownership and genetic discrimination?
- *Intergenerational Justice:* What assessment standards or process may best ensure that the production today of genetically modified plants/organisms is consistent with sustainable development or the needs of future generations?[10]
- *Duties to Nature:* Beyond any duties that current generations of humans may owe to future generations[11] regarding biotechnological uses, what relevant ethical duties are owed directly to animals[12] and the ecosystem[13, 14]because of their intrinsic value?
- *Process:* What processes and mechanisms should society rely on to address the ethical implications of biotechnology?

If all such issues have yet to come before the Government of Canada, an increasing number nevertheless have drawn governmental attention in the 1990s. From 1990–92, for instance, diverse federal institutions produced reports on biotechnology, government policy and

7. Bill C-3, *DNA Identification Act*, House of Commons of Canada, (proposed legislation introduced September 1997).

8. *Mayfield v. Dalton*, 901 F. Supp. 300 (Dist. Hawaii, 1995) (upholding mandatory requirement that U.S. military recruits provide sample for and storage in DNA bank, to facilitate identification of war fatalities), judgment vacated for mootness, 109 F.3d. 1423 (9th Cir. 1997).

9. U.S. Congress, Office of Technology Assessment, *Genetic Witness: Forensic Uses of DNA Data* (Washington, DC: GPO, 1990).

10. Norwegian Biotechnology Advisory Board, *Proceedings of the International Conference on Release and Use of Genetically Modified Organisms: Sustainable Development and Legal Control*. P. Sandberg, ed. (Oslo: Norwegian Biotechnology Advisory Board, 1995).

11. E. B. Weis, "What Obligation Does Our Generation Owe to the Next? An Approach to Global Environmental Responsibility: Our Rights and Obligations to Future Generations for the Environment," *American Journal of International Law* 84 (1990): 198.

12. J. Feinberg, "The Rights of Animals and Unborn Generations," in W. T. Blackstone , ed., *Philosophy and Environmental Ethics* (Atlanta: University of Georgia Press, 1974), pp. 43–60.

13. C. M. Rose, "Given-ness and Gift: Property and the Quest for Environmental Ethics," *Environmental Law* 24 (1994): 1–31.

14. D. A. Brown, "Ethics, Science and Environmental Regulation," *Environmental Ethics* 9 (1987): 331–49.

associated ethical implications in genetic testing,[15, 16] the ownership of human tissue,[17] gene therapy,[18] DNA banking and privacy.[19] In 1993, a federal Royal Commission concluded a study that advanced an ethico-legal framework for controlling the diffusion of reproductive aspects of some biotechnological research and applications.[20] In 1994, the government held an Interdepartmental Workshop on Ethics and Biotechnology,[21] which led to the establishment of interdepartmental working group on ethics and biotechnology. In 1995, the Commissioner of Patents denied a patent claim for a rDNA higher life form[22] — a transgenic "onco-mouse" for use in cancer research. The decision has been appealed.[23] That same year, the government outlined proposals related to the labelling of novel foods derived through genetic engineering[24] — an issue that has generated new laws[25] and ethical opinions[26] abroad. In 1996, a House of Commons committee report called for the

15. Science Council of Canada. *Report 42: Genetics in Health Care.* Ottawa: Science Council of Canada, 1991

16. Law Reform Commission of Canada, *Genetic Heritage*, study paper by B. M. Knoppers (Ottawa: Supply and Services Canada, 1991).

17. Law Reform Commission of Canada, *Procurement and Transfer of Human Tissues and Organs* (Ottawa: Supply and Services Canada, 1992).

18. Medical Research Council of Canada, *Guidelines for Research on Somatic Cell Therapy in Humans* (Ottawa: 1990).

19. Privacy Commissioner of Canada, *Genetic Testing and Privacy* (Ottawa: Supply and Services Canada, 1992).

20. Royal Commission on Reproductive Technologies, *Proceed With Care: Final Report of the Royal Commission on New Reproductive Technologies* (Ottawa: Supply and Services Canada, 1993).

21. *Proceedings of Interdepartmental Workshop on Ethics and Biotechnology: Moving from Confrontation to Engagement* (Ottawa: 1994).

22. *In the Canadian Patent Office Decision of the Commissioner of Patents, Application 484,723*: Hull, Quebec, August 4, 1995.

23. *President and Fellows of Harvard College v. Commissioner of Patents of Canada*, Federal Court of Canada, Trial Division, #T-275-96, May 1996.

24. Agriculture Canada, Food Inspection Directorate, *Communique: Labelling of Novel Foods Derived Through Genetic Engineering* (Ottawa: December 1995).

25. *Minnesotta Stats*, s. 32.75 (1996) (voluntary recombinant bovine growth hormone labelling since 1994); 6 *Vermont Stats Ann.*, s. 2754 (West 1997) (mandatory recombinant bovine growth hormone labelling since 1993). The Vermont law was recently adjudged likely unconstitutional as a violation of free speech. *International Dairy Foods Association v. Amestoy*, 92 F3d 67 (2d Cir. 1996).

26. European Commission, Group of Advisers on Ethical Implications of Biotechnology. *Opinion No. 5 of 5 November 1995 on the Labelling of Foods Derived from Modern Biotechnology* (identifying safety, informed

establishment of an independent advisory commission on biotechnology that would also address ethical considerations.[27] Finally, the landmark cloning of the first adult animal (Dolly the sheep),[28, 29] in Europe in 1997 intensified scrutiny of the anti-cloning provisions of the reproductive technology legislation that Health Canada had proposed following the Royal Commission report.[30]

A fundamental premise of this report is that such regulatory, legal and policy questions present ethical issues. It is argued that the ethical issues need to be identified, analyzed and imported into the policy-making responsibilities of government. It will also be shown that those policy-making responsibilites cast important roles for the government in the ethics and biotechnology domain. The issues, roles and responsibilites require new approaches, processes and governmental structures and resources.

1.1.2. The Ethics, Law and Policy Interface

Some of the governmental responsibilites in biotechnology arise at the very interface of policy, law and ethics. While a full discussion of that interface exceeds the scope of this paper, important facets of it should nevertheless be noted, if only because government has important responsibilities in the formulation of public policy and law. Indeed, ethics, law and policy interface at various levels that ultimately influence public policy, including philosophically, functionally and practically. The law, ethics and policy interface converges into what we shall call "public policy and regulatory ethics."

Philosophical Interface

The suggestion that there is an important interface between ethics and law raises basic questions: what is "ethics" and what is "law"? These are ancient issues that have fascinated classic philosophers and modern students of jurisprudence alike. While some analysts have long separated law from morality, others have noted an overlap and interaction. From the

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consumer choices, cultural and religious considerations, technology assessment, food education/information mechanisms, animal welfare, as ethical issues in food labelling).

27. Canada, House of Commons, Standing Committee on Environment and Sustainable Development, *Biotechnology Regulation in Canada, A Matter of Public Confidence* (1996). Cf, Law Reform Commission of Canada. *Toward a Canadian Advisory Council on Biomedical Ethics*, study paper by J. L. Beaudoin et al. (Ottawa: Supply and Services Canada, 1990).

28. T. Wilmut, A. K. Schneike, J. McWhir, A. J. Kind and K. H. S. Campbell, "Viable Offspring Derived from Fetal and Adult Mammalian Cells" *Nature* 385 (1997): 810–13.

29. Editorial, "One Lamb, Much Fuss," *Lancet* 349 (1997): 661.

30. *Bill C-47: Human Reproductive and Genetic Technologies Act*, section 41A (1996).

perspective of law as codified morals, the distance between the legal and moral enterprise becomes thin, but important:

> Law, in certain respects, is our agency for translating morality into explicit social guidelines and practices. . . . The law often appeals to moral duties and rights, places sanctions on violators and in general strengthens the social importance of moral beliefs. Nevertheless, the law rightly backs away from attempting to legislate against everything that is morally wrong. . . .[31]

If the letter of the law imposes minimal norms, then the spirit of law joins ethics in aspiring to higher norms.

Functional Interface

Beyond the arguments of abstract philosophy and the philosophy of law, however, the relation between law and ethics becomes more evident by analysis of their shared functions, interaction and evolution. First, it is unsurprising that there is an analytical and functional overlap, because both the law and applied ethics function in scholarly and pragmatic modes. Shifts in the history of thought or values are likely to influence both fields. Thus, one finds both classical and critical theories of thought in law and modern bioethics. If formalism/positivism in law has been criticized by the rise of empiricism, realism and feminist jurisprudence,[32] then the formalism and reliance on abstract principles in some fields of applied ethics have likewise been criticized by analysts from empiricist, pragmatist and feminist schools of thought.[33] Second, the oft-noted rights-and-duties discourse of law has been thought sometimes to enrich and sometimes to limit the analytical discourse of applied ethics in medicine.[34] Third, ethics may sometimes prove fruitful for elucidating the value choices embedded in legal doctrines of public policy. Thus, the moral principle of autonomy is given legal effect through the informed consent doctrine in health law and through the liberty principle in constitutional human rights law. Basic ethical principles of respect for the person, human dignity and justice are advanced by the legal doctrines of confidentiality, privacy and equality (non-discrimination). These legal doctrines are often expressed in human rights instruments or provisions.

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31. T. L. Beauchamp and L. Walters, eds., *Contemporary Issues in Bioethics* (California: Wadsworth Publishing, 1989), pp. 36–37.

32. R. Devlin, ed., *Canadian Perspectives on Legal Theory*, (Toronto: Emond Montgomery, 1991).

33. Bioethics and Law Symposium, "Deconstructing Traditional Paradigms in Bioethics: Race, Gender, Class and Culture," *St. Louis Univ. Pub. L. Rev.* 15 (1996): 183–469.

34. C. Schneider, "Bioethics in the Language of Law," *Hastings Center Rpt.* 24 (1994): 16–24.

Fourth, both the law and applied ethics often function by reliance on a methodological approach of procedural and substantive analysis to achieve their ends. Thus, absent consensus on substantive outcomes, applied ethics and law may emphasize and structure diligent processes to govern reflection on the merits of issues and to search for substantive doctrines or potentially governing principles. Finally, both law and applied ethics shape public policy by articulating and applying norms of morality through written codes of conduct. Written codes of professional ethics, written conflict of interest guidelines for institutions, and public laws may regulate and prohibit conduct in the biotechnology domain. Such parallels between law and ethics have led some analysts to regard them as an often complementary dynamic.[35] Ethics and law may thus work in tandem to inject qualitative values into, and thus guide, scientific, technological or commercial development.

Practical Interface

Practically, some examples illustrate the law, bioethics and policy interface. Legislation, for instance, sometimes directly expresses and enforces public values relevant to biotechnology initiatives. That the doctrine of "sustainable development" finds expression in numerous pieces of Canadian environmental legislation indicates that the values embedded in intergenerational justice issues have found formal societal expression in law. The values and ethical theories underlying the cruelty to animal provisions of the *Criminal Code* of Canada may prove relevant to defining duties, rights or interests in animal welfare ethics and agricultural and environmental ethics. In some countries, patent law has traditionally excluded from patentable subject matter inventions contrary to "public order or morality."[36] Indeed, ethical concerns about commodification of the human body in a biotechnological era have prompted other countries to include morality clauses in modern bioethics legislation on patent law.[37] A society that regards the patenting of the human body or its elements as violative of the respect due human dignity and the human person might construe such provisions as legally preempting the patenting of elements derived from the human body. Some European analysts have taken this position,[38] even as other analysts

35. D. Roy, J. Williams and B. Dickens, *Bioethics in Canada* (Scarborough: Prentice Hall Canada, 1994), pp. 68–86.

36. *Convention on the Grant of European Patents*, art. 53.

37. Article 7, *Loi no. 94-653 du 29 juillet 1994*, relative au respect du corps humain (France).

38. European Commission, Group of Advisers on Ethical Implications of Biotechnology, *Opinion No. 8 of 25 September 1996 on Patent Inventions involving Elements of Human Origin* (hereinafter GAEIB).

question whether patent protection is the proper forum for ethical discussions.[39] Beyond public law, the formal dispute resolution function of the courts may serve a societal mechanism for addressing novel bioethical and biotechnological disputes, legal contests and value conflicts. In 1990, in the landmark case of *Moore v. University of California*, for example, the California Supreme Court drew on established ethico-legal principles of loyalty to the patient and autonomy/informed consent to outline the duties of physician-researchers involved in the procurement of human biological materials for developing biotechnological products.[40] In *Moore*, the patient had alleged that, without his knowledge or consent, the physician had misappropriated the patient's tissue for use in producing a multimillion-dollar rDNA anti-cancer drug.

Public Policy and Regulatory Ethics

Finally, ethical reflection may be harnessed to divine or articulate guiding principles of an ethical framework for public policy or regulation:

> Most moral principles are already embedded in public morality and public policies generally in a vague and under analyzed form. But if they are already there, how can the philosophical development of these principles assist us in the enormously complicated task of creating law and public policy? There are at least two ways in which applied ethics often overlaps with, and provide foundations for, law and public policy. First, there are conceptual problems that require careful explication in order that people communicate clearly and efficiently. . . . The point of conceptual analysis of these fundamental terms is to be as clear and precise as possible without begging any substantive moral issue. . . .
>
> Second, normative problems require equally careful attention, in order that we determine what ought to be done in law and public policy. Here, philosophers must abandon the neutrality about issues involving conceptual clarification, for they are engaged in that controversial world of human affairs where there are conflicting interests, goals and ideals. Their objective should be to formulate and apply general principles that can be fairly used to guide public policy. . . .[41]

39. J. D. Morrow, "Patentable Subject Matter: Emerging Technologies," in *Patent Law of Canada*, edited by G. Henderson (Toronto: Carswell, 1994), pp. 24–25.

40. 793 P.2d 479 (Cal. 1990), discussed in Law Reform Commission of Canada, *Procurement and Transfer of Human Tissues and Organs* (Ottawa: Supply and Services Canada, 1992), pp. 72–77, 188; see also Nuffield Council on Bioethics, *Human Tissue: Ethical and Legal Issues* (London, UK: Nuffield Foundation, 1995).

41. Beauchamp, op cit., p. 35.

Some have described this as "regulatory and policy ethics;"[42] others, as "public ethics."[43] This report shall use the term, "public policy and regulatory ethics." However described, it has some history of effectiveness. In the health and social science ethics domains, the articulation of guiding ethical principles has a relatively long tradition. In Canada in the 1970s, the development of ethical norms for federally funded social science research was based, in part, on the articulation of guiding ethical principles.[44] Similarly, the discussion of the principles of justice, beneficence, and respect of the person in the Belmont Report[45] in the 1970s helped to provide the framework for subsequent public law regulation of human experimentation in the United States.[46] If such principles have spawned intense theoretical debate, they have nevertheless been applied in policy. They have recently been adopted in Dutch policy for regulating transgenic animal research.[47] More importantly, as will be shown below, the harnessing of public debate and expert reflection into an ethical framework or value system to guide public policy and law has emerged as a leading approach to the management of ethical and social issues in biotechnology.

1.2. Selected Ethics Case Studies: Research, Development and Diffusion of Biotechnology

The interaction between ethics, law and public policy tends to become more concrete when actual controversies arise regarding the research, development or diffusion of biotechnology. Accordingly, this chapter of the paper examines three biotechnology cases that have arisen over the past quarter-century. Each of the case studies implicates "pubic policy and regulatory ethics."[48] Case Study 1 recounts one of the first major public international controversies in biotechnology: genetic engineering or cloning in the 1970s. The case study is important because it exposes different meanings of ethics and the evolution of ethics discourse in debate and public policy formulation. The case also highlights the early models and processes through which society and government reacted to

42. W. T. Reich, ed., *Encyclopedia of Bioethics* (New York: Simon and Schuster MacMillan, 1995), pp. 250–51.

43. Roy et al., *op. cit.*, p. 35.

44. Canada Council, *Report of the Consultative Group on Ethics: Ethics* (Ottawa: Canada Council, 1977).

45. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Research* (Washington, DC: GPO, 1979).

46. R. J. Levine. *Ethics and Regulation of Clinical Research* (Baltimore: Urban and Schwarzenberg, 1986).

47. Netherlands, *Animal Health and Welfare Act of 1992*, articles 66–72.

48. See text accompanying notes 41–44, above.

biotechnology controversy to channel ethical considerations into public policy. Case Study 2 illustrates more modern preventive ethics approaches that governments have recently employed to manage ethics issues raised by some biotechnological research and developments. Case Study 3 examines ethical issues associated with a federally licensed rDNA drug. As with the other case studies, the case illustrates how the locus of ethical issues may shift through the development, diffusion and use of a biotechnology product.

Case Study 1. Contested Frontiers: The First Decade of rDNA — Circa 1970–80[49]

1970 • *Fabricated Man:* Paul Ramsey, a leading theological ethicist notes the following:

> The imminent providence of a morally blind biological technology decrees, of course, that men/gods *must* do what they *can* do. . . . the *sine qua non* of any morality at all, of any future for humanism, must be the premise that there may be a number of things that we *can* do that *ought* not to be done. Our common inquiry must be to fix on those things that are worthy of man from among the multitude of things he is more capable of doing. Any other premise amounts to a total abdication of human moral reasoning and judgment and the total abasement of man before the relentless advancement of biological and medical technology. . . . This is the edification to be found in the thought that we should not play God before we have learned to be men, and as we learn to be men, we will not want to play God.[50]

1971 • *Genetic Engineering:* Stanford University biochemist develops prototype method for recombining the DNA of a cancer virus into a bacterial virus. After safety concerns are expressed by fellow scientists, the researcher defers the experiment so the issues may be explored.

1973 • Participants in an annual scientific conference publish[51] a letter to the U.S. National Academy of Sciences requesting the appointment of a committee to examine the laboratory and public health hazards of rDNA.

49. Based, in part, on J. P. Swazey, J. R. Sorenson and C. B. Wong. Risk and Benefits, Rights and Responsibilities: A History of the Recombinant DNA Research Controversy, *Southern Cal. L. Rev.* 51 (1978): 1019–78; C. Grobstein, *A Double Image of the Double Helix* (San Francisco: Freeman and Co., 1979); and S. Krimsky, *Genetic Alchemy: The Social History of the Recombinant DNA Controversy* (Cambridge, MA: MIT Press 1982).

50. P. Ramsey, *Fabricated Man* (New Haven: Yale University Press, 1970), pp. 149–51.

51. *Science* 181 (1975): 1114.

1974
- *U.S. National Academy of Science* committee publishes a letter (a) requesting that the international scientific community join in a voluntary moratorium on rDNA experiments until the hazards can be studied; (b) requesting the U.S. National Institutes of Health to consider establishing an advisory committee for establishing recommendations on rDNA; and (c) calling for an international conference to examine scientific progress and the potential hazards of rDNA.
- *U.S. National Institutes of Health (NIH) Recombinant DNA Molecular Program Advisory Committee (RAC)* is established to assess the state of the art, possible hazards to the public health and environment and to recommend guidelines.[5252] The RAC would eventually establish a working subcommittee on gene therapy in the 1980s and continue its work into the 1990s.

1975
- *Asilomar Conference:* 155 U.S. invitees from research, governmental, industrial and legal communities and 51 participants from other nations assemble in California to review rDNA. The conference report recommends procedures and guidelines for the physical and biological containment of rDNA and proposes a moratorium on particular kinds of rDNA research.
- *Australian Academy of Sciences* issues guidelines on genetic engineering research.
- *UNESCO* sponsors meeting on ethical, legal and social implications of rDNA research.

1976
- *U.S. NIH* publishes guidelines on rDNA research.[53]
- *Public Law:* U.S. Congressional hearings on oversight and federal regulation of rDNA research, include a proposal to establish a national, multidisciplinary advisory commission to examine the medical, legal, ethical and social issues.
- *Cambridge City Council* proposes a two-year "good faith" moratorium on particular rDNA research and appoints a citizen review board to prepare recommendations, following the proposed construction of rDNA biological laboratories at Harvard University.
- *Advisory Committee to the British Department of Education and Science* issues a draft code of practice for rDNA research.

1977
- *Ecology:* U.S. government releases environmental impact statement on rDNA research.

52. *Federal Register* (U.S.) 39 (1974): 39,306.

53. *Federal Register* (U.S.) 41 (July 7, 1976): 17,902.

- *Biosafety:* A special *Advisory Committee of the Medical Research Council of Canada* recommends biosafety guidelines to govern rDNA research funded by the Council.[54]

1978
- *RAC Membership:* Membership of the rDNA Advisory Committee (RAC) to the U.S. NIH is broadened to increase public representation on the Committee.

1980
- *Pope John Paul II:*

> Scientific knowledge has its own laws by which it must abide. It must also recognize however, . . . an impassable limit in respect for the person and in protection of his right to live any way worthy of the human being. . . . Science is not the highest value to which all others must be subordinated.[55]

- *Patenting Lifeforms:* The U.S. Supreme Court holds that a human-made, genetically engineered bacteria capable of breaking down crude oil is patentable subject matter.[56] The decision prompts moral questions about patenting lifeforms.

1982
- *Council of Europe:* Parliamentary Assembly calls for a right to inherit a genetic pattern that has not been artificially changed to be made an official provision of European human rights law.[57]
- *U.S. President's Commission:* In a report on the social and ethical issues of genetic engineering in human beings, the Commission concludes that:

> [t]hese issues are not matters for a single day, deserving of occasional attention. They will be of concern . . . for the foreseeable future: indeed, the results of research and development in gene splicing will be one of the major determinants of the shape of that future. Thus, it is important that this field, with its profound social and ethical consequences, retain a place at the very centre of the conversation of mankind. . . .

54. Medical Research Council of Canada, *Guidelines for the Handling of rDNA Molecules and Animal Viruses and Cells* (Ottawa: 1977).

55. *L'Osservatore Romano*, October 27, 1980.

56. *Diamond* v. *Chakrabarty*, 447 U.S. 303 (1980).

57. Recommendation 934 of 26 Jan. 1982. *Intl. Dig. Hlth. Legs.* 33 (1982): 382–385.

> The commission advances recommendations to encourage continuing federal oversight, education, and the development of standards and procedures on rDNA.[5858]

Lessons from the First Decade of rDNA

Several enduring lessons emerge from the first decade of publicly controverted biotechnology issues.

Ethical Discourse: The first lesson concerns the evolution of the ethical debate from an implied ethics discourse to an express ethics discourse. Most of the debate during the decade centred on risk assessment, uncertainty, and procedures and strategies to contain potential risk posed by rDNA to human health and the environment. At first blush, the biosafety focus might not be regarded as an ethical discourse. Broader considerations may suggest otherwise, however. For example, a safety discourse and policy response are not value neutral. Indeed, beneath the crust of technical language flow ethically laden considerations. From a professional and societal perspective for instance, the public trust in and credibility of the scientific enterprise to advance knowledge for human welfare are positive values. More fundamentally, a discourse that leads to public policy regimes on safety advances the protection of human health and life, and thus accords with some of the most significant of modern public values. The prevention of bodily harm is, moreover, an ancient Western value that has long found formal expression in theological, philosophical, professional and legal codes of right conduct. Finally, a safety calculus involves risk–benefit analysis. The uninformed or informed assumption and allocation of risks implicate such ethical principles as autonomy and justice, which helps explain why government analysts, ethics committees and scholars have included competent risk assessment within an ethical framework for evaluating biotechnology.[59,60] In short, though the word "ethics" may not have been regularly employed by the preponderantly scientific participants in the early debate, the essentially consequentialist concern for safety bespeaks an implied ethical discourse.

58. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Splicing Life: The Social and Ethical Issues of Genetic Engineering with Human Beings* (Washington, DC: GPO, 1982), pp. 81–82.

59. M. J. Reiss and R. Straughan, *Improving Nature? The Science and Ethics of Genetic Engineering* (Oxford: Cambridge University Press, 1996): 43–68.

60. GAEIB, *op. cit.*

Ethical Frontiers: Secondly, if the consequentialist concerns over safety were the dominant theme, non-consequentialist and more explicit ethical concerns were also voiced. Concern that gene splicing may pose intrinsic wrongs, irrespective of its consequences, were voiced by non-scientists, religious authorities and ethics conferences. Some of the formalist or deontological questions of two decades ago still resonate in the biotechnology debates of the 1990s:

- Does genetic engineering, by intervening in the genetic lottery, contravene natural law?
- Are scientists playing God?
- Does the creation of new life forms, by transcending natural barriers, infringe the sanctity of life?

Together, the deontological and biosafety concerns point to a second lesson from the era: implied and explicit ethical concerns may sometimes set outer limits or boundaries for scientific inquiry and biotechnological development.

Processing Ethical Deliberation: Advisory Committees: A third lesson from the era lies in the process and structures through which society channelled the ethical debates into policy. Scientists responded to the call for an international interim moratorium on rDNA and displayed what might be regarded as the virtues of peer review and self regulation. They turned as well to professional consensus conferences to address scientific issues. The public initially participated in a limited capacity in some U.S. locales, like Boston, and through congressional hearings in the United States. Governments in the United States, Australia, the United Kingdom and Canada responded to the rDNA controversy by appointing committees to examine the issues and advise the government on norms and procedures. Typically, the committees (a) were largely composed of prominent research scientists from academia, (b) were attached to federal ministries of health or medical research, (c) had a mandate to address scientific issues, and (d) were time-limited. The rDNA Advisory Committee (RAC) to the U.S. NIH was a notable exception. As the chronology indicates, in 1978, the RAC membership was diversified to increase the public membership and interdisciplinary composition, and its mandate was extended into relevant social issues. It eventually became a standing advisory committee; today, it is regarded as a significant forum for the public discussion of ethical and social issues of such rDNA applications as gene therapy.[61] Such changes signal important shifts from a largely reactive toward a

61. In ongoing refinement of the role of the RAC, it was recently proposed that the Advisory Committee remain responsible *inter alia* for (a) identifying all the human gene transfer experiments deserving a public discussion, (b) identifying novel ethical issues relevant to specific human issues of gene transfer (c) identifying novel scientific and safety issues relevant to specific human applications of gene transfer, and (d) identifying broad scientific and ethical/social issues relevant to gene therapy research; see U.S. Department of Health and Human Services, National Institutes of Health, "Recombinant DNA Research: Proposed Actions Under the Guidelines," *Federal Register* 61 (November 22, 1996): 59725–42, at p. 59729.

planned, pro-active mode; from a technical, peer review committee to an interdisciplinary, more public, advisory committee model of oversight of biotechnology. The statutory creation in 1978 of the U.S. President's Commission[62] that *inter alia* examined gene splicing in the early 1980s became one of the prototypes for subsequent government management of social and ethical implications of biotechnology; namely, through an independent, expert, interdisciplinary advisory commission or committee.

Case Study 2. Preventive Ethics and the Human Genome Project

The Human Genome Project illustrates what might be regarded as a preventive ethics approach to biotechnology. Begun in the late 1980s, the Human Genome Project (HGP) is an international effort of scientists to map and sequence genetic information stored on the 23 pairs of human chromosomes. Researchers are intent on identifying an estimated 100 000 genes that compose the human DNA, the blueprint of heredity. The genesis behind the idea is that a better understanding of the functioning of the human genome will eventually lead to the treatment of thousands of genetic diseases, including those with a genetic predisposition.

What has become innovative about this odyssey into basic genetic research is the simultaneous initiative to study the relevant ethical, legal and social implications (ELSI). The so-called ELSI initiatives are financed by a small percentage of the national human genome research budgets. According to one ethicist, an ELSI program "occupies a unique place in the history of science: it is the first major scientific initiative to include from its inception a commitment to systematically exploring the ethical, legal and social issues it raises."[63] In Canada, for instance, the Genome Analysis and Technology Program (CGAT) was funded by Industry Canada, the Medical Research Council of Canada (MRC), the National Cancer Institute of Canada, the National Science and Engineering Council of Canada (NSERC) and the Social Science and Humanities Research Council of Canada (SSHRC). One of the objectives of CGAT was "to address and anticipate the medical, ethical and legal implications (MELSI) of genome research and related applications to individuals in society."[64] In 1995, some 7 percent of the CGAT budget was devoted to MELSI issues, such as commercialization and human genetics, multiculturalism, etc. In the U.S. Human Genome Project, where ELSI programs originated, in addition to providing

62. Public Law 95-622 of November 9, 1978, 92 Stat. 3438.

63. T. H. Murray, "Speaking Unsmooth Things about the Human Genome Project," in *Gene Mapping: Using the Law and Ethics as Guides*, edited by G. J. Annas, ed. (New York: Oxford University Press, 1992): pp. 246–54.

64. Canadian Genome Analysis and Technology Program (**http://cgat.bch.umontreal.ca**).

funding of basic genetics ethics research, an ELSI Working Group has been established to analyze critical issues, identify emerging trends and advance public understanding of such issues as informed consent, privacy, discrimination in genetic testing, intellectual property, etc. In an extension beyond the human genome project, the European Union has expressly included consideration of ethical and socio-economic implications of biotechnology in the 1994–98 funding of its biotechnology program.[65]

Thus, in the Canadian and U.S. HGP programs and in the European biotechnology program, strategic funding of basic ethics research has been established as a strategy for analyzing and anticipating major socio-ethical issues raised by biotechnology initiatives. The monies involved underscore the governmental role as a fiduciary and steward of publicly funded research. Indeed, a concurrent financial and programmatic commitment to independent, critical assessment of ELSI issues as part of the investment of society in particular scientific research constitutes a unique "social bargain" intended to ensure broad pubic accountability.[66] While the novelty of such programs precludes definitive evaluation of their effectiveness, major reports[67,68] and ethics research tools[69] have emanated from the U.S. ELSI program.

Within the United Nations community, the United Nations Education Scientific and Cultural Organization (UNESCO) has established an international bioethics committee that works with other national ethics committees, international and intergovernmental organizations to examine ethical issues raised by the genome project. In an initiative that unifies bioethics and human rights, it has been drafting a "Universal Declaration on the Protection of the Human Genome and Human Rights." The July 1997 draft Declaration encourages nations to promote the establishment of independent, interdisciplinary ethics committees to assess relevant ethical and social issues.[70] The declaration is targeted for

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65. *Off. J. Eur. Comm.* L. December 13, 1994, p. 361; European Commission Biotechnology Projects **(http://europa.eu.int/en/comm/dg12/biotech/biot-esl.html)**.

66. U.S. National Institutes of Health/Department of Energy, *Report of the Joint NIH/DOE Committee to Evaluate the Ethical, Legal and Social Implications Program of the Human Genome Project* (Washington, DC: 1996).

67. National Institutes of Health and Department of Energy, Working Group on ELSI, Task Force on Genetic Testing, "Proposed Recommendations of the Task Force on Genetic Testing," *Fed. Reg.* 62 (1997): 4539–47.

68. U.S. National Research Council, Institute of Medicine, *Assessing Genetic Risks: Implications for Health and Social Policy* (Washington: National Academy Press, 1994).

69. U.S. Department of Energy, Office of Energy Research, *ELSI Bibliography: Ethical Legal and Social Implications of the Human Genome Project* (Washington: DOE, 1993).

70. UNESCO, Draft of a Universal Declaration on the Human Genome and Human Rights, July 1997, article 16 **(http://www.unesco.org/ibc/uk/genome/projet/index.html)**.

presentation to the United Nations for adoption in 1998, the year that shall mark the 50th anniversary of the Universal Declaration of Human Rights. Some regard this initiative as a critical and "unique opportunity" to codify international consensus on such ethico-legal norms as autonomy, equity, privacy and justice, into a public instrument that shall provide proactive, "principled direction" to the emerging uses of the fruits of the human genome project.[71]

Hence, in contrast to the largely reactive response to rDNA in the 1970s, the ELSI branch of the HGP illustrates a "preventive approach" to addressing ethical implications of biotechnological research and development. The establishment of standing ethics advisory committees to anticipate and respond to issues illustrates another concrete instance of preventive ethics. Both examples are consistent with the recent call of the federal government for preventive, interdisciplinary strategies for managing science and technology into the next century:

> **PREVENTIVE APPROACHES:** There has been a growing recognition that the best and usually less expensive policy is to prevent problems from occurring. . . . Our S&T [science and technology] priorities should therefore shift from reacting and problem solving to anticipating opportunities and issues, assessing risk and bringing together the multidisciplinary resources required. These resources include not only the hard sciences but also the insights provided by the health and environmental sciences as well as social sciences and humanities. There is a central place for S&T in developing innovative means to make all Canadians aware of preventive approaches. . . .[72]

Case Study 3. rDNA Human Growth Hormone (HGH)

The recent societal shift from traditional human growth hormone therapy to rDNA HGH therapy illustrates how the locus of ethical issues in the development of a technology may evolve. The story specifically highlights at least three clusters of ethical issues: tissue procurement ethics, risk–benefit ethics and clinical ethics. HGH has been used for decades to treat children with HGH deficiency. For years, Canadian society had generated HGH through a federally sponsored[73] national program that involved the annual procurement of some 15 000 pituitaries, the extraction and purification of growth hormone therefrom and

71. B. M. Knoppers and R. Chadwick, "The Human Genome Project: Under an International Ethical Microscope," *Science* 265 (1994): 2035–36.

72. Industry Canada, *Science and Technology for the New Century: A Federal Strategy* (Ottawa: Supply and Services Canada, 1996), p. 26.

73. H. Guyda, H. Frieson, J. D. Bailey et al., "Medical Research Council of Canada Therapeutic Trial of Human Growth Hormone: First 5 Years of Therapy," *Can Med. Assoc. J.* 112 (1975): 1301–09.

the subsequent administration of HGH as a drug.[74] The national program relied on the collection of pituitary glands secured at autopsy from cadavers. Such procurement practices prompted ethical questions when some provinces proposed and enacted tissue donation laws: to increase supplies of HGH, should essentially non-consensual procurement of pituitaries be undertaken, when the general approach in Canada otherwise is express consent for tissue donation?[75]

A second cluster of ethical issues concerns the federal licensure of HGH as a drug. In the mid-1980s, increasing evidence emerged that cadaveric-derived HGH was likely contaminated with a slow but lethal virus.[76] This knowledge effectively shifted the risk and benefits of using cadaveric-derived HGH. Could pharmaceutical regulators and pediatrician ignore the new risk–benefit calculus, especially if potential alternatives were becoming available? Fortunately, rDNA HGH, which was then going through the federal licensure process, yields purer and larger quantities of the hormone. The circumstances prompted some nations, including Canada, to terminate use of cadaveric-derived HGH and to expedite the availability of a genetically engineered HGH.

Third, ethics issues regarding the diffusion and clinical use of the product arose after the federal licensure of rDNA HGH. Should rDNA HGH, which has traditionally been targeted to treat growth hormone deficient children, now be used to "treat" non-hormone deficient children, whose shortness traditionally has not be considered a medical issue?[77] The relatively unlimited supply of rDNA HGH thus raises ethical issues that implicate pediatricians, families, pharmaceutical companies.[78,79] That Health Canada has licensed rDNA HGH for the treatment of hormone deficient children does not necessarily dissuade Canadian pediatricians from prescribing the drug for non-hormone deficient children through "off-label drug use."

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74. H. J. Dean, H. G. Friesen, "Growth Hormone Therapy in Canada: End of One Era and Beginning of Another," *Can. Med. Assoc. J.* 135 (1986): 297–301.

75. Law Reform Commission of Canada, *Procurement and Transfer of Human Tissue and Organs* (Ottawa: Supply and Services Canada, 1992), pp. 44–46.

76. P. Brown, "Human Growth Hormone Therapy and Creutzfeld-Jakob Disease: A Drama in Three Acts," *Pediatrics* 81 (1988): 85–92.

77. American Academy of Pediatrics, Committee on Drugs and Committee on Bioethics. "Considerations Related to the Use of Recombinant Human Growth Hormone in Children," *Pediatrics* 99 (1997): 122–29.

78. J. Lantos, M. Siegler and L. Cuttler, "Ethical Issues in Growth Hormone Therapy," *J. Amer. Med. Assoc.*261 (1985): 1020–24.

79. G. B. White, "Human Growth Hormone: The Dilemma of Expanded use to Children," *Kennedy Institute of Ethics J.* 3 (1993): 401–09.

1.2.1. Evolution and Locus of Ethical Issues

Taken together, the case studies provide insights into the evolution and locus of ethical issues. For, logically, one may expect ethical issues to be raised across the continuum or life cycle of a biotechnological product or technique: from laboratory research, to broader testing, to product development, to general diffusion and use. The locus of ethical issues may well shift, as a product gradually moves from the laboratory toward general use. Thus, debates over genetic engineering reflect ethical discourse centred on the laboratory stage. Debates over testing genetically modified organisms reflect ethical discourse centred on the testing stage. Debates over patenting life reflect ethical discourse centred on the product development stage. Ethics debates over who should be prescribed rDNA Human Growth Hormone reflect ethical discourse centred on the general diffusion stage. Ethical debate about the intrinsic good or ill of a particular biotechnology product seems likely to be raised throughout the continuum and may gain particular force depending on the particular concrete issue. This is particularly so if such underlying concerns are not addressed in an earlier phase of the continuum. Debate about the ethical consequences of a particular product would seem much more sensitive to the particular stage on the continuum a proposed product is. Thus, arguments about the intrinsic good or ill of creating a genetically engineered fish seem likely to be raised at the outset and likely to ebb and flow through the "product"-development life cycle. Consequentialist concerns about the risk, benefits and impact on aquatic ecology seem likely to become most prominent when the fish is tested or released into the natural environment. Heightened understanding of the kinds, stages and locus of ethical debate and reflection should better enable government to discharge its responsibilities and roles in the ethics of biotechnology.

1.3. Models and Structures of Ethical Reflection

The foregoing case studies help to identify at least four models for the development of policy norms and the processing of ethical reflection: public laws, professional standards, litigation and government advisory committees or bodies. These fora provide diverse, imperfect but complementary models[80] that contribute their strengths and limits to the societal discussion of and response to biotechnology issues.

1.3.1. Professional Standards Model

Under the professional standards model, standards and ethics norms of the relevant professions are relied on to guide decision making and policy making. Thus, the technical

80. D. J. Jones, "Artificial Procreation, Societal Reconceptions: Legal Insight from France," *American J. Comparative L.* 36 (1988): 525, 540–45.

expertise and the professional codes of ethics or conduct are strengths of the model. The relatively singular or narrow focus of the profession, however, may prove insufficient to the multiplicity of interests and values that warrant consideration in the development of public policies on biotechnology. For example, the call by religious authorities for an examination of the ethical and societal implications of rDNA at the end of the 1970s signalled a call to move beyond the largely professional model of scientific codes of conduct that had prevailed in the first decade of modern biotechnology.

1.3.2. Case Law Model

Formal dispute resolution by the courts defines a second forum and model of decision making. The decisions by the Supreme Courts of Canada and the U.S. in the 1980s and 1990s that lower life forms are patentable subject matter, resolved a particular biotechnology dispute, removed some legal uncertainty, and announced principles to guide future conduct. Judicial independence is often regarded as a strength of the model. It helps to ensure that the merits of disputes are considered relatively free from political or majoritarian interests. Courts are also regarded as protective of human rights, as perhaps illustrated by the *Moore* case involving the "ownership" of human tissue and a bio-pharmaceutic derived from it. In terms of limitations, the adjudicatory model is reactive, provides few means for broad public participation, works best for disputes between two parties, and is ill-designed to address extra-judicial questions like the ethics of patenting life.

1.3.3. Public Law Model

In direct contrast to the adjudicatory model, the public law model is designed to address broad and multifaceted dimensions of issues through the legislative, regulatory and administrative process of making and reforming public laws. Ethics issues raised by the evolving regulatory regime for biotechnology thus may logically fall within the public law model. A strength of the model "lies in its potential to address related ethical, legal, [scientific], policy issues comprehensively and prospectively. . . . The public law model may fix future rights, duties, outcomes."[81] If insufficient consensus or political will exists to yield laws, the process side of the model may play a critical role. For an open "public law process serves important educative functions because it is relatively well equipped to amass facts, receive and digest divergent public views and generally orchestrate public debate and alternative policy approaches."[82] The model suffers limitations in that its majoritarian emphasis and political side may slight the merits of non-majoritarian substantive issues and

81. Jones, *op cit.*, 545.

82. Ibid.

views or yield stalemates when consensus cannot be achieved. Governments have turned to the public law model to establish national ethics or biotechnological commissions in such jurisdictions as the U.S., France, Denmark, Australia, Norway and the European Union.

1.3.4. Advisory and Ethics Committee Model

The independent, interdisciplinary advisory committee on biotechnology or ethics has emerged as a prominent model for addressing the social, policy and ethical implications of biotechnology. Government often wed such advisory committees to the public law model to ensure their public accountability. The committees (a) provide expert advisory opinions to government on ethical matters; (b) stimulate and channel public and governmental debate and reflection; (c) help build consensus toward a broad ethical framework and like norms that help define socially acceptable policy positions; and (d) thus inform public policy, regulation and law.

When properly structured, such committees play significant roles in responding to and anticipating ethical problems. The committees generally function by persuasion and consensus. They are typically comprised of natural scientists, health care personnel, social scientists, lawyers, theologians, philosophers, entrepreneurs, etc. The interdisciplinarity and diversity of their composition are critical elements to their purpose and function, and thus ensure a broad range of thought, values, voices and inclusiveness. As a forum for independent reflection for government and society, their pronouncements may influence the credibility of governmental initiatives. Their ultimate function and purpose will determine whether they are standing or *ad hoc* and whether they have explicit mandates to study ethics, biotechnology or both (see Appendix A, below).

Even if continuity or the opportunity for continuing review and debate would favour the standing committee model, the impact of even *ad hoc* or time-limited committees indicates that successful ones are most effective at channelling and stimulating both internal debate and public dialogue and reflection through consensus building.[83] Identifying and coming to agreement on a common set of moral principles or a broad ethical framework is a method of applied ethics that may facilitate the resolution of moral problems.[84] One concern about reliance on advisory ethics committees is that they may become so fractious or politicized that they become discredited or dysfunctional. Another concern is that their work may lull government or the public into complacency because some responsibilities for the ethics dialogue have been assigned to a committee. As is illustrated by the work of the U.S.

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83. J. D. Moreno, *Deciding Together: Bioethics and Moral Consensus* (New York: Oxford University Press, 1995).

84. Beauchamp, op cit., p. 5.

Commissions in the 1970s and 1980s, and the Royal Commission on New Reproductive Technologies in Canada in the 1990s, a common and effective methodology has been to channel consultation and dialogue into defining an ethical framework of principles to guide committee and societal reflection, or to apply a previously articulated policy or ethical framework to discrete issues. The committees and this methodology have emerged in prominence at the institutional, national and international governmental levels. Some of the prominent guiding ethical principles that have been adopted by committees in different countries are outlined below in Table A.

Table A. Sampling of International Ethical Principles and Norms

	Belmont Report[85]	RCNRT/ HC[86]	Denmark[87]	GAIEB[88]	UNESCO[89]	Norway[90]	United Nations[91]	Council of Europe[92]	Tri-Council[93]
Autonomy/ informed consent	X	X	X		X	X		X	X
Human dignity	X	X	X	X	X	X		X	X
Equality/Non-discrimination		X	X	X	X	X	X	X	X
Biological diversity			X	X			X		
Distributive justice	X	X	X	X	X		X	X	X
Beneficence	X								X
Risk assessment	X			X			X	X	X
Environmental safety				X			X	X	
Confidentiality/ privacy				X	X			X	X
Sustainable development						X	X		
Non-commercialization		X	X	X	X			X	
Protection of the vulnerable/ Solidarity		X			X	X	X		X
Animal welfare				X					

85. United States, National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Washington, 1978), pp. 4–12.

86. Canada, Royal Commission on New Reproductive Techonologies. *Proceed with Care: Final Report of the Royal Commission on New Reproductive Technologies*, vol. 1 (Ottawa: Supply and Services Canada, 1993), pp. 53–66.

87. Denmark, Danish Council of Ethics, *Patenting Human Genes: A Report* (Copenhagen: Danish Council of Ethics, 1994), pp. 31–34.

88. See generally, European Commission, *Group of Advisors to the European Commission on the Ethical Implications of Biotechnology of the European Commission* (Brussels: European Commission, 1996): pp. 21–22. For particular topics, see *Opinion of the Group of Advisors on the Ethical Implications of Biotechnology of the European Commission* (Brussels: European Commission, 1996): non-commercialization, pp. 22, 35 (human genetics and blood products); distributive justice, p. 50 (gene therapy); animal welfare, p. 35; confidentiality, p. 83 (pre-natal diagnosis).

89. UNESCO, Draft of a Universal Declaration on the Human Genome and Human Rights (Paris: UNESCO, July 1997).

90. Norway, Ministry of Health and Social Affairs, *Biotechnology Related to Human Beings* (Oslo: Ministry of Health, 1993), pp. 7–9; Sustainable Development: Law no. 38 of April 2, 1993 on the Production and Use of Genetically Modified Organisms *Int'l Digest of Health Leg.* 45 (1994): 48–49. See also I. L. Backer, "Sustainability and Benefits to the Community Concerning the Release and Use of Genetically Modified Organisms in the Norwegian Gene Technology Act," in *Proceedings of the International Conference on Release and Use of Genetically Modified Organisms: Sustainable Development and Legal Control*, edited by Per Sandberg (Oslo: Norwegian Biotechnology Advisory Board, 1995), pp. 41–47.

91. United Nations, *Convention on Biological Diversity,* June 5, 1992. 31 I.L.M. 818 (1992), Preamble, arts. 1, 2, 3, 8.

92. Council of Europe, *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine* (Strasbourg: Council of Europe, 1996). See also, Council of Europe, Parliamentary Assembly, Recommendation 934 on Genetic Engineering of 26 January 1982, *Int'l Dig. Hlth Legis.* 33 (1982): 382–85; Council of Europe, Parliamentary Assembly, Recommendation 1240 on Protection of Patentability of Material of Human Origin of April 14, 1994, *Int'l Digest of Health Leg.* 45 (1994): 564–66.

93. Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, *Code of Ethical Conduct for Research Involving Humans* (Ottawa: 1997).

Institutional and National Advisory Committees

Advisory committees that address ethical issues in biotechnology function at the institutional and national levels. At the institutional level, the committees may come in many forms. For instance, as indicated above, the rDNA Advisory Committee to the U.S. National Institutes of Health has been in existence for over two decades. Similarly, in Canada, since the mid-1980s an institutional advisory committee on the research ethics side has been the MRC Standing Committee on Ethics. Its work has included advice on the development of national research ethic norms for implementation at the local level. Indeed, over the past decades, many nations have come to rely partially on local institutional research ethics committees in universities and hospitals to implement and apply ethics norms in reviewing proposed human and animal research that sometimes involves biotechnology. More recently, under 1992 legislation, an interdisciplinary Animal Biotechnology Committee advises the Dutch Ministry of Agriculture on ethical considerations in licensing biotechnology animal initiatives.[94]

At the national level, advisory committees with an ethics mandate may also come in diverse forms. For example, the Danish Council of Ethics exemplifies how a general national standing committee on ethics may advance reflection on biotechnology through the creation of working agenda and committees on biotechnology. The Danish Council of Ethics recently concluded a study on patenting life.[95] In contrast, Norway illustrates the national specialized advisory committee model. Following a parliamentary proposal from 1989, a royal decree in 1991 and statutory authorization in 1993–94,[96] the Norwegian Biotechnology Advisory Board (NBAB) was appointed by government, as an official, independent advisory committee to the Ministry of Health. The board has some 20 members drawn from relevant professions; the ministries of environment, health, agriculture, industry, fisheries; farmers; consumers; environmental and industry organizations; natural and social sciences; theological and academic settings. The NBAB mandate includes:

- remaining abreast of biotechnological uses in Norway
- evaluating issues and advancing proposals for ethical guidelines
- offering recommendations to amend guidelines, regulations and laws
- offering specific recommendations on the human reproduction applications of biotechnology and gene technology
- promoting communications between the different players in the biotechnological field and to the public.

94. Netherlands, *Animal Health and Welfare Act 1992*, arts. 66, 69.

95. Danish Council of Ethics, Patenting Human Genes. (Copenhagen: 1994).

96. Norway, *Act No 38 of 2 April 1993: The Act Relating to the Production and Use of Genetically Modified Organisms*, sec. 26; Norway, *Act No 56 of 4 August 1994: The Act Relating to the Application of Biotechnology in Medicine*, sec. 8.4, reprinted *Bull. Med. Ethics,* June 1994, pp. 8–11.

International Ethics Advisory Committees

Independent advisory committees have been enlisted to address ethical issues at the international governmental level as well. The work of the UNESCO International Bioethics Committee has been alluded to. Within the European federation, the European Commission Group of Advisers on Ethical Implications of Biotechnology (GAEIB) was created in 1991. GAEIB has a mandate (a) to identify and define ethical issues presented by biotechnology; (b) to appraise such issues and impact on society and the individual; (c) to advise the commission on the exercise of its powers largely in the industry, science and research, agriculture, environment and social affairs. The committee is interdisciplinary and composed of some nine experts drawn from such fields as law, science, medicine, theology and philosophy. Practically, GAEIB balances its independence and policy aid functions by providing advisory ethical opinions on its own initiative or at the request of the commission. As of 1996, GAEIB had issued eight opinions, ranging from agricultural, health and environmental ethics of biotechnology.[97] Through case-by-case considerations, the group has derived basic ethical principles, such as preservation of biological diversity, respect for human dignity, scientific freedom, individual freedom and social rights, competent risk assessment to protect health and the environment, etc.

97. See Opinion No. 1 of March 12, 1993, on the ethical implications of the use of performance-enhancers in agriculture and fisheries; Opinion No. 2 of March 12, 1993, on products derived from human blood and human plasma; Opinion No. 3 of October 1, 1993, on the ethical questions concerning legal protection for biotechnological inventions; Opinion No. 4 of December 13, 1994, on Gene Therapy; Opinion No. 5 of November 5, 1995, on the Labelling of Foods Derived from Modern Biotechnology; Opinion No. 6 of February 20, 1996, on PreNatal Diagnosis; Opinion No. 7 of May 21, 1996, on the Genetic Modification of Animals; Opinion No. 8 of September 25, 1996, on Patent Inventions involving Elements of Human Origin.

2. Role of the Federal Government

2.1. Leading Government Roles and Responsibilities

As the foregoing case studies illustrate, government may play a multiplicity of roles in the ethics of biotechnology. Many of the roles are cast by the responsibilities that Canadian society has formally assigned to the federal government. Sometimes the roles and responsibilities are shared. Sometimes they are exclusive.

2.1.1. Advancing Public Process — Debate, Education and Participation

On grounds of participatory democracy, principled decision making and public governance of science, the federal government can and should play a significant role in orchestrating public debate, understanding and participation in the development of biotechnology. The federal government funds research, regulates testing, and licenses products of biotechnology. Its responsibilities in the legislative and regulatory process help shape both national biotechnology strategy and policy answers to the associated economic, social and ethical issues. Such roles and its public accountability for them place affirmative duties on government to advance effective processes for public dialogue to ensure informed societal decision making.[98]

Indeed, public opinion studies in Canada[99] and other countries[100] have identified "public perception" as a major determinant of societal acceptance of biotechnology. Public perception and acceptance will sometimes hinge on addressing underlying ethical and social issues.[101] If controversy and conflicting value choices make unlikely early agreement on the merits of ethical issues, then public process models for decision making become ever more critical. One commentator has noted that "public controversies aim at public decision making and they are eventually settled by public decision-making processes that aim not at

98. See M. Lappe and P. A. Martin, "The Place of the Public in the Conduct of Science." *S. Cal. L. Rev.* 51 (1978): 1535–54.

99. Optima Consultants in Applied Social Science Research, *Understanding the Consumer Interest in the New Biotechnology Industry* (Ottawa: 1994); Decima Research, *Final Report to the Canadian Institute of Biotechnology on Public Attitudes Toward Biotechnology* (Ottawa: 1993).

100. U.S. Congress, Office of Technology Assessment, *New Developments in Biotechnology: Public Perceptions of Biotechnology* (Washington DC: GPO, 1987).

101. Organisation for Economic Co-operation and Development, *Biotechnology: Economic and Wider Impacts* (Paris: OECD, 1989); OECD, *Science and Technology Policy: Review and Outlook* (Paris: OECD, 1994), p. 260.

consensus but at socially acceptable decisions."[102] Agreement on process and forums for reflection may seed constructive dialogue, trust, an openness to persuasion and like foundations for consensus building toward socially acceptable decisions on the merits. In this sense, fair and meaningful process bespeaks an opportunity to voice one's concerns. The debate, consultations, parliamentary hearings, calls for comments and the like that are common to the public law and policy process begin to afford the plurality of affected groups and interests in the public the opportunity to be heard and to participate. For even if one ultimately disagrees with the resolution of a particular biotechnology issue, legitimate process helps legitimize and add credibility to decision making. Public education on and participation in science policy, moreover, would seem critical to promoting "a stronger culture of science"[103] to which the federal science and technology strategy aspires. Such dynamics help explain why, as indicated above, governments in different nations have married the public law process and ethics advisory committees as predominant process models for addressing ethico-legal and social issues in biotechnology.

2.1.2. Fair Distribution of Benefits and Burdens

Distributive justice arguably imposes particular duties and roles on government. In response, government may play at least three roles for ensuring that the good and ills of biotechnology are distributed fairly and equitably. First, the government may make an explicit commitment to doing so in its policy framework for biotechnology. Second, government may adopt or endorse substantive policy principles to guide decisions. The adoption of "sustainable development" by the government of Canada in its science and technology strategy[104] and by the government of Norway in its biotechnology laws[105] expresses a commitment to intergenerational equity. Third, government processes may influence the actual distribution and the public decision-making process. In this sense, a government that affords the public a meaningful opportunity to participate in biotechnology affords the opportunity to help to distribute fairly the rights, duties, benefits and burdens of biotechnology.

2.1.3. Fiduciary of Public Monies and Public Trust

The federal government has high responsibilites as a fiduciary of public monies and the public trust. The citizens of Canada have delegated to the federal government broad societal responsibilities for overseeing national health and safety, preservation and management of

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102. A. Cambrosio and C. Limoges. "Controversies as Governing Processes in Technology Assessment," *Technology Analysis and Strategic Management* 3 (1991): 377–96.

103. Government of Canada, Science and Technology for the New Century: A Federal Strategy. (Ottawa: Supply and Services Canada, 1996), p. 34.

104. Ibid., p. 26.

105. See Table A above.

natural resources and the environment, commercialization, economic growth, fostering research and development, etc. All of these responsibilites implicate the government roles in the biotechnology revolution. Virtually each ministry and each branch of government active in biotechnology is entrusted with public monies to discharge its broad public responsibilities outlined in the relevant Act of Parliament. As such, the government stands in a fiduciary relation to the public. As the public's agent, it must act with upmost good faith, loyalty and honesty to promote the public's best interests in the biotechnology domain. Those best interests may seldom be self-evident. Sometimes they will cast the government in the role as a promoter of biotechnology; sometimes, as regulator. Virtually always, however, the monies and power are held in trust for public benefit.

2.1.4. Fostering Ethically Acceptable Conduct

Public credibility and trust in the governmental roles in biotechnology critically depends on those roles being ethically acceptable. Indeed, that trust is so critical that government should aspire to avoid even the mere appearance of misconduct or ethical lapses. Such a commitment touches such activities as government research or government regulation of biotechnology products and such government-funded or supported activities as university-based biotechnological research. Sometimes, fostering ethical conduct means defining and nurturing compliance with ethical norms and standards. The recent efforts of the NRC[106] and the Tri-Council[107] to articulate research ethic norms for government-funded research are examples. In extraordinary circumstances, ethical conduct and frontiers may be drawn and mandated by government moratoria or prohibitions on some biotechnology activity such as research. Such research prohibitions have recently been proposed in legislation by Health Canada, following the recommendations of the RCNRT.

2.1.5. Formal Dispute Resolution

The judicial branch of government plays a leading role in formal dispute resolution through the courts. The analysis above suggests the adjudicatory model of decision making affords a limited and often inapt forum for reflecting on the ethical dimensions of biotechnology. Still, legal issues before the courts will sometimes present ethical dimensions. The *Moore* case from California and the patenting of higher life forms litigation now before Canadian federal court illustrate the point. In such instances, coordination between the evolving policy of a government department and the governmental position in court would seem prudent. The optimum strategy for government in such circumstances may depend on many factors. In some instances, the optimum position may involve urging the court not to pronounce on a particular ethical matter because it is not central to the case and is under

106. National Research Council, *Research Involving Human Subjects: Guidelines for Institutes* (Ottawa: National Research Council, 1995).

107. Tri-Council (MRC, NSERC, SSHRC), *Code of Conduct for Research Involving Humans* (Ottawa: Tri-Council of Canada, 1997).

study. Sometimes, it may involve appraising the court of the best ethics thinking of the department, so the court may have the benefit of the position of the government on issues it is likely to address.

2.1.6. Protection of Public Health, Safety and the Vulnerable

The State has long played a role in protecting those who cannot protect themselves. The beneficiaries of such protection are those who by reasons of age, capacity or circumstance cannot act self-protectively. This protective role helps to prevent exploitation of the vulnerable, on the view that such exploitation violates both human dignity and basic notions of fairness. Such values have also been expressed in modern notions of solidarity, a principle that has been adopted into some ethical frameworks on biotechnology.[108] The protector role thus directly affects individuals and collectivities. If norms under development in the 1990s to prevent discrimination from new genetic tests illustrate the protection of individuals, biosafety norms originally developed in the 1970s illustrate the protection of public health and environment at the collective level. As argued above, regulatory protection of life, health and the environment is not value neutral; indeed, it is consonant with some of the oldest and highest of public values. The rDNA HGH case study discussed above indicates that the protective role of government sometimes involves exercising beneficent judgments to minimize harms based on competent risk–benefit assessment. Ethical reflection on these matters helps to identify the implicated values, analyze moral conflicts and communities, prioritize competing value choices, and evaluate alternative policies for advancing preferred norms.

2.1.7. Promotion of Research and Development

The government may play a significant role in promoting the research and development (R&D) of biotechnology, on the view that such research will advance the frontiers of knowledge and enhance the quality of life of Canadians. The promise of the biotechnology revolution is that it will help to enhance health, the economy, the environment. Government research, the granting of patents and the funding of research, illustrate three means through which the government promotes R&D. If the government assumes a primary role in promoting and developing biotechnology, then it has correspondingly higher obligations and accountability regarding the social and ethical dimensions of biotechnology.

2.1.8. Promotion and Protection of Human Dignity

108. See Table A above.

A shared theme of governmental technology assessment,[109] the recourse to ethico-legal and human rights principles,[110] and public governance of biotechnology, is for humankind to remain master of, and not subject to, the most powerful of tools of modern science. Such is the logic behind, and appeal to, the promotion and protection of human dignity in the face of the seemingly inexorable advances of science. This logic has inspired UNESCO, the Council of Europe and national governments to establish formal ethico-legal instruments that aim to protect privacy, equality, and other elements of human dignity perceived to be at risk by applications from human genome and like biotechnological research (see Table A above). Concretely, then, government may promote and protect human dignity by articulating substantive safeguards and by orchestrating process models for defining the content of such substantive safeguards.

2.2. Government Accountability: Norms and Process

The accountability of the federal government for "public policy and regulatory ethics" in biotechnology is largely a function of its paramount duties and roles, its substantive decisions or norms, and its processes for ensuring accountability.

2.2.1. Public Law Accountability

Much is expected of those to whom much is given much. As indicated in the preceding section, the people of Canada have delegated to the federal government unique responsibilites and roles. They have done so largely through the public law process. The delegation of duties has been accompanied by a delegation of power and trust. In modern democratic, pluralistic societies, governments are answerable for the exercise, or not, of power through both the political and the public policy, legislative and regulatory process. This is the essence of the public law model. Thus, if the federal government has important or sometimes exclusive responsibilities in the research, testing and product development or diffusion phases of biotechnology, then its roles, responsibilities and accountability in the ethics debates of those domains should be high.

Four examples underscore the point. If federal government scientists conduct biotechnological research on animals, humans or in the environment, then the government has responsibilities and accountability for ensuring that such research conforms to substantive and procedural research ethics norms. The same may be said of biotechnological research that is funded by the federal government. Systems of accountability should be in place for ensuring so. As well, if the federal government has

109. L. H. Tribe, "Technology Assessment and the Fourth Discontinuity: The Limits of Instrumental Rationality," *S. Cal. L. Rev.* 46 (1973): 617–60.

110. D. J. Jones, "Health Law and Bioethics: Requiem or Renaissance for the Law Reform Commission of Canada," *Annals of the Royal College of Physicians and Surgeons of Canada* 29 (1996): 167–70.

exclusive authority over the testing and licensure of biopharmaceutics, then it has high responsibilites for ensuring that the testing of those pharmaceutics on humans respects ethics norms. If the government has exclusive authority over the *Patent Act*, then it also has high and arguably non-delegable responsibilities concerning the ethics of patenting life forms. These latter two examples illustrate the dynamic interface between, and need to harmonize, federal regulatory and ethical responsibilities concerning biotechnology.

2.2.2. Conflicting Governmental Roles

Sometimes, in the exercise of legitimate functions, governmental roles will conflict. How, for example, should the government reconcile the potentially conflicting roles of promoting and regulating biotechnology? When such roles clash, the collisions may lend the appearance that government is in a "conflict of interest" over particular biotechnology issues. When the roles of different departments in a particular ministry collide, the conflict may seem acutely evident for government professionals.

In theory, the easier way to address the conflicts is through substantive agreement — in policy, law or other norms — on the predominant roles the government is to play. In practice, however, even if prompt and easy agreement were likely on the paramount roles the government shall play in cases of conflict, the rapid changes in biotechnology and the dynamic nature of governance indicate that process mechanisms again prove significant. For whether such collisions actually qualify as technical conflicts of interests, the associated concerns about divided loyalties, compromised judgment and breaches of trust to the detriment of the public clientele should not be dismissed. Conflicts may be addressed by ensuring that substantive norms, policies, and processes are in place to identify, manage or prevent them. When conflicts arise, the integrity and credibility of government may depend on whether it has effective mechanisms to identify, mediate, arbitrate, or resolve underlying value disputes for coherent policy development. This may often entail inclusive dialogue to identify administrative and policy options for managing, or governing through, conflict. Ideally, such process and fora will be in place at the departmental, institutional, interdepartmental level. Sometimes, to enhance the clarity of governmental purpose, roles, effectiveness and to maintain public credibility, it will prove prudent to transfer to a separate, independent entity some of the duties and roles of an institution dysfunctionally burdened with a diametrically conflicting mandate. As well, institutional and national ethics advisory committees may serve as a forum and process mechanism for addressing underlying value conflicts in the multiplicity of roles the federal government plays in biotechnology. When such deliberations are channelled into national biotechnology policy, as it evolves over time, the process may consciously yield the primacy of particular policies, roles, norms and values. Ethical pluralism means that values given paramountcy in public policies of different governments or across different jurisdictions may fall within a range of ethically acceptable conduct.

2.2.3. Decision-making Authority

Public law accountability bespeaks both governmental decision-making authority and responsibility. Who in the government should decide which particular ethical concerns in biotechnology? The question is in part political, part managerial/administrative and part ethical. The allocation and hierarchy of responsibilites in particular ministries, departments, or between ministries regarding ethical decisions are largely administrative, managerial and political decisions. The ethics part of the question concerns the criteria, process and accountability for such decisions. So long as systems and lines of public and governmental accountability are in order, the particular answer to the question of who decides ethical issues is less pressing. Some government ethical concerns today are thus likely to be reflective of a transitional phase — a phase between a prior era when there appeared to be few ethical issues of broad concern, and a rapidly approaching era when the diversity and volume of ethical issues necessitates broad and concerted governmental action, the development of systemic and proactive norms, process mechanisms, and the defining of new lines of accountability. Some uncertainty is likely to reign during this transitional phase. Absent a general ethics framework or guiding substantive norms derived from the public process, government officials, committees, and institutions are likely to address ethical issues on a case-by-case basis. The tenets of the public law model hold that even case-by-case decisions on the ethics of biotechnological initiatives shall be subject to general mechanisms of public and governmental accountability.

2.3 Federal Ethics Resources and Structures

If ethics questions arise in the discharge of the federal governmental roles as funder and conductor of research, granter of patents, protector of health and the environment, and regulator of biotechnology, does the government have the resources and structure to respond effectively to ethics issues? A coherent and effective ethics infrastructure would include ethics norms to guide decision making, clear processes to translate ethical reflection into policy development and sufficient expertise and resources to address the issues. As such, the government should have at its disposal competent and sufficient means to identify ethical issues, analyze them, and translate the analysis into appropriate standards or policies on biotechnology.

What, then, is the current state of federal governmental ethics resources and structures for undertaking these basic tasks? A response to that question involves an analysis of two kinds of governmental ethics resources: those that are specifically biotechnology-dedicated, meaning those personnel, committees, documentation, and monies that are devoted to ethics issues in biotechnology; and, general federal ethics resources and infrastructure that may be drawn on to respond to the ethical issues raised by biotechnology. Based on the results of a questionnaire (see Appendix B), interviews with government analysts and a review of available government reports, an initial portrait of governmental ethics resources for biotechnology has begun to emerge.

Before summarizing the portrait, a cautionary note should be sounded. The emerging portrait is preliminary. It is necessarily incomplete by virtue of the limited information on which it is based. The questionnaire was intended to elicit initial information and to prompt dialogue. It queried respondents on the kinds of ethical issues before their departments, and the committees, personnel, and documentation relied on in understanding and responding to ethical issues raised by biotechnology. It was sent to some 10 members of the Interdepartmental Working Committee on Ethics and Biotechnology. Six responses were received. Yet, information was neither sought nor received from government departments not represented on the interdepartmental committee but which are active in biotechnology, such as the National Research Council. Nor was the questionnaire sent to such departmental ethics resources as conflict of interest officers, whose functions or expertise may on occasion prove relevant to ethical issues raised by biotechnology.

In the context of those limitations, the results of the questionnaire and dialogue with individuals in different departments have yielded the following preliminary indications.

Ethical Issues: Biotechnology has begun to raise in the public policy and regulatory responsibilities of government a variety of ethical issues that may indeed be accelerating — from defining research boundaries; to the breadth of our moral communities, as registered by duties to animals, the environment, and future generations; to ethics norms in research; to choosing processes and structures for deliberating and determining the paramount values in ethics and biotechnology.[111] This trend has become particularly noticeable in the 1990s. Many expect the trend to continue or accelerate.

Ethics Committees: Part of the federal ethics infrastructure is comprised of federal committees that function at the national, interdepartmental and departmental levels with responsibilities for ethics and/or biotechnology. Some of the former and current committees are listed in Table B below. The committee infrastructure has grown markedly since the late 1980s. For example, the 1989–93 work of the Royal Commission on New Reproductive Technologies has been discussed above. Still, because such growth has tended to occur on an *ad hoc* basis, it has yet to yield structures for addressing ethics in biotechnology in a fully integrated and coherent manner. At the national level — and in contrast to structures or entities in several other countries — Canada has yet to designate an independent, interdisciplinary, publicly accountable advisory committee with responsibility for addressing ethical issues in biotechnology. In contrast to the National Biotechnology Advisory Committee (NBAC) of Denmark, for example, the National Biotechnology Advisory Committee of Canada has to date been charged with neither the specific mandate, reporting responsibilities nor the membership to examine ethical issues.

At the interdepartmental level, the Working Group on Ethics and Biotechnology has served as one forum for interdepartmental dialogue and study of ethical issues in biotechnology

111. See also subsection 1.1.1. above.

since 1994. At the institutional level, while departments like the MRC and NRC have standing committees on ethics, and other departments are considering their establishment, much of the ethics in science work across the government appears to be discharged by internal *ad hoc* working committees or by other existing institutional committees that address biotechnology issues. Moreover, as Table B below indicates, a long-standing government model for advancing ethics analysis and ethics norms in science has been the appointment of external, advisory committees to advise particular departments, and whose interdisciplinary membership sometimes includes ethics expertise. The model has been particularly relied on for the development of research ethics norms. The release in 1997 of the Tri-Council Code of Ethical Conduct for Research Involving Humans illustrates such recent reliance. If the external advisory committee model is to continue to operate as a prime mechanism for ethical guidance, then government accountability and responsibilites to the public suggest that rigorous standards and protocols be in place to ensure the integrity, competence and efficacy of the advisory committee process and work.

Table B. Selected Federal Committees with an Ethics/Biotechnology Mandate

Committee	Date	Mandate
Canadian Council on Animal Care* guidelines	1968–	Animal welfare and research ethics
Council of Canada, Consultative Group on Ethics	1976–77	Social science research ethics guidelines
Health Canada, Discussion Group on Embryo Research	1994–95	Human embryo research ethics
Health Canada, Advisory Committee on New Reproductive and Genetic Technologies	1996–	New reproductive technologies
Interdepartmental Working Group on Ethics and Biotechnology	1994–	Ethics and biotechnology
MRC, Working Group on Human Experimentation	1976–77	Biomedical research ethics guidelines
MRC, Standing Committee on Ethics and Integrity	1984–	Medical research ethics and integrity
MRC, Working Group on Guidelines for Somatic Cell Gene Therapy	1988–89	Gene therapy guidelines
National Biotechnology Advisory Committee	1983–	Guidance on biotechnological development
National Council on Bioethics in Human Research*	1989–	Human research ethics committees
NRC, Human Subjects Research Ethics Committee Protocols	1991–	Intramural review of NRC research
Royal Commission on New Reproductive Technologies	1989–93	Socio-ethical, legal, policy dimensions

Tri-Council Working Group on Ethics of Research with Human Participants	1995–97	Natural, social and health sciences research ethics code
Western Economic Development, Steering Committee on Social Implications of Biotechnology	1995–97	Socio-ethical issues of biotechnology

* Non-governmental recipient of government funding.

Ethics Personnel: Few, if any, of the departments employ so-called "ethicists or ethics officer." Some departments have designated individuals to assume responsibility for particular ethics functions. At least one department has formally designated an "ethics resource person" across the department. Some departments like Justice, which offers interdepartmental services on a regular basis might provide a fruitful focal point for the diffusion of ethics initiatives, dialogue or norms.[112] Even so, the general portrait that seems to be emerging is that ethics responsibilities typically are overlaid onto one's general legal, policy, technical or regulatory responsibilites; or, they blossom therefrom. This raises questions of whether one's primary professional responsibilites provide expertise commensurate with the needs for basic governmental ethics analysis — from identification, to analysis, to policy formulation. Such ethics responsibilities also tend to be assumed on a part-time basis. If this preliminary information is indicative, then it would appear that the human resources investment in in-house ethics personnel is limited and not consistently a component of strategic planning in the federal government.

Ethics Education and Documentation: Ethics education may be advanced through such initiatives as formal training or courses, participation in ethics education fora and self-education through the literature. While external coursework in ethics apparently has not been resorted to, respondents to the ethics and biotechnology questionnaire indicate that they have availed themselves primarily of occasional governmental educational ethics fora, external conferences and self-education. Within the past few years, it would appear that an increasing number of governmental workshops, retreats, roundtables and lectures on ethical issues relevant to biotechnology have been made available to individuals within federal departments. In part because they require more coordination and resources, large interdepartmental workshops are rare — e.g., an interdepartmental workshops on ethics and biotechnology was last convened in 1994.[113] In some departments, access to printed ethics periodicals and documentation has grown in recent years, while access to the electronic ethics literature is widely reported.

112. E. Marglose, *Ethics and Biotechnology: An Examination of the Role of Legal Advisors* (Ottawa: Department of Justice Legal Services, 1995); E. W. Keyserlingk, *The Relevance of Bioethics in the Provision of Legal and Policy Advice* (Ottawa: Department of Justice Legal Services, 1995).

113. *Proceedings of Interdepartmental Workshop on Ethics and Biotechnology: Moving from Confrontation to Engagement*, 1994.

External Ethics Resources: To supplement internal resources, several departments have had recourse to external ethics analysts for research, reports and ethics education. Moreover, as the list in Table B indicates, external expertise is also channelled into government through the federal advisory committee structure.

Even these preliminary indications have significant implications. First, a more extensive survey of governmental ethics resources should confirm or refute the accuracy of the emerging portrait and provide a more informed basis for decision making. Secondly, it would seem that some corners of the federal ethics infrastructure are relatively well developed. For example, the federal research ethics infrastructure seems relatively mature in terms of developing ethical norms, and evolving federal roles and structures. The ongoing Tri-Council initiative to develop revised research ethics norms and a parallel initiative to promote uniform research ethics norms in the federal government[114] are in progress. Since biotechnology research involving humans and animals regularly implicates research ethics, such initiatives to perfect the research ethics infrastructure are consistent with basic governmental responsibilites. Thirdly, it would also seem that some aspects of the federal ethics infrastructure remain in need of planned and coherent growth. This indication may not be surprising, but should stimulate searching analysis for reform that will better enable the government to discharge its role and responsibilites in ethics. If the experience of other countries is any guide, one would expect to find that as ethics issues become more visible and prominent before the government, more formal and concerted initiatives and resources should and will be developed as part of the Canadian societal response to, and management of, biotechnology.

2.4. Role of Non-governmental Players

While a study of the role of non-government players in ethics and biotechnology exceeds the scope of this report, the federal government should discharge its role and responsibilities in ethics and biotechnology in concert with a range of stakeholders. Some classes of ethical issues in biotechnology may fall within the province of others largely because they arise at the edge or beyond the pale of active or primary governmental responsibility. One may envision some three classes of such issues.

First, for example, ethical issues of a largely private nature or those beyond the jurisdiction of the federal government should likely be addressed by other societal entities. Secondly, issues may arise that are tangential to federal responsibilities, but which may be more effectively addressed by other models of ethical decision making. As discussed above, for example, the clinical use of genetically engineered human growth hormone, is an important ethical issue for the pharmaceutical industry, families and pediatricians. The federal government has licensed genetically engineered HGH for particular medical indications.

114. See Appendix C below.

The ethics of whether genetically engineered HGH should be administered to a broader class of patients would likely better be addressed in the first instance by other models of ethical decision making. The ethics committees of the Canadian Paediatrics Society or local ethics committees in hospitals and professional debate would seem more appropriate fora for deliberating and addressing such issues. In such instances, as discussed above in subsection 1.3., government and society primarily rely on the ethical norms and deliberations of relevant professionals and institutions to address the issues.

Thirdly, some ethical issues or projects that are within the purview of the federal government might be delegated to quasi-governmental or non-governmental institutions on the understanding that such entities have the expertise or competence, credibility, resources, and accountability which enable them to perform ably the function. The roles and responsibilites discharged by the Canadian Council on Care since 1968 in implementing ethical norms in animal research[115] for federally funded research is an example. The establishment of a national clearing house on biotechnology for the general public might also be delegated to an appropriate NGO, as may some responsibilities for some education initiatives. In the latter instance, an important consideration in so delegating those responsibilities, is the relationship between the entity and government, in terms of the formal structure, independence, reporting duties, policy formulation, and governmental and public accountability. An institution that has been given particular responsibilities yet remains largely accountable to other predominant interests may lack public credibility and may be serving in a conflict of purposes. It would seem imperative to the successful operation and discharge of such delegated responsibilities that such matters be scrutinized beforehand.

115. See, e.g., Canadian Council on Animal Care, *Guide to the Care and Use of Transgenic Animals* (Ottawa: 1997).

3. Refining the Government Role: Recommendations

The Government of Canada plays a number of significant roles in the research, development, and diffusion of biotechnology. These roles include the government as scientific researcher and experimenter; funder of research and commercial development; regulator; adjudicator of legal disputes; granter of patents; promulgator of standards and norms; protector of public health, safety and the environment; fiduciary of public monies and powers; law and public policy maker. Sometimes the roles may conflict. Sometimes they will require debate and choices about which underlying values should prevail in federal biotechnology policy. As the governmental roles evolve, they should be rethought and refined.

Today, the continually unfolding promise and potential perils of the biotechnology revolution, the evolving government role and responsibilities, and the obvious ethical dimensions of increasing policy and regulatory issues before the federal government together, make it an opportune time to affirm a new covenant between government, science, and ethics and the public in the biotechnology domain. The new covenant consists of at least four elements. It has important programmatic implications.

3.1. Four-point Ethics Covenant

Government, those involved in biotechnology, and the public should affirm a four-point covenant that includes the following elements.

3.1.1. Stewardship

While the federal government functions in a diversity of roles in the biotechnology domain, one of its paramount roles is to serve as the societal agent to whom Canadians entrust unique powers and responsibilities to act in the best interests of the public. The emphasis of the federal government science and technology strategy for the 21st century on sustainable development[116] evidences one guiding principle for husbanding the benefits of technology for both current and future generations. This is a stewardship principle. The stewardship role parallels the role of the federal government as fiduciary of the public monies it invests in science and technology. In its stewardship and fiduciary roles, the government serves as a trustee: the public monies, powers and responsibilities entrusted to it should be used to harness the promise and minimize the perils of biotechnology for attaining the social, environmental and economic goals of Canada.

116. Government of Canada, *Science and Technology for the New Century: A Federal Strategy* (Ottawa: Supply and Services Canada, 1996), p. 26.

3.1.2. Toward an Ethical Framework: From Ethical Pluralism to Ethical Frontiers

The federal government should make as an explicit cornerstone of its biotechnology strategy what has been implicit in the evolving societal debate about biotechnology: namely, that the research, development and diffusion of biotechnology should proceed "in a manner consistent with Canadian values and norms of ethical conduct." This is a policy goal toward which all can aspire. It recognizes that overarching principles like "sustainable development" and the "protection of human dignity" may be identified as part of a broader ethical framework that will guide government policies and public laws on biotechnology. It recognizes that there will be instances when moral boundaries or ethical frontiers may curtail some biotechnological initiatives. It recognizes, as well, that ethical pluralism is a healthy reality in democratic societies and that the fundamental challenge is to define ethical norms and an acceptable range of conduct for the scientific and biotechnological enterprise.

3.1.3. Preventive Ethics

Consistent with the federal strategy for science and technology for the 21st century,[117] part of the governmental stewardship role should involve adopting preventive approaches to addressing the ethical issues raised by biotechnology. A preventive ethics approach involves a basic commitment to going beyond simply reacting or responding to ethical issues, to anticipating them for policy analysis and development.

3.1.4. Ethics Resources and Structures for the Future

The commitment to preventive ethics entails new initiatives, new national and institutional resources, new committee structures and new mechanisms. The new structures and resources might be developed in partnership with centres of learning, industry, NGOs and the public.

Part of the new covenant, moreover, should include a renewed and explicit understanding regarding the investiture of public monies in ethics. Current governmental activities and investment in examining the ethical, legal, and social implications (ELSI) of biotechnology should be broadened and formalized into a cornerstone of the federal biotechnology strategy. An ELSI investment fosters ethical reflection and processes today and provides resources, structures and policy options for tomorrow. The government thus discharges its fiduciary and stewardship roles by ensuring that public monies and resources are concurrently invested in both the ethical and commercio-scientific aspects of biotechnology.

117. Ibid.

3.2. Programmatic Initiatives

A number of concrete initiatives might be developed to bring to fruition the new covenant and its elements.

3.2.1. Processes toward an Ethical Framework

Beyond the policy affirmation that biotechnology should develop "in a manner consistent with Canadian values and norms of ethical conduct," the federal government should commit to engaging stakeholders and the public in a process for defining a general ethical framework to guide the research, development and diffusion of biotechnology. Defining the framework should be included as an explicit policy objective in the national biotechnology strategy. Developing an ethical framework as a policy objective is consistent with the federal governmental roles in advancing public debate; reforming relevant federal laws, regulation and policy; and fostering ethical conduct. Such a framework may thus serve many purposes. If developed with appropriate public participation, an ethical framework is responsive to public accountability concerns and diffuses societal reflection on the evolution of particular values. An evolving ethical framework may serve as a policy guide for the diverse actors within the government community in the discharge of their public responsibilities. It affords a broad basis for the analysis or adjudication of particular issues, controversies and debates on ethical issues in biotechnology. It also affords courts broad parameters to guide legal and policy decisions on biotechnology disputes that present ethical dimensions. Moreover, in helping to establish norms and standards for both government and non-governmental players, the development of ethical frameworks help foster ethically acceptable conduct. The goal of defining an ethical framework may be advanced through a multifaceted preventive ethics strategy that engages new processes, mechanisms and resources.

3.1.3. A Preventive Ethics Strategy

The federal government, for instance, may begin to implement a preventive ethics strategy in part through its role as funder of biotechnology research and programs. Recent initiatives should be renewed and broadened into the establishment of a formal ELSI issues arm of the funding for the National Biotechnology Strategy (NBS) over the next three to five years. This might be done by allocating a certain percentage (e.g. 10 percent) of NBS monies to ELSI research, development and programs. The monies would be devoted to federal government ethics initiatives in and out of government. Thus, within the federal government, departments should be requested to develop a one- to three-year work plan for ELSI research and projects agenda; they might do so either as a condition of NBS funding or on a competitive basis for particular ELSI funds. To cultivate and enter into partnerships with centres of expertise and learning across Canada, an ELSI strategic grant program might be established to fund workshops, demonstration grants, and ethics and

biotechnology research on such issues as agriculture and animal ethics, ethics, biotechnology and sustainable development, etc.

Ethics Advisory Committees

The defining of an ethical framework and implementation of a preventive ethics strategy may be advanced through new structures like institutional or national ethics advisory committees. While we may not agree on the merits of difficult ethical issues, we may be able to agree on process models for decision making. Hence, the creation of such entities is responsive to governmental duties for orchestrating public processes and debate so that the rights, duties, benefits and burdens of biotechnology are fairly distributed across society. Indeed, especially when wedded to the public debate, legislative and regulatory elements of the public law process, the independent, interdisciplinary advisory committee has emerged as one of the prominent process mechanisms for addressing and managing the ethical issues of biotechnology in different countries. They (a) provide expert advisory opinions to government on ethical matters, (b) stimulate and channel public and governmental debate and reflection, (c) help build consensus toward socially acceptable policy positions, and (d) thus inform public policy, regulation and law.

As illustrated by the recent requests for opinions on cloning made by the U.S.[118, 119] and European governments to their respective ethics advisory committees in light of the cloning of Dolly the sheep, such entities may react to particular urgencies. They may also develop a working agenda that projects and anticipates the evolution of broad ethical issues and policy debate. Because they often serve different purposes, the creation of a national ethics entity should not detract from continuing, rigorous evaluation of departmental or interdepartmental ethics committees; indeed, national, departmental or interdepartmental ethics committees should function in partnership. Whether at the institutional or national level of government, the composition, mandate, independence, and resources of such committees constitute critical elements of their credibility and effectiveness (see Appendix A). Currently, Canada lacks an identified public entity with responsibilities for ethical reflection on these matters, even as such issues find themselves increasingly before government. For the foregoing reasons, the establishment of a national advisory committee — which has within its mandate, reflection, advice, and public participation on the ethics of biotechnology — is a policy option that warrants serious and utmost consideration by the federal government.

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118. U.S., National Bioethics Advisory Commission, *Cloning Human Beings: Report and Recommendations of the National Bioethics Advisory Commission* (Rockville, MD: 1997).

119. *Cloning Prohibition Act of 1997*; "Clinton Seeks to Ban Human Cloning But Not All Experiments," *New York Times*, June 10, 1997, p. C4.

There are at least three models for establishing a Canadian national advisory committee with responsibilities for ethics in biotechnology. First, a national ethics committee might be modelled on the French or Danish national ethics committee. While the mandate of such an entity would be broader than biotechnology per se, it would include ethics issues raised by biotechnology within its working mandate. Second, and in contrast to the standing committees in France and Denmark, the United States offers the model of the time-limited federal bioethics commission that has within its mandate ethics in biotechnology issues. To include sunset provisions in publicly created institutions has merit, but time-limited national commissions tend to be resource-intensive and sacrifice continuity. Third, Norway affords another alternative model. It has a statutorily created national biotechnology advisory committee with an explicit mandate for reflection and advice on ethics. Such models should be evaluated with the need for and role of institutional ethics committees and should generally be tailored toward perfecting the existing government ethics infrastructure. While such models, structures and their elements are being scrutinized in Canada, basic interim responsibilities for ethics might be assigned to a duly constituted interim advisory committee or its functional equivalent.

Internal Government Working Committees

To identify and examine ethical issues and translate such deliberations into policy, the roles, responsibilities and committee structures in government need to be clear, competently discharged and effective. These basic requirements implicate relations with any national advisory entity on ethics, between federal departments and within the particular ministries or departments themselves. Several steps may be taken to maximize the effectiveness of the biotechnology committee structure and work in ethics. First, for example, there should be an interdepartmental entity responsible for ethics in biotechnology that (a) facilitates, harmonizes and orchestrates biotechnology and ethics initiatives across the departments; (b) provides for the departments an interface with any national advisory committee with an ethics mandate; and (c) discharges ethics coordinating responsibilities under the NBS. The committee should have a clear written mandate, senior level operational and reporting duties, and the expertise and resources commensurate with the increasing importance of ethics on the government biotechnology agenda. Second, to build on the limited survey conducted in this report, this interdepartmental entity should oversee a larger and broader survey of ethical resources and structures within the government as a matter of priority. Such a survey might parallel and draw on the ongoing initiative of the MRC, NSERC, SSHRC, NRC and Industry Canada, to identify the issues, make uniform standards, and clarify lines of accountability in research ethics across the federal government (see Appendix C). Third, and as a matter of priority, initiatives should be undertaken to minimize duplication of efforts or resources in ethics and biotechnology undertakings across the federal government. Fourthly, to do so, the membership, terms of reference/mandate, resources and work plans of interdepartmental and departmental committees with responsibility in ethics should be reviewed and revised where appropriate. Such matters might be made part of the information requested in the proposed survey.

Finally, the interdepartmental entity should also assume primary responsibilities for coordinating the development and implementation of the one- to three-year ethics and biotechnology work agenda for the government departments, as outlined above in the preventive ethics strategy.

Governmental Ethics Policy Centres

At the institutional level, policy sectors of such ministries as Health Canada, Justice and Industry Canada are playing important roles in the evaluation of ethical issues in biotechnology. Policy sectors play a pivotal role in government policy by responding to current policy needs and planning and shaping policy development. Thus, if such policy sectors are provided with sufficient mandates, resources, expertise and reporting duties, then they may serve as models for centres of ethical reflection, analysis and policy development within departments across the government. The role requires interdisciplinary reflection, liaison and communication with the legal, regulatory and scientific resources in government.

Ethics Resource Persons

The designation of "ethics resource persons," often within the policy sectors, is a model that might be refined and cultivated more broadly within the federal departments. These individuals serve as contact persons, analysts, committee members and coordinators on ethics matters. This model may prove helpful to departments developing mechanisms for ethical analysis and an ethics work agenda over the next years. In departments that have a demonstrated need, ethics analysts might be designated with more formal and global responsibilities for ethics work agendas, education, coordination, committees and substantive ethics analysis. Continuing education offers important opportunities for enhancing the understanding and expertise of those with ethics responsibilities.

Ethics Education and Training

Education is a primary means of inculcating understanding and raising the ethics expertise of government actors. While some education may be imparted by the need to respond to particular issues, by self-teaching or as an incident of one's professional responsibilities, a preferred model would be for regular, planned and coherent ethics educational initiatives. Such initiatives might include intensive external ethics courses, conferences, departmental retreats, interdepartmental workshops/round tables, ethics policy seminars, ethics-for-lunch lecture series. Major educational initiatives may be undertaken in partnership with appropriate NGOs. Ethics committees and ethics resource persons should have prime responsibilities for, and be among the prime beneficiaries of, ethics education and training. An interdepartmental ethics education initiative should be developed. Agencies that identify a high or increasing number of ethics issues might be designated lead departments for demonstrating and developing educational programs. Moreover, to discharge governmental

responsibilites for fostering ethics norms, mechanisms should also be in place to ensure that government researchers are educated on, and complying with, appropriate ethics guidelines. Committees that have prime responsibilities for ethical issues and analysis in government, like the interdepartmental working group on ethics should include an education function within their terms of reference. So that individuals or resource persons from different departments may have occasion to participate in continuing education initiatives, a mechanism like an electronic ethics bulletin board might be established.

Ethics Documentation and the World Wide Web

To discharge the governmental role in education and policy formulation, ethics literature and documentation should be readily available for government committees, policy analysts, regulators and the public. While individuals or sectors of different departments have begun assembling ethics literature on particular issues or subject matters, initiatives should be undertaken to facilitate broadened and ready access to such literature. This will include published documentation and unpublished reports or papers. A simple listing of such documentation within a government ethics databank, which would be maintained and updated on a regular basis, would advance this goal. Consideration should be given to making public documents available within a "biotechnology and ethics" file of a Government of Canada and Biotechnology World Wide Web site/home page on the Internet or within a government intranet. It would also be consistent with the governmental role in fostering debate and education to consider publishing, in 1997–98, a selection of the background papers on ethics and biotechnology that have been written for the government. Responsibilites for assembling an ethics and biotechnology clearinghouse orientated more toward the public might be delegated to an appropriate NGO.

4. Conclusion

A quarter of a century ago the first reports of the scientific cloning of life catapulted ethical issues of genetic engineering from the laboratory into the public, governmental, policy and international arenas. In 1997, the cloning of a higher life form provoked a similar reaction. The parallels may inspire divergent views. Some may note the historic parallels to incite fear about unbounded or uncontrolled science. Others may draw on the parallels to calm those troubled by science and to suggest that beyond the clear fruits and unfounded fears of biotechnology, little has changed.

Both arguments tend toward hyperbole. Both miss the import of the historical juncture. Science has advanced beyond both the fears and dreams of many. Public participation and understanding have increased dramatically. Research has enhanced human welfare. The ethics discourse has matured. Government roles have diversified and expanded. Ethical norms are both increasingly sophisticated and conspicuously absent. In the end, the progress over the past decades has been born of experience, prudence and vigilance. New ethical thought, tools and structures must emerge to continue both scientific and moral progress.

As Canada embarks on another leg of the biotechnological and ethical revolutions, it makes for a rare and opportune time to affirm a new covenant between the government, the public, science and ethics. By virtue of the unique responsibilites it enjoys in public policy and regulatory ethics, the Government of Canada should take a creative leadership role in forging and implementing the elements of the ethics covenant proposed herein.

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Biomedical and Health Care Ethics Resources on WWW:
http://www.ethics.ubc.ca/papers/biomed.html

Canadian Biotechnology: **http://www.biotech.ca**

Canadian Genome Analysis and Technology Program:
http://cgat.bch.umontreal.ca

European Union and the New Biotechnology: Managing Environmental Risks: **http:/biosafety.ihe.be/GB/AbouEur2.html**

European Union Biotechnology Projets, Topic: Ethical, Social and Legal Aspects: **http://europa.eu.int/en/comm/dg12/biotech/biot-esl.html**.

Norwegian Biotechnology Advisory Board: **http://www.bion.no**

OECD Biotechnology: **http://www.oecd.org/dsti/biotech**

UNESCO International Bioethics Committee: **http://www.unesco.org/ibc**

University of Pennsylvania, Center for Bioethics: **http://www.med.upenn.edu/~bioethic**

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U.S. National Human Genome Research Institute: **http://www.nhgri.nih.gov**

U.S. National Bioethics Advisory Commission: **http://www.nih.gov/nbac/nbac.html**

U.S. Office of Recombinant DNA Activities (rDNA Advisory Committee): **http://www.nih.gov/od/orda**

Appendix A
Process Models for Decision Making:

The Advisory and Ethics Committee Model

- **Elements:**
  - Independent Expertise
  - Responsive
  - Interdisciplinary
  - Pluralistic

- **Function:**
  - Advise and Report
  - Channel Ethics Dialogue
  - Public Forum
  - Consensus Building
  - React and Anticipate
  - Ethical Framework
  - Potential Policy and Regulatory Base

- **Structure, Governance and Accountability:**
  - Ethics (Denmark) or Biotechnology (Norway) Committee
  - Institutional (MRC), National (Norway) or both (U.S.)
  - Standing or Time-Limited
  - Terms of Reference/Ethics Mandate
  - Composition
  - Work Agenda and Priorities
  - Budget and Staff
  - Reporting Duties
  - Government Relations
  - Operating Procedures

Appendix B
Federal Ethics and Biotechnology Questionnaire

To complement a review of the literature and personal communications, a brief questionnaire was circulated to:

- advance understanding of the ethical issues that biotechnology presents to the federal government
- identify some of the ways and resources implemented by government to address these issues.

The six responses from the ten members of the Interdepartmental Working Group on Ethics are summarized below.

Summary of Yes – No Responses

II.A. *Interdepartmental Ethics Resources*: Beyond the interdepartmental working group on ethics, are you aware of other interdepartmental committees that address ethical implications of biotechnology?	Yes – 2: Animal Biotechnology Working Group No – 4
II.B. *Institutional Resources* B.1. *Standing Committees*: Within your Ministry or institution do standing ethics committees exist?	Yes – 1 No – 5
B2. Is the formation of such committee or working group immanent or under consideration?	Yes – 3 No – 2 N/A – 1
B3. Have you been on, or served as, a staff person to the committee?	Yes – 1 No – 4 N/A – 1
B4. *Ad Hoc Committees/Working* Groups: Have *ad hoc* working groups or committees been struck to address biotechnology policy questions that contain ethical issues?	Yes – 3 No – 2 N/R – 1
B5. *Non-Ethics Committees*: Do other study or working committees have occasion to address biotechnology issues with ethical aspects?	Yes – 5 No – 0 N/R – 1

B6. *Ethics Personnel*: Do the following personnel exist in your institution or department?

Ethicist:	Yes – 0 No – 5 N/R – 1
Ethics officer:	Yes – 1 No – 5
Staff person responsible for ethics, etc.:	Yes – 3 No – 3
B7. *External Ethics Resources*: Does your department or institution have occasion to draw on academics, consultants, etc. to address the ethics implications of particular biotechnology initiatives?	Yes – 6 No – 0
Ethics Training and Education: Does your institution or department offer training and education on ethics issues?	Yes – 2 No – 4
Formal courses (internal/external)	Yes – 0 No – 5 N/R – 1
Internal lectures/seminars/brown bags?	Yes – 2 No – 3
Internal or governmental workshops?	Yes – 2 No – 3 N/R – 1
If not, have such offerings been discussed?	Yes – 1 No – 3 N/R – 2

B8. *Ethics Literature*: If you need to access ethics articles or literature, does your institution or section:

offer a collection of ethics literature or documentation?	Yes – 1 No – 4 N/R – 1
receive and circulate ethics periodicals?	Yes – 4 No – 1 N/R – 1
receive and circulate ethics articles?	Yes – 5 No – 1
provide Internet access to ethics resources?	Yes – 5 No – 1
Other?	Yes – 1 No – 0 N/R – 5

B9.	Does your institution or department conduct or sponsor ethics-related research:	
	in-house?	Yes – 1 No – 3 N/R – 2
	external (e.g., strategic grants or contracts)?	Yes – 3 No – 3
B10.	Has such research been specifically targeted at biotechnology?	Yes – 3 No – 3
B11.	Please list below departmental or institutional documents that have discussed ethics issues relevant to biotechnology. These might include published or internal documents or reports, including those in progress or confidential. If the latter, please so indicate.	A variety of documents, reports and journals listed. See comments below.
B12.	Are there other individuals within your department or Ministry who should be consulted to advance understanding on these matters?	Yes – 3 No – 3

The comments of the respondents are summarized on the following pages.

Summary of Comments

I.A. Respondents were provided with the following selective list of public policy issues:

- management of apparent governmental conflicts of roles and interests
- research limits
- regulation of human tissue storage, access and use
- labelling of genetically engineered products
- developments of transgenic organisms
- protection of animal rights, including transgenic developments
- patentability of life forms and cell lines
- DNA data banking — personhood and protecting human dignity
- intergenerational justice
- processes for addressing ethical implications of biotechnology

Respondents added the following:

- novel reproductive technologies
- environmental ethics
- ownership of genetic material
- privacy of genetic information
- culturing organism and bioremediation

See also attached list "Biotechnology Issues Related to Socioeconomics: Socio-economic Forum."

I.B. Pending Issues before the government. What are the leading ethical topics or issues that have become, or remain, before your ministry or the federal government, as a result of biotechnology?

Responses

- patenting
- transgenics
- intergenerational justice
- conflict management between promotion and regulation of biotechnology
- developing processes to address ethical implications of biotechnology
- human and animal research
- ownership of tissue

I.C. Forthcoming issues. Beyond those currently pending issues, do you foresee other ethical issues that may come before your institution or the federal government in the foreseeable future?

Responses

- genetic testing/screening (insurance issues, use and access to genetic information)
- human cloning
- determining who benefits from technology (large vs. small enterprises, developed vs. developing states)
- DNA sampling
- environmental ethics
- culturing of microorganisms and bioremediation.

III.B11. Documents, reports and journals listed:

- bioscience
- environmental ethics
- Harvard Business Review
- new reproductive and genetic technologies: setting boundaries, enhancing health.

Appendix C
Persons and Institutions Consulted

Individual	Institution
Anne-Christine Bonfils	Natural Resources Canada
Bart Bilmer	Agriculture Canada
Laure Benzing-Purdie	Health Canada
Christine Franklin	Industry Canada
Paula Desjardins	National Research Council
David Fraser	Agriculture Canada
Julie Griffin	Canadian Council on Animal Care
Mike Hudson	Justice/ Health Canada
Terry McIntyre	Environment Canada
Heather Mohr	Canadian Institute of Biotechnology
Mary Anne Mounce	National Biotechnology Network
Eugene Oscepella	Privacy Commissioner of Canada
Anthony Ridgeway	Bureau of Biologics Health Canada
Francis Rolleston	Medical Research Council of Canada
Pradip Shastri	Western Economic Development
Nina Stipich	Social Science and Humanities Research
Regan Walker	Industry Canada
Linda Williams	Health Canada
Susan Zimmerman	Justice/Health Canada

International

Danish Council of Ethics
European Commission
Norwegian Biotechnology Advisory Board
Nuffield Council of Bioethics (UK)
Organization of Economic Cooperation and Development (OECD)
United Nations Educational, Scientific and Cultural Organization (UNESCO), International Bioethics Committee
United States Department of Health and Human Services, rDNA Advisory Committee (RAC)

Making Ethically Acceptable Policy Decisions:

Challenges Facing the Federal Government

Prepared for:
Canadian Biotechnology Strategy Task Force
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This document has been prepared by:

Ted Schrecker
SCHRECKER – RESEARCH AND CONSULTING
176 York Street, Suite 31
London ON N6A 1B5
Tel.: (519) 432-5649
Fax: (519) 432-5649
E-mail: tschrecker@compuserve.com

and

Margaret A. Somerville
Centre for Medicine, Ethics and Law
3690 Peel Street
Montreal QC H3A 1W9
Tel.: (514) 398-7400
Fax: (514) 398-4668
E-mail somerv_m@falaw.lan.mcgill.ca

Contents

Executive Summary

The Meaning of Ethical Acceptability

Ethics is the activity of thinking about and deciding how people ought to act in their relationships with one another, or how human institutions and activities ought to be organized. In another formulation, it is the application of moral values to factual situations in order to determine how we ought to act in those situations.

Ethical statements are normative rather than descriptive, and are about values. Unlike statements about other kinds of values, however, statements about ethical or moral values demand **justification**. Ethics requires a distinctive point of view, sometimes called the "moral point of view," which takes the interests and perspectives of others into account. Ethics is also about process as well as outcome. It is therefore not just an end point, but also a **way of getting to answers.**

The reasons for our ethical judgments matter. This calls for "justifications of conclusions in the light of the strongest available counterarguments," in the words of ethicist Raanan Gillon. Reasons matter as well because our decisions about one individual case may influence subsequent decisions. Precedents, whether in ethical reasoning or in law, are important.

Policy outcomes are ethically acceptable if they respect the ethical values and principles that are appropriate and relevant to the situation or case at hand, and that have been justified as taking priority with reference to competing values or principles. When governments are deciding among policy options, they need at a minimum to be able to distinguish statements about ethics from statements about preferences, or values, of other kinds.

Considerations of process are also important, and governments may often begin trying to reconcile conflicting ethical positions by designing a process for understanding the basis for disagreement or conflict. At the very least, such a process should recognize the distinctive character of ethical inquiry, and should operate according to principles that are themselves defensible, including transparency and due process.

Ethics in Social and Historical Context

The values that determine what is considered ethically acceptable change over time, sometimes quite dramatically, because of a number of factors, among them culture and socialization, religion and mass media.

Comparisons are especially useful in understanding the role of culture and socialization. Comparing Canadian and U.S. political culture, Canadians are more sympathetic to concerns about the good of the community, somewhat more deferential toward authority,

and willing to accept a larger role for governments in social and economic affairs. We can see this with reference to a variety of policy issues. Contrasting policies on gun control are a particularly interesting example, because most Americans, like most Canadians, would identify respect for human life as one of their culture's most fundamental values. However despite an epidemic of firearms-related deaths and injuries that would be treated as a national public health emergency if an infectious disease were the cause, the individualism of the society is such that many Americans still assign a higher priority to the constitutionally entrenched right to keep and bear arms.

Why the differences? U.S. political culture began with the highly individualistic ideas that guided the American Revolution, while Canada's political origins were distinctly non-revolutionary. So societal or institutional memory, often as reflected in political institutions, can have a powerful and long-lasting influence on what is considered ethically acceptable.

The contrast between materialism and post-materialism is an important dimension of value change. Materialist values emphasize income, economic growth and social stability. Post-materialist values, on the other hand, emphasize such factors as personal fulfilment, quality of life, human rights and freedom of speech. Since the end of World War II, post-materialist values have become steadily more widespread in industrial societies, with each succeeding cohort (age group) containing a relatively higher percentage of post-materialists. One result is that values, rather than the distribution of the economic pie, are likely to become increasingly important in the political arena.

Another perspective on socialization comes from the work of philosopher Richard Rorty, for whom there are no authoritative foundations for ethics. Moral progress, says Rorty, is an increase in "the ability to think of people wildly different from ourselves as included in the range of 'us'" rather than as being separated by nation, tribe or race. We make moral progress, says Rorty, through identifying and empathizing with the victims of such practices as cruelty and racial discrimination.

Language is not neutral: the words and images we use to describe a situation have a powerful influence on what is considered ethically acceptable. Examples include the contrast between "life, liberty and the pursuit of happiness" in the U.S. Declaration of Independence and "Peace, order and good government" in the *British North America Act*, and the evocative impact of the word "welfare."

Historically, religion has been a primary basis for deciding what is ethically acceptable. This has gradually changed as societies became more secularized. However, the importance of religion as an influence on what is considered ethically acceptable continues, for instance, as an inspiration for the ideal of the "secular sacred" (reverence for life). According to some authors, the Judaeo-Christian ethic has historically justified the idea that nature exists to serve humanity. Comparisons are useful, again. In United States, there is a strong element of fundamentalism, and what sociologist Seymour Lipset calls "utopian

moralism," while in Canada there is a stronger tradition of coexistence among denominations.

Mass media are, for most people, the principal source of information about events outside everyday life. Media decisions about what is covered, and about how it is covered, are extremely important in explaining both **what** is considered ethically acceptable, and **how** people decide what is ethically significant and important.

The characteristics of "good media" include conflict and drama, heroes and villains, and accounts of courage and suffering with names and faces attached. Television news, in particular, is primarily "episodic" rather than "thematic," organized around personal stories rather than elements of the social, economic and political context. Effects on what is considered ethically acceptable include a focus on visible victims rather than statistical victims, and a strong focus on micro level issues. We may learn about human suffering in new and evocative ways, but also may succumb to "mediatization" and a dulling of our sensibilities.

Many attitudes that were until recently judged ethically acceptable now strike us as clearly unacceptable, because they are **unjust.** The key question for doing ethics is: Do we think today that the discriminatory practices of yesteryear are wrong only because of the transformation of social attitudes toward them, or is the wrongness at issue more fundamental? The wrongness of **some** practices (and conversely the rightness of others) is sufficiently fundamental that it cannot be reduced to a question of prevailing societal values or standards.

Admittedly, it may not be easy to identify impermissible or obligatory practices in our own place and time. However, governments (and the individuals who judge them) should identify **core** values or standards of ethical acceptability — principles that are especially basic, as in those now taken to comprise human rights. In addition governments (and the individuals who judge them) must always be sensitive to the nature of ethics as a learning process, and to the provisional nature of our ethical choices. While respecting cultural differences and the resulting emphases on different values, we must not renounce responsibility for making ethical judgments about social arrangements both within our own society and outside it.

Dimensions of Ethical Decision Making

Ethical decisions can be made on the basis of one of several **schools** of ethics: basic and necessarily quite general substantive principles. Ethical decisions can be made at a variety of **levels,** ranging from the individual to the societal and even the trans-national. Ethical decisions can be made based on standards specific to a particular **domain** of human activity.

The major schools of ethics include **utilitarianism,** which is an example of **consequentialist** ethics (in which the rightness or wrongness of an action is judged with reference to its consequences); **Kantian** or obligation-based ethics, which is an example of **deontological** ethics (in which some actions are held to be inherently right or wrong); **rights-based** ethics; **contractarian ethics; communitarian ethics;** the **ethics of care; character ethics,** or the ethics of virtue; **casuistry;** and **environmental ethics.** Each of these schools is described, already in oversimplified form, in the body of the report.

There is considerable overlap between many of the schools, which are not mutually exclusive approaches separated by clear boundaries. We can think of the different schools of ethics as various prisms or conceptual lenses through which a decision or situation can be viewed. When making choices about the ethical acceptability of courses of action or of public policies, we normally and appropriately incorporate elements from several schools of ethics, rather than relying exclusively on a single one.

Ethical analysis can be done at several levels. The **micro** level involves individuals. The **meso** level deals with the group, institution or organization. The **macro** level is society-wide, for example as reflected in the decisions of provincial or national governments about domestic policy. Finally **mega**-ethics operates at the transnational or cross-cultural level, as in the case of human rights. Illustrations of issues that arise at each of these levels are provided in the body of the report. Especially in the health care field, ethical analysis has focussed on the micro and meso levels. However, ethical analysis often must operate at multiple levels, and some recent studies show that it is possible to carry out rigorous ethical analysis of "big picture" questions of public policy.

Ethical analysis takes place within various domains of human activity, such as health care, education, business and the family. The strength of a "domain-sensitive" approach to ethical standards is that the domains do present specific demands and challenges. However, what values, if any, can we rely on as the basis for concluding that certain goals or purposes of a specific domain are unreasonable? Who decides? Thus, although very important as far as they go, domain-specific standards of ethical acceptability are not enough. Those standards must themselves be justified, and must stand up to critical examination.

Ethical Tensions or Conflicts and the Government of Canada

It is inappropriate for governments to adopt a particular school of ethics, such as utilitarianism, as the starting point for their decision making. This would be stepping in where philosophers fear to tread. Governments may, however, after careful consideration, decide on a policy that emphasizes the concerns that are central to one particular school of ethics. Similarly, it is inappropriate for governments to consider ethical issues only from the perspective of one domain, such as business or the medical or legal professions.

By their very nature, governments are decision makers for the society as a whole; this means that governments have a special obligation to consider the justifications for the

choices they make, and to think about the macro level in their decision making, even though they may ultimately decide not to **act** at the macro level.

Ethical issues often do not come neatly labelled with a tag saying: "This is an ethical issue!" Sometimes, a particular set of issues or questions is clearly acknowledged as ethical, and rules or guidelines are developed for addressing and resolving them. More often, however, frameworks for making decisions tacitly reflect particular ethical commitments, or the primacy assigned to a particular value, in ways that are so deeply "embedded" that policy makers and the public alike tend not to think about the underlying values and principles. As governments seek to clarify the nature of differences among schools of ethics, tensions between levels of ethical analysis, and the ethical commitments that are embedded in particular policies, they will find that analyzing policy positions by looking at their **initial presumptions** — their starting points — is a key strategy for learning and decision making.

To this end, it is essential that there be forums in which the ethical acceptability of the choices confronting governments can be discussed **as ethical issues.** The availability of such fora is especially important with respect to macro level policy issues whose ethical dimensions may seldom have been considered publicly in any kind of systematic way. Indeed, government is under an ethical obligation to allow the Canadian public to identify key ethical issues in the development and implementation of public policy and to engage in debate on those issues.

Consultations of various kinds are becoming increasingly frequent and useful in public policy. Three important sets of considerations should be taken into account in designing consultations on ethical issues. First, they should be structured in a way that reflects the distinctive character of ethical inquiry. This can be achieved through the following methods:

- specification
- getting facts
- clarifying definitions
- using examples and counter examples
- analyzing arguments.

Second, careful thought must be devoted to the issue of who should be consulted in a particular context, and why. Third, since reasons matter, agreement on the decision or policy in a particular case is no substitute for careful justification.

The process of ethical debate and consultation must normally occur with the recognition that ultimate decision-making power rests with governments. Four points need to be made here about the responsibilities and obligations of government in this context. First, decision-making processes must be transparent, in that the basis and reasons for decisions about ethical acceptability must be disclosed, and must conform to criteria of due process. Second, it is important to provide for chances to refine and rethink conclusions on ethical

issues. Third, governments may choose to delegate some decision-making power, in order to provide a greater degree of independence, both actual and perceived, from political considerations that may have nothing to do with ethics. Fourth, democratic governments may, and indeed must, exercise ethical leadership with respect to values that they — preferably after appropriate reflection and consultation — consider to be sufficiently fundamental. However, no convenient algorithms are available, or can be made available, for determining when and how it is appropriate for governments to do so.

Introduction

With funding from the National Biotechnology Strategy, an interdepartmental workshop was held in the winter of 1994 to explore ethical issues raised by biotechnology and relating to federal responsibilities. The workshop led to the establishment of an Interdepartmental Working Group on Ethics, which identified the need for research on a number of ethical issues raised by biotechnology.

This report addresses one set of issues of particular concern to the Working Group: What does it mean to say that an action, practice or policy is ethically acceptable? And how should the federal government respond in situations where the answer is unclear, or when considerable conflict exists about the appropriate answer?

The structure of the report is as follows. Chapter 1 introduces the topic by discussing the nature of ethical argument and the process of ethical inquiry — "doing ethics" — and suggests a preliminary definition of ethical acceptability. Here and throughout the report, we emphasize that ethics is about process as well as about outcomes. In other words, ethics is not only about making the right decisions, but also about the ways in which individuals, institutions, governments and societies as a whole make those decisions.

Chapter 2 discusses how standards of ethical acceptability change over time, with specific reference to the roles of culture, socialization, religion and the mass media. It then explains that such changes raise important questions about the nature and content of our ethical standards at any particular point in time, and suggests that decisions about ethical acceptability cannot always be made simply by canvassing prevailing values or accepting the most widespread or popular position.

Chapter 3 outlines several dimensions of deciding about the ethical acceptability of policies or courses of action. These include different schools of ethics, different levels of ethical analysis and different domains of ethical analysis. Ethical decision making has to be understood with reference to each of these dimensions, and choices may have to be made within each dimension — for example, about what level of analysis is most appropriate, or about which school of ethics can contribute most to resolving a particular question.

Chapter 4 outlines how governments should go about evaluating the ethical acceptability of different actions or policies. It argues that governments cannot adopt exclusively the point of view of one school or domain of ethics. However, in terms of levels of ethical analysis, governments must consider the macro level or societal impacts of their decisions when evaluating the ethical acceptability of their actions or policy choices. The chapter goes on to argue that it is very important, when trying to resolve ethical tensions, to identify the initial presumptions people bring to a particular policy choice. These presumptions determine what is taken for granted and, conversely, what has to be demonstrated in a particular situation. The chapter then emphasizes the role of dialogue, debate and ethical learning, and

suggests a number of methods governments can use to improve the quality of these as they relate to public policy.

Finally, Chapter 5 provides a summary of the main prescriptive findings and conclusions of the report.

1. The Meaning of Ethical Acceptability

1.1. Ethics and Ethical Inquiry: What Are They?

Defined most broadly, ethics is the activity of thinking about and deciding how people ought to act in their relationships with one another, or how human institutions and activities ought to be organized. In another formulation, ethics is the application of moral values to factual situations in order to determine how we ought to act in those situations. In other words, it is about doing the right thing and avoiding doing the wrong thing, with all the complexities that go along with such choices.

Statements about ethics are **normative** or **prescriptive.** They represent statements about how the world ought to work. They can be contrasted with **positive** or **descriptive** statements, which tell us about the state of the world as it now is.[1] In other words, statements about ethics deal with values. However, they are not just about "what people value," because people have very strong preferences (in other words, they may attach a very high value to certain states of the world) for reasons that are outside the scope of ethics.

This concept of ethical (or moral) values[2] as a special kind of values captures another distinctive characteristic of statements about ethics: they require **justification** or explanation. Douglas Amy has noted that:

> A preference for strawberry ice cream doesn't require justification. But when someone makes a moral claim — that capital punishment is good, for example — one expects such a position to be supported by reasons . . . and these reasons and justifications form the basis for the rational analysis of ethical positions.[3]

We can understand this point by imagining how we would respond to someone who, when questioned about why he/she supported capital punishment, replied: "because that's just the

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1. The distinction between prescriptive and descriptive statements is a very convenient one to make for analytical purposes. However, the distinction is often not clear-cut in practice, since the facts we generate may be affected by the values guiding the questions we choose to ask.

2. Although we have defined ethics in terms of the application of moral values, we have not assigned a separate meaning to "morality" as contrasted with ethics. We think this introduces unnecessary confusion, and have therefore used the nouns morality and ethics, and the adjectives moral and ethical, interchangeably. In this usage we follow Dan Brock, "Public Moral Discourse," in R. Bulger, E. Bobby and H. Fineberg, eds., *Society's Choices: Social and Ethical Decision Making in Biomedicine*, Report of the Committee on the Social and Ethical Impacts of Developments in Biomedicine, Institute of Medicine (Washington, D.C.: National Academy Press, 1995), pp. 216, 239.

3. Douglas J. Amy, "Why Policy Analysis and Ethics are Incompatible," *Journal of Policy Analysis and Management* 3 (1984): 575. For a very similar statement of the difference between moral judgments and judgments of taste see Brock, "Public Moral Discourse," p. 227.

way I feel" or "because it's the right thing to do." Much more needs to be said on a topic like this one.

Thinking about ethics and acting ethically require that we consider **others'** points of view, as well as our own. Acknowledging that other people count, too, is what distinguishes "the moral point of view"[4] from some other kind of point of view defined solely with reference to one's own interests or priorities. As an editorial writer for *The Economist* said in a leader on the topic of animal rights: "The most elementary form of moral reasoning — the ethical equivalent of learning to crawl — is to weigh others' interests against one's own."[5]

People may often disagree, of course, about what taking the moral point of view requires. Further, taking the moral point of view does not always mean giving the same weight to others' points of view as to our own, and we may also distinguish among various kinds of others. In some situations, for instance, there are good reasons to attach more importance to the interests of members of our families than to those of strangers. However, such choices are not always self-evident, and may themselves be the topic of ethical debate.

During the 1994 federal government workshop on ethics and biotechnology, one participant explained that:

> [T]he ethics of a decision are frequently related to the process of decision making rather than the outcome itself. There is frequently no single 'right' answer, but a right process of determining which of several ethically acceptable answers will be implemented on a given issue.[6]

In other words, it is important to pay attention to questions of process — the **how** part of doing ethics, as distinct from **what** we decide is ethically acceptable.[7] Furthermore, the conclusions we reach may not be permanent, and perhaps should not be. "You can be absolutely sure you tried to the best of your ability to make the ethically right decision. You can't be absolutely sure it will prove to have been absolutely the right decision."[8] Among other influences, both new knowledge and changing views of the world may lead us to rethink the answers we come up with today at some point in the future.

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4. Will Kymlicka, "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, 1993), pp. 15-16.

5. "What Humans Owe to Animals," *The Economist,* August 19, 1995, p. 11.

6. Bernard Dickens, in *Proceedings,* Inter-Departmental Workshop on Biotechnology (Ottawa, 1994), pp. 2–3.

7. This distinction is drawn from David Roy, John Williams and Bernard Dickens, *Bioethics in Canada* (Scarborough: Prentice-Hall Canada, 1994), p. 29.

8. Comments of Margaret A. Somerville in *Evidence,* House of Commons Standing Committee on Environment and Sustainable Development, Parliamentary Forum on Biotechnology, Roundtable No. 3: Ethical Considerations (October 8, 1996)(subsequently cited as Ethics Roundtable), 37: 22.

1.2. Reasons Matter

The example of capital punishment, discussed in the preceding subsection, shows that the reasons for our ethical choices matter.

> Ethics is more than a matter of individual conscience, although this is essential: it is the systematic application of informed, structured and disciplined discernment to analysis of situations in relation to the ethical issues they raise and to decision making in these situations.[9]

This does not mean that there is necessarily only one right answer to ethical questions, or one ethically acceptable direction for public policy in a particular field; there may be several. However, some answers are better than others, and some ways of defending or justifying answers are better than others. For example, statements about ethics should not be based on inappropriate analogies, errors in logic[10] or "epistemic mistakes" about what is at issue in a particular situation.[11]

Ethicist Raanan Gillon has said that "**justification** of conclusions in the light of the strongest available counterarguments . . . is at the heart of bioethics."[12] Some philosophers remain attached to a narrowly cognitive approach to justification, which self-consciously guards against "emotivism." "The working model of moral conflict," according to Sidney Callahan, "has been that of emotion warring against reason, with only reason's mastery offering trustworthy guidance."[13] However, she cautions against accepting this working model, and instead notes that "just as reason tutors and monitors emotion, so too can our emotions tutor reason."[14] In support of such a broader approach to ethical knowledge, Thomas Nagel, a political theorist whose primary concern is with issues of how society's available resources are distributed, similarly argues that:

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9. Margaret A. Somerville, "Societal Concerns and Reaction to Biotechnology," address to AFPC 50th Anniversary Pharmaceutical Biotechnology Conference, Vancouver, August 1993 (Montreal: McGill Centre for Medicine, Ethics and Law), 22.

10. A particularly useful catalogue of common errors in logic is provided in Sean O'Connell, *Dilemmas and Decisions* (Toronto: Harcourt Brace, 1994), pp. 35–51.

11. Barry Hoffmaster, "Morality and the Social Sciences," in G. Weisz, ed., *Social Science Perspectives on Medical Ethics* (Dordrecht: Kluwer, 1990), pp. 252–53.

12. Raanan Gillon, "Ethics of Genetic Screening: The First Report of the Nuffield Council on Bioethics," *Journal of Medical Ethics* 20 (1994), 92 (emphasis in original). For a similar argument about the importance of the best available arguments to support a particular position, see James Rachels, "Can Ethics Provide Answers?" in J. Howell and W. Sale, eds., *Life Choices: A Hastings Center Introduction to Bioethics* (Washington, D.C.: Georgetown University Press, 1995), pp. 9–16.

13. Sidney Callahan, "The Role of Emotion in Ethical Decision Making," in Howell and Sale, eds., *Life Choices*, p. 30.

14. Ibid., p. 31.

> To trust our intuitions, particularly those that tell us something is wrong even though we don't know exactly what would be right, we need only believe that our moral understanding extends farther than our capacity to spell out the principles which underlie it. . . . Intuitive dissatisfaction is an essential resource in political theory. It can tell us that something is wrong, without necessarily telling us how to fix it.[15]

And John Ralston Saul has argued that reason is just one of many human qualities, including imagination, intuition and memory (history), that must be kept in some sort of balance.[16] So the justifications that are relevant for purposes of ethics need not take the form only of logical, purportedly objective argumentation. Decision making about ethical issues must consider not only reason but also other ways of knowing, such as intuition, empathy and emotion.

Whether in ethical analysis or in law, precedents are important, and they are normally established not by the content of a particular decision but by the reasons that are given for it. It can make a great deal of difference in subsequent decisions, for instance, whether the choice to withdraw life-prolonging medical treatment is based on a patient's clear previous instructions that such treatment is not to be continued, or on concerns about limiting the costs of medical care.[17] The first reason, as applied to subsequent cases, would reinforce the principle of respect for persons' autonomy, including both informed consent to treatment and the right of informed refusal of treatment. The second reason, as applied to subsequent cases, might well be used to overrule individual patients' wishes once their continued care, including both life-prolonging and palliative measures, had become too expensive relative to the targets set by health care managers, whether in the public sector or the private.

1.3. What Do We Mean by Ethical Acceptability?

We are now in a position to state a very preliminary definition of what is meant by ethically acceptable, with specific reference to the decisions made by governments. First of all, policy outcomes are ethically acceptable if they respect the ethical values and principles that are appropriate and relevant to the situation or case at hand, and that have been justified as taking priority with reference to competing values or principles. The vagueness of this definition is not a cop-out. Instead, it recognizes that a range of values and principles may be relevant to a particular policy decision, and that tensions or conflicts may exist among these values and principles.

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15. Thomas Nagel, *Equality and Partiality* (New York: Oxford University Press, 1991), p. 7.

16. John Ralston Saul, *The Unconscious Civilization* (Toronto: Anansi, 1995), pp. 181–89. Saul, in fact, also considers ethics to be one of these qualities; however, he is using ethics in a narrower sense than the one used here, and his primary concern is to warn against situations in which ethics (like memory, or reason, or intuition) taken as an absolute "becomes a tool of ideology" (Ibid., p. 184).

17. *Cf.* Margaret A. Somerville, "The Song of Death: The Lyrics of Euthanasia," *Journal of Contemporary Health Law and Policy* 9 (1993): 65–66.

When governments are deciding among policy options, they need at a minimum to be able to distinguish statements about ethics from statements about preferences, or values, of other kinds. It makes a great deal of difference whether an individual, an industry or an interest group supporting a specific position can support it from "the moral point of view" rather than, for example, simply with reference to their own political or financial interests. Those interests may in fact be of ethical significance — for instance, when ensuring the availability of venture capital for the bio-pharmaceutical industry will make life-saving drugs available more rapidly than they otherwise would be — but the convergence of private interests with the public interest or, to put the matter another way, their ethical relevance must be demonstrated rather than assumed.

As noted earlier, ethics is not just about what we decide; it is also about how we decide. Substantive ethical principles, of the kind discussed in subsection 3.2, are important, but so are principles of procedure.[18] In fact, the values that are central to political democracy are first and foremost about process, and not about particular outcomes. Because of this point and because of the importance of providing reasons for ethical decisions, we should not be satisfied with outcomes that are ethically acceptable, independent of considering the process through which they were reached. In situations where ethical values conflict or the ethically acceptable course of action is unclear, it is often best for governments to begin the process of trying to reconcile conflicting principles or positions by designing a process for understanding the basis for disagreement or conflict. In doing so, it can be important to start from the points on which we agree; starting from agreement rather than disagreement gives a different tone to the debate and can well affect the outcome.

Not just any process will do, of course. At the very least, a process for trying to resolve ethical conflicts should recognize the distinctive character of ethical inquiry: it cannot be reduced, for instance, to reconciling competing financial interests. Such a process should provide for recognition of the values at stake in a particular context. We have argued in subsection 4.4 that examining the initial presumptions adhered to by various participants in debates over ethical issues is a useful method for ensuring that recognition. Finally, it should operate according to principles that are themselves defensible. These principles must include, although they are not limited to:

- **transparency** (the basis on which decisions are made must be disclosed)
- **due process** (the persons making the decision must not have a conflict of interest, and the individuals or groups with a stake in the outcome must not be denied an opportunity to be heard).

We further suggest in subsection 4.6 that governments are under an obligation to promote debate and learning about the ethical issues on which they must make decisions, and to provide a forum for public involvement in those decisions.

18. Margaret A. Somerville, "The Planet as Patient," *Ecosystem Health* 1 (2, June 1995): 65; Somerville, "Justice Across the Generations," *Social Science and Medicine* 29 (1989): 389.

This preliminary definition of what is ethically acceptable leaves many questions unanswered. Just a few of these are: Where do our conceptions of what is ethically acceptable come from? What is the significance of the fact that these conceptions change over time within a particular society and differ across societies? What are the key substantive principles that governments should consider in making policy decisions? How should conflicts among ethical positions be resolved? The remainder of this report explores these and related questions and provides ways of making the task of deciding what is ethically acceptable more manageable. Like the enterprise of doing ethics itself, however, the report does not and cannot provide a set of easy answers or convenient algorithms that do away with the need for continued reflection. Thoughtfulness and the willingness to tolerate a certain degree of ambiguity and indeterminacy are prerequisites for doing ethics responsibly, whether the context is our own, individual lives or the policies of a national government.

2. Ethics in Social and Historical Context

With tongue only partly in cheek, philosopher Annette Baier has written that: "Morality is the culturally acquired art of selecting which harms to notice and worry about."[19] She did not mean to say that ethical standards are just distinctive cultural peculiarities like styles of dress or table manners. She did mean that different cultures and social contexts, like different schools of ethics (see subsection 3.2 below), provide distinctive prisms or conceptual lenses through which we view the ethics of particular choices and situations. Even within a particular culture or society, standards of ethical acceptability change over time, sometimes quite dramatically.

Consider just one such change: the transformation of attitudes toward the natural environment in the industrialized countries. This transformation was dramatically illustrated in 1989 when *Time* magazine, instead of naming a newsmaker of the year, as it usually does, featured Endangered Earth on the cover as its planet of the year.

Several factors have contributed to this increase in concern for the environment. As human activity quite literally transforms the face of the earth,[20] we have become aware of the possible harms resulting from careless use of the environment. Dumping toxic chemicals in the nearest river or discharging them to the atmosphere may cause health problems downstream or downwind; burying them in landfills may cause such problems many years in the future. Our current attitudes toward these and other concerns are partly a response to increased scientific knowledge about the consequences of human activity; that is, **scientific learning** affects our concerns, our conduct and our ethics. We have simply learned important factual lessons from past mistakes. Partly, though, what is involved is a change in the values that determine what we consider ethically acceptable, in what we consider important or deserving of attention as an ethical issue. It may be useful to think of this process as one of **ethical learning.** Twenty, 50 or 100 years ago, many of the health hazards associated with pollution or the ecological impacts of mining and forestry might have been considered the price of progress. Today, we are much more demanding in the ways we judge whether or not such consequences are acceptable. We return to the theme of ethical learning at several points in this report.

This subsection first explores the ways in which culture, socialization, religion and the mass media shape the situations we regard as ethically significant and the choices we regard as ethically acceptable. This discussion, which emphasizes the value of cross-national comparisons, is primarily social-scientific in nature. In other words, it describes some of the

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19. Annette Baier, "Poisoning the Wells," in *Values at Risk*, edited by D. MacLean (Totowa, NJ: Rowman & Allanheld, 1986), p. 49.

20. B. L. Turner II *et al.*, eds., *The Earth as Transformed by Human Action: Global and Regional Change in the Biosphere over the Past 300 Years* (Cambridge: Cambridge University Press, 1990).

sources of value change, but does not actually engage in ethical argument. The subsection then goes on to explore differences in ethical acceptability over time and across cultures, with specific reference to what these differences should mean for governments as they make policy decisions. Here, in contrast to the first subsection, we are actually advancing an ethical point of view about how decisions ought to be made. Specifically, we argue that it is not good enough for governments to make, and defend, ethical decisions solely with reference to current values or prevailing standards, however widely shared those values or standards may be.

2.1. Shaping Values

2.1.1. Culture and Socialization

As Baier's observation suggests, it is only a slight exaggeration to say that there are no values, and therefore no decisions about ethical acceptability, without culture. Even many of the values most of us would probably consider universal, such as respect for human life, turn out to be filtered by what she calls a set of inherited moral codes,[21] and weighted in a different way against other values depending on the society in question. Distinctions between culture and socialization are largely artificial; more or less by definition, socialization is how we learn what our particular culture considers normal and appropriate. For this reason, we have combined the discussions of culture and of socialization for purposes of this report.

The Value of Comparisons

Comparisons and contrasts are useful ways, probably the best ways, to understand how culture and socialization shape what is considered ethically acceptable in a particular society. In comparisons between Canada and the United States, it is now almost commonplace to observe that the value structure of most individual Canadians, one both reflected in and shaped by our political institutions, tends to be: more sympathetic to concerns about the good of the community even at the cost of apparent intrusions into individual liberties; somewhat more deferential toward authority; and clearly willing to accept a larger role for governments in social and economic affairs.[22]

Such distinctions show up in contrasting approaches to public policy on issues as diverse as firearms control (whose severity in Canada would be unthinkable in most, if not all U.S. jurisdictions), radar detectors (banned in most Canadian provinces; legal in almost all U.S. states) and new reproductive technologies (a restrictive regulatory regime is embodied in draft legislation now before Canada's Parliament, while the U.S. has been described as a

21. Baier, "Poisoning the Wells," p. 46.

22. Seymour M. Lipset, *Continental Divide: The Values and Institutions of the United States and Canada* (London: Routledge, 1990), pp. 9–41, 98–100, 110–13.

"biomedical free trade zone"[23] or as epitomizing a laissez-faire approach to the use of such technologies[24]). The firearms control issue may be especially revealing, since most Americans, like most Canadians, would identify respect for human life as one of their culture's most fundamental values. However despite an epidemic of firearms-related deaths and injuries (roughly 40 000 deaths and an estimated 99 000 non-fatal gunshot wounds in 1993) that would be treated as a national public health emergency if an infectious disease were the cause,[25] the individualism of the society is such that many Americans still assign a higher priority to the constitutionally entrenched right to keep and bear arms than to reducing the number of firearms-related injuries.

Sociologist Seymour Lipset, much of whose career has been devoted to studying the value structures of Canadians and Americans, argues that the deeply rooted individualism, anti-government orientation and suspicion of egalitarian ideas distinctive to U.S. political culture are legacies of the ideas that guided the American Revolution; in contrast, Canada's political origins were distinctly non-revolutionary.[26] The contrast is reflected in the differences between U.S. political institutions, which emphasize checks on governmental authority and balances among the powers of the branches of government, and Canada's Westminster system, in which executive and legislative branches are fused and the supremacy of Parliament had seen few limits imposed by the judiciary until the advent of the *Charter of Rights and Freedoms*.

This line of explanation, variations on which are widely accepted in political science,[27] suggests the importance of what might be termed cultural or institutional memory, often as reflected in political institutions, which can have a powerful and long-lasting influence on what is considered ethically acceptable.

In another important example of societal memory, German revulsion to the Nazi-era ventures in eugenics and human experimentation is sometimes used to explain that

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23. In the words of one panelist at an international conference on medically assisted reproduction held at the University of Toronto in February 1996.

24. Andrea Bonnicksen, "National and International Approaches to Human Germ-Line Therapy," *Politics and the Life Sciences* 13 (1, 1994): 39–49.

25. Centers for Disease Contro,l "Deaths Resulting from Firearm- and Motor Vehicle-related Injuries: 1968-1991," *Morbidity and Mortality Weekly Report* 43 (1994): 37–42; Daniel M. Sosin *et al.*, "Trends in Death Associated with Traumatic Brain Injury, 1979 through 1992," *JAMA: Journal of the American Medical Association* 273 (1995): 1778–80; Phil B. Fontanarosa, "The Unrelenting Epidemic of Violence in America" [Editorial], *JAMA: Journal of the American Medical Association* 273 (1995): 1792–93.

26. Lipset, *Continental Divide*, pp. 19–56.

27. See, e.g., Louis Hartz, *The Liberal Tradition in America* (New York: Harcourt, Brace & World, 1955); for an application to the area of bioethics, see Harvey Fineberg et al., *Report* of the Committee on the Social and Ethical Impacts of Developments in Biomedicine, in Bulger et al., eds., *Society's Choices*, pp. 44–46.

country's current, extremely restrictive attitudes toward biotechnology in areas as diverse as bio-pharmaceuticals and human gene therapy. Intriguingly, Harold Edgar and David Rothman suggest that the revulsion felt in the United States, as expressed at Nuremberg, played an important role 20 years later in focussing public attention on the general issue of experiments on human subjects.[28] So too, they argue, did the distinctively rights-based U.S. political culture for which "a maximization of collective welfare was not a legitimate basis for imposing harms of whatever magnitude upon individuals."[29]

Materialism vs. Post-materialism

Political scientist Ronald Inglehart has identified a basic contrast between two value orientations he calls materialist and post-materialist. People with materialist values tend to emphasize income and financial security in their personal life choices and economic growth as a political objective. Post-materialists, on the other hand, are relatively less concerned with income and financial security (although many, as members of the so-called "new class," are well off in material terms) and tend to emphasize personal fulfilment, quality of life (including environmental quality) and such issues as protecting human rights and freedom of speech. The distinction between materialist and post-materialist value orientations is therefore relevant to changing standards of ethical acceptability with regard to a broad spectrum of issues, ranging from government policies on civil liberties to environmental pollution and nuclear power, which "has come to symbolize everything the Postmaterialists oppose."[30]

Inglehart's research is based on attitude surveys starting as early as 1970 in some industrialized countries. It is particularly interesting for what it suggests about why and how values change over time within particular societies. In many countries, he has found a pronounced increase over time in the proportion of the population with post-materialist values. The younger the people in a given cohort (age group), the more likely they are not only to have such values, but also to hold onto them as they grow older. Inglehart explains this shift with reference to two factors: changing material circumstances and the way these circumstances affect pre-adult political socialization.[31] In the postwar industrialized societies Inglehart has studied, the experience of successive cohorts during their pre-adult years was one of growing up in an environment of relative affluence, in which most of the

28. That public attention, and the governmental response to it in the 1970s, in turn helped shape the development of North American biomedical ethics; see David J. Rothman, *Strangers at the Bedside* (New York: Basic Books, 1991), pp. 70–100, 148–89.

29. Harold Edgar and David J. Rothman, "The Institutional Review Board and Beyond," *Milbank Quarterly* 73 (1995): 495; see generally pp. 494–97.

30. Ronald Inglehart, *Culture Shift in Advanced Industrial Societies* (Princeton: Princeton University Press, 1990), pp. 268–70.

31. Ibid., pp. 162–76, 248–64.

immediate material demands of life had been taken care of. (The contrast between this experience and that of the previous generation will be familiar to many "baby boomers" from conversations with members of their parents' generation about growing up during the Great Depression.) These societies, Inglehart wrote in 1981, "are a remarkable exception to the prevailing historical pattern: the bulk of their population does *not* live under conditions of hunger and economic insecurity."[32]

A number of changes are occurring simultaneously in the societies Inglehart studied, and it may be difficult to distinguish their relative contribution to value shifts. For instance, along with an increase in their overall affluence have come higher levels of urbanization and a substantial demographic shift away from agriculture and industrial employment and into the fast-expanding service sector. And obviously, very few people in a given society are ever pure materialists or post-materialists. However, Inglehart has found that these correspond to coherent positions, in the sense that people "who give top priority to one Materialist goal tend to give high priority to other Materialist goals as well. Conversely, the Postmaterialist items tend to be chosen together" in surveys.[33] In the future, Inglehart suggests that the tension between materialists and post-materialists will become an "emerging axis of polarization [that] cuts squarely across traditional left–right lines,"[34] and will become every bit as significant as a political cleavage.[35] In other words, future political conflicts are likely to be about values other than, and in addition to, those directly affecting the the distribution of the material product of those societies.

A Different Perspective: Socialization as Ethical Learning

A different perspective on how socialization shapes values, one that is more explicit about the nature of ethical learning, is suggested by Richard Rorty, who has antagonized many of his fellow philosophers by rejecting the idea that any solid foundations exist for even the most basic values. For example, he says that although most people would agree about the desirability of avoiding cruelty, he says that there is no final external authority to which we can appeal, "no noncircular theoretical backup," to defend this belief or to resolve such questions as when the interests of one's family should outweigh those of the broader community.[36]

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32. Inglehart, "Post-Materialism in an Environment of Insecurity," *American Political Science Review* 75 (1981): 881; see also Inglehart, *Culture Shift*, pp. 121–24, 162–68.

33. Inglehart, *Culture Shift*, p. 75.

34. Ibid., p. 270.

35. Ibid., pp. 248–88, 331–34.

36. Richard Rorty, *Contingency, Irony, and Solidarity* (Cambridge: Cambridge University Press, 1989), p. xv; see also p. 197.

This sounds like a recipe for ethical nihilism, a concession that anything and everything goes, but it isn't. Rorty concludes his most thought-provoking book, *Contingency, Irony, and Solidarity*, with an explicit statement that moral progress is possible and that he himself believes in it.[37] However, he sees moral progress as originating not in theorizing but in empathy for the plight of other beings, human and non-human, which he calls solidarity.

Rorty insists that such moral progress is possible only through learning about that plight through its most eloquent expressions — a form of socialization. Philosophy is far less important to that learning process, says Rorty, than literature, journalism and ethnography (the branch of sociology and anthropology that specializes in detailed and empathetic field observation of people's everyday lives). According to Rorty, we can best understand the ethically repugnant aspects of cruelty, for instance, by listening to the voices of its victims and thereby cultivating:

> the ability to see more and more traditional differences (of tribe, religion, race, customs, and the like) as unimportant when compared with similarities with respect to pain and humiliation — the ability to think of people wildly different from ourselves as included in the range of "us."[38]

Many of the ways in which definitions of ethical acceptability have changed over time — for instance, with reference to the impermissibility of inequalities based on race and gender — involve precisely this broadening of the idea of "us." However, Rorty would insist that learning about the repugnant aspects of cruelty in the manner he describes is quite different from being able to develop a formal, rational argument to the effect that cruelty is wrong.

For many philosophers, this remains a contentious position. Consequently, it is very important to note that we may accept as accurate Rorty's description of how ethical learning takes place without at the same time accepting his claim that there are no theoretical foundations at all for deciding what is ethically acceptable except those that emerge through solidarity. Also without accepting that claim, we can acknowledge that Rorty's approach is important because it emphasizes that there can be learning outside theory, and outside purely reason-based approaches, through the development of moral intuition and moral imagination.

Language and Ethical Acceptability

In discussing socialization, we must also consider language (including rhetoric, metaphors and images) and its relation to standards of ethical acceptability. "Language is not neutral. . . . We form our narratives and our narratives form us — we are, at least in part, the stories we tell"[39] and the words we use to tell them. For instance, someone growing up

37. Ibid., p. 192.

38. Ibid.

39. Somerville, "The Song of Death," p. 45.

in the United States, or exposed to U.S. culture for the first time, would quickly learn the language of individual rights, the constitutional history of that language and its reflections in popular culture. At least until recently someone growing up in Canada would have been far more familiar with the language of responsible government and even "peace, order and good government." So language both reflects and reinforces the orientations toward the world that are embodied in political institutions and codified in political culture.

Political leaders have long been aware of the potential payoffs from the strategic manipulation of language.[40] Outrage over civilian casualties in war can be defused, at least to some degree, by way of the sanitized vocabulary of "collateral damage"; and "sovereigntist" used to describe proponents of an independent Quebec has quite a different set of connotations from the juridically more precise "secessionist." However, the effect of language on what is considered ethically acceptable is not necessarily or even usually a product of deliberate manipulation; it can be much more subtle. The simple addition of words like racism and sexism to our vocabularies not only reflects a change in attitudes toward discriminatory practices, but also reinforces the conviction that they are unjust.[41]

In a particularly striking illustration of the evocative power of a single word, a nation-wide *New York Times* poll in 1992 asked respondents whether spending on "assistance to the poor" was "too much, too little or about the right amount"; 64 percent of respondents answered "too little" and just 13 percent said "too much." When the question was reworded to refer to "welfare" rather than "assistance to the poor," 44 percent of respondents answered "too much" and just 23 percent said "too little."[42] In a similar poll two years later, 47 percent of respondents said that "Government spending on programs for poor children" should be increased, and only 9 percent said it should be decreased. When respondents were asked instead about "government spending on welfare," only 13 percent said it should be increased and 48 percent said it should be decreased.[43] These few examples, which could easily be multiplied, show that the power of words, and of the choice of words, cannot be ignored in discussions of changing values. To some degree, the choice of words is affected by media coverage, which is discussed at greater length in a separate subsection of this report.

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40. Murray Edelman, *Constructing the Political Spectacle* (Chicago: University of Chicago Press, 1988), pp. 103–19.

41. Martin Benjamin, "The Value of Consensus," in Bulger et al., eds., *Society's Choices*, pp. 250–51.

42. New York Times/CBS News poll cited in Robin Toner, "Politics of Welfare: Focussing on the Problems," *New York Times*, July 5, 1992, pp. 1, 13.

43. New York Times/CBS News poll cited in Maureen Dowd, "Americans Like G.O.P Agenda But Split on How to Reach Goals," *The New York Times*, December 15, 1994, pp. A1, A14. The reference to children is significant because eligibility for Aid to Families with Dependent Children, the major U.S. federal income support program until the end of 1996, always depended on the recipient's status as provider of financial support for one or more children.

2.1.2. Religion[44]

Because of the growing secularization of all Western societies, we tend to forget that until recently religious belief has been a critically important source and shaper of values. It continues to be so in some important respects — for instance, the "pro-life" attitudes of certain Christian denominations. Indeed, a few commentators argue that any coherent ethical system is ultimately impossible without some sort of roots in religion. This is no longer a widespread view, and indeed many highly religious individuals acknowledge the primacy of secular authority in public life as a desideratum, not just as a political fact.[45]

Looking only at contemporary influences understates the long-term contribution of religious values to the development of secular ones. For instance, based on the idea of "secular sacred" — a principle of reverence for life defined without reference to any particular religious faith or doctrine[46] — we might oppose physician-assisted suicide not on the basis of a religiously ordained sanctity of life principle, but on the basis of a secular principle of respect for life, which nevertheless has important religious antecedents. Conversely, a widely reprinted 1967 article by Lynn White suggests that a Judaeo-Christian tradition in which the domination of humanity over nature was unquestioned, and indeed believed to be divinely ordained, helps to explain the persistence of an ecologically destructive view of the proper relations among science, technology and nature. "The fact that most people do not think of these attitudes as Christian is irrelevant. . . . [W]e shall continue to have a worsening ecologic crisis until we reject the Christian axiom that nature has no reason for existence save to serve man [*sic*]."[47] White's analysis, like the origins of Canadian and U.S. political culture, illustrates that approaches to ethical acceptability tend to have a long half-life.

Here again, comparisons are valuable. Lipset stresses the fact that "at the end of the 20th century, the United States remains the most devout of industrialized democratic nations, while Canada is much less so."[48] He elaborates on the distinction by contrasting the "utopian moralism" of the United States, which has a strong Protestant fundamentalist tinge, with the Canadian history of coexistence not only between Protestantism and Catholicism, but also between church and ecumenical traditions within particular

44. This subsection has benefited greatly from access to "The Horns of a Dilemma: The Contribution of Religion to Public Policy on Ethical Issues," an unpublished manuscript by Prof. Katherine Young of the Faculty of Religious Studies, McGill University (March 1997).

45. Kymlicka, "Approaches to the Ethical Issues Raised by the Royal Commission's Mandate," pp. 10–12.

46. Margaret A. Somerville, "Are We Just 'Gene Machines' or also 'Secular Sacred'? From New Science to a New Societal Paradigm," *Policy Options* (March 1996): 3–6.

47. Lynn White, "The Historical Roots of Our Ecologic Crisis," *Science* 155 (1967): 1203–07.

48. Lipset, *Continental Divide*, p. 4.

denominations.[49] Religious bodies were the basis of a coalition organized by Jeremy Rifkin that in May 1995 called for a reversal of the U.S. policy of allowing patents on genetically engineered animals and human genes, cells and organs. The statement announcing the establishment of the coalition said, in part: "We believe that humans and animals are creations of God, not humans, and as such should not be patented as human inventions."[50] Further, until recently the main exception to the laissez-faire approach taken in the United States to regulating reproductive technology was the prohibition of federal funding for human embryo research and research involving therapeutic uses of fetal tissue; this prohibition was directly traceable to the political salience of religiously motivated objections to abortion.

Generally, church groups have not taken a comparable interest in bioethical issues in Canada. One exception is the role of Catholic organizations in the deliberations of the Royal Commission on New Reproductive Technology. Katherine Young suggests that this involvement was attributable to: a general Church policy of public involvement; the existence of a policy on reproductive issues already approved by the Vatican; the Catholic Church's centralized institutional structure; and the Church's previous experience in mobilizing on other ethical issues, such as abortion. Other religious organizations have so far, she suggests, failed to rise to the challenge of articulating a secularized version of their principles that will be persuasive in "the public square." However, she predicts that in the future other religions and denominations are likely to be able to express their ethical concerns in a more accessible way.[51]

2.1.3. Mass Media

As this report was being written, the media were filled with reports of the first successful cloning of an adult mammal — the stuff of science fiction made fact. A few years ago, Sue Rodriguez undertook a highly publicized effort to avoid legal reprisals against a physician who might aid her in ending her own life; media coverage led to a national public debate about whether (and if so, when) criminal prohibitions on such assistance violate the *Charter of Rights and Freedoms*. Television coverage of the Newfoundland seal hunt and the destruction of the Amazon rain forest, both remote from the lives of most Canadians, turned both into national political issues. Almost 30 years ago, an article in a U.S. national magazine described how Seattle Swedish Hospital's Admissions and Policies Committee (the so-called God Committee) decided "which one patient out of 50 [would] be permitted to hook up to Seattle's life-giving [dialysis] machines, and which should be denied." At the time, dialysis treatment for kidney failure was both scarce and costly; the article contributed

49. Ibid., pp. 76–80.

50. Quoted in Richard Stone, "Religious Leaders Oppose Patenting Genes and Animals," *Science* 268 (26 May 1995): 1126; see also Edmund L. Andrews, "Religious Leaders Prepare to Fight Patents on Genes," *New York Times*, May 13, 1995, pp. A1, A19.

51. Young, "The Horns of a Dilemma."

to unprecedented federal legislation providing financial support for the cost of dialysis for all patients requiring it.[52]

For many people, mass media are the principal source of information about events outside the scope of everyday life. Their influence is therefore extremely powerful — so powerful, in fact, that studying media influence is sometimes compromised by the unavoidable absence of a control group. Decisions both about what is covered (what is newsworthy) and about how it is covered therefore assume special importance not only in explaining what is considered ethically acceptable, but also — and perhaps more critically — in explaining the priority attached to various ethical issues and the way in which people tend to approach them.

Conflict and drama, heroes and villains, and accounts of courage and suffering with names and faces attached (whether the protagonist is Terry Fox or Sue Rodriguez) are among the characteristics of "good media." Television news, in particular, carries with it its own distinctive structure (for instance, the 30-second sound bite) and dramaturgy. In the words of political scientist Shanto Iyengar, television news is primarily "episodic" rather than "thematic," organized around personal stories rather than elements of the social, economic and political context.[53] Reflecting this pattern, the recent evening news on one Canadian television network, for instance, led with the story that O. J. Simpson had been ordered to pay US$25 million in punitive damages, while "[a] detailed background report on cultural policy . . . [was] abandoned" and [a] report on Great Lakes pollution [was] reduced to a single sentence."[54] Bioethicists are routinely interviewed about individual cases like those involving physician-assisted suicide or transplant candidates unable to locate suitable organ donors; seldom are they asked about racial and economic disparities in health status and access to life-prolonging health interventions[55] or the impacts of budget cutbacks on access to and quality of care,[56] which are surely every bit as important in ethical terms.

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52. Shana Alexander, "They Decide Who Lives, Who Dies," *Life*, November 9, 1962, pp. 102–25. For a discussion of the impact of this article and of similar situations, see Harvey Fineberg, "Preface," in Bulger et al., eds., *Society's Choices*, pp. v–vi; Rothman, *Strangers at the Bedside*, pp. 148–67.

53. Shanto Iyengar, *Is Anyone Responsible? How Television Frames Political Issues* (Chicago: University of Chicago Press, 1991), pp. 14–15. See also Dean Alger, *The Media and Politics*, 2nd ed. (Belmont, CA: Wadsworth, 1996), esp. pp. 15–65, 119–236; Doug Saunders, "If It Bleeds, It Leads," The Globe and Mail, February 15, 1997, pp. C1, C7; Margaret A. Somerville, "'Front Page'/'Prime Time' Death: Euthanasia in the Media," *Humane Health Care International*, forthcoming.

54. Saunders, "If It Bleeds, It Leads," p. C7.

55. Laurie Kaye Abraham, *Mama Might Be Better Off Dead: The Failure of Health Care in Urban America* (Chicago: University of Chicago Press, 1993); Carol Hogue and Martha Hargraves, "Class, Race, and Infant Mortality in the United States," *American Journal of Public Health* 83 (1993): 9–12; C. McCord and H. Freeman, "Excess Mortality in Harlem," *New England Journal of Medicine* 322 (1990): 173–77.

56. Pat Armstrong and Hugh Armstrong, *Wasting Away: The Undermining of Canadian Health Care* (Toronto: Oxford University Press, 1996), pp. 66–86, 137–44; Kevin Sack, "Public Hospitals Around

The effects of such selective media coverage can be far-reaching. The spectacle of O. J. Simpson's criminal trial, which dominated television news for months, remained largely unconnected to the broader systemic issues of wife abuse and of racism in the criminal justice system, and arguably contributed to further polarization of U.S. society along racial lines. In another example, based on the best available measures, the incidence of crime is falling in Canada and in most U.S. jurisdictions. At the same time, the political salience of concern about crime and the possibility of criminal victimization is increasing in both countries. This phenomenon may be partly attributable to cynical efforts by some political leaders to cultivate that fear in order to increase the attractiveness of law-and-order policies. It is almost certainly also partly due to media emphasis on individual, high-profile crimes and their victims and on certain categories of crimes and offenders, such as violent crimes by young offenders.

News events and situations, as portrayed in the distinctive grammar of the mass media, may reinforce prevailing values or reassure us about their importance. For example, when large sums are spent on search and rescue operations for lost boaters or mountaineers, the effect is to reinforce the belief that the sanctity of life is a fundamental value in our society, even though "we fail to build railway lines above roads, to avoid level crossing accidents," which could save far more lives at less expense.[57] It is the visible victim, and not the statistical one, who attracts our ethical attention, especially when (as in crime reporting and coverage of a variety of technological hazards) there is an implied threat that we may share the victim's fate. Conversely, the situations in question may threaten prevailing values or beliefs, as when 12- or 13-year-old boys are charged with gang rapes or drive-by shootings. We do not want to believe that people that young can be so hardened to, or take such pleasure in, the suffering of others; certainly, we believe that this should not be the case.

Mass media coverage can connect people with ethically significant situations of which they would otherwise be unaware, often with effects that appear to confirm the validity of Rorty's model of the development of solidarity. James Rachels cites the example of a wire service photo of two Vietnamese orphans who slept on the streets of Saigon by night and begged by day, and asks:

> What difference did the picture make? I don't believe it was a matter of people being presented with new information — it wasn't as though people did not know that starving orphans have miserable lives. Rather, it brought home to people in a vivid way things that they already knew.[58]

Country Cut Basic Service," *The New York Times*, August 20, 1995, pp. A1, A13.

57. This point is made by Margaret A. Somerville in "Justice Across the Generations," p. 388, citing Guido Calabresi, *The Cost of Accidents*. See also Calabresi and Philip Bobbitt, *Tragic Choices* (New York: W. W. Norton, 1978).

58. Rachels, "Can Ethics Provide Answers?" p. 18.

So the mass media are, potentially at least, an important resource for ethical learning. On the other hand, their role in this respect may not be a benign one. Medical anthropologist Arthur Kleinman has warned that the "mediatization of life," specifically graphic media coverage of violence and the associated suffering, may generate a "voyeuristic sensibility . . . in which there is no engagement with a local social reality, but rather a heightened desire to consume image after image of horror."[59] Needless to say, this is exactly the opposite of the process of ethical learning as envisioned by Rorty.

Further, to the extent that public policy is influenced by public opinion, which in turn is influenced by the mass media, the overwhelming prevalence of the personal and the episodic in mass media coverage can be expected to bias views of ethical problems toward to what we have called the micro level of analysis in subsection 3.3 of this report — toward individual concerns, spectacular issues and short-term solutions to perceived problems that neglect the broader social and ethical context.

2.2. Ethical Standards Change over Time, But What Does This Mean?

The previous subsection of the report identifies one example of a drastic change over time in ethical standards: attitudes toward the natural environment. Another example is the treatment of non-human animals, where conduct that was once routine now is considered repugnant, and for legal purposes sometimes even criminal. Even more fundamental is an increasing, if still uneven, sensitivity to racial and gender inequality in a multitude of other contexts. This phenomenon leads us to ask some critically important questions about the nature of ethical judgments, specifically about how confident we can be about making such judgments in the first place.

This point is best illustrated by way of an example. Until recently a wide variety of inequalities that would now be regarded as impermissible, both ethically and quite often legally, were accepted and in fact entrenched in law. For example, the legal subordination of women in many ways, including the lack of the right to vote, was taken for granted until well into this century. So, until even more recently, was the subordination of African-Americans in the United States. The Supreme Court decision (*Brown* v. *Board of Education*) that provided a legal basis for desegregation of public schools did not come until 1954; the *Civil Rights Act*, which in many respects was the first legislative embodiment of the contemporary concept of equality of opportunity, was not passed until a decade later. Similar observations could be made about attitudes and policies toward other racial, ethnic and religious minorities (including Canada's aboriginal peoples),[60] toward

59. Arthur Kleinman, "Pitch, Picture, Power: The Globalization of Local Suffering and the Transformation of Social Experience," *Ethnos* 60 (3–4, 1995): 183–184, 190

60. In addition, on the extent to which anti-Semitism was an accepted and largely unquestioned part of Canadian political culture in the 1930s and 1940s, see Irving Abella and Harold Troper, *None is Too Many: Canada and the Jews of Europe, 1933–1948* (Toronto: Lester & Orpen Dennys, 1992).

people with physical disabilities, and indeed toward children: widespread recognition of child abuse as a social, legal and ethical problem deserving of specific policy attention is surprisingly recent.

There are important lessons for any discussion of ethical acceptability in how we think about such laws and practices today. They do not strike us just as the quaint customs of an earlier, less enlightened time. Our response to such practices is more severe and judgmental: they strike us as clearly ethically unacceptable, because they are unjust. At the same time, laws and legal practices that subordinated women and African-Americans, to stick with those particular examples, at one time commanded widespread public support. In other words, they were judged ethically acceptable — or, perhaps, not thought of as matters for ethical concern at all. They were just part of the way the world was.

Thomas Nagel argues that "[t]ransformations in the tolerance of inequality" reflect a shift in attitudes, so that benefiting economically or politically from "the advantages of membership in a dominant race or sex is no longer respectable."[61] Recent instances of backlash suggest that he may be too optimistic on this point,[62] but **some** transformation of attitudes has clearly taken place. For purposes of determining what is ethically acceptable, the extent of the transformation is less important than the answer to a basic question about how we should decide on standards of ethical acceptability. Do we think today that the viciously discriminatory practices of yesteryear are wrong only **because** of the transformation of social attitudes toward them, or is the wrongness at issue more fundamental? If we take the first position, are we comfortable with the implied corollary, which is that the pervasive racism directed against African-Americans in the United States was wrong in 1964 but all right at (say) the end of the nineteenth century, when efforts to ensure the continued segregation of the South after the ratification of the Fourteenth Amendment were at their peak? Did racially segregated schools become wrong only in 1954, when the Supreme Court said so, presumably reflecting the transformation of attitudes as well as trying to lead it? Was such a policy ever ethically defensible . . . and if so, when did it become wrong?

The answers to such questions are important because, if we think that racial discrimination was wrong in 1890 or before 1954, and that gender discrimination as wrong before 1918 (the year in which women were granted the vote in Canadian federal elections), then we have conceded that ethics cannot necessarily be reduced to "social values," however broadly shared among members of the general public, legislators, or both, and however much they may have become part of our cognitive landscape. Those values must be defended on some basis other than, or in addition to, public and legislative acceptance. This

61. Nagel, *Equality and Partiality*, p. 97.

62. See, e.g., Susan Faludi, *Backlash: The Undeclared War Against American Women* (New York: Crown, 1991); and Manning Marable, *Beyond Black and White* (London: Verso, 1995), and *Speaking Truth to Power: Essays on Race, Resistance and Radicalism* (Boulder, CO: Westview, 1996).

conclusion should not be taken as a defence of ethical absolutism, which presents dangers all its own, or as an adequate discussion of the complex issue of retrospective moral judgment. It does indicate the need for caution about deciding what is ethically acceptable based entirely on current values or prevailing standards, however widely shared they may be. A democratic government must try to reflect those values, but it is also entitled (and some would say obligated) to provide ethical leadership in terms of inquiry into their meaning and implications. On one view, at least, this is what the Canadian government did by way of the *Charter of Rights and Freedoms*, and what the U.S. government did by way of the *Civil Rights Act*.

Somewhat similar questions arise when we compare the approaches taken in different societies at the same time to ethical questions. For example, Canada and the United States have taken quite different approaches to financing access to health care, control of firearms as a public health hazard, reproductive technologies and any number of other public policy areas with an important ethical dimension. We have to ask whether each country's resolution of that particular issue is ethically acceptable within its own borders, but would be unacceptable in the other jurisdiction. This is another version of the earlier discussion of how ethical standards change, but with the comparison carried out across space rather than time.

The tension that exists here cannot be resolved easily, and perhaps cannot be resolved at all. Philosophically, the discussion in the preceding paragraphs strongly suggests that the wrongness of **some** practices (and conversely the rightness of others) is sufficiently fundamental that it cannot be reduced to a question of prevailing societal values or standards. Practically, it may not be easy to identify ethically impermissible (or for that matter ethically obligatory) practices in our own place and time, since it is impossible to set ourselves entirely outside the cultural assumptions of our own society. On the other hand, it is important to note that there was substantial opposition and resistance to such practices as racial segregation and the subordination of women for many years before they were officially regarded as impermissible and politically suspect. In other words, the politics of the time provided ample opportunities for ethical learning, although those opportunities were for a long time ignored and denigrated, if not actively suppressed. For purposes of suggesting directions for governmental decision making, the best that can be done here is to propose two courses of action.

First, in making ethical decisions, governments (and the individuals who judge governments) should identify **core** values or standards of ethical acceptability — principles that are especially basic. The emergence of human rights as a "modern tool of revolution,"[63]

63. Irwin Cotler, "Human Rights as the Modern Tool of Revolution," in K. Mahoney and P. Mahoney, eds., *Human Rights in the Twenty-first Century: A Global Challenge* (Dordrecht: Kluwer, 1993), pp. 7–20. This book as a whole provides a remarkable explanation of how human rights are relevant to a range of ethical issues including gender discrimination, political repression, health care and access to food, to name but a few.

a category and a set of concerns that can be (and indeed must be) applied across national boundaries while respecting differences in national capacities and cultures, suggests that this can be done effectively. Human rights provide a basis for insisting that (for instance) race-based or gender-based exclusions from opportunities to participate fully in the life of a society were wrong a century ago just as they are today, and for the same reasons.

Second, governments (and the individuals who judge governments) must always be sensitive to the nature of ethics as a learning process, and to the provisional nature of many of our ethical choices. Those choices that depend on changing situations must be intellectually rigorous yet fluid, and must always be interrogated and re-examined in light of new options and new potential consequences. While respecting cultural differences and the resulting emphases on different values, we must not renounce responsibility for making ethical judgments about social arrangements both within our own society and outside it.

3. Dimensions of Ethical Decision Making

This chapter considers three dimensions of ethical decision making. First, ethical decisions can be made on the basis of one of several **schools** of ethics or ethical traditions — that is, sets of basic and necessarily quite general substantive principles. Second, ethical decisions can be made at a variety of **levels**, ranging from the individual to the societal and even the trans-national. Third, ethical decisions can be made based on standards that are specific to a particular **domain** of human activity, such as business or education.

An adequate basis for deciding on the ethical acceptability of particular actions or policies at the governmental level must take into account the implications of choices made within each dimension — for instance, about the appropriate level of analysis, or about which schools of ethics can contribute the most to resolving a particular policy question. In other words, it is important to ask how the government's decision on a particular question would be different if those choices were made differently.

3.1. Major Schools of Ethics

There are numerous schools of ethics, or ethical traditions. Here we can only provide a brief and highly simplified overview.[64] We must also emphasize that, although classifying ethical positions into "isms" as we have done here is convenient, this exercise is no substitute for careful, often time-consuming efforts to understand the reasoning behind ethical positions that are advanced with respect to specific cases or policy choices. To come back to a point made in Chapter 1, reasons matter.

Utilitarianism holds that the ethically best decision, or in some variants of utilitarianism the best rule for making decisions, is the one that will produce the greatest good for the greatest number. Utilitarianism is the most familiar example of a general approach to ethics that is called **consequentialist**, because it judges the ethical acceptability of actions or policies based on their consequences. However, the approach taken to consequences can be much broader; the consequences that are considered to be of ethical importance can be environmental, social or even spiritual. As this example shows, it is important to be clear in any form of consequentialist argument about the values that define what counts as a benefit or as a harm. What is the greatest good, and how do we measure it? An influential variant of utilitarianism that is sometimes applied to public policy is cost-benefit analysis, which tries to identify the greatest good and ease the problem of comparing different people's

64. Readers interested in more detail can find it in literally dozens of introductory texts. One particularly useful one, which combines original writings and contemporary commentary both by philosophers and by social scientists, and thus provides a sense of the history of various ethical traditions, is Peter Singer, ed., *Ethics* (New York: Oxford University Press, 1994). Another, which has the advantage of being organized around both critical and constructive evaluations of the various schools of ethics, is Thomas Beauchamp and James Childress, *Principles of Biomedical Ethics*, 4th ed. (Oxford: Oxford University Press, 1994), pp. 44–119.

conceptions of the good (what philosophers call the problem of interpersonal comparisons of utility) by attaching dollar values to all the consequences of a particular policy choice; the preferred policy option is simply the one showing the highest ratio of benefits to costs.

Kantian or obligation-based ethics, named after the philosopher Immanuel Kant, with whom it is most closely associated, holds that the ethically acceptable decision is one that conforms to certain fundamental principles. For Kant, the most important of these principles was the "categorical imperative," which has two formulations. In the first, to be ethically acceptable, one should conduct oneself according to principles that one could wish to see universally applied to everyone. In other words, before deciding to commit fraud or make promises we have no intention of keeping, we must ask whether it even makes sense to think about a society in which everyone acted as we propose to act. The second formulation requires that we avoid treating other people exclusively as means to an end, rather than as ends in themselves. Kantian ethics is the most familiar example of a more general category of ethics known as **deontological** ethics, whose key characteristic is that some actions are held to be inherently or intrinsically right or wrong — that is to say, right or wrong independent of their consequences.

In contemporary philosophy, a particularly influential form of Kantian argument is John Rawls's attempt to define principles of distributive justice based on an intriguing application of the categorical imperative: asking how we would want the society to be organized if we had to make that choice from behind a "veil of ignorance" that prevented us from knowing in advance whether we were to be born rich or poor, male or female, athletic or physically disabled.[65] Paradoxically, the Rawlsian approach to distributive justice shows that many Kantian ethical judgments cannot be easily isolated from consideration of their consequences.

Rights-based ethics, familiar because of Anglo-American legal systems' recent emphasis on individual liberty and their much older tradition of the primacy of property rights, is organized around a set of claims (such as freedom of speech, freedom of assembly, and the ownership of private property) that individuals are presumed to have with respect to one another and to society. Rights-based ethics is embodied in the reference to "life, liberty and the pursuit of happiness" in the U.S. Declaration of Independence, in the Bill of Rights that is an integral part of the U.S. Constitution, and more recently in the Canadian *Charter of Rights and Freedoms*. The question "where do rights come from?" can be answered in different ways. Sometimes, as in the case of the U.S. Declaration of Independence, rights are held to be "self-evident"; at other times, they are justified with reference to more basic principles such as respect for persons, or to the idea of a contract among members of the society. In the latter respect rights-based and Kantian ethics overlap.

The idea of a contract is central to what many philosophers regard as a distinct school of ethics: **contractarian** ethics, which tries to derive principles of morality from the idea of a

65. John Rawls, *A Theory of Justice* (Cambridge, MA: Harvard University Press, 1971).

(hypothetical) contract entered into by members of a society. Implied consent to the terms of such a contract becomes the source of both rights and duties. Some variants of contractarian ethics have strongly Kantian elements: Rawls, for example, bases his analysis on the kind of contract individuals (actually, heads of households) would rationally enter into from behind the veil of ignorance. Both rights-based and contractarian ethics are characterized by what might be called intense individualism. In direct contrast, **communitarian** ethics, which is often defended partly with reference to limitations of the idea of rights, focusses less on individuals' rights than on the importance to individual well-being and fulfilment of membership in a community. In the words of one of the leading contemporary communitarians, "if we are partly defined by the communities we inhabit, then we must also be implicated in the purposes and ends characteristic of those communities . . . the story of my life is always embedded in the story of those communities from which I derive my identity."[66]

It may be possible to define a middle ground between the intense individualism associated with the idea of a contract and the relative unconcern with the individual that is associated with many statements of communitarianism. At least one author has explored the idea of a covenant among individuals as the defining basis for moral obligations;[67] unlike a contract, a covenant is not motivated primarily by considerations of self-interest, and can include a notion of obligation arising from sources other than individual human will or consent. We have coined the rather awkward neologism **covenantial ethics** to describe this middle ground.

The **ethics of care,** which according to many accounts originated with psychologist Carol Gilligan's efforts to describe women's orientation to ethical decision making as "in a different voice,"[68] resembles communitarian ethics in that rather than starting from a conception of human beings as isolated individuals, it emphasizes their relationships with one another. However, the ethics of care tend to be suspicious of claims about the welfare of the community, partly because such claims have often been used to justify women's inferior status within a society. It is strongly egalitarian in its conception of how people ought to treat one another, and is especially sensitive to inequalities of power. At the same time, writers in this school or tradition emphasize the limitations of rights-based or contractual conceptions of an ethical point of view toward others, pointing out that in many situations just leaving people alone is not enough, and that in some relationships (like those

66. Michael Sandel, "Introduction" to Sandel, ed., *Liberalism and Its Critics* (Oxford: Blackwell, 1984), pp. 5–6.

67. Robert M. Veatch, *A Theory of Medical Ethics* (New York: Basic Books, 1981), pp. 120–37.

68. Carol Gilligan, *In a Different Voice: Psychological Theory and Women's Development* (Cambridge, MA: Harvard University Press, 1982); for more recent statements, see E. Kittay and D. Meyers, eds., *Women and Moral Theory* (Totowa, NJ: Rowman & Littlefield, 1987).

between mothers and children) a strictly rights-based conceptions of respect for others make no sense.[69]

As its description implies, **character ethics,** or the ethics of virtue, focusses on the character of those making ethical decisions. Virtuous people (that is, those who act according to such motives as generosity, compassion or fidelity to their obligations) are those most likely to make ethically acceptable decisions. Ethical acceptability is thus determined at least in part by one's motives for acting in a certain way, as well as by principles and consequences. Ethical acts are not necessarily those carried out by following rules, but from motives like doing good or fulfilling obligations. This formulation is especially attractive in situations where people are faced with a set of choices imposed by circumstances outside their control, all of which are ethically repugnant in different ways, or when the consequences of a particular action simply cannot be known. This school sometimes carries out ethical analysis starting with the premise that people have a right to fulfil their obligations to others, for instance, parents to decide for their young children on medical treatment.

Casuistry is an ethical tradition or style holding that we are too concerned with principles. For the casuist, ethical decisions can be made only on a case-by-case basis, although the decisions made in previous cases can provide a source of wisdom to draw upon; indeed, ethical judgments can be made when there are no principles to draw upon, or when disagreement on principles is profound. An appropriate analogy may be with the operation of precedent in the legal system. Particularly in biomedical ethics, which often have to focus on individual cases in a clinical setting, there has recently been a revival of interest in casuistry as a response to what is viewed as excessive preoccupation with abstract principles in that field.

In subsection 2.1.2, we noted Lynn White's argument that Western values are rooted in a Judaeo-Christian tradition in which the dominion of humanity over nature was unquestioned. This may explain why the preceding schools of ethics deal primarily with the relationships among human beings. Although many people are concerned about problems like pollution primarily because of their effects on human beings, it is also possible to argue that **environmental ethics** is now a distinct school of ethics, because many variants explicitly hold that human beings have duties and obligations not only to each other, but also to non-human beings and to the natural environment as a whole. One line of thought in environmental ethics, for instance, holds that preservation of "ecological integrity" is a principle that should take precedence over all others.[70]

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69. Virginia Held, "Non-contractual Society: A Feminist View," *Science, Morality and Feminist Theory, Canadian Journal of Philosophy* 13 (Supplementary, 1987): 111–37.

70. Laura Westra, "Ecosystem Integrity and Sustainability: The Foundational Value of the Wild," in L. Westra and J. Lemons, eds., *Perspectives on Ecological Integrity* (Dordrecht: Kluwer, 1995), pp. 12–32.

Key Points about the Differences among Schools of Ethics

This listing of schools of ethics is not a comprehensive one, and many professional philosophers would recoil in horror at some of the necessary oversimplifications. In addition, there is considerable overlap between many of the schools, which are not mutually exclusive approaches separated by clear boundaries. For example, the overlap between rights-based and Kantian ethics has already been noted, and environmental ethics may be deontological, consequentialist or a combination of both.

The discussion does illustrate, however, the range of perspectives that can be brought to bear on the decisions governments must make. We can think of the different schools of ethics as various prisms or conceptual lenses through which a decision or situation can be viewed. When the situation looks similar through all the prisms or lenses, governments are likely to find their choice relatively simple to make. However, different schools of ethics will often want to treat a situation quite differently. For instance the issue of contract pregnancy (or as it is more often but less accurately called, surrogate motherhood) looks quite different through the prisms of a rights-based ethics and of the ethic of care. Choices about how thoroughly to treat industrial pollutants that may threaten human health, or about where to locate hazardous waste landfills, look quite different through a Kantian or Rawlsian prism than they do when made on the basis of a cost-benefit analysis.

Philosopher Will Kymlicka has observed, with masterful understatement, that: "Moral philosophers have not yet discovered a knockout argument for or against these different theories."[71] When making choices about the ethical acceptability of courses of action or of public policies, we normally and appropriately incorporate elements from several schools of ethics, rather than relying exclusively on a single one. For instance, particular policies might be acceptable on strictly utilitarian grounds, but be judged ethically unacceptable because they would harm certain vulnerable members of the community — an invocation of justice, of the ethics of care, or perhaps even of communitarian ethics (a community's fabric is threatened when it harms its most vulnerable members). Conversely, various infringements of rights are justified, in ethics and in Canadian law, with reference to the good of the community, or the protection of certain kinds of valued relationships. Thus prohibitions on contract pregnancy, which on some accounts infringe on individual rights in the area of bodily security and freedom of contract, were before Parliament when it was dissolved in Spring, 1997. The tradeoff between equity and efficiency in economic policy is another commonly mentioned example.

In response to the possibility of disagreement among schools of ethics, one approach is to seek what Kymlicka has called "mid-level principles"[72] to govern decision making. This is the route that has been followed by many biomedical ethicists in North America since the

71. Kymlicka, "Approaches to the Ethical Issues Raised by the Royal Commission's Mandate," p. 13.

72. Ibid., pp. 15–16.

publication in 1979 of the first edition of *Principles of Biomedical Ethics,* by Thomas Beauchamp and James Childress. The text is organized around four "clusters of principles": respect for autonomy, non-maleficence (not doing harm), beneficence (doing good), and justice.[73] These are now widely applied in both research and clinical settings, largely because people who disagree about whether (for instance) utilitarianism or rights-based ethics is ultimately more defensible may nevertheless be able to agree on these principles as the basis for ethical decision making.

This does not mean ethical decision making in such settings has thereby become easy or routine; far from it. None of the four principles can be regarded as binding in all cases; since situations in which applicable principles conflict are relatively common, the best that can be done is to treat each principle only as *prima facie* binding — in other words, binding in the absence of more compelling moral considerations involving a competing principle.[74] In addition, the four principles illustrate that any principle broad enough to cover the spectrum of relevant cases will remain abstract enough so that judgment and interpretation on the part of the relevant decision maker(s) will invariably be involved, most notably about what is ethically relevant to decisions in a particular case.[75] For these reasons among others, an expanding body of work in biomedical ethics now questions the usefulness of what critics of the Beauchamp and Childress approach call "principlism."[76] As noted in subsection 4.6, however, there are important reasons not to carry scepticism about principles too far when dealing with the ethical analysis of public policy questions.

3.2. Micro, Meso, Macro and Megaethics

> In ethics we sometimes do an analysis at three different levels. It's very simple: micro-level, meso-level — which is institutional or group level — and macro-level, which is governmental or societal level.[77]

The micro level refers to interactions between individuals, whether they are members of families, strangers or people whose roles carry a particular institutional meaning (for example, doctor and patient). The meso level involves ethics within the group, institution or organization (such as a hospital, university or government department). The macro level

73. Beauchamp and Childress, *Principles of Biomedical Ethics,* 4th ed., pp. 37–38, 120–394.

74. Ibid., pp. 32–37.

75. Timothy C. Callahan, Sharon J. Durfy and Albert R. Jonsen, "Ethical Reasoning in Clinical Genetics: A Survey of Cases and Methods," *Journal of Clinical Ethics* 6 (1995): 248–53; Barry Hoffmaster, "Can Ethnography Save the Life of Medical Ethics?" *Social Science and Medicine* 35 (1992): 1421–32; Bruce Jennings, "Ethics and Ethnography in Neonatal Intensive Care," in Weisz, ed., *Social Science Perspectives on Medical Ethics*, pp. 261–72.

76. E. DuBose, R. Hamel and L. O'Connell, eds., *A Matter of Principles? Ferment in U.S. Bioethics* (Valley Forge, PA: Trinity Press International, 1994).

77. Margaret A. Somerville, comments in Ethics Roundtable, 37: 12.

involves ethics at the society-wide level, for example, as reflected in the decisions of provincial or national governments about domestic policy. To this list, we should add mega-ethics, which refers to ethics at the transnational or cross-cultural level. Human rights is an illustration of a mega-ethical concept, although it has applications at other levels and indeed is probably most meaningful when applied to specific policy situations at the micro, meso or macro-levels.

Table I illustrates these four levels as they play out in analyzing various issues related to medicine and health care, and suggests the interplay among different levels of analysis. It may be useful to take a single example — access to costly and therefore scarce therapy — and to work through the issues and tensions, in a way that is necessarily a bit dogmatic.

Table 1. Levels of Analysis — Illustrations from Medicine and Health Care

Level of analysis	Kinds of issues that arise
Micro (individual)	• Should a patient who faces the possibility of progressively more serious disability and more intense pain from amyotrophic lateral sclerosis (ALS) be granted her request for medical assistance in committing suicide once her pain has become unbearable? • Should physicians inform patients about the possible benefits and risks of all available treatments? • Should physicians always try to seek organ transplants or bypass surgery for patients who might benefit? • How should physicians decide which of two potential recipients is to receive an organ transplant, when only one organ or donor is available? • How should physicians decide which of two patients should be placed in the one available intensive care bed?
Meso (group or institutional)	• What policies should a hospital adopt with respect to DNR (do not resuscitate) orders for terminally ill patients? • As a group or profession, what are physicians' obligations in cases where patients are in extreme pain and who will not regain normal functioning — for example, because of ALS? • Should health maintenance organizations (HMOs) prohibit physicians from informing patients about the existence and possible benefits of treatments whose costs the HMO will not cover? • What principles or codes should transplant centres adopt for prioritizing transplant recipients when available organs are scarce? • How should hospitals allocate available intensive care beds? How should they allocate their budgets between various functions such as emergency medicine, chronic care and specialized surgical units (e.g. for coronary bypasses)? • Does an institutional policy of giving priority for coronary bypass surgery to patients younger than a certain age violate human rights, by amounting to impermissible discrimination based on age?

Macro (society-wide)	• What is society's interest in the issue of physician-assisted suicide? What values are at stake? How should the criminal law treat physician-assisted suicide? • What is society's interest in the disclosure by psychiatrists or psychotherapists in cases where patients are likely to do harm to themselves or others? • Should Parliament legalize physician-assisted suicide? Should the courts treat existing prohibitions as deprivations of fundamental rights? • How should health care be financed? • Is there a right to a basic minimum of health care? If so, what constitutes the basic minimum, and how should its provision be financed? • Does a policy of not providing insurance coverage for coronary bypass surgery on patients above a certain age violate human rights, by amounting to impermissible discrimination based on age? • Is health care a human right? Why, or why not?
Mega (across societies)	• Is health care a human right? Why, or why not? • If so, how does the content of that right differ as between rich and poor societies — say, those with GNP per capita of $1 000 and of $20 000-plus?

At the micro level, not only is it entirely appropriate for a physician to seek the best treatment for his or her patient, but on many accounts the physician is obliged to do so, and for him or her to make decisions about treatment options based on other priorities, like cost containment, is almost certainly unethical.[78] At the meso level, however, an institution confronted with scarce resources **must** organize a basis for making such choices as which candidates will receive transplant organs or bypass surgery, or for that matter whether priority should be given to expanding the transplant unit, the cardiac surgery unit or the provision of some other service. The institution cannot get away from these choices; as in many other situations, making no decision is a decision in itself. Such choices can be and have been made in a variety of ways, and more than one principle for doing so (including the apparent non-principle of first-come, first-served, which is really a variant of the lottery principle) may be ethically defensible. What is probably **not** defensible is leaving the decisions to be made on the basis of whichever patient has the most effective, most persistent or loudest advocate in the form of his or her physician.

Also not defensible, however, are meso level policies that interfere with the physician-patient relationship and the ability of the physician to act as an advocate for the patient, for instance by prohibiting physicians under contract to a particular health management organization (HMO) from telling patients about treatments that the HMO will not cover. Such policies, which have threatened to become widespread in the United States, have a strictly commercial motivation. They have in turn led to macro level policies, in the form of legislation in many states that prohibits such practices. A more basic macro level choice,

78. This view is not universally held, however. Another view is that "both roles of patient advocate and gatekeeper [to society's resources]" can be justified ethically; see John Williams and Eric Beresford, "Physicians, Ethics and the Allocation of Health Care Resources" *Annals of the Royal College of Physicians and Surgeons of Canada* 24 (no.5, August 1991), p. 309

which exists in every country and affects the choices available at all the other levels, is how the health care system should be financed, and how access will be governed.

In Canada, where much health care provision is publicly financed, a range of other macro and meso level choices, all of which should be subjected to ethical evaluation, follow from governments' control of the global health care budget. A number of resource allocations may all be ethically acceptable, but there will probably also be some clearly unacceptable ones — for example, closing hospital units primarily in opposition-held constituencies in order to make a political point, or locating a new unit in a remote area where utilization rates will be low, but which happens to elect a member of Cabinet. As suggested in the Table resource allocations that have the effect, even if not the intent, of discriminating on the basis of age should probably also be judged ethically unacceptable.[79]

Ethics and the "Big Picture"

Until recently, ethical analysis of medical and health care issues has emphasized the micro and meso levels of analysis. However, there are signs that this emphasis is changing. For example, one author has responded to the challenges presented by the growth of managed care in the United States by saying that: "Medical ethics must stop being case oriented and become institutionally oriented. We bioethicists must stop approaching problems from a philosophical perspective and adopt a political science perspective."[80] This should be taken as an endorsement not of an either/or disjunctive approach, but rather of a conjunctive one that combines ethics and political science. Two examples will serve to demonstrate the value of such macro level analysis.

In 1993 a report from the Science and Human Rights Program of the American Association for the Advancement of Science (AAAS), based on a series of consultations with a variety of stakeholders, highlighted the need for an ethical framework for health care reform and proposed "using a human rights approach as the basis for a public debate to set the framework for health care reform and to establish criteria for evaluating specific proposals."[81] Such an approach was found to imply "a right to a basic and adequate standard of health care consistent with societal resources."[82] Among other implications, the human rights approach was found to require that special attention be paid to the most

79. Jerry Avorn, "Benefit and Cost Analysis in Geriatric Care," *New England Journal of Medicine* 310 (1984): 1294–1301; Margaret A. Somerville, "'Should the Grandparents Die?' Allocation of Medical Resources with an Aging Population," *Law, Medicine and Health Care* 14 (1986): 158–63.

80. Ezekiel Emanuel, "Medical Ethics in the Era of Managed Care," *Journal of Clinical Ethics* 6 (1995): 335.

81. Audrey R. Chapman, *Exploring a Human Rights Approach to Health Care Reform* (Washington, DC: Science and Human Rights Program, American Association for the Advancement of Science, 1993).

82. Ibid., p. 17.

disadvantaged and vulnerable individuals and groups[83] and "that health care be publicly financed." Of special interest was the report's proposal for a human rights report card for evaluating alternative approaches to health care reform, showing that the abstract concept of a human right to health care could be translated into quite specific criteria.[84]

More recently, an effort has been made to apply ten "benchmarks of fairness" to the ways in which health care is made available in the United States. The benchmarks were then used to evaluate the status quo as well as four specific legislative proposals for health insurance reform, ranging from one organized around remedying market failures, defined in relatively narrow economic terms, through President Clinton's ultimately unsuccessful proposal to mandate coverage while retaining a market for private insurance, to a proposal for a Canadian-style, single payer system of publicly financed insurance.[85] Careful reflection on "what health care does for us and what roles it plays in our lives" leads, according to the authors of the proposal, to the conclusion that provision of health care services is morally important because "disease or dysfunction restrict access to life's opportunities."[86]

> By aiming to keep us functioning normally, health care aims to preserve for us the range of opportunities we would have, were we not ill or disabled, given our talents and skills. . . . By designing a health care system that keeps all people as close as possible to normal functioning, given reasonable resource constraints, we can in one important way fulfill our moral and legal obligations to protect equality of opportunity.[87]

This evaluation of policy at the macro level is of special interest because the benchmarks were devised by interpreting fairness (always a difficult concept) in terms of the "commitment to equality of opportunity, a widely avowed and institutionalized feature of our [that is, the United States'] system of public values."[88] In other words, the benchmarks are not intended as a set of criteria used to judge a particular society from outside; instead, they are derived from a value the society often uses, or says that it uses, to judge itself.

These examples are crucially important outside the area of medicine and health care because policy analysts may shy away from explicitly ethical analysis at the macro level as being too difficult or politically contentious. There are, after all, substantial risks associated

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83. Ibid., pp. 23, 25.

84. Ibid., pp. 55–60.

85. Norman Daniels, Donald Light and Ronald Caplan, *Benchmarks of Fairness for Health Care Reform* (New York: Oxford University Press, 1996).

86. Ibid., p. 21.

87. Ibid., p. 22.

88. Ibid., p. 18.

with making an argument that the policy or course of action supported by agency administrators, ministers (in a Westminster system) or politically important client groups is ethically unacceptable, or even in suggesting the possibility.[89] However, it is important to acknowledge both the need for ethical analysis of "big picture" questions of public policy and to acknowledge that such analysis can be as rigorous as in the clinical or laboratory setting.

3.3. Domains of Ethical Analysis

Ethical analysis takes place at multiple levels; it also takes place within various "domains" of human activity.[90] Human beings interact with one another in a variety of capacities, and many of those interactions carry with them a distinctive and specialized set of expectations and obligations, often as a matter of law as well as matter of ethics. Physicians and lawyers thus have certain obligations to maintain confidentiality with respect to information about their patients and clients. Fiduciary duties and respect for trade secrecy are required in a variety of business settings. It has been argued that distinctive sets of ethical principles are appropriate to govern the conduct of scientists and of environmental professionals.[91] The principles that are appropriate for guiding the relationships between family members are clearly distinct from any of these and widely understood, although until recently no one would have thought of codifying them.

An author who has promoted the idea of "domain-sensitive" ethical standards argues that:

> Roughly, each domain is characterized by a set of socially recognized goals or purposes and by a set of "structures." . . . Unless they can be shown to be unreasonable, these goals count as justificatory values for their respective domains. And moral standards that obtain in a domain are justified in relation to them (as well as in relation to other values).[92]

This approach is acceptable, and indeed necessary, to a point. However, the idea of domain-sensitive ethics leaves a key question unanswered. What values, if any, can we rely on as the basis for concluding that certain goals or purposes of a specific domain are unreasonable? What happens when the goals and purposes of two domains, such as business and medicine, come into conflict?

89. Amy, "Why Policy Analysis and Ethics Are Incompatible," pp. 582–88.

90. Michael Philips, "How to Think Systematically About Business Ethics," in E. Winkler and J. Coombs, eds., *Applied Ethics: A Reader* (Oxford: Blackwell, 1993), p. 188.

91. Charles Malone, "Ecology, Ethics, and Professional Environmental Practice: The Yucca Mountain, Nevada, Project as a Case Study," *The Environmental Professional* 17 (1995): 271–84; Kristin Shrader-Frechette, *The Ethics of Scientific Research* (Lanham, MD: Rowman & Litlefield, 1994).

92. Philips, "How to Think Systematically About Business Ethics," p. 188.

This is not merely an academic issue. The argument is often made that business should be assessed based on standards related to human rights or environmental performance — in other words, that it should be ethically accountable to stakeholders other than its shareholders and customers. This argument might be rejected after careful consideration, but cannot be dismissed out of hand, or by reference solely to the goals of business. The purposes of business and medicine are now clashing frequently in the United States health care system, as a result of the rapid expansion of for-profit managed care provision.[93]

For example, one surgeon regarded a lab test to confirm that tumors removed from a patient's scalp were benign as a routine precaution, but the patient's HMO refused reimbursement. He decided to pay for the procedure out of his own pocket, but the HMO subsequently assigned him a negative "practice pattern" rating for having ordered the test. This apparently had much less to do with protecting patient interests than with protecting the profits of the HMO.[94] As the authors who cite this case point out, the physician's course of action is not a viable response to the HMO's exercise of financial power on a routine basis: in other situations the costs (for instance, of additional days in an intensive care unit) might be ruinous. They further state that:

> On our bioethics rounds and in our ethics educational programs, perhaps the single most pressing problem cited by staff nurses and managers is a concern that practice standards are changing to enhance profits. . . .[95]

More basically, their concern is that managed care is turning the patient into a commodity, someone whose presence is necessary to generate profits, but whose interests are routinely subordinated to the organizationally mandated quest for improved returns on investment.

Engineers, research scientists and a variety of other professionals may similarly find themselves working in settings (such as a private firm or a government department) where the "management culture" emphasizes the values and purposes of the organization. These may not be compatible with the ethical standards distinctive to the profession,[96] such as full disclosure of all findings in the case of scientists, or with more general obligations to protect public health or environmental quality. In such situations, when does the legitimate reach of organizational goals end? When, for example, are life-shortening decisions about

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93. Emanuel, "Medical Ethics in the Era of Managed Care"; Edmund G. Howe, "Managed Care: 'New Moves,' Moral Uncertainty, and a Radical Attitude," *Journal of Clinical Ethics* 6 (1995): 290–305; Wendy Mariner, "Business vs. Medical Ethics: Conflicting Standards for Managed Care," *Journal of Law, Medicine & Ethics* 23 (1995): 236–46; Laurie Zoloth-Dorfman and Susan Rubin, "The Patient as Commodity: Managed Care and the Question of Ethics," *Journal of Clinical Ethics* 6 (1995): 339–57.

94. Zoloth-Dorfman and Rubin, "The Patient as Commodity," pp. 342–43.

95. Ibid., p. 344

96. David J. Mattson, "Ethics and Science in Natural Resource Agencies," *BioScience* 46 (10, November 1996): 767–71.

the allocation of health care resources justified by the goals of the business world, or with reference to politically mandated cost containment objectives? Who decides?

So while acknowledging the value of standards of ethical acceptability, such as professional codes of ethics, which address the distinctive ethical challenges in a particular domain, governments must recognize that actions or policies are not necessarily ethically acceptable simply because they meet certain standards that are specific to a given domain. Domain-sensitive standards of ethical acceptability are not enough. Those standards must themselves be justified, and must stand up to critical examination. If we regard politics, or government, as a domain with its own standards of ethical acceptability, the same is true: there may be practices that are acceptable according to the norms or standards of that domain, but which fail to stand up to a more general and demanding form of ethical scrutiny.

On this point, it should be noted that the four principles approach to bioethics, organized around respect for autonomy, beneficence, non-maleficence and justice, derives much of its power from the fact that the principles in question **are not** specific to the domain of medicine and health, although their application and interpretation may be. Beneficence and justice, for example, are norms with broad applicability in other domains as well. Some observers might see this generality as a weakness, but it can also be considered a strength. Further, as the "benchmarks of fairness" study[97] shows, it is possible to use at least one of the principles (justice) as the basis for resolving potential conflicts among domains such as business and medicine.

97. Daniels, Light and Caplan, *Benchmarks of Fairness.*

4. Ethical Tensions or Conflicts and the Government of Canada

As the preceding discussion shows, determining what policy choices are ethically acceptable is hardly an easy task, yet it is one that governments cannot avoid. They seldom have the luxury of not making a decision. Deciding not to decide, or to postpone a decision, is itself a decision — one that may have important ethical implications. For instance, if the legal status of the child of a so-called surrogate mother or the fragile habitat of an endangered species of fauna is unclear, then postponing a decision to enact legislation clarifying their status pending further study amounts to accepting the *status quo,* with all that entails.

Without reference to a specific situation or policy field, it is impossible to determine in advance what an ethically acceptable decision or outcome, or the range of ethically acceptable decisions and outcomes, might be. Reflecting our emphasis on ethics as process and as learning, we outline here several axioms that should guide government in making those decisions. Each of these axioms is discussed at greater length later in this chapter.

First, government cannot use a single school of ethics (for example, utilitarianism) as the starting point for its decision making, although it may in the end choose to emphasize the considerations that are central to one particular school. Likewise it should take into account all the relevant domains of ethics, rather than limiting itself to considering the domain that looks most directly relevant at first glance, or is most widely accepted. An approach to decision making that incorporates inputs from various disciplines, sectors and cultures is likely to be particularly valuable.

Second, government must always carry out ethical analysis at the macro level before making a decision, although it need not ultimately assign priority to macro level or societal ethical concerns.

Third, identifying the ethical assumptions underpinning government policies is crucial. The commitments that go along with these assumptions often remain "embedded," meaning that the conclusions they imply about ethical acceptability remain unexamined. Identifying and clarifying the initial presumptions guiding the various participants in an ethical debate is a crucial learning and problem-solving device. Being clear about where people are coming from, in ethical terms, is essential to understanding the policy positions they adopt.

Fourth, good faith debate among committed proponents of particular ethical positions is critical for governmental efforts to arrive at ethically acceptable policy positions. Principles for structuring consultation with a view to achieving such debate are briefly outlined.

Fifth and finally, there may be situations in which all the relevant perspectives on a particular decision or policy have been considered; the different perspectives yield different

outcomes; and government must choose and give priority to one perspective in its decision making. The question of how governments should proceed in such situations simply cannot be answered in the abstract, without reference to the particular issues at stake. Governments, like individuals, must live with the uncertainty that accompanies hard ethical choices in such cases. At the same time, they have not only the opportunity but also the obligation to exercise moral leadership, by making decisions that embody a clear commitment to certain ethical principles.

4.1. When Domains or Schools of Ethical Analysis Conflict

As suggested in subsection 3.2, were governments to adopt a particular school of ethical analysis as a starting point for their decision making, they would be stepping in where philosophers fear to tread, and it is inappropriate for them to do so. Consider, for example, the implications of a government's taking a utilitarian perspective on a particular policy issue, neglecting the role of individual rights — or, conversely, adopting a rights-based perspective that is completely indifferent to social consequences.[98] Instead, in cases where different schools of ethics suggest different policies — as in the example used earlier, where a utilitarian approach to siting hazardous waste disposal facilities might yield quite different outcomes from an approach that emphasized considerations of justice — governments must look through the prism of each school of ethics, and must design processes and institutions that will facilitate dialogue among proponents of the various schools.

This does not mean that governments have no guidance in situations where different schools of ethics yield different answers. There are important but not absolute commitments to rights-based ethics in the *Charter of Rights and Freedoms*[99] and in federal and provincial human rights legislation, for example. Both the letter and the spirit of such commitments should be respected. In addition, **in some cases or situations**, it will be entirely appropriate for governments to select a policy that emphasizes the concerns that are central to one particular school of ethics. For example, in response to concerns that hazardous industrial plants and waste disposal facilities were disproportionately located near African-American and other minority neighbourhoods, U.S. President Clinton issued an Executive Order in 1994 directing federal agencies to identify and address disproportionately high environmental and health effects of their policies on minority and low-income populations.[100] Here is a situation in which considerations of justice, related

98. Many critics of the policy toward firearms control in most U.S. jurisdictions would say this is what the governments concerned have done, despite serious negative impacts on public health and safety.

99. Significantly, the *Charter*, probably our most important policy commitment to a rights-based ethical discourse, incorporates both the s. 1 qualifier and, with respect to many of the rights enumerated, the s. 33 legislative override.

100. Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations," 59 Fed. Reg. 7629-33 (February 11, 1994).

primarily although not entirely to civil rights against racial discrimination, were identified after careful consideration as having priority over other values such as efficiency.[101] In addition to substantive principles for making decisions on ethical issues, democratic values embody a commitment to the use of various processes for public involvement in decision making.

For reasons explained in subsection 3.4 of this report, it is also inappropriate for governments to consider ethical issues only from the perspective of one domain — say, that of business or of the medical or legal profession. What government would be doing in such a case is, in effect, saying that the values of one domain deserve priority over all competing considerations. In some cases, this may be a defensible conclusion, but it should only be reached **after** appropriate debate and consultation with those who might be affected by such a choice. As the example of restrictions on health maintenance organizations (HMOs) suggests, the more common and more easily justified role for government is that of determining the **limits** beyond which the values and ethical commitments that characterize a particular domain must yield to questions of the broader public interest, or to the higher priority assigned to certain values that transcend the boundaries of particular domains. This is true not only of domains of ethical analysis but also of levels of analysis.

4.2. When Levels of Ethical Analysis Conflict

Governments must make their decisions based on ethical analysis at the macro level. In order to do this, they will need to consider ethics at other levels, especially the individual level. By their very nature, governments are decision makers for the society as a whole; at least under some circumstances, the choices they make are binding on everyone living under their jurisdiction. This means that governments have a special obligation to consider the justifications for the choices they make. It also means that governments must think about the macro level in their decision making, in ways that individuals do not necessarily have to. The tendency of mass media coverage to focus on individual stories and micro level concerns only makes this role for governments more important.

These ideas can be illustrated with respect to the issue of physician-assisted suicide, where Margaret Somerville argues that the tension between ethical concerns at the micro and macro levels should be resolved as follows:

> [I]f one accepts that persons have a right to a dignified death, and if one accepts that this includes a right to euthanasia and that at an individual level the benefits of recognizing this right outweigh its harms, nevertheless, the impact at a macro or societal level of recognizing such a right would still need to be considered. It is proposed that at this level, the harms and risks of such recognition would outweigh any claim of an individual to have euthanasia made available. Stated another way, we cannot only consider

101. A strong case could be made that on grounds of economic efficiency, most of the environmentally hazardous activities characteristic of an industrial society ought to be located in its poorest quarters, where land acquisition costs and property damages from pollution might be expected to be lower than elsewhere.

> individual rights, including any right to euthanasia, from the point of view of the individual, we must also consider the macro or societal level impact of recognition of such individual rights. The need for protection of human networks which, at their most macro level, establish the web which constitutes society, itself, must also be given proper consideration. It is proposed that euthanasia is not acceptable at the societal level, even if one has no personal moral inhibitions against it at the individual level and that its unacceptability at the societal level outweighs the acceptability of the best case argument for it at the individual level.[102]

Notice that thinking about the macro level of ethical analysis does not mean that governments must necessarily decide to give societal or macro level concerns priority over concerns or rights at the individual level.

For instance, a group of U.S. scholars in bioethics have reached a different conclusion in the case of physician-assisted suicide, arguing that micro level concerns should prevail. They believe that physician-assisted suicide should be permitted "for patients who are dying or whose suffering is so severe that it is beyond their capacity to bear" because:

> The most basic values that support and guide all health care decision making, including decisions about life-sustaining treatment, are the same values that provide the fundamental basis for physician-assisted suicide: promoting patients' well-being and respecting their self-determination or autonomy.[103]

Rather than supporting prohibition, they have drafted a model statute to authorize and regulate physician-assisted suicide under certain conditions. These authors were not ignoring the societal implications or deciding that they were ethically irrelevant. Rather, having considered them, they found the societal implications outweighed by the values just identified. So priority here has been given to the individual level after a macro level analysis, based on assigning highest priority to certain values rather than to others. Indeed, one of the most controversial issues within the euthanasia debate is whether the prohibition of physician-assisted suicide or its legalization would cause greater erosion of values that are central to health care decision making, and in doing so have negative consequences for the society as a whole.

The requirement for macro level analysis also does not mean **acting** at the macro level; a government might decide that no such action is necessary, but that is itself a policy choice of some significance. For example, former Prime Minister Trudeau famously said that the state has no place in the bedrooms of the nation. The philosophical commitment here was and is simply that, however individual citizens might choose to interact with one another in intimate sexual relationships that did not raise concerns of serious harm to them, no societal interest existed that was sufficiently strong to justify intervention in those decisions. This is a macro level choice about the priority to be accorded to individual liberty and privacy, and not an abdication of responsibility for macro level analysis. It also

102. Somerville, "Song of Death," p. 27.

103. Charles H. Baron et al., "A Model State Act to Authorize and Regulate Physician-assisted Suicide," *Harvard Journal of Legislation* 33 (1996): 4–5.

was, and is, a choice to which some people objected on philosophical grounds having to do with the impact of individual conduct on the social fabric.[104]

When the circumstances of individual cases are particularly compelling, governments resort to various devices to resolve them while remaining (or appearing to remain) committed to a particular macro level ethical position. For instance, although the Supreme Court of Canada rejected Sue Rodriguez' efforts to have prohibitions on physician-assisted suicide declared unconstitutional, which would have had the effect of legalizing the practice at least temporarily, a determined effort was apparently not made to prosecute the anonymous physician who ultimately aided her. Depending on the observer's own commitments, this can be interpreted either as an acknowledgment that sometimes the circumstances of individual cases should be assigned priority over macro level principles (for example, for compassionate reasons); as a simple failure of nerve in the face of a particularly troubling application of such principles; or as a very troubling omission to ensure that existing criminal prohibitions are upheld and applied. Thus whether such exceptions are justifiable, and if so when, remains an issue for debate.

Another example, which combines levels and domains of analysis, may serve further to illustrate the complexity of the issues and the range of values that come into play at both micro and macro levels. Psychiatrists are normally under an obligation to treat all information provided by their patients as strictly confidential; this practice not only builds the trust that is a prerequisite for successful treatment, but also conforms to the principle of respecting patient autonomy. What happens, however, when a patient indicates that he or she plans to injure or kill someone, and the psychiatrist is reasonably certain the threat will be carried out? Does the psychiatrist's obligation to the patient always, or ever, outweigh the interest of third parties in being protected from threats to life and health? The public as a whole arguably has a stake in maintaining therapeutically necessary rapport between psychiatrists and patients — rapport that may be destroyed in a large number of cases if confidentiality is breached even in one — but does that one macro level concern outweigh the value of protecting one, or a few, innocent victims of crime?[105] If we attach a high ethical priority to gender equity and protection of the vulnerable, do any of our conclusions against disclosure change if the targeted woman is the estranged partner of the male patient?

In this case as in a multitude of others, depending on the values that are assigned the highest priority, it is possible to reach quite different balances between micro level and macro level concerns and values, but neither can responsibly be ignored for purposes of public policy. There is, as Nagel says, no "default position"; governments must always

104. Maureen McTeer, "A Role for Law in Matters of Morality," *McGill Law Journal* 40 (1995): 893–903.

105. This example is closely modeled on the facts of an actual U.S. court case, *Tarasoff* v. *Regents of the University of California*, excerpted in Beauchamp and Childress, *Principles of Biomedical Ethics*, 4th ed., pp. 509–12.

think about all levels of analysis including the societal or macro level, and must always be prepared to explain, in ethical terms (i.e. not with reference to other factors such as political expediency), the basis on which their decisions were arrived at. Even more importantly, they should encourage debate and learning about the basis for making such decisions.

4.3. Initial Presumptions: Examining the Familiar Moral Underpinnings of Public Policy

Governments must acknowledge that in the routine of making and implementing public policy, ethical issues often do not come neatly labelled with a tag saying: "This is an ethical issue!" Ellen Moskowitz, a former staff lawyer with New York State's Task Force on Life and the Law, points out that:

> Values drive public policy. This is true when policy makers knowingly articulate the societal and cultural norms that root and shape government action. It is also true when the moral underpinnings of policies seem so accepted and familiar that officials act without describing the normative ends that motivate their conduct.[106]

Sometimes, a particular set of issues or questions is clearly acknowledged as ethical, and rules or guidelines are developed for addressing and resolving them. This is now the case with respect to publicly supported research involving human subjects, which must be approved by committees known as Institutional Review Boards (IRBs) in the United States or Research Ethics Boards (REBs) in Canada. In Canada, such review is a precondition for funding by the federal granting councils, which have set out both substantive guidelines to be used in determining ethical acceptability and procedural guidelines to be used by REBs.

More often, however, institutions for making and implementing decisions tacitly reflect particular ethical commitments, or the primacy assigned to a particular value. Indeed, ethical commitments may be so deeply "embedded" in policies, institutions and procedures that policy makers and the public alike tend not to think about them because they are taken for granted — the familiar moral underpinnings referred to by Moskowitz. Improving the quality of decisions on ethical issues requires that these commitments and priorities be made explicit and carefully examined. As governments seek to clarify the nature of differences among schools of ethics, tensions between levels of ethical analysis, and the ethical commitments that are embedded in particular policies, they will find that analyzing policy positions by looking at their **initial presumptions** — their starting points — is a key strategy.

Apart from the polar positions of complete permissibility or laissez-faire ("yes, of course") or complete prohibitions ("no, never"), initial presumptions about the ethics of a particular

106. Ellen H. Moskowitz, "The Ethics of Government Bioethics," *Politics and the Life Sciences* 13 (1994): 96.

situation are of two kinds: "yes . . . but" or "no . . . unless." As applied to the example of policy toward providing artificial insemination using donor sperm (AID):

> For instance, "yes," single women ought to be given access to AID, "but" there may be exceptions to, or conditions precedent to such access. Alternatively, "no," single women ought not to be given access to AID, "unless," for example, they are living in a stable relationship with a man. The choice of the initial presumption is not neutral in terms of decision outcome. This is so because the persons challenging the initial presumption will have the burden of proving that it should not apply. . . .[107]

The non-neutrality of initial presumptions is made clearer by considering the criminal trial process. Common-law countries generally require proof beyond a reasonable doubt (standard of proof) and require the prosecution to bring forward evidence that proves guilt to this standard, rather than requiring defendants to prove their innocence (burden of proof). The choice of a standard of proof reflects the depth of the legal system's commitment to the initial presumption; the harder it is to meet the standard of proof, the more difficult it is to override or rebut the initial presumption (in this case, that of the defendant's innocence). Thus in the two recent trials of O. J. Simpson, one jury found him not guilty based on the criminal law standard of proof beyond a reasonable doubt, but another found him liable for damages in the deaths of Nicole Brown and Ronald Goldman based on the less demanding standard of proof on the balance of probabilities.

Initial presumptions in the criminal justice system reflect a deeply held conviction that because the consequences of a criminal conviction are so serious, the chances of convicting an innocent defendant should be guarded against even if doing so means letting a substantial number of guilty persons go free. This is not a view whose ethical merits are self-evident. On a strictly utilitarian basis, if all we were concerned about was deterring others from committing crimes, we might achieve this objective just as effectively by making an example of innocent defendants, as long as their guilt were authoritatively pronounced. However there are good reasons to recoil from such a ruthlessly pragmatic approach, because of the injustice of punishing the innocent — turning them, as it were, into conscripts in service of a broader utilitarian goal.

The contrast between the moral underpinnings of the Canadian and the U.S. health care systems provides another illustration of the importance of initial presumptions in ethical analysis. In the United States, health care is provided primarily through the private marketplace and roughly 40 million people are without health insurance; millions more have incomplete or inadequate coverage.[108] Nevertheless, departures from the initial

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107. Margaret A. Somerville, "Weaving 'Birth' Technology into the 'Value and Policy Web' of Medicine, Ethics and Law: Should Policies on 'Conception' be Consistent," *Nova Law Review* 13 (1989): 539; see also Somerville, "Song of Death," pp. 64–68. For a similar analysis that refers not to initial presumptions but rather to "baselines" and to definitions of what constitutes inaction or neutrality, with specific reference to judicial decision making, see Cass Sunstein, "*Lochner*'s Legacy," *Columbia Law Review* 87 (1987): 873–919.

108. David Himmelstein and Steffie Woolhandler, *The National Health Program Chartbook* (Cambridge, MA: Center for National Health Program Studies, 1992), pp. 4, 13.

presumption that health care should be allocated through the market, like cars or condos, are seen as demanding justification. In Canada, by contrast, the initial presumption is the desirability of universal access to health care, largely if not entirely independent of ability to pay. Justification is demanded, instead, for actions that might undermine that state of affairs; in fact, the principles of universal access to comprehensive, publicly funded health care that reflect this initial presumption are codified in the *Canada Health Act*.

The examples just provided involve initial presumptions as embodied in policies and institutions. Initial presumptions are, however, also a key feature of arguments about the ethical acceptability of various policy choices, whether those choices involve physician-assisted suicide, the allocation of health care resources, or the conditions under which new products should be given regulatory approval. Identifying the initial presumptions in arguments about ethical acceptability, and providing an opportunity for debate among those who adhere to contrary initial presumptions, is a crucial strategy for governments to use in addressing ethical issues. **It is probably the single strategy that most productively combines consideration of differences about the appropriate school of ethics, the appropriate level of ethical analysis and the appropriate domain of ethical analysis.**

For example, rights-based ethics and utilitarian ethics will normally start from quite different presumptions. Even within the framework provided by the four principles approach to biomedical ethics, it is crucial to identify which of the principles will be used as the initial presumption in particular cases, and to justify this choice. It must be recognized that starting by assigning highest priority to respect for autonomy might well lead to a different outcome than if one started by assigning highest priority to the principle of beneficence. Starting from an initial presumption in favour of individual autonomy in the case of assisted suicide or, for that matter, firearms control is likely to generate quite different conclusions than would follow from an initial presumption that emphasizes the values or interests of the community.

4.4. Dialogue, Debate and Learning

Some of these observations will seem frustratingly imprecise, and will leave the reader saying: "Okay, but what should government **do**" in situations of ethical conflict or uncertainty? Without reference to a specific situation, but within the constraints identified in subsection 4.2 such as a broad societal commitment to individual (and perhaps some group) rights, the only answer that can responsibly be given is: it depends. As the preceding discussion shows, governments cannot decide ahead of time about the school, domain or level of ethical concern that should govern decision making in a particular case, although macro level analysis (as distinct from macro level action) is obligatory.

To some extent, shared values provide a background for governmental decision making. For instance, a recent political commentary makes the important point that we in the industrialized democracies are all liberals now. We do **not**, of course, agree about such issues as the design of social policy, about how progressive the tax system should be, or

about such issues as physician-assisted suicide and abortion. However, "Bill Clinton, Robert Dole and (yes) Newt Gingrich are all liberals" in the sense that they, and we, "share a belief in . . . a society that provides constitutional government (rule by laws, not by men) and freedom of religion, thought, expression and economic interaction; a society in which infringements of individual liberty must be justified."[109] The same generalization could be made about Jean Chrétien, Alexa McDonough and Preston Manning. This leaves a lot to disagree about, yet the intensity of the high-profile controversies that sensitize us to new kinds of ethical issues sometimes distracts our attention from underlying areas of agreement.

However, shared values will take us only so far, and we return here to the question of process, keeping in mind that ethics is about how we decide as well as about what we decide. One variant of democratic theory holds that the role of government should be to aggregate and reflect the preferences of its citizens, providing a framework for bargaining as necessary. This is not good enough to satisfy the demands of ethical decision making, however. It fails to acknowledge either the differences among **kinds** of preferences (to return to our earlier example of ice cream and capital punishment) or the importance of justification for decisions about what is ethically acceptable. Rather than just accepting the policy positions of various parties as given, governments have an **obligation** to promote ethical discourse and debate (as distinct from simple negotiation) on such questions as whether to give priority to individual or societal values when these conflict.

Several years ago, it was observed that: "Ethical issues . . . evolve generally in four stages: threshold, open conflict, extended debate, and adaptation."[110] The cynical view is that adaptation simply reflects acquiescence or resignation. A more optimistic view is that the process of debating ethical issues and seeking agreement is a learning and reasoning process that leads (over time, and sometimes erratically) to a genuine increase in understanding and at least a clarification of the range of disagreement. Debate among committed proponents of particular ethical positions, each acting with honesty, integrity and good faith on the best available factual information, is the activity that should define governmental efforts to arrive at ethically acceptable policy positions.

To illustrate the importance of the learning process, it is important to recall that the substantive principles now widely applied to the ethics of research involving human subjects, and in various clinical settings, did not spring full-blown onto the policy landscape. They owe a great deal to the work of the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, established in

109. "The perils of complacency," *The Economist*, December 21, 1996, p. 18. A similar point is made by Thomas Nagel, in *Equality and Partiality,* pp. 61–62.

110. John Fletcher, "Evolution of Ethical Debate about Human Gene Therapy," *Human Gene Therapy* 1990: 1–56.

1974, whose activity culminated in the influential 1978 *Belmont Report.*[111] Essentially similar principles were outlined in the first (1979) edition of *Principles of Biomedical Ethics*, one of whose authors (Childress) was a staff member of the commission. They have been refined over the intervening years as the result of ongoing discussions, not only in the academic community but also in a multitude of REBs and IRBs.[112] In order to appreciate this refinement, one need only compare the first edition of *Principles of Biomedical Ethics*, published in 1979, with its fourth edition, published in 1994.

Today's policy toward research involving human subjects, and toward the ethical issues that arise in a variety of clinical settings, is therefore the culmination of more than two decades of learning, reflection and iteration. For this reason, we have concentrated in the remainder of this report on conditions under which debate and learning about ethical issues can most effectively take place, rather than on proposing rules for governmental decision making under specified conditions.

4.5. The Merits and Methods of Consultation

Forty years ago, C. P. Snow observed that "two cultures" were emerging in the intellectual life of England. He argued that the "traditional culture, which [was], of course, mainly literary," was in a state of decline while a new intellectual culture based on the scientific disciplines was ascendant.[113] The idea of two cultures, between which there is usually relatively little communication, is valuable in understanding public policy debates about the ethical implications of new scientific and technological capabilities.

In seeking ethically acceptable solutions to public policy questions, we must add to Snow's insights the distinctive point of view of various domains of activity (such as laboratory science, business and the law) and the complexities of an increasingly multicultural Canadian society. Keeping in mind the prefix "trans" can serve a useful function. We need transdisciplinary, transsectoral, transcultural input, to name just some of the wide range of elements that need to be taken into account. We need to examine and contrast the initial presumptions people from various academic and professional disciplines, various sectors of

111. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Washington, DC: Department of Health, Education and Welfare, 1978). On the events that led to the establishment of the Commission and the fate of its recommendations, see Rothman, *Strangers at the Bedside,* pp. 70–100, 148–89. On legislative initiatives to protect human subjects in the United States before the Commission's establishment, see also Steven Coughlin and Tom Beauchamp, "Historical Foundations," in Coughlin and Beauchamp, eds., *Ethics and Epidemiology* (Oxford: Oxford University Press, 1996), pp. 11–16.

112. Charles Weijer, "Evolving Ethical Issues in Selection of Subjects for Clinical Research," *Cambridge Quarterly of Healthcare Ethics* 5 (1996): 334–45.

113. C. P. Snow, "The Two Cultures," *New Statesman and Nation,* October 6, 1956, pp. 413–14.

human activity and various cultures bring to the determination of what is ethically acceptable.

It is essential that there be fora in which the ethical acceptability of the choices confronting governments can be discussed **as ethical issues.** Much of the learning that has gone on in bioethics has occurred because the issues at stake were explicitly treated as ethical in character, rather than primarily as matters of science, technology or professional judgment. Depending on the situation, the forum might involve everything from televised town meetings to stakeholder workshops, a royal commission, a reference to a parliamentary committee, or an advisory body like the National Bioethics Advisory Commission (NBAC) recently established in the United States.[114] The availability of such fora is especially important with respect to macro level policy issues whose ethical dimensions may seldom have been considered publicly in any kind of systematic way.

There are encouraging developments along these lines in Canada. One is the Values Working Group set up by the National Forum on Health as it examined the future of Canadian health care.[115] Another is the Ethics Roundtable, which concluded a series of hearings on biotechnology held by the House of Commons Committee on Environment and Sustainable Development.[116] In recognition of the need for fora on ethical issues, the committee's report recommended the establishment of a National Advisory Commission on Biotechnology, reporting directly to the Prime Minister, whose mandate would include "the ethical aspects of biotechnology" as well as study of potential risks, public understanding of biotechnology, and the design of biotechnology regulation.[117]

This is one instance of recognition that more needs to be done to advance the processes of ethical debate and learning. As noted earlier, government must acknowledge an obligation to allow the Canadian public to identify key ethical issues in the development and

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114. For an overview of institutional models for ethical deliberation in bioethics within government, which concentrates on the United States experience but includes illustrations from other jurisdictions as well, see Fineberg et al. *Report* of the Committee on the Social and Ethical Impacts of Developments in Biomedicine, in Bulger et al., eds., *Society's Choices*, pp. 87–122. A detailed examination of the record of past advisory bodies of this type in the United States is provided in Bradford Gray, "Bioethics Commissions: What Can We Learn from Past Successes and Failures?" in Ibid., pp. 261–306.

115. "Values Working Group Synthesis Report," in *Canada Health Action: Building on the Legacy*, Final Report, Vol. II (Ottawa: National Forum on Health, 1996).

116. The transcript of that Roundtable is reproduced in *Evidence*, House of Commons Standing Committee on Environment and Sustainable Development, Parliamentary Forum on Biotechnology, Roundtable No. 3: Ethical Considerations (October 8, 1996). The Committee's findings from the entire series of hearings, which considered the scientific dimension of a variety of regulatory issues as well as the ethical dimension, are provided in *Biotechnology Regulation in Canada: A Matter of Public Confidence*, Report of the Standing Committee on Environment and Sustainable Development (Ottawa: Canada Communication Group, November 1996).

117. Ibid., p. 38–39.

implementation of public policy and to engage in debate on those issues. Although the point cannot be explored further here, it may be that in some policy fields this function should include actively bringing emerging ethical issues to public attention, and providing necessary background information, as well as providing an accessible forum through which to involve the public.

Ideally, it would be possible to achieve agreement or consensus among the stakeholders in a particular debate on the proper ethical principles to apply and about their interpretation in specific cases. Furthermore, if we accept that no absolute foundations exist for the authority of moral claims, then the search for consensus provides a useful starting point that is consistent with very widely shared democratic values.[118] It is preferable to begin discussion of ethical choices in public policy by identifying areas of agreement rather than of disagreement; this is likely to lend a less adversarial tone to the interactions that follow. When agreement appears elusive, debate and dialogue among those with sharply contrasting points of view are nevertheless important as a way of clarifying the actual sources of disagreement in a way that proves helpful both for governments, the ultimate decision makers in matters of public policy, and for the public.

As a means of seeking agreement, or at least of clarifying the nature and range of disagreements, consultations of various kinds are becoming increasingly frequent and useful in public policy, whether conducted on an *ad hoc* basis or institutionalized. Here, the term "consultation" is used generically to refer to any formal or informal process that facilitates the debate on ethical issues we have already identified as central to the process of arriving at ethically acceptable decisions. Three important sets of considerations should be taken into account in designing such processes.

First, consultations should be structured in a way that reflects the distinctive character of ethical inquiry. The following set of methods for structuring consultation has been adapted from a discussion of ethical issues in epidemiology,[119] but can be applied much more widely, both in relatively formal settings like stakeholder workshops and elsewhere.

- *Specification:* identify the general principles, domains and levels of analysis that may apply to the case in question. Focussing on initial presumptions is likely to be an effective way of doing this.
- *Getting the facts:* good ethical decision making always requires the best available factual information, drawing on both natural and social sciences. It is particularly important to identify areas of uncertainty or conflict about interpretation of the

118. Bruce Jennings, "Possibilities of Consensus: Toward Democratic Moral Discourse," *Journal of Medicine and Philosophy* 16 (1991): 447–63; Brock, "Public Moral Discourse," pp. 216–17.

119. Tom Beauchamp, "Moral Foundations," in Coughlin and Beauchamp, eds., *Ethics and Epidemiology,* pp. 38–41.

available information, and to ask how different values or initial presumptions would deal differently with such issues.

- *Clarifying definitions:* for example, is everyone in a debate using "risk" to mean the same thing? Can the different definitions be reconciled — and if not, how are the differences important?
- *Using examples and counter examples,* including hypothetical examples, to illustrate and explore the application of different values and levels of analysis, and the appropriateness (or inappropriateness) of various possible analogies.
- *Analyzing arguments*, with reference both to internal flaws or inconsistencies and to the merits of competing positions.

In using these methods, it must be kept in mind that: "Our pragmatic goal should be a method that helps push the discussion forward through refinements, not a method that will always resolve the problems."[120]

Second, careful thought must be devoted to the issue of who should be consulted in a particular context, and why. Not every member of society necessarily has a stake in a particular policy choice, and their stakes are not necessarily comparable. What weight should be accorded the views of various participants in policy debates about ethical issues? For instance, are animal welfare advocates necessarily regarded as stakeholders in debates about approving veterinary biologicals or developing transgenic animals? Are members of the community to be regarded as stakeholders in discussions about the ethics of research involving human subjects at the local hospital?[121] How should we decide what it means to be "affected" by a particular decision or policy? Who should decide? Such questions become critical for government when views conflict after appropriate consultation, and differing views on this point may themselves may reflect deep conflicts within society about the relative weight that should be given to (for instance) considerations of economic growth and environmental protection.[122] As they address these questions of "standing" (in a broad policy sense rather than in a narrow, legal one), governments should encourage debate about these value conflicts, rather than just leaving them for "the political process" to sort out. Unfortunately, there are no easy or generalizable resolutions.

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120. Ibid., p. 41.

121. The answer to this question reached in the Medical Research Council of Canada Guidelines for such research is a qualified yes, in that community representation on REBs is strongly encouraged. However, this does not always happen in practice at the level of the individual institution. A study carried out between 1990 and 1993 by the National Council on Bioethics in Human Research found that "few REBs had committee memberships composed in conformity with the relevant MRC recommendations," specifically with reference to community membership and ethical expertise; see "Special Report: Protecting and Promoting the Human Research Subject: A Review of the Function of Research Ethics Boards in Canadian Faculties of Medicine," *NCBHR Communiqué* 6 (no. 1, Winter 1995), pp. 5, 20.

122. Joan Sherman, Michael Gismondi and Mary Richardson, "Not Directly Affected: Using the Law to Close the Door on Environmentalists," *Journal of Canadian Studies* 31 (1, Spring 1996): 102–18.

Third, it must be remembered that reasons for agreement or disagreement are often as important as the outcome of a particular case or decision, and may guide future decisions in quite different ways depending on which reasons are accepted. Further, agreement on the decision or policy in a particular case is no substitute for justification; indeed, agreement can be reached for a multitude of reasons, ranging from self-interest to the simple exhaustion of some participants. Ellen Moskowitz warns that:

> The fact that a proposal is adhered to by a group offers no guarantees that the proposal is good. It may or may not be good, and we depend upon explicit, carefully crafted reasons and arguments to satisfy our need for ethical justification.[123]
>
> . . .
>
> Government efforts ought to seek the benefits and guard against the risks of moral consensus. The democratic values served by moral consensus will not be realized unless the consensus relied upon has developed through a broadly participatory, ethically reasoned, and fair process. Thus government actors ought to probe the moral agreements they [i.e., consensus-seeking efforts] identify as central in order to evaluate how well these requirements are met.[124]

The importance of this point is (unintentionally) emphasized in an article by Stephen Toulmin, like Childress a former staff member of the commission that produced the *Belmont Report*. Toulmin reported that agreement on detailed recommendations for dealing with a particular "difficult class of cases" was frequently reached, even while profound disagreements persisted about the principles underlying that agreement.[125]

Such an approach to decision making, which allows decisions to be reached without examining the principles underlying them, is undeniably attractive in practical terms — it gets the job done — yet governments must treat it with great caution. Without referring to principles of some sort, it is hard to see how governments can decide what constitutes a class of cases for purposes of making policy choices, much less why a particular situation does or does not fall into one particular class rather than some other. Returning to the example of physician-assisted suicide, it makes a great deal of difference — indeed, the difference between regarding an act as showing respect for a person or as murder — whether one decides that physician-assisted suicide is "like" the withdrawal of life-prolonging treatment at a patient's request or "like" the active ending of human life in other contexts. Reasons matter!

4.6. Making Final Decisions and Exercising Ethical Leadership

The process of ethical debate and consultation must normally occur with the recognition that ultimate decision-making power rests with governments, which are at least in theory

123. Moskowitz, "Moral Consensus in Public Ethics: Patient Autonomy and Family Decision making in the Work of One State Bioethics Commission," *Journal of Medicine and Philosophy* 21 (1996): 163.

124. Ibid., p. 165.

125. Stephen Toulmin, "The Tyranny of Principles," *Hastings Center Report* (December 1981), p. 31.

accountable to the general population, and — to restate a point made earlier — that governments rarely have the luxury of not making a decision. Four points need to be made here about the responsibilities and obligations of government in this context.

First, to return to a point made in Chapter 1, decision-making processes must be transparent, in that the basis and reasons for decisions about ethical acceptability must be disclosed, and must conform to criteria of due process: the persons making the decision must not have a conflict of interest, and individuals or groups with a stake in the outcome must not be denied an opportunity to be heard.

Second, given what has been said earlier about the provisional nature of ethical conclusions (governments' and everyone else's) it is important to provide for chances to refine and rethink those conclusions. This can be done informally, or — perhaps more reliably — by way of such devices as a requirement that a policy or statute be reviewed by a parliamentary committee five years after coming into force. Like individuals, governments cannot responsibly take a set-and-forget approach to ethics.

Third, governments may choose to delegate some decision-making power. One way of doing this, which raises various problems outside the scope of this paper, is leaving an issue for the courts to resolve. Another, perhaps preferable one involves setting up a semi-autonomous regulatory tribunal operating within broad legislative authority, like the Human Fertilization and Embryology Authority (HFEA) in the United Kingdom. One advantage of such semi-autonomous bodies is a greater degree of independence, both actual and perceived, from political considerations that may have nothing to do with ethics. Another form of partial delegation characterizes the Canadian approach to research ethics, in which REBs must approve research protocols involving human subjects before federal research funding is approved. REBs enjoy some discretion in interpreting the granting councils' guidelines not only about substantive issues but also, subject to rules such as a prohibition of conflicts of interest, about their own composition.

When actual decision-making power is not delegated, governments may rely on arms-length advisory bodies whose conclusions, although not binding on governments, nevertheless carry a certain ethical force. The NBAC in the United States will operate this way. So would the National Advisory Commission on Biotechnology proposed by the House Committee on Environment and Sustainable Development, if it were to be established. Indeed, such bodies need not be government appointed or financed. The reports of the Nuffield Council on Bioethics in the United Kingdom, for instance, are widely read and referred to, but it has no formal relationship with government.

Fourth, there are times when democratic governments may, and indeed must, exercise ethical leadership with respect to values that they — preferably after appropriate reflection and consultation — consider to be sufficiently fundamental, and the denial of which they regard as sufficiently destructive in ethical terms. The U.S. *Civil Rights Act* and the Canadian *Charter of Rights and Freedoms* have earlier been identified as examples of such

leadership. These highest order legal documents can be regarded as statements of the most fundamental ethical principles to which the societies in question have committed themselves. Thomas Nagel identifies the element of leadership by noting that "the legal abolition of overt discrimination — practised, enforced, or protected by the state — has had a deep mental effect, which gives the legal result stability."[126]

Other instances where governments have exercised ethical leadership include: the *Canada Health Act*, which embodies a clear commitment to certain principles of distributive justice; Parliament's rejection of capital punishment in Canada, despite apparently high levels of public support for the return of the noose; and the proposed prohibitions of human cloning and a number of other reproductive technologies that were before Parliament in Spring 1997 as the end result of a process that began with the establishment of the Royal Commission on New Reproductive Technologies almost a decade earlier.

Internationally, recognition is gradually being achieved for the principle that governments have not only an obligation to supply humanitarian aid to victims of war or natural disaster, but indeed a right to do so regardless of the wishes of the government within whose borders the victims are located.[127] This is a specific example of the process in which human rights concerns are being acknowledged, slowly, imperfectly and unevenly, as legitimately taking precedence even over the national sovereignty that has been the cornerstone of the system of international relations over roughly the last three centuries.

All these examples indicate commitments on the part of government that some courses of action, some practices are ethically impermissible, and others ethically obligatory. However there is no convenient algorithm that will enable governments to decide when such leadership must be exercised in the face of the weight of public opinion or the views of key stakeholders.

4.7. Afterthoughts

The search for ethically acceptable decisions and policies is a process, not an event. It involves matters that range from whether we should approve new food colouring to searching for the soul of society itself. It is at base a search for shared meaning and respect in our individual and societal lives. We usually do not, often cannot and sometimes should not, search for these elements directly. But we need to have at least a peripheral awareness that this is what we are doing when we engage in debates about what is ethically acceptable.

126. Nagel, *Equality and Partiality*, p. 97.

127. Bernard Kouchner (founder of Médecins sans frontières), "Right of Interference: Progress and Failure in Conflict Prevention," Beatty Memorial Lecture, Mc Gill University, November 4, 1996 (citing several U.N. resolutions on specific national situations).

5. Summary of Conclusions

At the risk of being repetitive, it is worthwhile briefly to restate the major prescriptive conclusions of this report.

Policy outcomes are ethically acceptable if they respect the ethical values and principles that are appropriate and relevant to the situation or case at hand, and that have been justified as taking priority with reference to competing values or principles. When governments are deciding among policy options, they need at a minimum to be able to distinguish statements about ethics from statements about preferences, or values, of other kinds.

Considerations of process are also important, and governments may often begin trying to reconcile conflicting ethical positions by designing a process for understanding the basis for disagreement or conflict. At the very least, such a process should recognize the distinctive character of ethical inquiry, and should operate according to principles that are themselves defensible, including transparency and due process.

Standards of what is considered ethically acceptable are influenced by a variety of factors including culture and socialization, religion, and media coverage. In addition they can change drastically over time, even within a particular society. How should governments deal with the fact that (for instance) practices in such areas as racial or gender discrimination that were taken for granted within the lifetime of many Canadians now living are now regarded with revulsion? The wrongness of **some** practices (and conversely the rightness of others) is sufficiently fundamental that it cannot be reduced to a question of prevailing societal values or standards. It may not be easy to identify impermissible or obligatory practices in our own place and time.

However, governments, and the individuals who judge them, should identify **core** values or standards of ethical acceptability — principles that are especially basic, as in those now taken to comprise human rights. In addition governments, and the individuals who judge them, must always be sensitive to the nature of ethics as a learning process, and to the provisional nature of some of our ethical choices. While respecting cultural differences and the resulting emphases on different values, we must not renounce responsibility for making ethical judgments about social arrangements both within our own society and outside it.

This does not mean that governments should adopt a particular school of ethics, such as utilitarianism, as the starting point for their decision making. This would be stepping in where philosophers fear to tread. Governments may, however, after careful consideration, decide on a policy in one particular case that emphasizes the concerns that are central to one particular school of ethics. Similarly, it is inappropriate for governments to consider ethical issues only from the perspective of one domain, such as business or the medical or legal professions, even in cases that primarily involve the activities of those sectors.

Governments must make their decisions based on ethical analysis at the macro level. In order to do this, they will need to consider ethics at other levels, especially the individual level. By their very nature, governments are decision makers for the society as a whole; this means that governments have a special obligation to consider the justifications for the choices they make, and to think about the macro level in their decision making, even though they may ultimately decide not to **act** at the macro level.

Ethical issues often do not come neatly labelled with a tag saying: "This is an ethical issue!" Sometimes, a particular set of issues or questions is clearly acknowledged as ethical, and rules or guidelines are developed for addressing and resolving them. More often, however, frameworks for making decisions tacitly reflect particular ethical commitments, or the primacy assigned to a particular value, in ways that are so deeply "embedded" that policy makers and the public alike tend not to think about the underlying values and principles. As governments seek to clarify the nature of differences among schools of ethics, tensions between levels of ethical analysis, and the ethical commitments that are embedded in particular policies, they will find that analyzing policy positions by looking at their **initial presumptions** — their starting points — is a key strategy for learning and decision making.

To this end, it is essential that there be fora in which the ethical acceptability of the choices confronting governments can be discussed **as ethical issues.** The availability of such fora is especially important with respect to macro level policy issues whose ethical dimensions may seldom have been considered publicly in any kind of systematic way. Indeed, government is under an ethical obligation to allow the Canadian public to identify key ethical issues in the development and implementation of public policy and to engage in debate on those issues.

Consultations of various kinds are becoming increasingly frequent and useful in public policy. Three important sets of considerations should be taken into account in designing consultations on ethical issues. First, they should be structured in a way that reflects the distinctive character of ethical inquiry. This can be achieved through the following methods:

- specification
- getting the facts
- clarifying definitions
- using examples and counter examples
- analyzing arguments.

Second, careful thought must be devoted to the issue of who should be consulted in a particular context, and why. Third, since reasons matter, agreement on the decision or policy in a particular case is no substitute for careful justification.

The process of ethical debate and consultation must normally occur with the recognition that ultimate decision-making power rests with governments. Four points need to be made

here about the responsibilities and obligations of government in this context. First, decision-making processes must be transparent, in that the basis and reasons for decisions about ethical acceptability must be disclosed, and must conform to criteria of due process. Second, it is important to provide for chances to refine and rethink conclusions on ethical issues. Third, governments may choose to delegate some decision-making power, in order to provide a greater degree of independence, both actual and perceived, from political considerations that may have nothing to do with ethics. Fourth, democratic governments may, and indeed must, exercise ethical leadership with respect to values that they — preferably after appropriate reflection and consultation — consider to be sufficiently fundamental. However, no convenient algorithms are available, or can be made available, for determining when and how it is appropriate for governments to do so.

Biotechnology, Ethics and Government:

Report to the Interdepartmental Working Group on Ethics

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This report has been prepared by:

Ted Schrecker
SCHRECKER – RESEARCH AND CONSULTING
176 York Street, Suite 31
London ON N6A 1B5
Tel.: (519) 432-5649
Fax: (519) 432-5649
E-mail: tschrecker@compuserve.com

Barry Hoffmaster
Department of Philosophy
University of Western Ontario
London ON N6A 3K7
E-mail: choffmas@julian.uwo.ca

Margaret A. Somerville
Centre for Medicine, Ethics and Law
3690 Peel Street
Montreal QC H3A 1W9
Tel.: (514) 398-7400
Fax: (514) 398-4668
E-mail somerv_m@falaw.lan.mcgill.ca

and

Alex Wellington
251 Concord Avenue
Toronto ON M6H 2P4
E-mail: alexw@nexus.yorku.ca

Westminster Institute for Ethics and Human Values
McGill Centre for Medicine, Ethics and Law

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It must be emphasized that this report does not necessarily reflect the views of any of the above-named individuals, or their institutions; responsibility for the contents rests exclusively with the authors. It must also be emphasized that none of the views expressed here is an opinion of the members of the Interdepartmental Working Group on Ethics or the Government of Canada.

An earlier draft of this report was completed in March 1996. It has subsequently undergone revision in response to comments from members of the Interdepartmental Working Group, and in light of some subsequent developments. However, no comprehensive attempt has been made to update the report with reference (for example) to the hearings on biotechnology regulation held by the House of Commons Committee on the Environment and Sustainable Development in May, June and October 1996, or to the resulting reports.

Contents

Executive Summary

Both promoters and critics of biotechnology agree that it has the potential to revolutionize industry and profoundly alter everyday life. The biotechnology industry and scientists who are involved in biological and genetic research with commercial applications often view biotechnology as just another high technology. Conversely, a variety of critics of biotechnology are sceptical about its benefits and are concerned that it will have unintended and unforeseen negative consequences of great scope and magnitude.

Ethics and Public Policy

Values are the basis on which we assess the world, rather than just describing it. In the simplest terms, ethics is the process or set of principles by which we decide how individuals ought to act in their relations with other individuals and, at least for some environmental ethicists, in their relations with the non-human world. Ethics requires taking others' points of view seriously, as well as one's own. Ethical claims demand justification, in a way that other kinds of values do not. In addition to examining justifications, ethical inquiry often needs to ask how conflicts between values are to be resolved.

At the risk of oversimplifying, ethical arguments can be broadly classified in terms that reflect the two dominant traditions in Western moral philosophy. One tradition holds that actions can be judged intrinsically right or wrong based on duties, obligations, rights or principles whose operation is independent of the consequences an action produces. Such arguments are often referred to by philosophers as deontological. The other tradition assesses an activity with reference to the nature of its consequences. The most familiar consequentialist position is utilitarianism, according to which the action that is right is the one that produces the greatest good for the greatest number. As this example shows, arguments about consequences presuppose an existing moral background, on the basis of which we decide what is to count as beneficial or harmful.

Most ethical reasoning in practice combines the two forms of argument. The question of distribution (who benefits from a particular policy and who is harmed by it) is often at least as important as the overall quantum of benefit. Policies that harm the vulnerable may be presumed ethically unacceptable even if they deliver important potential benefits to others. Conversely, fairness and distributive justice may be pursued as elements of public policy, but usually not at all costs.

Both supporters and opponents of biotechnology invoke the findings of natural and social science in the course of making ethical arguments. Getting the facts right is crucial, but this will often not be enough to resolve ethical disagreements for several reasons. First, the distinction between facts and values is not always as clear as it might seem. Second, sometimes agreement on the facts may actually intensify ethical conflict. Third and most importantly, uncertainty is pervasive in both natural and social science. In public policy,

ethical analysis is especially important with respect to choices about how to deal with such uncertainties, which generate the following set of practical and institutional questions:

- How much evidence is enough? (The standard of proof)
- Who should have to produce it? (The burden of proof)
- Who makes the final decision? (The locus of decision making)

The way each category of decision is made within government reflects particular values and particular ethical commitments that may vary depending on the jurisdiction, the policy field, and the issues at stake. Very often, those values and commitments are "embedded" in the design of decision-making institutions. They are not stated explicitly, but nevertheless have a powerful influence on the outcomes that emerge.

People making ethical arguments must be clear about the principles or values they Are applying, and about why they are relevant to the case under discussion. Although there are no "right answers" to many of the questions that arise in applied ethics, some ways of going about answering ethical questions are better than others.

What kind of tools can we use to identify weaknesses in ethical arguments? First, they must be logically valid arguments, free of a number of relatively common errors. Ethical arguments also must avoid epistemic mistakes: inaccurate or misleading conceptions of what is really at issue in a particular situation. In general, careful attention to the structure of an argument is essential, as illustrated by a discussion of claims about "slippery slopes," which are relatively common in discussions of biotechnology. As Margaret Somerville points out:

> Ethics is more than a matter of individual conscience, although this is essential: it is the systematic application of informed, structured and disciplined discernment to analysis of situations in relation to the ethical issues they raise and to decision making in these situations.

Ethical Conflicts Raised by Biotechnology: An International Perspective

Discussion in this chapter focusses on agricultural biotechnology, human gene research and intellectual property rights in biotechnology.

The strongest critics of biotechnology argue that anything produced by genetic engineering should be regarded as suspect and accorded strict regulatory scrutiny. Many researchers counter with the assertion that there is no reason to think that transgenic organisms necessarily pose distinctive risks. Despite a large number of field trials that have so far failed to reveal such hazards, many critics remain unconvinced. It is important to ask whether the key issues are scientific in nature, or whether they involve choices about how much uncertainty with respect to ecological effects plants constitutes an acceptable environmental risk.

Some similar issues emerge in the regulatory approaches taken in the United States and the European Union (EU) toward the use of synthetic bovine somatotropin (rBST) to increase

milk production in dairy cows. In the United States, where rBST received regulatory approval, critics objected on grounds related to human health, animal welfare and the socio-economic effects on the agricultural industry. In the EU, a moratorium extending through 1999 appears to have been motivated by socio-economic concerns related to already large agricultural surpluses.

One of the highest-profile areas of biotechnology involves the mapping of the human genome and the expanding range of genetic tests, screens and therapies that promise to become available. We identify four sets of ethical issues or questions that have emerged in the international context. First, how will access to newly developed (but potentially very expensive) diagnostic tests and therapies be allocated? Second, when, if ever, should genetic information (for instance, about an individual's inherited predisposition to a certain disease) be made available to third parties such as employers and insurance companies, whose primary stake is financial? Third is the challenge by a distinctively feminist intellectual approach already found throughout the Western world in debates about medically assisted reproduction. On this view, neither medically assisted reproduction nor some of the uses to which genetic information will probably be put in other contexts can be viewed in isolation from the social subordination of women. Fourth is a range of concerns about how expanding knowledge of the genetic basis of human behaviour and identity, and our ability to act on that knowledge, will alter human beings' relationships with one another. For example, will "genetic essentialism" lead to redefining the conception of human beings as responsible moral agents, as genetic bases for (or predispositions to) certain kinds of behaviour are identified? How will the parent–child relationship change with the possibility of specifying desired traits in offspring? Will we come to regard other persons, in general, as just bundles of traits?

There have been at least four milestones in the history of the transnational debate about biotechnology patenting. First was the Moore case, in which surgeons patented a cell line cultured from a patient's excised spleen; the patient sued for a share of the profits and lost. Second was the U.S. Supreme Court's decision in 1980 that living organisms (in this case, a genetically engineered micro-organism) constituted patentable subject matter. Third, shortly after the U.S. Patent and Trademark Office announced in 1987 that it would consider issuing patents on multicellular organisms, it issued its first patent on a living animal: the Harvard or Onco-Mouse. Fourth was a 1991 application by the U.S. National Institutes of Health (NIH) for patents on more than 2 000 DNA sequences identified as part of the Human Genome Project. U.S. patent authorities rejected the application in 1992, and in 1994 NIH withdrew these and subsequent patent applications rather than appealing the initial rejection; the British Medical Research Council did the same with the applications it had filed.

There are ethical arguments for biotechnology patents, having to do, for example, with fairness to investors and researchers, who are thereby ensured a return on their commitments of money and time. Objections to biotechnology patenting involve two lines of argument. The first has to do with distributive justice: will patenting, for example, make

small farms uncompetitive (by raising the cost of patented, high-yield crop and animal varieties) or create new economic divisions in access to health care? It is harder for existing institutions to come to grips with the second objection: that patenting will lead to deterioration in the respect for life that is a key element in almost all moral systems.

Addressing the Ethical Challenges of Biotechnology in Canada

Ethical issues related to biotechnology have arisen in a number of contexts within the Canadian federal government. Some of these, like the guidelines for research on human subjects developed by the Medical Research Council of Canada and the National Research Council, involved an institutional attempt to deal explicitly with ethical issues. However others, such as parliamentary committee hearings on the regulatory process involving rBST, were not organized primarily around dealing with ethical issues and did not have an explicit mandate to do so. Such issues nevertheless arose in the course of discussing policy options. For reasons of brevity, the reader is referred to Chapter 4 of the full report for discussion of the Canadian cases dealt with in the report. Of greater interest are our findings about key ethical tensions in the biotechnology debate, both in Canada and elsewhere.

Key Ethical Tensions from the Biotechnology Debate

Four such tensions link various debates about various aspects of biotechnology; the term "tensions" rather than "conflicts" is used deliberately, since each area involves areas of agreement as well as of disagreement.

The first tension involves how acceptable risk is defined, and the difference between risk assessment and risk perception. Some people who may be affected by the potential risks of biotechnology reject a linear definition of risk in terms of probability times consequences, insisting instead that broader social factors should be included as well. Other issues include whether risks are viewed as producing compensating benefits (and for whom); whether risks are voluntary or involuntary; the degree of control over a risk; and the amount of uncertainty associated with it; and how familiar the source of the risk is. All these factors feed into individual choices about what risks are acceptable, and into public reactions to policy decisions about risk.

Risk perception and risk acceptability are ultimately functions of trust. The second tension involves trust (or lack of trust) in the institutions making decisions about biotechnology, and accountability, which is the flip side of trust. When such institutions are not viewed as adequately accountable, a "trust gap" develops. The perceived credibility of institutional authorities, and of other sources of information about biotechnology, is important in determining whether or not such a gap develops. As in other areas of health and safety regulation, and as in the context of research ethics, there is a growing, if occasionally reluctant, recognition of the role of public participation.

The third tension involves claims that the consequences of biotechnology applications are socially undesirable, that they require balancing individuals' interests against those of the community, or that the likely benefits and burdens will be distributed unfairly. Justice in the distribution of these benefits and burdens is viewed as critically important; so is the proper role of the market in determining how new technologies are used. Such issues may pit the interests of individuals as consumer or employees against the commercial imperatives driving the adoption of biotechnology, and raise questions about what degree (if any) of social control of new technologies is appropriate above and beyond the control provided by the market.

The fourth tension involves respect for life, and concerns about how biotechnology might erode that respect through the commodification or objectification of life and living beings. Scientific knowledge here can lead either to reductionism or to reverence, but what happens when that knowledge is transferred into commercial applications? For example, if and as biotechnology patenting becomes more widespread, will the lack of distinction in patent law between living and non-living matter change our attitudes and sensibilities toward life? How should we evaluate the potential hazards of commodification and objectification?

The Way Forward

Developing an ethical framework for biotechnology in Canada means both developing principles for resolving ethical questions related to biotechnology, and considering processes or institutional designs. The institutions of public policy can become involved with ethical issues in at least three distinct ways. First, a particular institution can have an explicit mandate to deal with ethical issues. Second, frameworks for making decisions that are not clearly acknowledged as ethical can be set up in ways that reflect particular values or ethical principles. Third, ethical commitments may be "embedded" in policies, institutions and procedures, in ways that policy makers and the public alike tend not to think about because they are taken for granted.

Ethics can in many respects best be understood as a process of developing, testing and refining the principles by which decisions are reached. Considerations of process are important in explaining dissatisfaction with the outcomes of decisions about biotechnology. There is often not an institutional mechanism that facilitates dealing with ethical issues openly and explicitly as ethical issues. An ethical perspective on public policy is crucially important, and policy analysis and policy decision making may need to incorporate that perspective explicitly.

1. Introduction

1.1. What Is Biotechnology?

Biotechnology can be defined in a variety of ways. The Organisation for Economic Co-operation and Development (OECD) defines it as "the application of scientific and engineering principles to the processing of materials by biological agents to provide goods and services."[1] In the *Canadian Environmental Protection Act*, biotechnology is defined as "the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified form." Although this is a more expansive definition than some others, it is perhaps the most appropriate one, given the broad terms of reference for this report.

1.2. Who Cares about Biotechnology?

In Canada, two of the highest-profile controversies related to biotechnology have involved medically assisted reproduction and the use of synthetic bovine growth hormone (rBST). In the first case, "a two-year, large-scale, intensive lobby effort by . . . a nation-wide coalition of women's groups, health groups, other groups and many individuals"[2] led to the establishment of the Royal Commission on New Reproductive Technologies (RCNRT) and, eventually, to proposals for a new federal regulatory framework. Opposition to the use of rBST to increase dairy yields resulted in House of Commons Committee hearings and, subsequently, the establishment of a federal government task force on its impacts.[3] At this writing, a decision on regulatory approval for the use of rBST in Canada has not been made by Health Canada, which is the responsible department.

Neither of these controversies is distinctively Canadian. Feminist opposition to the technologies of medically assisted reproduction and their associated institutional forms was and is an international phenomenon.[4] Opposition to rBST on the part of environmentalists, animal rights advocates and some portions of the farming community has been intense both in the countries of the European Union, where (as in Canada) the use of rBST is currently under a moratorium, and in the United States, where it has been permitted since November

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1. Robert Bud, *The Uses of Life: A History of Biotechnology* (Cambridge: Cambridge University Press, 1993), p. 1.

2. Margrit Eichler, "Frankenstein Meets Kafka: The Royal Commission on New Reproductive Technologies," in G. Basen, M. Eichler and A. Lippman, eds., *Misconceptions: The Social Construction of Choice and the New Reproductive Technologies*, vol. 1 (Montreal: Voyageur Publishing, 1993), p. 196.

3. Mary Pickering, "The Canadian review of rBGH: Confusion, politics and alleged bribery," *Alternatives: Perspectives on Society, Technology and Environment* 21 (3, 1995): 7.

4. The opposition, organized through a group called FINNRAGE, actually produced an international journal beginning in 1988; unfortunately for students of the issue, *Issues in Reproductive and Genetic Engineering* ceased publication in 1992.

1993.[5] These are not isolated examples. In an age of rapid global communication through print and electronic media, it is difficult to anticipate that any significant controversy related to biotechnology will remain confined within the borders of one country. The continued liberalization of trade restrictions and the international nature of much leading-edge scientific research facilitate the widespread diffusion of scientific and technological innovations across national borders.[6]

As uses of the products and processes of biotechnology become more widespread, a variety of stakeholders will be involved in public policy debates about biotechnology. At the risk of oversimplifying, it may be useful to think in terms of three different clusters of stakeholders:

- "those who have a commercial interest in biotechnology and its applications"
- "those who deal with biotechnology for political and social reasons" (comprising public authorities as well as public interest groups)
- "[t]he general public as consumer" of the benefits "as well as 'consumer' of the risks and the more general socio-economic consequences involved."[7]

Clearly, there are differences between and among the three clusters. Firms engaged in commercializing biotechnology, and scientists who stand to gain both financially and professionally from policies that promote their areas of research, are likely to have distinctive perceptions of the evolution of biotechnology practice and policy. People with professional responsibilities in government departments and agencies will have concerns distinct from those of all other involved groups.

There are also differences among the different elements of each cluster. There is no one uniform industry or scientific community position on each and every element of biotechnology practice and policy. Some human genome researchers, for instance, resist the industry-initiated trend toward attempting to patent any and every discovery; they are worried that extensive patenting would impede the free exchange of information, but also that the proprietary claims of others could interfere with their own prospective commercial ventures.[8]

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5. Greta Gaard, "Recombinant Bovine Growth Hormone Criticism Grows," *Alternatives: Perspectives on Society, Technology and Environment* 21 (3, 1995): 6–9.

6. In addition, European activist opposition to Canadian harvesting practices in the fur trade and both European and U.S. concerns about Canadian forest management illustrate that even when confined within national borders, practices that are viewed as ethically reprehensible can quickly become the focus of international attention.

7. Olaf Diettrich, "Biotechnology and Social Perception," in *Science, Morality and Politics*, edited by R. von Schomberg (Dordrecht: Kluwer, 1993), p. 209.

8. See Christopher Anderson, "Genome Project Goes Commercial," *Science* 259 (January 15, 1993); Eliot Marshall, "A Showdown over Gene Fragments," *Science* 266 (October 14, 1994): 208–10.

Within government, individual departments and agencies are subject to different sets of obligations (for instance, related to their statutory mandates) and motivations, and may thus take different positions on issues. A government agency whose statutory responsibilities emphasize the protection of human health may take a different view of scientific uncertainties from that adopted by an agency whose primary responsibility involves promoting a particular industry, and for which that industry represents an important client group.

There is also not a homogenous and unified public interest group position, even if we leave aside for the moment the question of what constitutes a defensible claim to represent the "public interest."[9] Some groups and individuals advocate complete bans on patenting transgenic mammals or absolute prohibitions on environmental releases of genetically modified organisms. Others take more modest positions, calling for increased avenues for citizen participation in policy making processes and for increased monitoring of activities they view as potentially hazardous.[10]

Finally, individual consumers without any organized representation may nevertheless have distinct interests and views on the diffusion of biotechnology and its products. Particularly if we define "consumers" broadly, as suggested above, the mechanism of the marketplace may not provide an adequate vehicle for articulating those interests and views.

1.3. Why Care about Biotechnology?

Both promoters and critics of biotechnology agree that it has the potential to revolutionize industry and profoundly alter everyday life. The biotechnology industry — a convenient shorthand for a collection of firms that have diverse interests and may not speak with a single voice — emphasizes the many beneficial uses of its processes and products. Examples include development and use of transgenic mammals for cancer research and for the bulk production of biopharmaceuticals and proteins; production and use of genetically modified organisms for pollution control, and improvements in agricultural crops to increase pest or disease resistance or to increase productivity; and the use of an expanding body of knowledge about the human genome to develop new diagnostic techniques and therapies.

9. Some social scientists have argued that the idea of the public interest is itself questionable, and is best understood as rhetorical camouflage for a variety of private interests. See e.g. W. T. Stanbury, "Definitions of 'The Public Interest,'" in *Public Policy Decision Making and Regulation* by Douglas Hartle (Montreal: Institute for Research on Public Policy, 1979), pp. 213–18.

10. See Bernard Dixon, "Who's Who in European Antibiotech," *Bio/Technology* 11 (January 1993): 44–48, for an indication of the range of positions to be found among European advocacy groups.

For the more philosophically minded, biotechnology stands to "affect the way we think about the living world and the way we understand our relationship to it."[11] James D. Watson, one of the co-discoverers of the structure of DNA, has likened the Human Genome Project to President Kennedy's 1961 commitment to send a man to the moon, but argues that "the implications of the Human Genome Project for human life are likely to be far greater."[12] The implications may indeed include fundamental changes in our understanding of notions such as opportunity, morality and responsibility.[13]

Both the biotechnology industry and scientists who are involved in biological and genetic research with commercial applications often view biotechnology as just another high technology. Even those scientists and entrepreneurs, particularly in the medical field, who concede the distinctiveness of the capabilities made possible by advances in human genetic research do not necessarily regard the new breakthroughs as raising any distinctive ethical or policy issues. According to one comparative study of European attitudes toward human germ-line therapy, this fundamentally pragmatic view is optimistic about the "ethico-legal capability to promote good and prevent evil without, as it were, throwing the baby out with the bathwater."[14]

Conversely, a variety of critics of biotechnology are sceptical that biotechnology will provide the promised benefits. As well, there is concern that biotechnology will have unintended and unforeseen negative consequences of great scope and magnitude. Opponents of biotechnology may accuse scientists, researchers and industrialists of "reducing to industrial and commercial practice that which ought to be exempt," namely, life.[15] In their view, biotechnology poses "distinctive threats to the environment and to culture"[16] and may even constitute "a biological time bomb."[17] Critics are worried not only about the risks of biotechnology, but also about the equity issues surrounding the distribution of benefits and risks. For example, Canada's National Action Committee on the Status of Women has claimed that new techniques of medical intervention in human reproduction open the door to "a technological handmaid's tale," invoking an image of the

11. Mark Sagoff, "The Biotechnology Controversy," in *Values and Public Policy*, edited by C. Mills (New York: Harcourt Brace Jovanovich, 1992), p. 43

12. Watson, "The Human Genome Project: Past, Present and Future," *Science* 248 (6 April 1990): 44.

13. Dan W. Brock, "The Human Genome Project and Human Identity," *Houston Law Review* 29 (1992): 7–22.

14. Alex Mauron and Jean-Marie Thévoz, "Germ-line Engineering: A Few European Voices," *Journal of Medicine and Philosophy* 16 (1991): 650.

15. Bud, *supra* n. 1, p. 207.

16. Ibid., p. 217.

17. Russ Hoyle, "Unfortunately, the Biodiversity Treaty Is Dead," *Bio/Technology* 12 (October 1994): 968.

future drawn from a Margaret Atwood novel in which economically vulnerable women are reduced to the subordinated status of "breeders."[18]

The importance of determining public sentiment is obvious for scientists and investors alike who have a stake in the future of biotechnology. As the British Advisory Council on Science and Technology has said: "The power of public feeling must not be underestimated; consumer resistance and fears for safety and pollution, for example, can seriously encumber commercial prospects."[19] The findings of many opinion polls and attitude surveys indicate that even when people have heard little or nothing about biotechnology,[20] they express an appreciation of its significance, whether they are negatively or positively disposed toward it.

At the end of the last decade, a large majority (77 percent) of the readership of a Japanese science magazine called *Newton* "predicted that biotechnology will develop into the same sort of 'major social problem as atomic energy'— which is, in Japan, saying a lot."[21] Fully 90 percent of the respondents "rejected researchers' claims of environmental safety," and 88 percent of the respondents said that "biotechnology researchers and institutions are concealing information which is potentially damaging to their fields of study."[22]

In Canada, a 1993 Decima poll of 1 500 Canadians found no comparably strong feelings, but considerable ambivalence: "while two thirds of respondents believe that it offers 'some/a lot of benefit,' two thirds also believe that biotech poses 'some/a lot' of danger to society." The survey also "indicated that public confidence in biotechnology companies is moderately low, and trust in government to ensure the safety of biotechnology is only moderate. A majority of respondents do not believe that the established [industrial biotechnology] sector takes account of the human consequences of biotechnology."[23] Public attitudes, therefore, could change rather rapidly. A more recent Optima study, combining a questionnaire survey with subsequent focus groups, found most survey respondents and focus group participants alike expressing support for a stronger regulatory role for

18. National Action Committee on the Status of Women, "The New Reproductive Technologies: A Technological Handmaid's Tale," *Issues in Reproductive and Genetic Engineering* 4 (3, 1991): 279–96 (this was also NAC's brief to Canada's Royal Commission on New Reproductive Technologies).

19. *Report on Developments in Biotechnology* (London: HMSO, 1990), p. 23; as quoted in Bud, *supra* n.1, p. 189.

20. For instance, consider the finding from a public opinion study published in 1989 that "at the time of the survey, a maximum of about one-third of the Dutch adult population had even a passive notion of the term biotechnology." Anneke Hamstra, "Consumer Research on Biotechnology," in *Biotechnology in Public: A Review of Recent Research*, edited by J. Durant (London: Science Museum for the European Federation of Biotechnology, 1992), p. 46.

21. D. McCormick, "Not as Easy as It Looked," *Bio/Technology* 7 (1989): 629.

22. Ibid.

23. Summarized in Michelle Mullen, *Biotechnology: Social and Ethical Issues, Industry's Commitment and Public Policy* (Toronto: Ontario Biotechnology Advisory Board, 1994), pp. 10–11.

government in the biotechnology field, and also found support for "a government policy based on zero risk tolerance."[24]

Polls generate one kind of information about public attitudes. Different, and perhaps more in-depth information is provided by workshops, particularly when they involve diverse participants and provide ample opportunity for interaction. The list of concerns about biotechnology raised by participants in a series of stakeholder workshops in Europe gives a good indication of the range and scope of sources of debate and controversy. These workshops apparently generated considerable debate and elicited heated exchange about the following issues: access to information about the possible hazards of biotechnology; the need for regulation and control; opportunities for public participation; socio-economic impacts; health and safety in the workplace; implications for biomedical ethics; and environmental considerations.[25]

Potential conflicts also exist between public interest or advocacy groups and some members of the public who are consumers or potential consumers of new technology. The strongly stated preference of some women for access to in vitro fertilization, in contrast to the position of some advocacy groups that the promotion and use of this technology should be severely restricted, is a case in point. Another example involves conflicts between animal rights advocates opposed to the use of transgenic animals as sources for organ transplants into human beings — a use that is already attracting venture capitalists in the United States, although such xenotransplants are not yet in clinical use[26] — and the potential recipients of such transplants. More than 2 800 patients in the United States died waiting for transplants in 1994,[27] and xenotransplants from non-transgenic animals have already occasioned at least one clash between two sets of demonstrators in Canada.[28]

In trying to understand the concerns of biotechnology opponents or sceptics, it is useful to keep in mind a distinction made by Sheila Jasanoff between "*physical* risks to health and the environment" and "*social* risks, ranging from the commodification of nature to the elimination of family farms in the west and to severe economic dislocations in developing

24. Optima Consultants, "Study Findings: Understanding the Consumer Interest in the New Biotechnology Industry" (Ottawa: November 1994), pp. 25–27.

25. Lewis Lemkow, *Public Attitudes to Genetic Engineering: Some European Perspectives* (Luxembourg: Office of Official Publications of the European Communities, 1993).

26. Lawrence M. Fisher, "Down on the Farm, a Donor: Genetically Altered Pigs Bred for Organ Transplants," *The New York Times*, January 5, 1996, pp. C1, C6; see also Joseph Alper, "Companies Settle Brave New Frontier of Xenografting," *Bio/Technology* 11 (July 1993): 772–73; Jeffrey L. Fox, "Analyzing the science and ethics of xenografts," *Bio/Technology* 13 (August 1995): 737–38.

27. Fisher, *supra* n. 26.

28. This occurred at London's University Hospital, a national centre for research on baboon-to-human organ transplants, between animal rights advocates and friends and relatives of prospective transplant recipients.

countries."[29] Among its other uses, this distinction enables us usefully to classify public concern about various applications of biotechnology with respect to whether the **primary** concerns are physical or social in nature. Indeed, the concept of a risk may be too narrow to encompass concerns such as the commodification of life, but Jasanoff's distinction does direct our attention to the question of **why** particular applications of biotechnology are seen to raise distinctive ethical issues.

1.4. Objectives of the Study

This report was commissioned by the the federal government's Interdepartmental Working Group on Ethics to assist in developing a framework for addressing the ethical issues rased by the rapid progress of biotechnology research and the prospects for rapid diffusion of a variety of products of biotechnology. In writing it, we undertook five distinct tasks.

First, we examined the way ethical choices are involved in a variety of public policy decisions, often in ways that remain unexamined. Among other subtasks, this required clarification of the nature of ethical decision making itself. The results of this examination are presented in Chapter 2.

Second, we examined the way in which ethical controversies about biotechnology have unfolded outside Canada's borders, based on an extensive literature review. Rather than providing an exhaustive chronicle of names, dates and places, we tried to identify key issues that would help decision makers to understand similar controversies in the Canadian policy context. The results of this examination are reported in Chapter 3.

Third, we reviewed a number of efforts by the Canadian federal government to address policy issues associated with biotechnology applications. These efforts range from routines based on well-established policies, such as those concerning ethical review of projects funded by federal granting councils, to exploratory studies such as those commissioned by Industry Canada and the Department of Justice. It must be emphasized that some of the studies and processes we reviewed did not specifically address, and were not intended to address, the ethical dimensions of public policy toward public policy. However, ethical issues nevertheless arose and became an inescapable part of the discussion. The results are reported in Chapter 4.

Fourth, we used the information gathered in the process of completing the first three tasks to identify four key ethical tensions that emerge from debates about the ethics of biotechnology in Canada and elsewhere. These tensions can be described under the following headings: risk assessment and risk perception; trust and accountability; distribution, equity and the social control of technology; commodification and respect for

29. Sheila Jasanoff, "Product, Process, or Programme: Three Cultures and the Regulation of Biotechnology," in *Resistance to New Technology: Nuclear Power, Information Technology and Biotechnology*, edited by Martin Bauer (Cambridge: Cambridge University Press, 1995), p. 313 (emphasis in original).

life. This analysis of the issues, reported in Chapter 5, provides a way of linking the Canadian and international contexts and providing a conceptual basis for further work in this area.

Fifth and finally, we identified three distinct ways in which the institutions of public policy may become involved with ethical issues. Returning to a point made in Chapter 1, we would stress that ethical issues often arise in connection with public policy, even in contexts where they are not explicitly identified. It is therefore particularly important to pay attention to situations where ethical commitments are "embedded" in the way public policy is made and implemented. More generally, we identified attention to the process by which decisions are made as an important part of any effort by government to develop a framework for addressing the ethics of biotechnology. We expand on these observations in Chapter 6.

2. Ethics In Public Policy

2.1. Why Bother Talking about Ethics and Public Policy?

This chapter of the report explains why ethical considerations are important in public policy, and why discussions of ethics probably cannot and certainly should not be avoided in public policy analysis.

A simple example serves to makes this point. Determining the radius of curves on a newly constructed (or reconstructed) highway looks at first like a straightforward engineering and economics decision. However, decreasing the radius might well save on land acquisition and construction costs, and reduce environmental impacts, but could also predictably increase the number of accidents on that particular stretch of road.[30] Similarly, it is widely agreed in the traffic safety field that lives could be saved by the elimination of railway level crossings, but governments often give other capital expenditures a higher priority.

These everyday examples show that decisions about public policy, even with respect to matters that are apparently mundane, must be understood as embodying or reflecting commitments to certain **values** such as economic efficiency, preserving the environment, and protecting the safety of highway users; these commitments and values can be in conflict.

What are values? Trying to answer this question is itself a daunting philosophical challenge. In general, we can say that values are the basis on which we assess, rather than merely to describe, the world. Our values are prisms through which we view the world. To use a concept borrowed from cognitive psychology, where the term "framing" refers to the set of conceptual cues or mental maps that people use all the time to make sense of the phenomena that surround them, values are the mental frames we use as a starting point for deciding what states of affairs are desirable or undesirable.

Values can be understood in different ways, for example, as interests, desires, or objectives, and can be assigned different relative weights or priorities. What is the connection between values and **ethics** or **morality**?[31]

In the simplest terms, ethics is the process or set of principles by which we decide how individuals **ought** to act in their relations with other individuals and (at least for some environmental ethicists) in their relations with the non-human world. An important task for

30. We are indebted to Geoff Oliver of the Intellectual Property Policy Directorate, Industry Canada for this example.

31. Although some writers might disagree with this strategy, we have used the nouns "ethics" and "morality," the adjectives "ethical" and "moral," and the phrases "ethical inquiry" and "moral inquiry" interchangeably in this report. Original usage has of course been preserved in all quotations.

ethical inquiry is that of distinguishing what values are distinctively ethical. There is no easy or uncontroversial way of doing so, and the question of whether a set of core ethical values that apply to all societies can be identified remains contentious.

It is fair to say, however, that one requirement of ethics is openness or even empathy: taking seriously not just one's own values, but the values of others. This stance is commonly called "the moral point of view." As an editorial writer for *The Economist* recently put the issue in a leader on the topic of animal rights: "The most elementary form of moral reasoning — the ethical equivalent of learning to crawl — is to weigh others' interests against one's own. This in turn requires sympathy and imagination. . . ."[32] Ethics further requires recognizing and accepting that the outcome of this weighing will not always be in one's own favor. The dictates of ethics can compete with self-interest, and the whole point of morality is that sometimes these dictates win.

A further characteristic of ethics is that ethical claims — claims about how people ought to act, and ought not to act — demand **justification**, in a way that other kinds of values do not:

> A preference for strawberry ice cream doesn't require justification. But when someone makes a moral claim — that capital punishment is good, for example — one expects such a position to be supported by reasons . . . and these reasons and justifications form the basis for the rational analysis of ethical positions.[33]

That ethical claims demand justification does not mean we can prove or disprove them in the same way we can prove or disprove, say, claims about the conditions under which the flight of heavier-than-air vehicles is possible. It does mean that a promising place to begin addressing the ethical dimensions of public policy is to examine how (or whether) ethical choices have been justified in particular situations.

Thus, if we start from the position that saving lives is a good thing, we might ask whether anyone involved in making the relevant highway design choices had ever asked how much a society should be willing to spend to save a life on the roads. This would also illustrate that public policy choices often involve multiple values that may conflict. For example, since resources are not infinite, we might be able to save lives through highway redesign only by giving up opportunities for saving lives elsewhere in the society.

Another important task for ethical inquiry involves figuring out how conflicts between values are to be resolved. One approach tries to develop substantive principles or theories that can be applied to such conflicts. In health care, for instance, principles such as respecting autonomy and doing no harm are often taken to be at the heart of biomedical

32. "What Humans Owe to Animals," *The Economist*, August 19, 1995, p. 11.

33. Douglas J. Amy, "Why Policy Analysis and Ethics are Incompatible," *Journal of Policy Analysis and Management* 3 (1984): 575.

ethics.[34] However, such principles may not yield a ready answer to a complicated moral problem, or people may disagree about which principles should be applied or take priority.

In such situations, which are quite common, a procedural approach to ethical questions may be taken. Because no unambiguous answer can be determined, the demand for acting ethically may be satisfied by setting up a defensible procedure for arriving at an answer. But not just any procedure will do. As we shall see, defensible procedures must themselves embody certain values or principles, and the fact that they do so must be acknowledged.

2.2. Basic Forms of Ethical Argument

At the risk of oversimplifying, we borrow from earlier work by the authors and others to classify ethical arguments in terms that reflect the two dominant traditions (although not the only two traditions) in Western moral philosophy.

One tradition holds that actions can be judged intrinsically right or wrong — that is to say, right or wrong in principle. Such arguments characteristically appeal to duties, obligations, rights or principles in virtue of which an activity is right or wrong, independent of whatever good or bad consequences it produces.[35] Even if the activity would lead to a net balance of benefits over harms or costs, however one wishes to define these, it nevertheless would be wrong, in this view, if an important moral duty, obligation, right or principle were violated. Such arguments are often referred to by philosophers as **deontological**, and "if deontological theorists are right, they can establish the moral status of human activities — such as genetic engineering — quite independently of the expected consequences of those activities."[36] Objections to modifying human germ cells on the ground that the genetic material transmitted between human generations should be regarded as sacred or inviolable illustrate claims about the incompatibility of at least some forms of biotechnology with a basic moral principle, and thus their intrinsic wrongness.[37]

The other tradition assesses an activity with reference to the nature of its consequences. Within philosophy, the most familiar **consequentialist** position is utilitarian. According to this perspective, the action that is right is the one that produces the greatest good for the greatest number. The attempt to apply cost–benefit or risk–benefit analysis to various kinds of public policies is a familiar and much-criticized variant of utilitarianism. Among the

34. See section 2.3, *infra.*

35. An excellent discussion of the character of such objections to biotechnology is provided in Ministry of Agriculture, Fisheries and Food, *Report of the Committee to Consider the Ethical Implications of Emerging Technologies in the Breeding of Farm Animals* (London: HMSO, 1994), p. 12 (para. 3.2).

36. Matti Häyry, "Categorical Objections to Genetic Engineering — A Critique," in *Ethics and Biotechnology*, edited by A. Dyson and J. Harris (London: Routledge, 1994), p. 202.

37. Another example from the agricultural context is provided by MAFF, *supra* n. 35, pp. 12–13 (paras. 3.4–3.9). For a sceptical analysis of such claims, see Häyry, *supra* n. 36, pp. 205–09.

frequent grounds for criticism are: the presumption in cost–benefit analysis that all benefits and harms can be valued using a single framework and a single (monetary) denominator, implying in effect that everything is for sale; the implicit choice of (economic) efficiency as the only value to be maximized; and the fact that discounting has the effect of making even catastrophic future consequences appear insignificant.[38]

Arguments about consequences should not suffer from guilt by association with this particular (mis)application. They need not be strictly economic in content or utilitarian in form. The consequences taken into account may be environmental, social or even spiritual, depending upon the criteria used to define, identify and measure benefits and harms; adopting a consequentialist perspective does not mean accepting the claim that consequences can be compared using any single quantitative measure. In fact, debates about the appropriate basis for comparison illustrate that all arguments about consequences presuppose an existing moral background. When we decide, as individuals or as a society, what is to count as a beneficial or a harmful consequence of a particular policy, we rely on an existing set of values or ethical commitments — for instance, to justice, fairness or the avoidance of suffering. Simply pointing to a particular set of consequences of a policy does not itself constitute an ethical argument. So, for example, even if we could demonstrate convincingly that allowing patents on genetically engineered laboratory animals would lead to increased use of laboratory animals in painful experimental procedures, and therefore to increased animal suffering, someone who did not attach ethical importance to the prevention of animal suffering might simply reply: so what?

Most ethical reasoning in practice combines the two forms of argument. The question of who benefits from a particular policy, and who is harmed by it is often taken to be at least as important, in ethical terms, as the overall quantum of benefit. Policies that harm the vulnerable may be presumed ethically unacceptable even if they deliver important potential benefits to the advantaged, although the presumption is not absolute. Conversely, fairness and distributive justice may be pursued as elements of public policy, but usually not at all costs; the tradeoff between equity and efficiency in economic policy is one common example. Despite the Roman maxim, there are sometimes good reasons for not pursuing justice if doing so would cause the heavens to fall.[39]

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38. Among the many worthwhile critiques of cost–benefit analysis are Kenneth T. Bogen, "Quantitative Risk–Benefit Analysis in Regulatory Decision Making," *Journal of Health Politics, Policy and Law* 8 (1983): 120–43; Nicholas Rescher, "Economics versus Moral Philosophy: The Pareto Principle as a Case Study," in *Unpopular Essays on Technological Progress*, by Rescher (Pittsburgh: University of Pittsburgh Press, 1980), pp. 69–78; Ted Schrecker, *Political Economy of Environmental Hazards*, Study Paper, Protection of Life Series, Law Reform Commission of Canada (Ottawa: Law Reform Commission of Canada, 1984), pp. 39–58; Ted Schrecker, "Risks versus Rights: Economic Power and Economic Analysis in Environmental Politics," in *Business Ethics in Canada*, edited by D. Poff and W. Waluchow (Scarborough: Prentice-Hall, 1987), pp. 265–84.

39. An extreme and particularly troubling example arises in countries that have recently undergone a transition from authoritarian rule to democracy, but in which the commitment of key segments of the society to democratic institutions is still fragile. In some such situations, refusal by the new political leadership to grant amnesty for the vicious acts of state officials during the authoritarian period would almost certainly precipitate a coup leading to the

The distinction between forms of argument is not just an academic one; it is important in public policy for at least two reasons.

First, it helps to clarify what is being endorsed or objected to in the sometimes heated public policy debates about biotechnology.

Second, objections to the consequences of particular applications of biotechnology can be answered by demonstrating that the anticipated negative consequences are factually implausible, or else can be mitigated. If mitigation measures can reliably and effectively be put in place, the ethical force of the objection is reduced. This is not true of claims that a particular practice is intrinsically wrong. As one philosopher observes: "One valid deontological objection against gene technology would be enough to put all consequentialist moralists out of business in this field."[40]

Although important, the distinction between forms of ethical argument does not supply us with content. We still need what might be called the raw material for defining our rights, duties and obligations, or for deciding what kinds of consequences should count as beneficial or harmful. The author of a key background document for the RCNRT identified a need for "mid-level principles"[41] that will provide such raw material. The next section of the report outlines how such principles have been developed and applied with reference to decisions about ethics in clinical and medical research settings.

2.3. Biomedical Ethics as a Case Study

The branch of philosophy known as applied ethics has to do with the interaction of general philosophical principles with concrete social, economic and policy issues. Biomedical ethics is probably the area of applied ethics which has been most extensively tested against the day-to-day realities of the situations to which it claims to be relevant.

At least in North America, biomedical ethics arose in response to a series of ethically troubling situations. One of these was the operation of Seattle's Swedish Hospital's Admissions and Policies Committee (the so-called God Committee). This body of seven people, none of them medical professionals, was established in the early 1960s to decide "which one patient out of 50 [would] be permitted to hook up to Seattle's life-giving

reinstitution of authoritarian rule. See Adam Przeworski, "Some Problems in the Study of the Transition to Democracy," in *Transitions from Authoritarian Rule: Comparative Perspectives*, edited by G. O'Donnell et al. (Baltimore: Johns Hopkins University Press, 1986), pp. 47–63.

40. Häyry, *supra* n. 36, p. 202.

41. Will Kymlicka, "Approaches to the Ethical Issues Raised by the Royal Commission's Mandate," in *New Reproductive Technologies: Ethical Aspects*, Research Studies of the Royal Commission on New Reproductive Technologies, vol. 1 (Ottawa: Supply and Services Canada, 1993), pp. 15–16.

[dialysis] machines, and which should be denied."[42] At the time, dialysis treatment for kidney failure was both scarce (only a few hospitals in North America had the machines) and extremely costly; it was this scarcity that created the necessity for the "tragic choices" made by the committee.[43] Theoretically, the committee's work is important because it illustrates the importance of process and locus of decision making in resolving extremely difficult ethical issues. Politically, the committee's work became important not only because of the dramatic, life-and-death character of the decisions it made, but also because of the visibility that followed a high-profile journalistic account of its deliberations. Partly as a consequence of the continued advance of high-technology medicine, such issues of life and death have multiplied in recent years, and promise to continue to do so.[44]

Another set of issues, which contributed more directly to the institutionalization of biomedical ethics, arose because of public concern about research on human subjects. A 1966 article in the *New England Journal of Medicine* documented 22 examples of postwar medical experiments in the United States that had exposed human subjects to hazards about which they had not been informed, or about which they had been actively misled.[45] Subsequent revelations of other such abuses included the infamous Tuskegee syphilis experiment, in which African-American men were left untreated as a way of studying the disease's progress. The eventual result, after U.S. Senate hearings in which some members of the medical and scientific communities expressed bitter opposition to any external oversight of the ethics of experimentation, was legislation establishing (in 1974) an advisory National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. In the words of David Rothman, the commission's establishment "made apparent that the monopoly of the medical profession in medical ethics was over. The issues were now public and national — the province of an extraordinary variety of outsiders."[46]

The commission's 1978 *Belmont Report* set out respect for persons, beneficence (defined as the obligation both not to do harm and to "maximize possible benefits and minimize

42. Shana Alexander, "They Decide Who Lives, Who Dies," *Life*, November 9, 1962, pp. 102–25. For a discussion of the impact of this article and of similar situations, see David J. Rothman, *Strangers at the Bedside* (New York: Basic Books, 1991), pp. 148–67.

43. Guido Calabresi and Philip Bobbitt, *Tragic Choices* (New York: Norton, 1978), pp. 186–89.

44. See among many other sources Renée C. Fox, "The Entry of U.S. Bioethics into the 1990s: A Sociological Approach," in *A Matter of Principles? Ferment in U.S. Bioethics*, edited by E. DuBose et al. (Valley Forge, PA: Trinity Press International, 1994), pp. 21–71; Margaret A. Somerville, "Introduction: Reproduction, Technologies and Human Rights," in *Human Rights in the Twenty-First Century*, edited by K. E. Mahoney and P. Mahoney (Dordrecht: Kluwer, 1993), pp. 873–74.

45. Henry K. Beecher, "Ethics and Clinical Research," *New England Journal of Medicine* 74 (1966): 1354–60. For a discussion of the background to this article's appearance and its subsequent impact, see David Rothman, *Strangers at the Bedside* (New York: Basic Books, 1991), pp. 70–100.

46. Ibid., p. 189; on the events that culminated in the establishment of the commission, see generally pp. 148–89.

possible harms") and justice as the basic principles that should guide research ethics.[47] In the following year, the first edition of what is probably the most widely used text on biomedical ethics, *Principles of Biomedical Ethics*, was published by philosophers Tom Beauchamp and James Childress. (Beauchamp had been on the professional staff of the National Commission.) The text is now in its fourth edition,[48] and has continued to be organized around a set of principles (or in their most recent formulation, "clusters of principles") fundamentally the same as those in the *Belmont Report*: respect for autonomy; non-maleficence (not doing harm); beneficence; and justice.[49] These are now widely applied in both research and clinical settings:

> Rapid general acceptance of this theoretical framework brought with it a sense of unification and definition for what was then a disparate and adolescent field struggling to identify itself. Synoptic versions of the theory became the standard fare in introductions for the most popular textbooks in bioethics; and it served repeatedly as the theoretical framework for various influential government reports in Canada, the U.S. and elsewhere.[50]

Although these have become identified as the core principles of biomedical ethics, they are mid-level principles in the sense that their application does not depend on the resolution of such basic philosophical issues as the relative merits of deontological and consequentialist forms of ethical argument. Across a broad range of situations and conflicts, these two forms of argument will both support the same mid-level principles, although not ultimately for the same reasons.[51] This convergence will not necessarily occur in other areas of applied ethics; indeed there are reasons to suspect that in some controversies related to biotechnology, different forms of argument will yield quite different conclusions. It is also important to emphasize that biomedical ethics in continental Europe is generally less individualistic in orientation, and more concerned with group or community values. In developing countries where resource scarcities are an omnipresent constraint on health care provision, yet another kind of balancing of individual and community interests is encountered.

Even in North America, there are problems in applying these mid-level principles.

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47. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Washington, DC: Department of Health, Education and Welfare, 1978). For discussion of these principles and how they have evolved in the intervening years see Charles Weijer, "Evolving Ethical Issues in Selection of Subjects for Clinical Research," *Cambridge Quarterly of Healthcare Ethics* 5 (1996): 334–45.

48. Tom L. Beauchamp and James F. Childress, *Principles of Biomedical Ethics*, 4th ed. (New York: Oxford University Press, 1994).

49. Ibid., pp. 37–38, 120–394.

50. Earl Winkler, "Reflections on the Relevance of the Georgetown Paradigm for the Ethics of Environmental Epidemiology," *Science of the Total Environment* 184 (1996): 114.

51. Beauchamp and Childress, *supra* n. 48, pp. 109–11.

First, none of them can be regarded as binding in all cases, particularly because clinical situations in which two or more of these core principles conflict are relatively common. According to Beauchamp and Childress, each principle is best regarded not as absolute, but rather as *prima facie* binding — in other words, binding in the absence of more compelling moral considerations involving a competing principle.[52] However, situations in which there is no relevant competing principle are the exception, rather than the rule: this sort of tension is characteristic of applied ethics in general, and is not unique to biomedical ethics.

Second and more important, without further elaboration, these principles are often still too abstract to be directly useful in actual clinical contexts. If there is no disagreement on such principles such as respect for autonomy, the way in which they should apply to particular cases is not self-evident. In other words, there is "a crucial 'application gap' between general norms and specific facts. . . ."[53] Even in the presence of agreed-upon principles, we face "the problem of determining the morally relevant features of the world."[54] In bringing mid-level principles to bear upon an issue, judgment and interpretation on the part of the relevant decision maker(s) are involved.

Thus the principle of autonomy (for instance) does not itself supply criteria for deciding when patients' choices about treatment are genuinely autonomous, when consent to treatment can meaningfully be called voluntary and informed, or what mental or emotional states render individuals incapable of informed consent. Similarly, the principle of justice is, in and of itself, of limited usefulness with respect to specific allocations of health care resources at both the micro-level (for example, choosing among candidates for organ transplants) and the macro-level (for example, deciding what proportion of society's resources should be devoted to health care; deciding how many services, of what quality, should be covered by public health insurance) without supplementary criteria for distinguishing just from unjust allocations of resources. These are not factual questions answerable on the basis of further research; the task of answering them itself involves value judgments and interpretations.

Some academic writers now argue that such problems reveal the basic weakness of "principlism" in biomedical ethics.[55] We are too concerned, say the critics, with fitting situations to principles, and are not concerned enough with the specifics of individual situations. In response to such comments, Childress notes that their application was never intended to be mechanical or formulaic. It is a two-way, interactive process, one that is sensitive to the specific context, rather than one that proceeds rigidly from the general to the specific. Childress further suggests that most critics of principlism are not genuinely calling

52. Ibid., pp. 32–37.

53. C. Barry Hoffmaster, "Morality and the Social Sciences," in *Social Science Perspectives on Medical Ethics*, edited by G. Weisz (Dordrecht: Kluwer, 1990), pp. 242–43.

54. Ibid., p. 245.

55. See generally DuBose et al., eds., *supra* n. 44.

for an abandonment of a principled approach to biomedical ethics in favour of one, which presumes that defensible solutions in morally troubling situations will arise out of the features of the particular case.[56] Rather, they are calling for a richer, more context-sensitive and culturally aware approach to integrating principles with the actual situations confronted by health care providers, patients and their intimates, and policy-makers.

Fortunately, acknowledging the importance of these and other considerations does not require abandoning the effort to achieve a principled resolution of troubling ethical situations. As Childress says:

> The fundamental question is not whether to invoke principles and rules in the identification, interpretation and resolution of moral problems. . . . The legitimate and perplexing questions surround which principles and rules should be adopted, how they can be justified, how they should be interpreted and specified in particular cases, how they should be modified in light of particular cases, how much weight and strength they should have, which should have priority if they conflict in particular circumstances, and what significance they have in various contexts and relations. . . .
>
> Answers to those questions are not easy, or uncontroversial, but seeking the answers in the context of science, medicine and health care remains a fundamental responsibility in biomedical ethics.[57]

The case for refining, rather than abandoning, a principled approach is even stronger outside the clinical context. Considerations of fairness in public policy strongly suggest a requirement that similar cases and issues be treated consistently, although such matters as the criteria of similarity and the strength of the consistency requirement are likely to be contested, as they should be.

When multiple levels of society, groups and institutions become involved, each one articulating both distinctive ethical claims and distinctive interests, there is a particularly strong requirement for an intellectually rigorous yet fluid set of guidelines or principles. Those principles need not be accepted by everyone, but they must at least be generally understandable and consistent, in the sense that they imply broadly similar procedural approaches to dealing with similar cases, and provide a candid or "transparent" definition of why some cases are considered different from others. *What cannot be defended is an approach to public policy that simply says, in effect: well, that's just the way things are*, or: that's what elected officials have decided so the debate is now closed. A particular action may be legal, but this does not mean that it is ethically necessary, or even permissible: even legislation does not necessarily close ethical debate.

For example, it is frequently observed that the amount industrialized societies are prepared to spend to protect a single human life, whether through regulation or public expenditure,

56. James F. Childress, "Principles-Oriented Bioethics: An Analysis and Assessment from Within," in Ibid., pp. 72–98.

57. Ibid., p. 95.

varies by several orders of magnitude depending on the context.[58] Here we are back to the example of highway design. Many such variations can and should be justified with reference to morally relevant differences among the contexts being compared. This is not always an easy task. With respect to "tragic dilemmas" in which societies cannot live up to all their possible commitments to protect human life because of resource scarcities of one sort or another, Calabresi and Bobbitt point out that the search for principles for making such choices may be sometimes unstable, involving recurrent shifts among policies each of which is only provisionally acceptable. However, the search cannot be abandoned;[59] doing so would constitute a socially destructive denial of the importance of the issues at stake. Moreover, engaging in the search in good faith is to engage in "doing ethics."

2.4. Evaluating Ethical Positions: Dealing with Uncertainty

Both supporters and opponents of biotechnology invoke the findings of natural and social science in the course of making ethical arguments. In order to develop regulatory policy to guide the use of genetically modified crop varieties, we need to understand (among other things) the possible mechanisms through which such varieties could become weeds or serve as conduits through which new genes move to wild plants and modify their characteristics in undesirable or unpredictable ways.[60] Factual evidence from the social sciences as well as the natural sciences may be of importance. For example, supporters of patent protection for biotechnological innovations often argue that patenting is necessary if society and the economy are to realize the beneficial results of research that requires long-term financial and intellectual investment.[61] In principle at least, this claim is subject to empirical investigation and, if it cannot be supported, the validity of the argument based on it is called into question, even if one agrees that the results of such research are beneficial.

Getting the facts right is always important, but it is often not enough to resolve ethical questions, for several reasons.

First, the distinction between facts and values is not always as clear as it might seem; the facts we generate are shaped by the values we have and the questions we ask. Human genome research, for example, is seen by some commentators "as influencing not only the

58. Calabresi and Bobbitt, *supra* n. 43, pp. 40–41; Margaret A. Somerville, "Justice Across the Generations," *Social Science and Medicine* 29 (1989): 388.

59. Calabresi and Bobbitt, *supra* n. 43, pp. 147–99.

60. James M. Tiedje et al., "The Planned Introduction of Genetically Engineered Organisms: Ecological Considerations and Recommendations," *Ecology* 70 (1989): 297–315.

61. This is not, we should emphasize, the only argument for patenting. For example, another argument is one from fairness to inventors, who in the absence of patenting (or other forms of intellectual property protection, such as copyright) might be unable to defend the results of their intellectual labour from unrestricted and uncompensated appropriation. Still another is that the legal protection extended under patent law in return for disclosure of findings is necessary to ensure that science does not become a closed, secretive competition among researchers who must independently duplicate each others' efforts in order to avoid such appropriation.

factual answers available to the decision-making process, but also the questions that are framed and the terms that are used in the debate."[62]

Second, sometimes agreement on the facts may actually intensify ethical conflict. One of the key arguments in support of extending patent protection to the products of biotechnology is that it provides a necessary incentive for investing in research, development and commercialization. For some critics of biotechnology, however, the speed of its diffusion *is precisely the problem*. If further research clearly established that patenting would lead to more and faster use of biotechnology and its products, at least one set of ethical disputes would only grow more intense.

Third and most importantly, uncertainty is pervasive in both natural and social science. In an ideal world, ethics would operate according to the axiom that: "Good law and good ethics must be grounded in good data."[63] However, good ethics is not impossible in the absence of adequate data. Indeed, ethical analysis is especially important because factual findings can seldom be stated with certainty, which requires choices about how to deal with the uncertainties.
The problem is familiar from numerous controversies in environmental policy and occupational medicine.[64] As an illustration, Thomas McGarity characterizes a variety of issues that come up routinely in the process of making regulatory decisions about toxic substances as "science policy" questions (Table 1). It is important to acknowledge, says McGarity, that "both scientific and policy considerations play a role in their resolution."[65] Policy makers commonly confront a need to make decisions based on incomplete facts, and do not have the luxury of postponing a decision.

62. Rachelle Cooper Dreyfuss and Dorothy Nelkin, "The Jurisprudence of Genetics," *Vanderbilt Law Review* 45 (1992): 315.

63. Michael Kirby, "Bioethics 89: Can Democracy Cope?" *Law, Medicine and Health Care* 18 (Spring–Summer 1990): 5.

64. Thomas D. Crocker, "Scientific Truths and Policy Truths in Acid Deposition Research," in *Economic Perspectives on Acid Deposition Control*, edited by T. D. Crocker, Acid Precipitation Series vol. 8 (Boston: Butterworth, 1984), pp. 66–67; John Lemons, ed., Scientific Uncertainty and Environmental Problem Solving (Cambridge, MA: Blackwell Science, 1995); Thomas O. McGarity, "Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions," *Georgetown Law Journal* 67 (1979): 729–49; Talbot Page, "A Generic View of Toxic Chemicals and Similar Risks," *Ecology Law Quarterly* 7 (1978): 207–44; Ted Schrecker, *The Pitfalls of Standards*, P86-4E (Hamilton: Canadian Centre for Occupational Health and Safety, 1986), pp. 6–13; Barbara Taylor and Tim Gerrodette, "The Uses of Statistical Power in Conservation Biology," *Conservation Biology* 7 (1993): 489–500.

65. McGarity, *supra* n. 64, p. 732.

Table 1. A Typology of Science Policy Issues

- Trans-scientific issues, which are resolvable by scientific methods in theory but not in practice given such constraints as intrinsic limits to sample sizes and finite resources for experimental work. In these cases, "a regulator must make a subjective, or policy-dominated decision. Moreover, the very nature of such trans-scientific issues deprives a regulator of any legitimate excuse for delaying a decision. . . ."
- Decision making based on incomplete scientific data. In such cases, although further research might resolve the relevant uncertainties, "a regulator should weigh the costs and benefits of delaying a decision until the research required to resolve the issue can be completed," including in this balancing such factors as the health damage that could be done meanwhile and the reversibility of the harms involved. It must be recognized that "to the extent that the costs and benefits of delay are uncertain, the decision whether to decide must be policy dominated."
- Varying scientific interpretations, for example, of the nature of the lesions observed in experimental animals.
- Disagreement over inferences, for example the validity of conclusions about carcinogenicity in human beings based on bioassay results.

Source: Thomas O. McGarity, "Substantive and Procedural Discretion in the Administrative Resolution of Science Policy Questions," *Georgetown Law Journal* 67 (1979): 732–47.

McGarity's distinctions were developed with specific reference to the regulation of health and safety hazards, although science policy issues are by no means confined to this area of public policy. Wherever they arise, they generate a further set of practical and institutional questions:

- How much evidence is enough? (The standard of proof)
- Who should have to produce it? (The burden of proof)
- Who makes the final decision? (The locus of decision making)

The way each category of decision is made within government itself reflects particular values and particular ethical commitments that may vary depending on the jurisdiction, the policy field, and the issues at stake. Very often, those values and commitments are "embedded" in the design of decision-making institutions. They are not stated explicitly, but nevertheless have a powerful influence on the outcomes that emerge.

A classic illustration of this point is how values structure procedures in the criminal trial process. Common-law countries generally require proof beyond a reasonable doubt (standard of proof) and require the prosecution to bring forward evidence of guilt, rather than requiring defendants to prove their innocence (burden of proof). This choice reflects the deeply held conviction that because the consequences of a criminal conviction are so

serious, the chances of convicting an innocent defendant should be guarded against even if doing so means letting a substantial number of guilty ones go free.[66]

Determining where the burden of proof rests can significantly affect the outcome of an issue. It is, therefore, important to recognize that the burden of proof is established by

> . . . the *initial presumption* from which our decision making commences or ought to commence. These presumptions are of two kinds: "yes . . . but" or "no . . . unless." For instance, "yes," single women ought to be given access to AID [artificial insemination using donor sperm], "but" there may be exceptions to, or conditions precedent to such access. Alternatively, "no," single women ought not to be given access to AID, "unless," for example, they are living in a stable relationship with a man. The choice of the initial presumption is not neutral in terms of decision outcome. This is so because the persons challenging the initial presumption will have the burden of proving that it should not apply. . . .[67]

There are direct parallels in the regulatory context, and since the factual issues at stake are seldom as unambiguous as the ones in the example just quoted, questions not only about the burden of proof but also of standard of proof (how much evidence is enough) become critically important.

For purposes of health and safety regulation, we sometimes take for granted that the burden of proof should be on the applicant for approval (say, of a new pesticide) to demonstrate that it presents no hazard to public health. It is less well understood that considerations of standard of proof and burden of proof interact in such situations, because waiting for more evidence before making a decision is itself a decision.[68] When the burden of proof is on regulators, waiting for more evidence before taking action to restrict the sale of a product or the operation of a process implies that the risks associated with whatever uncertain level or kind of damage might be done while waiting for that evidence are acceptable, at least pending resolution of the evidential issues.[69] When, as in the case of recombinant bovine somatotropin, the burden of proof is on the applicant to demonstrate safety, adhering to a high standard of proof with respect to the lack of adverse effects may lead to delays that are thoroughly frustrating to the applicant, but necessary to ensure the protection of public health or environmental quality.

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66. Page, *supra* n. 64, p. 220. This is not a view whose ethical merits are self-evident. If all we are concerned about is deterring others from committing crimes (what criminologists call general deterrence), we could often achieve this objective just as effectively by making an example of innocent defendants, as long as their guilt were authoritatively pronounced. However, we believe most, if not all, Canadians would recoil from the evils of such a ruthlessly pragmatic approach.

67. Margaret A. Somerville, "Weaving 'Birth' Technology into the 'Value and Policy Web' of Medicine, Ethics and Law: Should Policies on 'Conception' be Consistent" *Nova Law Review* 13 (1989): 539 [emphasis added].

68. Stephen Jellinek, "On the Inevitability of Being Wrong," in *Management of Assessed Risk for Carcinogens,* edited by W. Nicholson, *Annals of the New York Academy of Sciences* 363 (New York, 1981): 43–47.

69. One environmental economist has talked about a "cigarette company standard of proof" in cases of environmental contamination, invoking the analogy of the tobacco industry's long-standing claim "that the etiology of cigarette smoking and lung cancer has not been 'scientifically demonstrated.'" Crocker, *supra* n. 64, pp. 66–67.

The key point here is that, although scientific evidence is crucial to the decision-making process, choices about burden of proof and standard of proof are just as important. *As in the example of the trial process, those choices cannot be made on scientific grounds alone. They involve an ethical component, and must be examined and justified on that basis.*

Like the way in which initial presumptions are specified, the locus of decision making can affect outcomes in a variety of ways; some are obvious and others less so. To go back once more to our example of the criminal trial, it is axiomatic that in jury trials questions of fact are to be decided by the jury, who are instructed by the judge on issues of law. However, whether a charge is to be heard by a judge alone or by a jury is itself a choice of considerable importance.[70] Quite apart from the criminal justice system, in the U.S. political and legal system, many kinds of policy decisions ultimately end up in the courts. Increasingly, this is true of Canada as well. The result, according to some observers, is an adversarial approach in which important questions of scientific fact fall by the wayside.[71] On the other hand, the adversarial scrutiny provided in the courts can sometimes reveal the values implicit in, for instance, the way regulatory agencies have dealt with scientific uncertainty. It is also the case that judges cannot be (or, at least are not supposed to be) lobbied through the offering of mutually advantageous exchanges. In this respect they are quite unlike legislators, which leads some commentators to regard the resolution of complex policy issues by the courts as undemocratic, and others to regard such resolution as a last hope for those without the political resources to engage in effective lobbying.

Other examples also illustrate the importance of the locus of decision making. It can make a great deal of difference whether decisions about the ethics of particular research directions are made by committees of professionals and "experts," or by panels with significant participation from the broader community. Other important factors include the relationship of such panels to funding agencies, and the question of whether their recommendations are advisory or binding. And as suggested earlier, it can also make a difference whether the department of government responsible for a particular decision is (for instance) mandated to promote human health or mandated to promote the interests of a particular industry.

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70. In Canada, many criminal charges (those of a less serious nature, punishable on summary conviction) are automatically heard by a judge sitting alone; this fact embodies an important and seldom recognized judgment about the appropriate locus of decision making in those cases. Historically, the reluctance of juries to convict in certain kinds of criminal cases has been a significant form of political resistance in situations where the option of trial by jury could not be avoided under existing statute and common law; see e.g. Douglas Hay, "Property, Authority, and the Criminal Law" in *Albion's Fatal Tree*, edited by D. Hay et al. (New York: Pantheon, 1975), pp. 17–63.

71. See e.g. Joan Bertin and Mary Sue Henifin, "Science, Law, and the Search for Truth in the Courtroom: Lessons from *Daubert v. Merrell Dow*," *Journal of Law, Medicine and Ethics* 22 (1994): 6–20.

2.5. Evaluating Ethical Positions: A Conceptual Tool Kit

> Ethics is more than a matter of individual conscience, although this is essential: it is the systematic application of informed, structured and disciplined discernment to analysis of situations in relation to the ethical issues they raise and to decision making in these situations.[72]

It is crucial that facts be accurate and accurately stated, and that uncertainties be explicitly acknowledged and addressed. It is also crucial that people making ethical arguments be clear about the principles or values they are applying, and about **why** they are relevant to the case under discussion. This does not mean that there are "right answers" to many of the questions that arise in applied ethics. It does mean that some ways of going about answering ethical questions are better than others.

How can we decide about this — or, to put the matter another way, what kind of tools can we use to identify weaknesses in ethical arguments? First, they must **be** logically valid arguments. They must not contain internal inconsistencies (claims about facts which are mutually exclusive) or errors in logic. As noted earlier, simply identifying consequences does not constitute an argument. Even when they are consequences the ethical significance of which everyone accepts in principle, more usually needs to be said.

For instance, in the recent debate over repealing national highway speed limits in the United States, it was sometimes claimed that "states should not be permitted to raise speed limits because if they do, lives will be lost." Assuming for the sake of argument that this statement about consequences is factually accurate, it is not a valid argument without further elaboration, as ethically appealing as the notion of saving lives may be. Lives were arguably being "lost" by not setting and enforcing speed limits lower than the ones currently mandated, and of course by not regulating a variety of behaviours more aggressively, on the road and elsewhere. Missing is a premise or a set of premises (really, a subargument) sufficient to establish claims such as (a) that the fatality levels associated with today's speed limits are acceptable, or (b) that **any** measure that would have the effect of increasing fatalities, other things being equal, is unjustifiable.

Other logical errors to be avoided include the fallacy of composition, which involves generalizing from the attributes of parts of a whole, or individual elements of a collection, to the attributes of the whole or the entire collection; the fallacy of division, which involves reasoning from the attributes of the collection or the whole to the attributes of individual members or units; and the attempt to infer causation from correlation without adequate and

72. Margaret A. Somerville, "Societal Concerns and Reaction to Biotechnology," address to AFPC 50th Anniversary Pharmaceutical Biotechnology Conference, Vancouver, August 1993 (Montreal: McGill Centre for Medicine, Ethics and Law), p. 22.

plausible specification of the intervening steps or causal mechanisms, and without consideration of alternative explanations.[73]

Apart from ensuring both the factual correctness and the logical soundness of ethical arguments, the compatibility of the conclusions they generate with our moral intuitions, or "our deepest, pretheoretical moral convictions (ones which are not psychologically suspect),"[74] also should be considered. Ethical conclusions cannot be rejected simply because they are theoretically troubling or practically inconvenient. To do so would mean abandoning most kinds of ethical inquiry, certainly ethical inquiry in any form that promises to help resolve public policy conflicts. Moreover, asking about compatibility with sincere and considered moral convictions is a way of checking that all the aspects of a situation that individuals deem morally relevant have been canvassed.[75]

Epistemic Mistakes

Ethical arguments also must avoid epistemic mistakes: inaccurate or misleading conceptions of what is really at issue in a particular situation. Transferring Raymond Geuss's analysis of ideologies to the analysis of ethical arguments, Hoffmaster outlines four categories of epistemic mistakes.

"One type involves mistakes about epistemic status, for example, thinking that additional scientific evidence could answer the question of when a fetus becomes a person."[76] Neither will such evidence alone resolve the issue of whether a new reproductive technology should be regarded as standard medical therapy. In the environmental policy context, thinking that additional scientific evidence will in itself answer the question of whether a particular pollutant presents an unacceptable risk is a common example of this epistemic mistake.

"A second is falsely believing that a social phenomenon is a natural phenomenon, for example, the belief that a woman's place is in the home because women as a matter of fact spend so much time doing housework"[77]; to this observation could be added, at least according to some philosophers and social scientists, a variety of claims about women's

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73. A particularly useful and succinct catalogue of common fallacies is provided in Sean O'Connell, *Dilemmas and Decisions* (Toronto: Harcourt Brace, 1994), pp. 35–51.

74. Donald VanDeVeer and Christine Pierce, "An Introduction to Ethical Theory," in *The Environmental Ethics and Policy Book*, edited by D. VanDeVeer and C. Pierce (Belmont, CA: Wadsworth, 1994), p. 15.

75. Examples from biomedical ethics suggest that the aspects of a situation regarded as morally relevant are not necessarily the ones that appear most significant to "outsiders": for example, prospective parents undergoing genetic counseling appear to be less concerned with the probabilities of giving birth to a "defective" child than they are about what the experience of raising such a child would actually be like. See Hoffmaster, *supra* n. 53, pp. 253–57 (citing research by Abby Lippman and F. Clarke Fraser); see also Zaner, "Experience and Moral Life," in DuBose et al., eds., *supra* n. 44, pp. 213–23.

76. Hoffmaster, *supra* n. 53, p. 252.

77. Ibid.

"natural" affinity for child-rearing. In evaluating public policy options, it is particularly important that we avoid the tendency to view patterns of activity or distributions of resources as natural when, in fact, they are socially generated.

"A third is falsely believing that the particular interest of a subgroup represents the general interest of a group, for instance, the belief that what is in the interest of doctors is in the interest of society."[78] An analogous presumption is that the interests of society are best served by policies that maximize the security of financial returns on investment in biotechnology . . . or, for that matter, by preserving the economic viability of the family farm under the rhetorical cover provided by ideals of self-sufficiency. Both claims **may** in fact turn out to be the case, but each needs to be examined carefully with reference to the societal values that are at stake.

"The fourth is mistaking self-fulfilling beliefs for beliefs that are not self-fulfilling. Two examples are beliefs concerning the abilities of mentally handicapped persons and beliefs about the abilities of patients to handle bad news."[79] Thus, if mentally handicapped persons are presumed to have limited availability to deal with the mechanics of daily living, then those around them, whether family or professional caregivers, are likely to act in ways that do not provide the opportunity to demonstrate the range of their abilities and may even discourage the people in question from demonstrating them.

To this list can be added a fifth epistemic mistake, one that may be particularly important in biotechnology debates: inferring the acceptability of new or contested social arrangements based on their resemblance to arrangements already in place that command either acceptance or acquiescence, without careful scrutiny of whether the existing arrangements being invoked are themselves defensible. This mistake occurs, for example, in arguments that germ-line modification to enhance desired characteristics of future generations is permissible because society already permits, and even encourages, parents to "improve" their children in various ways.[80]

This fifth kind of mistake, which Donald Brown has referred to as confusing the normal with the moral,[81] is similar to the second. However, the error lies not in confusing the socially constructed with the natural, but rather in unwillingness to question the defensibility of existing institutions and allocations of resources, and in an unexplained assignment of the burden of proof to those who would raise such questions. Arguing that

78. Ibid.

79. Ibid.

80. For an example of a defence of human germ-line modification that commits this mistake, see David Resnik, "Debunking the Slippery Slope Argument Against Human Germ-line Gene Therapy," *Journal of Medicine and Philosophy* 19 (1994).

81. Donald A. Brown, "Ethics, Science and Environmental Regulation," in *Social Conflict and Environmental Law*, vol. 2, edited by A. Greenbaum, A. Wellington and A. Baar (North York, ON: Captus Press, 1995), pp. 134.

biotechnology proponents should not have to demonstrate social benefit, because the proponents of other new technologies and the products derived from them do not have to do so, is another example. Perhaps the changing circumstances of human beings' relations with each other and the natural world mean that demonstration of social benefit should become routine.

Slippery Slopes[82]

Claims about "slippery slopes" are often encountered in discussions of biotechnology policy and intellectual property rights.[83] The thin edge of the wedge is an image that communicates the same idea: "a series of gradual steps from an acceptable to an unacceptable position, where it is difficult to determine the exact point at which the crucial transition is made."[84] Such arguments are especially common in discussions of human gene therapy, but they occur in many other contexts as well.

How can the soundness of slippery slope arguments be assessed?[85] First of all, they are only relevant to situations where the conduct or technology in question is **intrinsically** acceptable, but where there is fear that some of the applications that would be ethically unacceptable will probably or certainly occur if the conduct is permitted or the technology developed in any form.[86] With specific reference to the controversial aspects of human genetic engineering, Krimsky distinguishes a deterministic and a probabilistic form of such arguments: whereas the deterministic version holds that sliding down the slippery slope is inevitable, the probabilistic form says that it may be probable because (for instance) of "economic forces and professional motivation," but there is still room for human intervention to stop the slide down the slope.[87]

These categories help us classify slippery slope arguments, but are of limited use in assessing their individual strength or weakness. By contrast, political theorist Richard

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82. This section is adapted from earlier work on patenting higher life forms: Ted Schrecker, Carl Elliott, C. Barry Hoffmaster, E.W. Keyserlingk and Margaret A. Somerville, "Ethical Issues Associated with the Patenting of Higher Life Forms," a study for Industry Canada (London, ON: Westminster Institute for Ethics and Human Values, 1994). It is included here because of the frequency with which slippery slope arguments are invoked by some of the strongest critics of biotechnology, whether or not patenting is specifically at issue.

83. For example, Mauron and Thévoz have described European opponents of human germ-line modification as having "a view of technology where intended good and unintended evil, innocent experimentation and large-scale catastrophic consequences are connected by a tight network of 'slippery slopes.'" Mauron and Thévoz, *supra* n. 14, p. 650.

84. David Lamb, *Down the Slippery Slope: Arguing in Applied Ethics* (London: Croom Helm, 1988), p. vii.

85. For a detailed discussion see Ibid.; Wibren van der Burg, "The Slippery Slope Argument," *Ethics* 102 (1991): 42–65.

86. In other words, slippery slope arguments are always consequentialist in form, and only apply in situations where activities that are intrinsically wrong are not at issue.

87. Sheldon Krimsky, *Biotechnics and Society: The Rise of Industrial Genetics* (New York: Praeger, 1991), p. 163.

Vernon instead points out that to be sound, such arguments must "contain a genuine causal element linking the top of the slope with the bottom."[88] It may help to think of the process of searching for this causal element as looking for the lubricant that makes the slope slippery and deprives us of traction as we slide down it.

One such lubricant is what Vernon calls precedential force: the creation of precedents that will subsequently be applied in ways that lead to undesirable consequences.[89] However, precedent provides a credible lubricant only "when the action which we are to take runs the risk of being mistaken, by other people, as a precedent for other kinds of action, of an undesirable sort. It is a reminder about the 'frailty' of others."[90] This definition of a slippery slope thus has both logical and sociological elements. In a common-law legal system, in which decision making is explicitly organized around precedents, that frailty is arguably institutionalized: the rule of *stare decisis* can provide lubrication for the slide down the slippery slope, if the relevant precedents are liberally interpreted. However, there are moral and political precedents as well as legal ones. Having accepted a particular situation, people may view themselves as logically bound to accept a subsequent situation if its key elements seem relevantly similar. (Indeed, such consistency would seem to be the hallmark of acting on principle.) In some circumstances, stepping onto the slope itself may be viewed as the relevant precedential change: once a threshold is first crossed or a prohibition broken, its subsequent inhibitory power may be lost.

A second kind of lubricant is found in situations where "previous expenditures of effort are regarded as an investment that it would be costly to abandon,"[91] for any one of a number of reasons. The costs may be financial, political, or emotional. Governments that have made a commitment to support failing industrial enterprises, or to pursue unpopular wars like the U.S. campaign in Vietnam, may attempt to justify additional investments in the firm or the war with reference to the need to salvage some return on the financial or political resources already committed. Conversely, the prospect of sliding down a slippery slope can be invoked as a credible argument against initiating such ventures in the first place, when the ultimate costs in the event of failure may be substantial and the probability of success is uncertain.

A third, related type of lubricant is at work when particular actions or policies either create altogether new actors, or strengthen the commitment and expand the resources of existing ones. For example, granting patents on higher life forms may encourage investment of time and money in research based on anticipated commercial returns that could not be realized without patents. Researchers' desire to protect the returns on their investments of dollars

88. R. Vernon, "Slippery Slopes and Other Hazards," University of Western Ontario, London, February 1994, p. 18.

89. Ibid., p. 5.

90. Ibid., p. 7.

91. Ibid., p. 9.

and years might combine with the financial strength of the emerging industry to provide formidable opposition to regulatory measures that might be identified as justified at a later date. A version of this argument might be: Do we want to create the preconditions for the emergence of industries based, for instance, on the patenting of segments of the human genome?

Fourth and finally, the slope may be lubricated by:

> cumulative effects on our political culture: if we become accustomed to seeing government as a parenting institution in one area, will we not tend to lose our resistance to seeing it this way in other areas? If we inure ourselves to the toleration of some vices, will we not tend to lose our hatred of all vice?[92]

Even in retrospect, it is difficult to demonstrate the existence of this effect in a way that will convince sceptics. With reference to biotechnology, thinking about this lubricant suggests questions such as: if our society becomes accustomed to treating animals as protein factories, will we treat them in a similarly instrumental way in other contexts? This is the argument from commodification outlined in Chapter 5, and as noted there the fact that such questions are difficult to answer does not mean we should pay less attention to them.

For purposes of public policy, we need to ask whether the effects of the lubricant that makes the slope slippery can be offset — for example, by measures directed at preventing or mitigating the likely negative impacts in a particular situation? What can individuals, societies and governments use to put traction on the slippery slope, or to ensure that solid and reliable barriers are put up at certain points on the slope to indicate boundaries between the permissible and the impermissible? The barrier may, of course, be placed at the very top of the slope, corresponding to a situation in which **any** departure from a particular norm is impermissible. Even if this **could** happen, we must further ask whether it is reasonable to believe that it **will** happen, given what we know about the constellation of interests promoting the policies that created the prospect of the slippery slope in the first place.

Slippery slope arguments of all kinds must be distinguished from a number of superficially similar arguments, most importantly those about the cumulative effects of large numbers of seemingly insignificant or isolated decisions, which may be unanticipated and/or perverse. Each individual decision considered alone will appear rational and defensible, yet the combined effect of the decisions, which was neither planned nor necessarily anticipated, is inconsistent with particular societal values.[93] This is not a pure slippery slope argument, since no causal link between successive points on the slope is invoked. The claim, rather, is that decisions which are defensible viewed in a local or individualized context may be indefensible and even irrational when the society-wide impacts of large numbers of similar

92. Ibid., p. 18.

93. A legal analogy to this situation is the tort of nuisance. Although the noise or pollution created by one person would not constitute a nuisance, in combination with that contributed by other persons, the total may cross a threshold that renders each individual contributing to the problem legally liable.

decisions are taken into account. Many critiques (although not all) of medical interventions in human reproduction take this form.

Finally, the preceding discussion is concerned with the idea of a slippery slope as it is usually used: in situations where something ethically troubling is presumed to lurk at the bottom of the slope. However, this is not necessarily the only kind of slippery slope. As Thomas Nagel points out with respect to "the expansion of the concept of equality of opportunity," there can also be benign slippery slopes.[94] The logic of precedents may lead us to revise our conduct after examining familiar situations in new ways. Changes in law or public policy may shift the distribution of resources within a society, forcing hard looks at practices that have remained unchallenged. (For instance, both the *Charter of Rights and Freedoms* and various provincial statutes have given people confined to wheelchairs or otherwise physically challenged a resource they previously lacked.) "Cumulative effects on our political culture" can likewise be benign; they may lead us to hold our governments, or each other, to more demanding ethical standards than before.

2.6 Summary

At first glance, ethical choices appear to be involved in only a limited number of public policy decisions. However, a closer look reveals that the list is far longer than it appears at first. This point is underscored by several of the cases and controversies examined in Chapters 3 and 4. For this reason, it is particularly important to understand the basic forms of ethical argument and the ways in which claims about the ethics of particular situations can be evaluated. This understanding helps decision makers in government, as well as the general public, to deal with the claims and counterclaims to be found in controversies about biotechnology and its applications, and to understand why some people insist that ethical choices are involved in policy decisions when others insist that the issues are just factual, scientific or technical.

94. Thomas Nagel, *Equality and Partiality* (New York: Oxford University Press, 1991), p. 90.

3. Ethical Conflicts Raised by Biotechnology: An International Perspective

Biotechnology includes a diverse range of applications, some of which seem to have little in common. In order to provide as useful a guide as possible to the ethical conflicts given the limited time within which this report was prepared, we focus discussion in this chapter on three sets of applications: agricultural biotechnology; research and therapy based on expanding scientific knowledge of the human genome; and intellectual property rights in biotechnology. Each set of applications raises distinctive ethical questions, and some applications within each set have been ethically and politically controversial. Rather than providing an exhaustive chronicle of names, dates and places, we try to identify key issues that will help decision makers to understand similar controversies in the Canadian policy context.

3.1. Risk Assessment and Agricultural Biotechnology

One of the most frequently mentioned economic benefits of biotechnology involves improvements in crop plants, such as those designed to achieve more rapid growth, improved tolerance for adverse climatic conditions or insect-, disease- and herbicide-resistance. Without going into detail about the respective regulatory regimes in the U.S. and various European countries, it is essential to note that the debates over genetically modified plants involve two key issues with ethical dimensions. The first is the potential environmental hazards of the deliberate environmental release and commercialization of genetically modified plants. The second is whether transgenic plants (that is, plants that have been modified by incorporating into their genetic makeup one or more genes from another species) should be treated differently from other plants, in the sense of being subjected to greater levels of scrutiny and oversight.

Generally, the strongest critics of biotechnology argue that anything produced by genetic engineering should be regarded as suspect for regulatory purposes. The implicit, and often explicit, claim is that the physical risks associated with biotechnology are "different in kind or magnitude from risks created by 'natural' processes of genetic combination and recombination."[95] In the United States many environmentalists have called for "an indefinite moratorium on the commercialization of transgenic plants, particularly those engineered with natural and synthetic toxins for protection from crop pests and herbicides."[96] Outside North America, an example of the calls for a strict approach to transgenics can be found in the position of "a rainbow assortment of some 50 non-

95. Jasanoff, *supra* n. 29, p. 313.

96. Russ Hoyle, "EPA Okays First Pesticidal Transgenic Plants," *Bio/Technology* 13 (May 1995): 434.

governmental organizations from the Philippines."[97] These NGOs have opposed plans by the International Rice Research Institute (IRRI) of the Philippines to import transgenic rice that has been genetically modified by adding genetic material from the bacterium *Bacillus thuringiensis* (Bt), thus enabling the plant to produce its own insecticide. They called instead for "a stop of [*sic*] genetic engineering of plants" and "a moratorium on the transfer/importation of all genetically engineered organisms" until an international protocol on biosafety has been developed and implemented.[98]

Many researchers counter with the assertion that "there is no evidence of unique risks conferred by the use of the newer molecular techniques."[99] A 1987 white paper from the U.S. National Academy of Sciences concluded that: "Assessment of the risks of introducing rDNA-engineered organisms into the environment should be based on the nature of the organisms and the environment into which the organism is introduced, not on the method by which it is produced."[100] The U.S. National Research Council has stated that "no conceptual distinction exists between genetic modification of plants and micro-organisms by classical methods or by molecular techniques that modify DNA and transfer genes."[101] A report approved by the Executive Committee of the Ecological Society of America and released in 1989 concluded that "transgenic organisms should be evaluated and regulated according to their biological properties (phenotypes), rather than according to the genetic techniques used to produce them."[102]

Nevertheless, critics of biotechnology identify several areas of concern with respect to the risks presented by genetically modified plants.[103] These concerns include: the development of pests resistant to toxins in plants engineered for pest resistance; the disappearance of traditional and wild relatives of genetically engineered plants; and unknown effects of toxins like Bt on human health.[104] Thus, one worry is that crop pests will develop unintended resistance to the biological pesticides that are supposed to eradicate them.[105]

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97. Mima Predich and John Hodgson, "Rice and the Greenpeace Counterrevolutionaries," *Bio/Technology* 14 (1996): 140.

98. Ibid., p. 141.

99. Henry I. Miller, Suzanne L. Huttner and David W. Altman, "Misunderstanding Risk," Letter to Editor. *Bio/Technology* 14 (1996): 9.

100. Ibid.

101. *Field Testing Genetically Modified Organisms: Framework for Decisions* (Washington, D.C.: National Academy Press, 1989).

102. Tiedje et al., *supra* n. 60, p. 302.

103. See generally Jane Rissler and Margaret Mellon, *Perils Amidst the Promise: Ecological Risks of Transgenic Crops in a Global Market* (Cambridge, MA: Union of Concerned Scientists, December 1993), pp. 17–40.

104. Predich and Hodgson, *supra* n. 97, pp. 140–41.

105. Hoyle, *supra* n. 96, p. 434.

Another worry is the potential for genetic migration of the genetically engineered traits from the transgenic plants to wild relatives. Although endorsing a regulatory approach based on phenotypes rather than production techniques, the Ecological Society of America report nevertheless warned against the presumption that the characteristics of a genetically altered plant would remain unchanged except for those directly affected by the inserted gene,[106] and argued:

> Although the capability to produce precise genetic alterations increases confidence that unintended changes in the genome have occurred, precise genetic characterization does not ensure that all ecologically important aspects of the phenotype can be predicted for the environments into which an organism will be released.[107]

However, this is not necessarily a valid argument for a special type of risk assessment for transgenics, but rather for careful risk assessment along the same lines as for those novel traits introduced by conventional breeding techniques, with special reference to the uncertainties identified in this conclusion.

Herbicide tolerance has been the novel trait most frequently added by genetic modification, but others (quality improvements and enhanced resistance to insects, viruses, fungi and bacterial pests) are catching up.[108] As of May 1995, seven genetically modified plants (GMPs) had "been approved for unrestricted [as distinct from limited or controlled] trials: one is in the EU (herbicide tolerant tobacco); one is in Canada (herbicide tolerant flax); and five are in the U.S. (tomatoes with delayed ripening, oilseed rape with modified oil, virus resistant squash, and herbicide tolerant cotton and soybean)."[109] Also in 1995, the U.S. Environmental Protection Agency approved commercial use of insecticide-producing corn and potato plants, again using genetic material from *Bacillus thuringiensis*.[110]

The relative ease or difficulty of obtaining regulatory approval appears to be a key determinant of how many field trials are conducted in a given jurisdiction. The United States has had in place a fairly comprehensive system for reviewing and approving field trials for transgenic plants since 1987, and in August 1995 a change in the U.S. Department of Agriculture's procedures for evaluating proposed field tests of transgenic plants meant that most such trials can now be conducted following notification procedures only,[111] rather than undergoing the same detailed scientific review that occurs the first time field trials of a

106. Tiedje et al., *supra* n. 60, p. 300.

107. Ibid., p. 302.

108. Patricia Ahl Goy and John H. Duesing, "From Pots to Plots: Genetically Modified Plants on Trial," *Bio/Technology* 13 (1995): 454; Rissler and Mellon, *supra* n. 94, pp. 8–9.

109. Ibid., p. 458.

110. Hoyle, *supra* n. 96; Jeffrey Fox, "EPA Okays Bt Corn; USDA Eases Plant Testing," *Bio/Technology* 13 (1995): 1035–36.

111. Fox, Ibid., p. 1035.

particular transgenic variety are proposed. The effect will be to facilitate rapid trials leading to commercialization. The European Union adopted a common framework (Directive 90/220) for approval of GMP trials in 1990, but some member states "have still not enacted the corresponding national law,"[112] meaning that until full harmonization is achieved separate applications and approval processes are required for field trials of the same organism in multiple EU countries.[113] This is partly because of considerable country-to-country differences in the intensity and level of organization of opposition to biotechnology.

Researchers who work for two leading agricultural biotechnology firms (Ciba-Geigy Ltd, Seeds Division and Pioneer Hi-Bred) have reviewed the results of 391 European field trials up until the end of 1993, and report that in no case did a trial result indicate significant "high potential environmental impact," defined in terms of a high probability of gene transfer to wild relatives as well as a high probability that the transferred traits would confer survival and reproductive advantages on those wild relatives.[114] Probability of gene transfer "depends on the reproductive characteristics of the crop, the existence of sexually compatible wild relatives, the population density of these wild relatives, if any, in the vicinity, the presence of necessary vectors for pollen, and seed persistence."[115] For 91 percent of the trials, the researchers concluded that environmental impact of uncontrolled cultivation would be minimal or zero; in the remaining 9 percent, potential environmental impact was identified as low.[116]

Despite the number of trials done to date, and the positive reviews of the results, many critics remain unconvinced. For instance, Margaret Mellon and Jane Rissler argue that the data collected by the U.S. Department of Agriculture are of little value for risk assessment. They are sceptical of claims that the field test record provides strong evidence for the safety of genetically engineered crops, and contend that the reports of field tests did not pay sufficient attention to factors such as weediness, gene flow or the production of new viral strains. They blame the design of the tests for the inadequate results, and have proposed an alternative tiered testing protocol to produce what they deem to be meaningful test results.[117] This has not been a popular position with industry-oriented observers, who view

112. Ahl Goy and Duesing, *supra* n. 108, p. 457; for an earlier account of the internal EU politics surrounding the Directive, see Simon Shackley, "Biotechnology Regulation in Europe," *Bio/Technology* 9 (1991): 1056–61.

113. Ibid.

114. Patricia Ahl Goy and John H. Duesing, "Assessing the Environmental Impact of Gene Transfer to Wild Relatives," *Bio/Technology* 14 (1996): 40.

115. Ibid., p. 39.

116. Ibid.

117. Margaret Mellon and Jane Rissler, "Transgenic Crops: USDA Data on Small-Scale Tests Contribute to Commercial Risk Assessment," *Bio/Technology* 13 (1995): 96; see generally Rissler and Mellon, *supra* n. 94.

it as "a quixotic assault on transgenic plants" and an effort to reopen settled scientific issues for no demonstrable reason.[118]

Given our earlier discussion of science policy issues and the treatment of uncertainty, it is important to ask whether the key issues are scientific in nature, or whether they involve the value-driven choice about how much uncertainty with respect to the ecological effects of introducing genetically modified plants constitutes an acceptable environmental risk. Questions about acceptable risk are ultimately ethical questions, which should not and indeed cannot be answered on the basis of consensus among scientists.

Some similar issues emerge in the regulatory approaches taken in the United States and the European Union toward synthetic bovine somatotropin (rBST),[119] which provides an "imitation of the pituitary hormone that stimulates lactation in cows."[120] It enhances the natural metabolic process and "supplements the growth hormone produced by the cow on its own."[121] According to one commentator on the conflict as it unfolded in the United States, there are "virtually no biochemical or aesthetic differences between milk from cows treated with synthetic BST and cows relying only on natural hormone production."[122] Yet from the perspective of many critics of biotechnology and potential consumers, there is a difference. To use Jasanoff's categories, this perspective involves the apprehension of a potential physical (health-related) risk to consumers. In the category of social risks, the potential impact of the adoption of BST on the structure of the dairy industry is of concern to many people. Concerns about the welfare of the animals to which rBST is administered arguably bridge the two categories.

The simple story on rBST is that it was approved by the Food and Drug Administration (FDA) in the United States, but the European Union Agricultural Council implemented and then extended a moratorium on the commercial use of rBST. Only Great Britain and Denmark voted against extending the moratorium,[123] which continues to the end of 1999. Superficially at least, an important role appears to have been played in the European rBST debate by the European Group of Advisers on Ethical Implications of Biotechnology. This multinational advisory body, established in 1991, has no direct Canadian or U.S. counterpart. Its opinion on the ethical considerations associated with rBST identified four

118. Russ Hoyle, "A Quixotic Assault on Transgenic Plants," *Bio/Technology* 12 (1994): 236–37.

119. The "r" in rBST stands for recombinant, a term that refers to the method of production of the synthetic variant.

120. Christopher L. Culp, "Sacred Cows: The Bovine Somatotropin Controversy," in *Environmental Politics: Public Costs, Private Rewards*, edited by Michael S. Greve and Fred L. Smith (New York: Praeger, 1992), p. 47.

121. Ibid.

122. Ibid.

123. Mike Ward, "EU Agrees on Patents But Nixes BST for 5 Years," *Bio/Technology* 13 (1995): 212.

sets of ethical concerns: human health and safety; animal welfare; consumer choice; and biological diversity.[124] The Group's Recommendation was that:

> . . . the use of rBST to increase lactation in cows is ethically unobjectionable, and safe for both human and animals, provided that the following measures are adopted:
>
> 4.1 assurance should be provided that rBST-treated animals do not suffer *extreme* pain or even discomfort that is *disproportionate* to the human good expected from the use of the product;
>
> 4.2 treatment should be stopped when increased lactation of milk is associated with mastitis or other inflammatory reactions;
>
> 4.3 these reactions should be controlled through the application of simple hygienic measures or — if cured with antibiotics — the milk produced by the animals so treated should be banned from human consumption until the antibiotics are totally eliminated;
>
> 4.4 the level of somatic cells per millilitre of milk should not be higher than the concentration found in the milk thus far produced by high-yield lactation cows obtained through selective breeding;
>
> 4.5 if it becomes possible to distinguish milk derived from rBST-treated cows from other milk, then the vendors should be required to label it and its derivatives to allow free choice to the buyers.[125]

However, most commentators attribute the decision instead to political and socio-economic factors not officially considered by the Group of Ethical Advisers. They point out that in the past, "commission agriculture and environment officials . . . [have pressed] hard for socio-economic criteria to be applied routinely in the evaluation of biotech products."[126] Although that idea was rejected, the European Commission's (EC) farm commissioner has "argued that rBST is an exceptional case."[127] and the report of the moratorium in the journal *Science* stated flatly that: "The proposed ban has nothing to do with safety concerns. Instead, the [European] Commission wants to keep BST off the market because it could undermine the EC's efforts to reduce farm surpluses" by increasing milk production "enough to lead to the slaughter of 4% to 6% of dairy cattle in the EC, given current milk quotas."[128] However a representative for Monsanto Europe, the producer and marketer of rBST, claimed that the calculations on which the Commission based this conclusion were flawed.[129]

Interview research with a small sample of Dutch consumers on their attitudes toward rBST milk, carried out in the 1980s, provides a useful typology of attitudes toward rBST and the risks and benefits involved. The views expressed fell into four main groups:

- rBST is acceptable as long as it is safe and the milk tastes the same. A low price for milk is an added bonus.

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124. "The Ethical Implications of the Use of Performance-Enhancers in Agriculture and Fisheries," Opinion of the Group of Advisers on Ethical Aspects of Biotechnology (Brussels: European Commission, March 12, 1993), p. 3.

125. Ibid., p. 5 (emphases added to indicate possible sources of indeterminacy).

126. Ibid., citing Michael Balter, "How Europe Regulates Its Genes," *Science* 252 (7 June 1991): 1366.

127. Ibid.

128. Peter Aldhous, "Thumbs Down for Cattle Hormone," *Science* 261 (23 July 1993): 418.

129. Quoted in Ibid.

- rBST may be acceptable if it is safe and the milk has a pleasant taste but if the price difference is small this consumer prefers the tried and trusted product.
- rBST is not acceptable because it is unnatural; this consumer doubts that the product is harmless and would be prepared to pay more for milk without rBST.
- rBST is useless because there is already a milk surplus. Possible benefits are irrelevant.[130]

The first attitude corresponds to the reasoning of conventional risk–benefit analysis, whether carried out formally (by regulatory agencies, for example) or informally (at the supermarket shelf). Relevant factors are deemed to be the properties of the commodity itself, which are presumed to be determined scientifically, and the price.

The second attitude seems to express some uncertainty, which manifests itself in a kind of "splitting the difference" in the balance between risk and cost.

The third attitude incorporates concerns about risks to the natural or symbolic order. Note, however, that these latter kinds of risks are not automatically separable from concerns about health risks to the consumer; those who regard rBST to be unnatural are also likely to doubt its safety (to themselves). Their position does not invoke considerations of social justice, and could probably be accommodated by an expansive economic analysis (based on willingness to pay), although people may feel that more is at stake than their preference for the "natural."

The fourth attitude directly addresses value issues that are distinct from the welfare of milk consumers; it invokes broader distributional impacts and points to a concern about social justice. It may also be the case, however, that (at least in the case of smaller-scale milk producers) considerations of social justice and economic self-interest intermingle!

In the United States, where rBST was eventually approved, a similar debate occurred. Opponents of regulatory approval claimed that:

- milk and meat from rBST-treated cows might be unsafe for human consumption[131]
- rBST-treated cows would be more likely to get mastitis and would thus be treated with more antibiotics
- the widespread use of rBST would "increase milk production, depress milk prices, and result in diminished farm income, and hence, the failure of marginal 'family' farms."[132]

Some promoters argued that rBST would not have a significant negative impact on the industry. Others argued, alternatively, that it might have a negative impact on some small dairy farmers, but that they were inefficient and should not continue to be propped up

130. Hamstra, *supra* n. 20, p. 46.

131. See Samuel Epstein, "RBST: The Public Health Hazards," *The Ecologist* 19 (September/October 1989): 191–95.

132. Culp, *supra* n. 120, p. 52.

artificially in any case.[133] In this vein, a conservative critic of the campaign against rBST has flatly characterized it as "an effort, not to advance public interest, but rather to protect a small group of inefficient farmers from the market forces of competition."[134]

The FDA's Veterinary Medicine Advisory Committee, which focussed on safety issues rather than on issues of animal welfare, "concluded that, although rBST increases the incidence of mastitis when used to augment milk production by dairy cows, its use does not pose a significant risk to public health."[135] FDA Commissioner David Kessler said that "[t]here is virtually no difference in milk from rBST-treated and untreated cows."[136] In an unusual step,[137] the FDA published its own evaluation of the evidence (as of 1990) supporting its conclusions about the human health effects of rBST in the peer-reviewed journal *Science*.[138] Perhaps because of these findings, the campaign against rBST has focussed more on the consumer's right to know than on the potential health impacts. The FDA also issues voluntary labeling guidelines, which allow signs to indicate that dairy products were made from or consisted of "rBST-free milk." The guidelines were "intended to appease critics and inform consumers by allowing milk retailers to make a distinction in the marketplace that scientists were unable to make in the lab."[139] Retailers could say that milk from rBST-treated cows was different from milk from untreated cows, as long as they did not say that the former was worse.

Companies have been prompted to create a variety of niche or "boutique products," to give "a minority of consumers, uncomfortable with biotechnologically produced . . . [products] an alternative in the dairy marketplace."[140] However, one spokesperson from the industry says that "[t]he vast majority of consumers just don't seem to care one way or another about rBST-treated products."[141] Those who do care have the choice to buy untreated products. Consumers can also put their dollars behind their concerns about providing opportunities for small or family farms, which will be the most likely sources of the untreated products.

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133. Ibid.

134. Ibid., p. 47.

135. Jeffrey Fox, "FDA Finally Approves RBST for Milk Production," *Bio/Technology* 11 (December 1993): 1502.

136. Ibid.

137. An interesting question, of course, is why such publication of the basis for decisions about scientific evidence that may have a bearing on public safety should not be routine, and indeed perhaps required on the part of regulatory decision makers.

138. Judith C. Juskevich and G. Greg Guyer, "Bovine Growth Hormone: Human Food Safety Evaluation," *Science* 249 (August 24, 1990): 875–84.

139. Russ Hoyle, "RBST Off To A Fast Start, Despite Early Stumbles," *Bio/Technology* 13 (1992): 13.

140. Ibid.

141. Ibid. The spokesperson is Terry Nagle, from Land O'Lakes.

With an eye to understanding similar controversies in the Canadian context, one of the more interesting questions that comes out of the comparison of different regulatory responses is: What effects do the ways in which different legal regimes allocate burdens of proof, determine standards of proof and locate decision making within the apparatus of government actually have on the progress of industry and on the resolution of specific science policy controversies? Do some legal regimes provide for more extensive and thoughtful discussion of ethical issues than others? In other words, quite apart from ethical arguments in support of certain **outcomes**, are there convincing arguments for adopting certain kinds of **procedures**, rather than others, for resolving conflicts like those surrounding the physical and social risks of agricultural biotechnology?

3.2. Genetic Diagnosis and Human Gene Therapy: The International Spectrum of Views

Genetic screens, which detect distinctive characteristics in the genetic makeup of individual human beings that predispose them to certain kinds of illnesses, have been available for more than a quarter of a century for a few conditions, and are already recognized as raising distinctive ethical concerns.[142] Human genetic research now under way promises to multiply the number of such tests and screens: "Thanks to rapid private sector advances in molecular biology and a $3-billion federal Human Genome Project (HGP) that will map and sequence the genetic make-up of humans, a plethora of population screens, diagnostic tests and therapies will be available — perhaps commonplace — in the next decade."[143] The HGP is in reality not a single project but a variety of initiatives in several countries, and is only the latest step in the expansion of scientific knowledge about the genetic basis of all life that began with the description of the DNA molecule almost half a century ago, and continues with such dramatic recent developments as the isolation of the BRCA1 gene, mutations in which confer high hereditary susceptibility to breast cancer in human beings.

With specific reference to the potential for understanding and manipulating the human genome, how will that information be used? In the words of a recent discussion of eugenics and intelligence, are we wise to "jump off the cliff into the Valley of Possibilities" opened up by that knowledge?[144] The perspective that could be called technological optimism holds that even the potential for altering the human germ-line, in other words, altering the genetic make-up of individual human beings in ways that can be passed on to their descendants,

142. Lori B. Andrews et al., eds., *Assessing Genetic Risks: Implications for Health and Social Policy,* Report of the Committee on Assessing Genetic Risks, Division of Health Sciences Policy, Institute of Medicine (Washington, D.C.: National Academy Press, 1994), pp. 39–58.

143. Philip J. Boyle, "Shaping Priorities in Genetic Medicine," Special Supplement, *Hastings Center Report* 25 (3, 1995): S2; this entire supplement provides a useful overview of issues raised by the profusion of genetic tests. See also Rachel Nowak, "Genetic Testing Set for Takeoff," *Science* 265 (July 22, 1994): 464–67.

144. Jodi Lackman, "Are We Wise Enough? Eugenics, Genetics and Intelligence?" (Montreal: Faculty of Law, McGill University, 1995), p. 3.

may not be qualitatively different from the ways in which our society transfers advantages (or conversely, reproduces disadvantages) from generation to generation.[145] Several European jurisdictions have chosen the approach of prohibiting human germ-line modification altogether.[146] Others have avoided blanket prohibitions, perhaps on the basis that such prohibitions would turn out to be "sanctimonious and misguided" in view of potential disease prevention benefits that have yet to be identified.[147] Indeed, one can envision a situation in which humanitarian considerations might make it very difficult in the future to defend such blanket prohibitions.[148]

Philosophers Edward Berger and Bernard Gert observe that a key question in setting limits on germ-line modification is "whether everyone involved in these matters [is] appropriately thoughtful"[149] with respect to the issues involved. In addressing this question, we might do well to recall that various jurisdictions in the United States enacted numerous eugenics-based sterilization laws "for the purposes of preventing a degeneration of the quality of society" in the early twentieth century,[150] that the constitutionality of such laws was upheld by the U.S. Supreme Court in 1927,[151] and that legislation in the Canadian provinces of Alberta and British Columbia authorized the compulsory sterilization of mental hospital patients until 1972 and 1973, respectively.[152] They might also warn that the cumulative impact of the diffusion of a variety of applications of human genome research might lead to

145. Resnik, *supra* n. 80, pp. 25–27, 37.

146. In addition to Germany, these include Austria, France, Norway and Switzerland; Bartha Maria Knoppers and Ruth Chadwick, "The Human Genome Project: Under an International Ethical Microscope," *Science* 265 (1994): 2035.

147. Robert M. Cook-Deegan, "Germ-line Gene Therapy: Keep the Window Open a Crack," *Politics and the Life Sciences* 13 (2, August 1994): 220; on some of the potential medical benefits, including the prevention of some types of malignancy and monogenic deficiency diseases, see Nelson A. Wivel and LeRoy Walters, "Germ-line Gene Modification and Disease Prevention: Some Medical and Ethical Perspectives," *Science* 262 (October 22 1993): 533–38.

148. The European Group of Advisers on the Ethical Implications of Biotechnology took this contingency into account in its opinion on "The Ethical Implications of Gene Therapy" by concluding that: "Because of the important controversial and unprecedented questions raised by germ-line therapy, and considering the actual state of the art, germ-line gene therapy on humans is not *at the present time* ethically acceptable [emphasis added]." Opinion reproduced in *Politics and the Life Sciences* 14 (August 1995): 268.

149. Edward M. Berger and Bernard M. Gert, "Genetic Disorders and the Ethical Status of Germ-line Therapy," *Journal of Medicine and Philosophy* 16 (1991): 679.

150. Lackman, *supra* n. 144, p. 10.

151. Compulsory sterilization laws were upheld with the terse conclusion that: "It is better for all the world, if instead of waiting to execute degenerate offspring for crime, or to let them starve for their imbecility, society can prevent those who are manifestly unfit from continuing their kind. The principle that sustains compulsory vaccination is broad enough to cover cutting Fallopian tubes. Three generations of imbeciles are enough." *Buck v. Bell*, 274 U.S. 200 at 207 (1927), as cited in Ibid., p. 2.

152. R. P. Kouri and M.A. Somerville, "Comments on the Sterilization of the Mentally Retarded in Canadian Civil and Common Law," *Revue de Droit Université de Sherbrooke* 10 (1980): 599–628.

a change in our attitudes toward one another,[153] which has been referred to variously as "geneticization," "genetic essentialism" and "geneticism."[154]

The ethical questions raised by new forms of knowledge about the human genome range from the familiar to the esoteric. Perhaps the most familiar involve the conditions under which clinical trials of somatic cell gene therapy are permitted; they are familiar not in the sense that such trials are widespread (they are not, as yet) but because such therapy "is generally regarded as similar in principle to existing medical procedures such as organ transplantation and has met with broad ethical acceptance."[155] Ethical issues having to do with matters such as informed consent and the minimization of potential harm to the patients involved likewise resemble those associated with clinical trials of other new treatments. They are clinical risks rather than social ones, and extensive institutional review mechanisms are already in place to ensure that generally accepted ethical requirements are met. Indeed, somatic cell gene therapy is normally subjected to particularly demanding review procedures,[156] in the course of which the ethical issues are explicitly dealt with **as** ethical issues by governments, on a case-by-case basis and in exhaustive detail. Perhaps as a consequence of this careful scrutiny, one recent article reported that "there are over 100 gene therapy protocols approved worldwide [and] no adverse outcomes have been reported on any protocol."[157]

This plethora of institutional safeguards aimed at guarding against one particular category of risks can be viewed as eliminating the need for more organized and explicit attention at the level of public policy. Eric Juengst, a former Chief of the Ethical, Legal and Social Issues Office of the U.S. National Center for Human Genome Research (NCGHR), argued in 1990 that the ethical questions about the limits of human gene therapy "are ultimately questions for professional conscience and vision, not public policy. Fortunately, they are

153. Brock, *supra* n. 4.

154. Abby Lippman, "Prenatal Genetic Testing and Screening: Constructing Needs and Reinforcing Inequalities," *American Journal of Law and Medicine* 17 (1991): 15–50 (on geneticization); Dreyfuss and Nelkin, *supra* n. 62 (genetic essentialism); Susan M. Wolf, "Beyond 'Genetic Discrimination': Toward the Broader Harm of Geneticism," *Journal of Law, Medicine and Ethics* 23 (1995): 345–53.

155. Ian D. Dubé and Denis Cournoyer, "Gene Therapy: Here to Stay," *Canadian Medical Association Journal* 152 (May 15, 1995): 1605.

156. See e.g. Odile Cohen-Haguenauer, "Overview of Regulation of Gene Therapy in Europe: A Current Statement Including Reference to U.S. Regulation," *Human Gene Therapy* 6 (June 1995): 773–85; "Guidance on Making Proposals to Conduct Gene Therapy Research on Human Subjects," Report of the United Kingdom Health Ministers' Gene Therapy Advisory Committee, *Human Gene Therapy* 6 (March 1995): 335–46; Eric T. Juengst, "The NIH 'Points to Consider' and the Limits of Human Gene Therapy," *Human Gene Therapy* 1 (1990): 425–33; Medical Research Council of Canada, "Guidelines for Research on Somatic Cell Gene Therapy in Humans: (Ottawa: MRCC, 1990); Subcommittee on Human Gene Therapy, Recombinant DNA Advisory Committee, [U.S.] National Institutes of Health, "Points to Consider in the Design and Submission of Protocols for the Transfer of Recombinant DNA into the Genome of Human Subjects," *Human Gene Therapy* 1 (1990): 93–105.

157. Dubé and Cournoyer, *supra* n. 155, pp. 1609–10.

also questions that . . . are already available for analysis in multiple, less exotic variants."[158] In other words, Juengst is saying that the questions are not unique or unprecedented; they do not raise issues medical and scientific professionals have not dealt with successfully in the past.

However, for reasons that will become clearer in the pages that follow, we are sceptical about Juengst's approach. Certainly, there is a need **both** for public policy **and** for informed professional judgment about many clinical applications of biotechnology, including but not limited to applications of research on the human genome. Governments have already responded to this need, in a variety of ways. With specific reference to medical intervention in human reproduction, it is worth considering three recent reviews of governmental responses.

The first of these reviews was concerned specifically with pre-implantation diagnosis (PID), the ability to screen human embryos produced through in vitro fertilization (IVF) for hereditary genetic defects before implantation in the mother's uterus, which was first demonstrated successfully in 1992.[159] PID is significant not only for its clinical potential, but also because it exemplifies links between genetic research and a variety of clinical interventions in human reproduction, and thus provides a useful illustrative case study. In describing public policy responses to PID, Andrea Bonnicksen distinguishes among "restrictive, permissive and laissez-faire"[160] approaches. As an example of a restrictive policy, Bonnicksen cites the 1990 German legislation that imposed criminal prohibitions for certain kinds of embryo research, including any manipulation of the genetic information of a human germ cell. The German legislation was apparently motivated at least in part by the unique preoccupation of present-day Germans with prohibiting or subjecting to extraordinary popular scrutiny any research that invokes the Nazi-era spectre of eugenics.[161]

By contrast, Bonnicksen calls the United Kingdom's approach to pre-implantation diagnosis (and a range of other techniques involving human reproduction) permissive. This does not mean that "anything goes" in the United Kingdom; far from it. Rather, it means that a licensing and inspection scheme exists under the *Human Fertilization and Embryology Act* of 1990,[162] with a Statutory Licensing Authority that implements and interprets the provisions of the Act and carries out inspections of licensed facilities. Similar approaches have been used in other jurisdictions as well, but the British scheme is

158. Juengst, *supra* n. 156, p. 431.

159. Alan H. Handyside et al., "Birth of a Normal Girl after In Vitro Fertilization and Preimplantation Diagnostic Testing for Cystic Fibrosis," *New England Journal of Medicine* 327 (September 24, 1992): 905–09.

160. Andrea Bonnicksen, "National and International Approaches to Human Germ-line Therapy," *Politics and the Life Sciences* 13 (1, 1994): 41.

161. Ibid., pp. 41–42; personal communication to one of the authors (T. S.) from V. Schild, Department of Political Science, University of Western Ontario.

162. Reproduced in *International Digest of Health Legislation* 42 (1, 1991): 69–85.

particularly interesting because it was the result of a lengthy and well documented public debate beginning with the birth of the first "test-tube baby" in 1978.[163]

Finally, Bonnicksen identifies the laissez-faire approach, which, she says, is characteristic of the United States in that although some states apparently prohibit embryo research, there are no explicit legislated prohibitions on preimplantation diagnosis at the federal level. However, embryo research is perhaps the biomedical area in which the U.S. approach is **least** accurately described as laissez-faire. Despite the absence of a national legislative prohibition, embryo research was effectively foreclosed at least until very recently by a *de facto* moratorium on all federal funding of any research involving human embryos,[164] arising out of political leaders' perception that funding such research encouraged, or at least appeared to condone, abortion.[165]

The laissez-faire description would appear more applicable to other areas of medically assisted reproduction, where the United States in some respects approximates a wide-open medical marketplace or "biomedical free trade zone,"[166] albeit with the crucial proviso that access to services of all kinds is limited by the willingness and ability of the patient (or the patient's insurer) to pay.[167] The laissez-faire characterization is also not applicable to most medical research involving human subjects, since federal regulations require ethical review by institutional review boards both for federally funded research and for clinical trials conducted as part of the process of seeking regulatory approval;[168] there are also specialized review procedures in areas such as recombinant DNA research. The lesson here is probably that rather than characterizing any given jurisdiction's overall approach as restrictive, permissive or laissez-faire, it may be more useful to apply this characterization to specific areas because, as we have seen, combinations of these approaches within a single jurisdiction can reflect distinctive national values and political circumstances.

The case study of pre-implantation diagnosis suggests two points. First, there is a role for public policy about the social risks (and, of course, about the benefits) of genetic knowledge and its medical applications as well as for "professional conscience and vision."

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163. For a description both of the debate and of the operations of the Human Fertilization and Embryo Authority, see Jennifer Gunning and Veronica English, *Human In Vitro Fertilization: A Case Study in the Regulation of Medical Innovation* (Aldershot, UK: Dartmouth, 1993).

164. Bonnicksen, *supra* n. 160, pp. 42–43.

165. On the deliberations of the National Institutes of Health advisory panel that proposed a set of guidelines for ethically acceptable embryo research in the United States, see Ronald M. Green, "The Human Embryo Research Panel: Lessons for Public Ethics," *Cambridge Quarterly of Healthcare Ethics* 4 (1995): 502–15.

166. In the words of one panelist at an international conference on medically assisted reproduction held at the University of Toronto in February 1996, with partial support from Health Canada.

167. See e.g. the four-part series on "The Fertility Market," *New York Times*, January 7–10, 1996.

168. Harold Edgar and David Rothman, "The Institutional Review Board and Beyond," *Milbank Quarterly* 73 (1995): 490–91.

In many circumstances, the judgment of even the wisest and most experienced professionals is not enough. The blanket German prohibition on germ-line manipulation may correspond to the verdict of professional conscience in that country, but some of its defenders would probably argue that such correspondence is largely irrelevant to the ethical values in question.[169] Second, particularly given our emphasis in Chapter 2 on the careful analysis of both explicit ethical arguments and implicit or embedded ethical positions, a critical question is that of **why** a particular approach was adopted in a given jurisdiction, and whether the approach's adoption reflects careful consideration of what it means and whom it affects.

A second comparative review of policy responses in the area of medically assisted reproduction sheds some light on this last point. Derek Morgan and Linda Nielsen contrast the British HFEA, which they (like Bonnicksen) regard as "permissive," with the policy approach taken in the Scandinavian countries, and in particular Denmark,[170] where temporary prohibitions on embryo research and restrictions on the use of assisted conception were enacted by legislation in 1987, pending review by a legislatively established Council of Ethics. In 1992, revised legislation permitted many forms of biomedical research involving human reproduction and a number of medical interventions in human reproduction, but only following approval by both regional and central ethics committees.[171] Superficially, the Danish approach would not seem to differ significantly from the British. The differences are subtle, and are best captured in Morgan and Nielsen's conclusion that the Scandinavian approach tends toward "saying 'no' until we are sure that 'yes' is well debated and accepted."[172] For instance, while the British approach views child-bearing (and by extension assisted conception) "largely . . . as a private area of human affairs" that should be shielded from state intervention,[173] the Scandinavian approach places greater emphasis on "the interests of the child in later life" relative to those of the parent(s) at the time of conception.[174] Morgan and Nielsen further suggest that:

> Maybe there is a greater concern in Scandinavia as to the impact of IVF, surrogacy and donation on ethics and the child's life. These possibilities are not seen as just pragmatic solutions as to childlessness, but as means that may change our view of procreation and humankind in an unwarranted way.[175]

169. Indeed it might be claimed by opponents of germ-line modification that such a prohibition is even more important in the absence of such a professional consensus.

170. Morgan and Nielsen, "Prisoners of Progress or Hostages to Fortune?" *Journal of Law, Medicine and Ethics* 21 (1993): 30–42.

171. Ibid., pp. 32–33.

172. Ibid., p. 37.

173. Ibid., p. 36.

174. Ibid., pp. 35–36.

175. Ibid., p. 36.

At stake, then, are not just the interests of children and parents as individual human beings, but also societal values of a kind that cannot be easily redefined in terms of individuals' interests.

Third, the most comprehensive published review (as of 1991) of national positions on medically assisted reproduction, by Bartha Knoppers and Sonia LeBris,[176] deals not only with legislation and regulation but also with "over 100 reports of special commissions worldwide." The authors identify a number of areas of **qualified** international agreement:

> (1) access to fertilization techniques should be limited to heterosexual married couples or to those [heterosexual couples] living in stable unions; (2) clinics and physicians offering these techniques should be subject to medical supervision and regulation; (3) paternity and maternity should be provided for by law for all birth technologies; (4) medical records should be kept and medical records concerning participants should be confidential; (5) embryonic life in vitro should be limited to fourteen days; (6) storage of gametes or embryos should be subject to time limitations; (7) post-mortem insemination or implantation should be prohibited; (8) commercial surrogacy agencies or intermediaries should be prohibited; (9) the consent of the participant and standardized conditions of [gamete] donation should be imposed; (10) reproductive technologies should be free from commercialization; (11) neither sex selection of embryos, except for sex-linked diseases, nor eugenic selection should be allowed; and (12) extreme forms of genetic engineering (for example, cloning, creation of chimeras, parthenogenesis, inter-species fertilization) should be prohibited.[177]

Knoppers and LeBris also identify several other areas in which there was profound international disagreement, including "remuneration of [gamete] donors," the conditions, if any, under which experimentation on human embryos is considered permissible, and "the genetic diagnosis of embryos."[178]

As we have seen from the work of Bonnicksen and Morgan and Nielsen, different jurisdictions can reach widely divergent ethical conclusions despite agreement on certain principles. This is not a sign of perversity on the part of those jurisdictions, or of inaccuracy in the identification of principles. Rather, it shows that basic principles are like prisms rather than like checklists. We look **through** them to try to achieve an ethically defensible resolution to specific problems, rather than mechanically checking off features that will lead us to one conclusion rather than to another.

For purposes of asking the questions we have suggested, it may be less important to identify elements of a consensus than to identify principles which can be used as the basis both for identifying areas of agreement and for clarifying differences. The indeterminacy of

176. Bartha Knoppers and Sonia LeBris, "Recent Advances in Medically Assisted Conception:Legal, Ethical and Social Issues," *American Journal of Law and Medicine* 17 (1990): 329–61.

177. Ibid., pp. 332–33.

178. Ibid., p. 333. It is also worth noting that some disagreements have subsequently emerged in the areas where Knoppers and LeBris identified general agreement: for example, the Danish Council of Ethics argues in favour of extending artificial fertilization to lesbian couples and single women, and Danish legislation leaves this up to individual hospitals and clinics; Morgan and Nielsen, *supra* n. 170, p. 35.

such principles, even when there is widespread agreement on them, underscores the importance of process in arriving at policy solutions to ethical questions — a theme we emphasize throughout this report. Knoppers and LeBris identify five such principles:

> (1) respect for human dignity; (2) the security of human genetic material; (3) the quality of services; (4) the inviolability of the human person; and (5) the inalienability of the human body.[179]

Each of these principles can, in turn, be brought to bear on a variety of issues. For instance, implementing the principle of respect for human dignity requires making some decisions about the status of the embryo, about the extent to which it merits protection, and about why it merits that protection.[180] Protecting the security of human genetic material involves striking balances such as that "between total condemnation of embryonic research and facile pragmatism" about the use of human embryos for research purposes,[181] with reference to considerations such as the therapeutic benefits that may be anticipated from that research and, conversely, the need "to ensure the individuality as well as the continuity of the human species."[182] Ensuring the quality of services likewise encompasses a variety of areas, including criteria for access to services (most crucially the definition of health and of medical necessity) and maintaining confidentiality of records.[183]

Whereas Knoppers and LeBris view the first three principles primarily as "mechanisms to protect the human person," they view the last two as necessary to "ensure control over scientific and personal freedom."[184] Protecting the inviolability of the human person is viewed with reference to "genetic patrimony," and to donors' control over the use of donated gametes.[185] Finally, protecting the inalienability of the human person is viewed *inter alia* as requiring limitations on so-called surrogate motherhood, as well as requiring the limitation or actual prohibition of commercialization of parts of the human body (possibly including gametes).[186]

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179. Knoppers and LeBris, *supra* n. 176, pp. 333–34; these principles were also accepted by the World Health Organization's Scientific Group on Recent Advances in Medically Assisted Conception in 1990. See also "Sixty-third Conference of the International Law Association (Warsaw, August 21–27, 1988) adopts resolution on reproductive technologies," *International Digest of Health Legislation* 41 (1990): 723–24; this resolution sets out all of the principles identified in the 1991 article except quality of services.

180. Knoppers and LeBris, *supra* n. 176, pp. 334–38.

181. Ibid., p. 339.

182. "Sixty-third Conference," *supra* n. 179, p. 723.

183. Knoppers and LeBris, *supra* n. 176, pp. 344–52.

184. Ibid., p. 334.

185. Ibid., pp. 352–56.

186. Ibid., pp. 356–60.

Efforts to identify principles that are shared across national borders have not been confined to examinations of official responses. John Fletcher and Dorothy Wertz identify a common set of eight ethical problems for medical genetics, based primarily on a 16-country survey of medical geneticists, the people on the front lines of clinical decision making rather than those charged with setting public policy (Table 2).[187] A complex attempt to analyze their respondents' moral reasoning with reference to the four core principles of biomedical ethics as well as two others (strict monetary utilitarianism and dogmatic religious beliefs) suggested a relatively high level of consensus around the protection of autonomy, although the importance attached to this principle rather than to others varied from nation to nation. Interestingly, though, very few responses could be interpreted as referring primarily to justice as a guiding principle.[188]

Table 2. Eight Common Issues Facing Medical Geneticists

1. Fairness of access to genetic services, with particular reference to the influence of economic inequalities.
2. Abortion choices for genetic reasons.
3. Confidentiality in patient–geneticist relationships.
4. Protecting privacy from institutional third parties, such as government agencies, insurers and employers.
5. Dilemmas in which geneticists' knowledge might involve psychological harm or create tension among intimates if disclosed.
6. Indications for prenatal diagnosis.
7. Voluntary vs. mandatory screening, e.g., for potential carriers.
8. Against the background of a strong preference for "nondirective" genetic counseling, the kind of counseling that should be provided to incapacitated persons.

Source: Synthesized from John C. Fletcher and Dorothy C. Wertz, "Ethics, Law, and Medical Genetics: After the Human Genome is Mapped," *Emory Law Journal* 39 (1990): 761–65.

Cross-national variation is probably to be expected. Perhaps more significant is the conclusion of Fletcher and Wertz that "strong agreements are present worldwide on *some* crucial approaches to several of the major ethical problems in the old and new genetics"; and even in the absence of such consensus, "there are at least strong *trends* in many nations that can be a basis for *creative debate* among geneticists. . . ."[189] For reasons already suggested, however, that debate should certainly not be restricted to geneticists.

187. John C. Fletcher and Dorothy C. Wertz, "Ethics, Law, and Medical Genetics: After the Human Genome is Mapped," *Emory Law Journal* 39 (1990): 747–809.

188. Ibid., pp. 768–76. For discussion of why this might be the case, see C. Barry Hoffmaster, "Challenges to Health Care Ethics in Canada," Presidential Address to 1994 Annual Meeting, Canadian Bioethics Society, *Westminster Affairs* 8 (1, Winter 1995): 2–7.

189. Fletcher and Wertz, *supra* n. 187, p. 785; all emphases added.

Finally, a more recent review by Knoppers and Ruth Chadwick covers a related (and partially overlapping) set of concerns raised by the Human Genome Project, which is rather unlike other fields of scientific research in that it has operated almost from its beginnings "under an international ethical microscope."[190] Based on "international, regional and national reports and guidelines and . . . some legislation," Knoppers and Chadwick discern the beginnings of an international consensus around five basic principles: autonomy, privacy, justice, equity and quality. Like the four principles widely accepted in biomedical ethics, which this list closely resembles, each of the identified principles leaves abundant room both for international variation and for disagreement. Once again, we must think in terms of prisms, rather than checklists.

3.3. Genetic Diagnosis and Human Gene Therapy: Four Key Sets of Ethical Issues

From among the many issues identified in these cross-national surveys, we focus on four sets as illustrations of the need for public policy that goes beyond professional considerations of clinical risk. Other authors would no doubt select a somewhat different mix, but the point is not thereby weakened.

First, there is the question of how access to newly developed (but potentially very expensive) diagnostic tests and therapies is to be determined. In the United States, which is unique among industrialized countries in the degree to which it relies on private purchase of health care and private insurance, "genetic disability could become a mark of low social class, because your parents had neither the education nor the money to prevent your birth. Today's inequality of access could increase the stigma of tomorrow's disability."[191] Such constraints are particularly important given efforts to restructure U.S. health services under managed care, with associated increased pressures for cost containment. Indeed, Fletcher and Wertz presume for purposes of their study of ethical issues in human genetics that because "the moral case for a universal health plan grounded in distributive justice has been made in a broad body of literature and commentary," and because of the evidence of both waste and harsh economically based inequities in access to health care in the United States that: "The burden of proof is on those who oppose a national health plan. As these contradictions accumulate, new reserves of power to effect change will come to elected and other leaders."[192] This has yet to happen, of course. Meanwhile Canadians and others who live with public health insurance should not be complacent, because the same economic pressures that drive inequalities of access in a price-based system will drive choices about

190. Knoppers and Chadwick, *supra* n. 146.

191. Dorothy Wertz, "Ethical and Legal Implications of the New Genetics," *Social Science and Medicine* 35 (1992): 496; see also Andrews et al., eds., *supra* n. 142, pp. 234–40.

192. Fletcher and Wertz, *supra* n. 187, p. 757.

access in a system that tries to maintain universal access to "medically necessary" services in the face of increased cost constraints.[193]

Second is the question of the confidentiality of information with respect to third parties whose primary stake in genetic information is financial (i.e. parties who are not relatives or intimates who might be put at biophysical risk of nondisclosure). The proliferation of genetic tests and screens creates the possibility of "presymptomatic diagnosis," and of the creation of a new social category of the not-yet-ill.[194] The results of such tests, regardless of the context in which they were performed, are likely to be of great interest to potential employers and insurers[195] even though, as is frequently pointed out, their results are only probabilistic. Simply adopting guidelines to the effect that consent must be given before such results are disclosed[196] raises the obvious question of how "voluntary" such consent would be in many circumstances.[197] The importance of this question is heightened in the U.S. context by the prospect that private health insurers may require access to the information for underwriting purposes[198] and by the rapid expansion of managed care organizations, which may function simultaneously as insurers and providers of care.[199]

In response to such concerns, several U.S. states have passed legislation providing privacy protection for insurance applicants or limiting the use of genetic information in underwriting decisions,[200] although the protection they provide against discrimination may be limited by the failure to distinguish between genetic tests and "genetic information

193. *Cf.* Bartha Maria Knoppers and Sonia LeBris, "Genetic Choices: A Paradigm for Prospective International Ethics?" *Politics and the Life Sciences* 13 (2, August 1994): 228–30, on the "social responsibility and policy choices" that follow from the existence of a universal health care system.

194. C.T. Caskey, "Presymptomatic Diagnosis: A First Step Toward Genetic Health Care," *Science* 262 (1993): 48; Dreyfuss and Nelkin, *supra* n. 48, p. 318.

195. Elaine Draper, *Risky Business: Genetic Testing and Exclusionary Practices in the Hazardous Workplace* (Cambridge: Cambridge University Press, 1991); Neil Holtzman, *Proceed With Caution: Predicting Genetic Risks in the Recombinant DNA Era* (Baltimore: Johns Hopkins University Press, 1989).

196. As proposed in several jurisdictions; see Knoppers and Chadwick, *supra* n. 147, p. 2035.

197. Such constraints were recognized in a report to the National Advisory Committee on AIDS, which distinguished among voluntary, mandatory and compulsory testing. Whereas voluntary testing is done only with informed consent as normally defined, mandatory testing is a necessary prerequisite for or consequence of "obtain[ing] a specified status, benefit, service or access to a given situation," and compulsory testing "is required by law, or policy, and the person . . . cannot legally avoid it." Margaret A. Somerville and Norbert Gilmore, *Human Immunodeficiency Virus Antibody Testing in Canada* (Montreal: McGill Centre for Medicine, Ethics and Law, 1988), p. 22.

198. Andrews et al., *supra* n. 142, pp. 239–40.

199. Karen H. Rothenberg, "Genetic Information and Health Insurance: State Legislative Approaches," *Journal of Law, Medicine and Ethics* 23 (1995): 315.

200. Ibid., pp. 312–16.

generated from family history, physical examination, or the medical record."[201] Three scholars in the field have drafted a proposed Genetic Privacy Act, in an effort to provide more comprehensive protection of genetic information throughout the United States.[202] (The bill was introduced into the Maryland legislature, although rejected in committee.[203]) At the national level, at least three working groups have recently recommended broad legislative prohibitions against the use of any form of genetic information in deciding whether or not to issue health insurance or in setting individual premiums.[204] Although the specific issue of insurance coverage may be of less significance in countries with universal health insurance, questions of employment discrimination will nevertheless arise; so, too, will the more general implications of designating at-risk populations on the basis of probabilistic genetic test outcomes. There are abundant questions, then, requiring resolution at the level of public policy.[205]

Third, there is the challenge to decision making in the area of human genetics that is presented by a distinctively feminist intellectual approach already found throughout the Western world in debates about medically assisted reproduction. Although there are a variety of feminist approaches, most of them share an insistence that neither medically assisted reproduction nor some of the uses to which genetic information will probably be put in other contexts can be viewed in isolation from the social subordination of women. Techniques of medically assisted reproduction are viewed as undermining women's control over reproduction, while reinforcing the definition of women primarily in terms of their

201. Ibid., p. 313.

202. George J. Annas, Leonard H. Glantz and Patricia A. Roche, "Drafting the Genetic Privacy Act: Science, Policy and Practical Considerations," *Journal of Law, Medicine and Ethics* 23 (1995): 360–66. Interestingly enough the draft legislation "itself does not prohibit the use of genetic information by employers," although its drafters "believe it would be reasonable public policy to prohibit both employers and health insurance companies from using genetic information in making employment and coverage decision"; Ibid., 361.

203. Neil Holtzman, "Panel Comment: The Attempt to Pass the Genetic Privacy Act in Maryland," *Journal of Law, Medicine and Ethics* 23 (1995): 367–70.

204. The Working Group on Ethical, Legal, and Social Implications of the Human Genome Project and the National Action Plan on Breast Cancer, as cited by Rothenberg, "Genetic Information and Health Insurance," pp. 317–18; and the Institute of Medicine Committee on Assessing Genetic Risks (Andrews et al., eds., *supra* n. 142, pp. 280–82.

205. To understand this point, compare the comment of the Institute of Medicine committee to the effect that "new laws on a variety of other topics may also be necessary to protect autonomy, privacy and confidentiality in the genetics field, and to protect people from inappropriate decision based on their genotypes" (Ibid., pp. 281–82) with another recent observation that "tradeoffs are inevitable. Permitting the Human Genome Initiative to proceed unabated will have costs in personal privacy. While careful security safeguards will not provide complete privacy, the public should be assured that genomic information will be treated in an orderly and respectful manner and that individual claims of control over those data will be adjudicated fairly." Lawrence Gostin, "Genetic Privacy," *Journal of Law, Medicine and Ethics* 23 (1995): 328.

biological capacities.[206] In some situations, the opportunities offered by a new medical intervention would appear fully compatible with the principle of expanding women's control by expanding their range of choices (for example, genetic testing for a range of embryonic or fetal abnormalities). Even then, though, some feminist writers argue that the social context in which the technology is used serves to reduce women's autonomy by increasing pressure on them to make a decision that conforms to social expectations that reflect biased or misogynist beliefs about the appropriate role of women.[207] Sometimes the imagery invoked is of women's bodies as a battleground, and of their conquest by a (primarily male) scientific and medical establishment.[208]

Many of the risks or hazards cited by feminist authors are social risks rather than physical ones (to use Jasanoff's terminology). There are exceptions, such as the effects on women's health of the hormones frequently used to stimulate superovulation for purposes of the IVF treatment cycle.[209] Even in these cases, feminist critiques emphasize social context as well as hazards to individuals' health. They ask questions such as: Is it because the drugs are administered to women that their hazards are not taken more seriously, or are sometimes concealed? Is it because a male-dominated social order views the ability of women to reproduce as uniquely important that even when women are informed of the risks, they are "willing" to be exposed to them? What does this say about the limitations of the concept of informed consent, so central to biomedical ethics?[210]

Fourth and finally, there are concerns about how expanding knowledge of the genetic basis of human behaviour and identity, and our ability to act on that knowledge, will alter human beings' relationships with one another. It is conceivable that the conception of human beings as responsible moral agents, a conception that is central both to moral philosophy and to many aspects of the legal system, will be redefined as genetic bases for (or predispositions to) certain kinds of behaviour are identified.[211] In a complex and subtle

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206. See among many other sources Bette Vanderwater, "Meanings and Strategies of Reproductive Control: Current Feminist Approaches to Reproductive Technology," *Issues in Reproductive and Genetic Engineering* 5 (3, 1992): 215–30.

207. See, e.g., Abby Lipman, "Mother Matters: A Fresh Look at Prenatal Genetic Testing," *Issues in Reproductive and Genetic Engineering* 5 (2, 1992): 141–54; Anne C. Thacker, "Social Implications of Developing Medical Knowledge in the Field of Human Reproduction: A Case of Ignoring Some Human Rights," *Issues in Reproductive and Genetic Engineering* 5 (2, 1991): 127–36.

208. Jyotsna Agnihotri Gupta, "Women's Bodies: The Site for the Ongoing Conquest by Reproductive Technologies," *Issues in Reproductive and Genetic Engineering* 4 (2, 1991): 93–108.

209. Renate Klein and Robyn Rowland, "Women as Test-Sites for Fertility Drugs: Clomiphene Citrate and Hormonal Cocktails," *Reproductive and Genetic Engineering* 1 (3, 1988): 251–73.

210. Eva Fleisher, "Ready for Any Sacrifice? Women in IVF Programmes," *Issues in Reproductive and Genetic Engineering* 3 (1, 1990): 1–12; Renate D. Klein, "IVF Research: A Question of Feminist Ethics?" *Issues in Reproductive and Genetic Engineering* 3 (3, 1990): 243–52; Jocelyne Scutt, "A Question of Choice? IVF and the Politics of Coercion," *Issues in Reproductive and Genetic Engineering* 5 (3, 1992): 265–73.

211. Brock, *supra* n. 13, pp. 13–18.

critique of what they term genetic essentialism, Rachelle Cooper Dreyfuss and Dorothy Nelkin have already identified case law suggesting that "genetic predisposition could support an argument for enhancing rather than mitigating punishment," creating "a sort of status offense. While the offender is not branded responsible for bad acts, the practical effect is that liberties are truncated and opportunities circumscribed."[212] In an only slightly more speculative vein, it has been suggested that the ability of parents to select desired characteristics in their offspring, or perhaps even just the knowledge that this might be possible, could contribute to "the erosion of noncontingent bonds" between parents and children.[213] How will the parent–child relationship change should the possibility of trait specification undermine the idea "that we are supposed to accept [and love] unconditionally whatever children we receive, whatever traits they have"?[214] Will we come to regard other persons, in general, as just bundles of characteristics that are (supposedly) genetically determined, even before the techniques become available to design in or design out particular traits?

Of all the concerns we have identified, these are probably the most intractable in terms of the existing institutions of public policy. However, this does not justify ignoring them, at least not unless we have already made (and are prepared to defend) a commitment to the view that nothing more than incremental change in those institutions will be demanded as the frontiers of biological knowledge advance. This is another illustration of how, and why, it matters whether or not we regard biotechnology and the ethical issues it raises as fundamentally familiar, or as fundamentally special and perhaps even unique.

3.4. Intellectual Property Rights in Living Matter

There have been at least four milestones in the history of the transnational debate about biotechnology patenting, and it is very much a transnational debate. The first is the case of John Moore, a surgical patient whose spleen was removed at the University of California hospital in 1976. His surgeon and other researchers proceeded to culture and to patent a cell line from which both they and the University will earn substantial profits. When Moore became aware of this fact, he sued both surgeon and university, seeking a share of the royalties on the patent.[215] Moore's lawsuit was ultimately rejected by the California

212. Dreyfuss and Nelkin, *supra* n. 62, pp. 330–31.

213. Michael Shapiro, "Fragmenting and Reassembling the World: Of Flying Squirrels, Augmented Persons, and Other Monsters," *Ohio State Law Journal* 51 (1990): 350.

214. Ibid., p. 348.

215. For discussion of this case see George Annas, "Outrageous Fortune: Selling Other People's Cells," *Hastings Center Report* 20 (November/December 1990): 36–39; C. Barry Hoffmaster, "Between the Sacred and the Profane: Bodies, Property, and Patents in the Moore Case," *Intellectual Property Journal* 7 (August 1992): 115–48; I. Jane Churchill, "Patenting Humanity: The Development of Property Rights in the Human Body and the Subsequent Evolution of Patentability of Living Things," *Intellectual Property Journal* 8 (July 1994): 273–79; T. Wells, "The Implications of a Property Right in One's Body," *Jurimetrics Journal* 30 (Spring 1990): 371–82.

Supreme Court, based on legal reasoning that at least some commentators find strongly suspect; they say the Supreme Court went to extraordinary lengths, for reasons rooted in its view of desirable public policy rather than in legal precedent, to avoid recognizing that Moore retained a property right in cells taken from his body.[216] Perhaps understandably, in December 1994 Moore was in Europe assisting advocacy groups opposed to the draft European Union directive on patenting higher life forms.[217]

The second milestone involved a chain of events that began even before the removal of John Moore's spleen. In a 1980 ruling, the U.S. Supreme Court ruled on an application filed in 1972 for a patent on a genetically engineered bacterium capable of degrading crude oil.[218] The court held that a living organism was patentable subject matter and indeed, quoting a 1952 Congressional committee report on the 1952 recodification of the *Patent Act*, that Congress intended patentable subject matter to "include anything under the sun that is made by man."[219] There followed an expansion of patent activity in a number of areas related to micro-organisms and cells, including the cell line developed from John Moore's spleen. However, until 1987, biotechnology-related U.S. patents applied only to micro-organisms, to processes involving them, and to tissue and cell culture processes and products. In that year the U.S. Patent and Trade-mark Office announced that it would henceforth consider issuing patents on multicellular organisms.

The third milestone occurred in April 1988, when the U.S. Patent and Trade-mark Office (PTO) issued its first patent on a living animal: the Harvard or Onco-Mouse.[220] According to Sheldon Krimsky, who has investigated and written about biotechnology and public policy for almost 20 years:[221] "The decision to patent a mammal brought many of the advocacy groups that opposed the patented bacterium into the latest policy fray. It also

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216. Annas, *supra* n. 215, p. 37; Churchill, *supra* n. 215, pp. 276–78.

217. Philip L. Bereano, "Body and Soul: The Price of Biotech," *Seattle Times*, August 20, 1995, p. B5.

218. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). For commentaries on this ruling and its effects, see among many other sources John S. Hudson, "Biotechnology Patents after the 'Harvard Mouse': Did Congress Really Intend *Everything Under the Sun* to Include Shiny Eyes, Soft Fur and Pink Feet?" *Journal of the Patent and Trademark Office Society* 74 (1992): 510–37; Leon Kass, *Toward a More Natural Science* (New York: Free Press, 1985), pp. 128–53.

219. *Diamond v. Chakrabarty*, at 309.

220. Harvard mouse because the patent was issued to the President and Fellows of Harvard College, where the genetic engineering research was carried out; Onco-Mouse, a registered trademark of the firm that now breeds the mice and sells them to experimenters, because the mouse's genome has been modified by the insertion of a human gene that confers high susceptibility to cancerous tumors and consequently makes the mouse highly useful for purposes of cancer research. U.S. Congressional Office of Technology Assessment, *New Developments in Biotechnology: Patenting Life* (New York: Marcel Dekker, 1990), p. 99.

221. Krimsky, *Genetic Alchemy: The Social History of the Recombinant DNA Controversy* (Cambridge, MA: MIT Press, 1982); Krimsky and A. Plough, *Environmental Hazards: Communicating Risks as a Social Process* (Dover, MA: Auburn House, 1991), ch. 3; Krimsky, *supra* n. 87; Krimsky, "The Role of Theory in Risk Studies," in *Social Theories of Risk*, edited by Krimsky and D. Golding (New York: Praeger, 1992), pp. 3–22.

attracted another formidable constituency, animal rights groups."[222] There is an important convergence here between existing concerns for animal welfare, which were already on the rise at the time the patent was issued, and the rejection of the idea that animals could be regarded as just another "manufacture or composition of matter." The issuance of an animal patent suggested to animal rights advocates "that society was regressing to an extreme Cartesian view of animals as soulless, unfeeling creatures that may be treated like machine parts."[223]

Legislators had begun to act on these interest group concerns even before the 1988 patent decision was issued. A subcommittee of the House of Representatives' Committee on the Judiciary held hearings on proposed legislation to impose a moratorium on the patenting of animals in 1987,[224] and on essentially the same legislation in 1989,[225] although in neither case was the proposed legislation passed. The roster of participants in the 1987 Congressional hearings on biotechnology patenting reflects the coalitions supporting and opposing patenting in the United States. In addition to the Foundation on Economic Trends (FET), set up by policy entrepreneur Jeremy Rifkin largely to oppose the diffusion of many forms of biotechnology, participants included farmers' organizations worried that expansion of patenting would lead to intensified corporate control of agriculture, and would thereby threaten the already tenuous viability of the family farm. The National Council of Churches and a variety of animal rights organizations were concerned about the potential for a "shift in how humanity relates to the natural environment."[226] To this list of actors one must add, of course, supporters of patenting in the biotechnology and pharmaceutical industries and the expanding number of academic researchers with a direct or indirect economic stake in the fortunes of that industry.[227]

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222. Krimsky, *supra* n. 87, p. 49. See also Andrew Kimbrell, *The Human Body Shop* (New York: Harper Collins, 1993), pp. 188–202.

223. Krimsky, *supra* n. 87, p. 49.

224. For discussion of these hearings, see B. Hanson and D. Nelkin, "Policy Responses to Genetic Engineering," *Society*, November/December 1989, pp. 76–80.

225. *Transgenic Animal Patent Reform Act of 1989*, Hearings on H.R. 1556 Before the Subcommittee on Courts, Intellectual Property and the Administration of Justice of the House Committee on the Judiciary, 101st Congress, 1st Session, 1989 (Washington, DC: GPO, 1990).

226. Quoted in Hanson and Nelkin, *supra* n. 225, p. 78. Daniel Kevles has referred to opponents of patenting as "a disparate collection of overlapping groups . . . united by a common dissatisfaction with the reductive manipulation of living organisms, as well as with what they regard as a deplorable disassembly and exploitation of nature." "Vital Essences and Human Wholeness: The Social Readings of Biological Information," *Southern California Law Review* 65 (1991): 271.

227. Hanson and Nelkin, *supra* n. 224, p. 77; Martin Kenney, *Biotechnology: The University–Industrial Complex* (New Haven: Yale University Press, 1986); Sheldon Krimsky *et al.*, "Academic–Corporate Ties in Biotechnology: A Quantitative Study," *Science, Technology and Human Values* 16 (1991): 275–87; J. Rule, "Biotechnology: Big Money Comes to the University," *Dissent*, Fall 1988, pp. 430–36.

However, the 1987 hearings were not just, or even primarily, about economics. Two observers of the hearings noted:

> The dispute reflected in part the concerns of those with direct economic interests. But opposition to the patenting decision was mainly driven by values and beliefs — about the moral rights of animals, the threat to democratic values, the repugnance of commodifying living things, and the ethics of tampering with life.[228]

The contours of the opposition to patenting have remained largely unchanged, and the controversy has not gone away. In May 1995, a coalition of religious bodies organized by Rifkin called for a reversal of the U.S. policy of allowing patents on genetically engineered animals and human genes, cells and organs. The statement announcing the establishment of the coalition said, in part: "We believe that humans and animals are creations of God, not humans, and as such should not be patented as human inventions."[229] The following month, a coalition of consumer and environmental groups and organizations claiming to represent indigenous peoples issued a broader statement (the Blue Mountain Declaration) calling on "the world and the Congress of the United States to enact legislation to exclude living organisms and their component parts from the patent system."[230]

The debate about patenting has also heated up on the other side of the Atlantic. In most EU countries, although not all, patenting decisions are broadly governed by the provisions of the European Patent Convention (EPC), to which some non-EU countries are signatories as well. Decisions about patentability under the EPC are made by the European Patent Office (EPO). The application for a patent on the Harvard mouse was originally rejected by the Examining Division of EPO, on the grounds that animal varieties were excluded from patentability under Article 53(b) of the EPC.[231] On appeal to the EPO's Technical Board of Appeal, an internal tribunal roughly analogous to the PTO Board of Appeals in the United States, the case was returned to the Examining Division with the finding that animals *per se* were not excluded from patentability by the EPC prohibition on patenting of animal varieties. In addition, according to one of the lawyers for the patent applicants, "in differing from the Examining Division, the Appeal Board took the view that use of oncogenes in the Harvard animals does raise questions of animal suffering which make it critically important to reconsider the morality issue. . . . This issue was thus also remitted to the Examining Division for reassessment."[232]

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228. Hanson and Nelkin, *supra* n. 224, p. 80.

229. Quoted in Richard Stone, "Religious Leaders Oppose Patenting Genes and Animals," *Science* 268 (May 26, 1995): 1126; see also Edmund L. Andrews, "Religious Leaders Prepare to Fight Patents on Genes," *New York Times*, May 13, 1995: A1, A19.

230. Reproduced in Bereano, *supra* n. 217, p. B5.

231. Article 53 deals with Exceptions to Patentability, and provides that: "European patents shall not be granted in respect of . . . (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof."

232. R. Bizley, "Patenting Animals in Europe," *Bio/Technology* 9 (July 1991): 620.

As a result of that reassessment, the Examining Division decided that the Onco-Mouse was patentable, at least partly on the basis that granting the patent would not offend against the ethical exclusion in Article 53(a) of the EPC. That exclusion provides that patents shall not be granted on "inventions the publication or exploitation of which would be contrary to *ordre public* or morality, provided that the exploitation shall not be deemed to be so contrary, merely because it is prohibited by law or regulation in some or all of the Contracting States. . . ." This exclusion, which has no parallel in Canadian or U.S. legislation, provided the legal basis for a consequentialist balancing of benefits against harms, in which the relevant authorities concluded that the basic interest of mankind in remedying dangerous diseases was furthered by the Onco-Mouse in ways that did not endanger the environment or involve unnecessary cruelty to animals.[233] This conclusion was in keeping with the reasoning of the patent applicants,[234] but clearly left the door open to denying patents in situations where different values were involved or different weights were attached to those values. The Harvard mouse patent is now undergoing review through the process of opposition under the EPC, in which third parties have the opportunity to oppose the grant of a patent. As with the exclusion in Article 53(a), there is no comparable provision in U.S. or Canadian patent law.

Even before the initial rejection of the Harvard mouse patent application by the EPO's Examining Division, the Commission of the European Communities had proposed a draft Directive to Harmonize Intellectual Property Rights for Biotechnology Inventions, which would have provided for expansive patent protection of biotechnological innovations within the nations of the European Union.[235] An amended proposal was released in December 1992 after consultations with the European Parliament, during which it became clear that two issues were of particular importance to the Parliament's directly elected members.

One was the protection of farmer's privilege, which would enable farmers to use seeds from crops grown from patent-protected seeds, and to breed patent-protected livestock without incurring a further financial obligation to the patent holder as long as the subsequent use was for their own purposes only and not for resale. The other concerned a number of specific exclusions from patentability in the amended Draft Directive:

233. Rudolf Teschemacher, "Legislation, Existing Practice in the EPO, Japan and U.S.A.," Conference Document for the Symposium Biotechnology and Intellectual Property, Stockholm, November 23–24, 1993 (Munich: EPO), pp. 7–8.

234. "Although some animal subject matter may be 'immoral,' our position has always been that the Harvard mouse is the essence of a moral invention because it offers the possibility of more expeditious development of potential new cancer treatments (surely a desirable aim), and allows overall for a reduction in the amount of animal testing and the extent of animal suffering. . . . Using animals for testing purposes (in a strictly controlled manner) is a 'necessary evil,' given the requirements of drug clearance authorities. The provision of a type of animal which might actually reduce the amount of experimentation has, we feel, rightly to be regarded as moral." Bizley, *supra* n. 233, p. 620.

235. At present, all member nations of the EU except Portugal are signatories to the EPC.

(a) the human body or parts of the human body *per se*;
(b) processes for modifying the genetic identity of the human body for a non-therapeutic purpose which is contrary to the dignity of man;
(c) processes for modifying the genetic identity of animals which are likely to inflict suffering or physical handicaps upon them without any benefit to man or animal.

Many members of the European Parliament found these exclusions too ambiguous, leading to further revisions in which the EU Council of Ministers accepted some but by no means all of the revisions proposed by the European Parliament.

On the one hand, the range of biotechnological inventions excluded from patentability would have been expanded by requiring that genetically modified animals and processes for carrying out such modification offer "substantial benefit to man or animal" before they are considered patentable; on the other hand, the council extended farmer's privilege only to seeds and not to livestock, arguing that although farmer's privilege is already provided for in forthcoming Community regulations on plant breeders' rights, there is no justification for creating an exception from "the fundamental principle of patent law according to which the holder of a patent may prohibit any third party from using the protected invention."[236] In other words, the reasoning was that farmers do not deserve special treatment simply because of the distinctive nature of the economic activity in which they engage — a position that, although there is much to recommend it on grounds of economic efficiency, contrasts dramatically with the general direction of the EU's Common Agricultural Policy.[237]

In the end, and after further revisions, the directive was rejected in a vote of 240 to 188 by the European Parliament in March 1995.[238] In December 1995, yet another Draft Directive on the legal protection of biotechnological inventions was proposed by the European Commission.[239] The new proposal:

> . . . completely excludes from patentability methods of germ-line (but not somatic cell) gene therapy on humans. In highly convoluted language . . . the new directive does appear to allow patenting of body parts "not in their natural state." It would also introduce directly into law an exception for livestock farmers that would allow them to use part of their breeding stock to replenish stock numbers.[240]

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236. Session Document C3-0087-94, Common Position of the Council of Ministers (January 1994), Addendum 1 (Statement of the Council's Reasons), s. III.3.2.

237. "Grotesque: A Survey of Agriculture," *The Economist*, December 12, 1992.

238. R. Stephen Crespi, "The European Biotechnology Patent Directive Is Dead," *Trends in Biotechnology* 13 (May 1995): 162–64.

239. "Proposal for a European Parliament and Council Directive on the legal protection of biotechnological inventions," Brussels, December 13, 1995. For reasons of time, this proposal has not been reviewed in detail for purposes of the present study. See also Mike Ward, "Biopatents in Europe Reopened," *Bio/Technology* 14 (1996): 139.

240. Ibid.

It remains to be seen whether this new proposal will secure the approval of the European Parliament.[241]

The coalition of stakeholders challenging biotechnology patenting in Europe is similar to that in the United States. Farmers' organizations are concerned about the possible economic impacts of patents on higher life forms, just as they are concerned about the impacts of rBST on the structure of European agriculture. Existing concerns for animal welfare, already on the rise in Europe[242] have been magnified by the prospect of patenting just as they have been in the United States. In many European countries, new advocacy organizations have been formed specifically to support more restrictive biotechnology patenting policies, and have been joined by existing organizations such as Greenpeace. A crucial difference between the North American and European situations is the existence in Europe of vocal and strategically influential Green or ecology parties, not only at the national level but also in the European Parliament. Thus whereas in the United States opponents of patenting are limited to the courts and to asserting influence through policy networks and communities that exist largely outside formal legislative institutions, ecology parties provide an additional conduit through which European policy outcomes can be influenced.

A fourth milestone was reached in 1991, when the U.S. National Institutes of Health (NIH) filed patent applications for more than 2 000 DNA sequences identified as part of the Human Genome Project. These were not, it should be emphasized, entire genes but rather DNA sequences whose functions were unknown. U.S. patent authorities rejected the application in September 1992 on a number of grounds that apparently had to do with the conventional requirements of novelty, non-obviousness and utility that must be satisfied by every patent application rather than with the complex ethical issues raised by a claim for intellectual property rights in a portion of the human genome.[243] In February 1994, NIH withdrew these and subsequent patent applications rather than appealing the initial rejection; the British Medical Research Council did the same with the applications it had filed.[244]

241. Ibid.

242. "People and Animals: Also a Part of Creation," *The Economist* (August 19, 1995), pp. 19–21.

243. L. Roberts, "Rumours Fly over Rejection of NIH Claim," *Science* 257 (1992): 1855; Comments of B. Healy, Director, National Institutes of Health in *The Genome Project: The Ethical Issues of Gene Patenting,* Hearing Before the Subcommittee on Patents, Copyrights and Trademarks, Committee on the Judiciary, United States Senate, 102nd Congress, 2nd Session, September 22, 1992 (Washington, DC: GPO, 1993), p. 25. For an argument that the NIH patent applications should have been rejected based on failure to demonstrate utility, see Stephen B. Maebius, "Novel DNA Sequences and the Utility Requirement: The Human Genome Initiative," *Journal of the Patent and Trademark Office Society* 74 (1992): 651–58.

244. C. Anderson, "NIH Drops Bid for Gene Patents," *Science* 263 (1994): 909–10.

Meanwhile, the NIH patent filing led to Congressional hearings on human gene patents held in September 1992,[245] and at least two private firms involved in human gene sequencing have subsequently applied for patents on human gene sequences.[246] At the September 1992 Congressional hearings on gene patenting, a key witness was Craig Venter, a former senior NIH scientist and the founder of one of those companies, who defended the patentability of portions of the human genome on several grounds. He argued that in the absence of patent protection academic and industry researchers would seek trade secrecy as an alternative route to intellectual property protection, while "[s]cientists in other countries, who will not be subject to this constraint, will continue to publish their work and reap its benefits."[247] Further, without patent protection "[t]he American public would be denied the benefits of pharmaceuticals and other products of the biotechnology industry," because the capital needed to develop new pharmaceutical products "can only be raised if the risks are balanced by adequate patent protection"; otherwise "American companies could be forced to move their markets and their operations overseas."[248] A number of scientists and scientific organizations have opposed patenting gene sequences whose function is unknown, on the grounds that allowing such patents will create a barrier rather than an incentive to further research.[249] However, no international consensus appears to exist in either the scientific or the biomedical ethics community against patents on human biological materials more generally, or against patents on other innovations such as the Harvard mouse.[250]

If biotechnology patents provide an incentive for beneficial scientific research that would not otherwise take place, and for the commercialization of its results, then patenting may be ethically attractive because, for instance, it will indirectly contribute to the reduction of human suffering by hastening the commercialization of high-yield crops or therapies for disabling diseases. If patents enhance the economic viability of the biotechnology industry, then that too may make patenting ethically attractive. Jobs and income are important, and economic insecurity is quite reliably linked with a range of adverse effects on human health and well-being.

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245. *The Genome Project: The Ethical Issues of Gene Patenting, supra* n. 243.

246. Testimony of J. Craig Venter in Ibid., p. 55.

247. Ibid.

248. Ibid., pp. 55–57.

249. International Council of Scientific Unions, "Statement on Gene Patenting (June 1992), *International Digest of Health Legislation* 44 (2, 1993): 363.

250. The European Commission's Group of Advisers on Ethical Aspects of Biotechnology has concluded that "there are no ethical objections to the patenting of biotechnological innovations *per se.*" It did, however, argue that "[human] genes and partial gene sequences whose functions are unknown should be made expressly unpatentable"; that the Community "should take a stand against the commercial exploitation of the human body," and that safeguards be taken to ensure that transgenic animals not suffer "inadequate [*sic*] pain." "Opinion of the Group of Advisers on Ethical Aspects of Biotechnology of the Commission of the European Communities, no. 3 (September 30, 1993), p. 9.

On the other hand, such arguments do not appear to satisfy a substantial number of people, and dismissing opposition to biotechnology patenting with reference to "special interest" groups[251] and "pseudo-ethical" concerns[252] is too facile. Biotechnology patents have been defended on the grounds that the grant of a patent is "**ethically neutral**" because it is logically and legally independent from actual commercialization of an innovation as well as from public policy decisions about particular uses.[253] However, if biotechnology patenting provides an important if not indispensable stimulus to innovation and profitable commercialization, as many proponents say it does, then the claim of neutrality is questionable whether one is enthusiastic or sceptical about the benefits of biotechnology.

A further issue is that the intellectual property policy community, like the biomedical ethics community, tends to be highly circumscribed and occasionally rather insular. In a variety of public policy fields, the prerogatives of the "experts" who comprise such communities are now being challenged because of the absence of alternative fora in which people who feel very strongly about the ethical issues but who are not part of the policy community can voice their concerns; this trend can be expected to continue until and unless there are other places where the issues can be dealt with.

When we consider ethical objections to patenting itself rather than to the range of applications it can be seen as facilitating, at least two distinct lines of argument emerge. The first of these involves questions of distributive justice. Depending on the context, patenting is seen (for instance) as accelerating the concentration of agricultural production either within or between nations by giving those producers who can afford genetically engineered crops or livestock a further competitive advantage, and thereby accelerating the decline of the family farm in industrialized countries and facilitating agribusiness's rapid market penetration in developing countries.[254] In the industrialized countries, the question (which arises in any number of policy contexts, including the regulation of rBST) is that of how much value we attach to the preservation of certain kinds of agricultural units of production, and what kind of value it is.[255] In the case of medical innovations, concern

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251. R. Stephen Crespi, "Biotechnology Patenting: The Wicked Animal Must Defend Itself," *European Intellectual Property Review* 9 (1995): 434.

252. Ibid., p. 436.

253. Ibid., p. 435 (emphasis in original).

254. See e.g. F. H. Buttel and J. Belsky, "Biotechnology, Plant Breeding and Intellectual Property: Social and Ethical Dimensions," *Science, Technology and Human Values* 12 (1987): 31–49; Cary Fowler and Patrick Mooney, *Shattering: Food, Politics, and the Loss of Genetic Diversity* (Tucson: University of Arizona Press, 1990).

255. It may be that extremely large-scale agribusiness is the most efficient way of feeding Canadians, in terms of narrow economic criteria. Is the "family farm," then, really shorthand for a much more complex set of beliefs about the value of stable and economically viable communities, which happen to be sustained by agriculture and for whose continued survival the society is willing to pay at least some premium? If so, given the larger percentage of the work force employed in manufacturing, why is it often more difficult to defend policies that would support the "local manufacturing plant"? This may be because the symbolism associated with farming is completely different from that associated with manufacturing, with the former equated with self-sufficiency and the latter with alienation

arises because patents that are lucrative for researchers and commercializers may be associated with high costs for consumers and insurers, thus worsening existing inequalities of access to health care.

Such arguments deal with costs and benefits, albeit very broadly defined. They can therefore be incorporated or assimilated into existing policy debates, conceptually if not always institutionally, without great difficulty. It is much harder for existing institutions to come to grips with a second category of claims: that the ownership of intellectual property in living organisms is **intrinsically** wrong,[256] or else that permitting such ownership will lead to undesirable deterioration in the respect for life that is a key element in almost all moral systems.[257] The former argument is sometimes countered with the claim that holding a patent on a particular genetic modification of an organism is in no way equivalent to owning either life in general or the affected organisms themselves. However, a leading European defender of biotechnology patents concedes that "[a] successfully sued infringer of a cell-line patent may be required to destroy or deliver up his stocks of infringing material. In this situation the patentee is entitled to behave as though this material per se were his own property. . . ."[258] This concession leads to interesting conjectures about transgenic crops, animals and the like!

There is a strong convergence between the latter argument, frequently made in terms of the commodification or objectification of life or living organisms, and a more general set of concerns about the social risks of human genome research. Like those concerns, arguments that link biotechnology patenting with changes in social attitudes are singularly difficult to evaluate because they rely on anticipations of the way technological change will affect human experiences and perceptions.[259] One response is that such anticipations, which Scott Altman calls "modified-experience claims," should not be used as the basis for public policy,[260] for instance, because precedents suggest that most people's respect for life and for other individuals will not deteriorate in response to more complete scientific knowledge of the genetic basis of human behaviour.[261] However, this response may not adequately

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from the products of one's work. It may also be because small-scale farmers, at least, are simultaneously investors and workers, with the greater political clout that entails; policies aimed at preserving "uneconomic" local manufacturing plants, in contrast, are likely to come into direct conflict with the economic objectives of the plants' owners, at least in multiplant firms.

256. *Cf.* The Blue Mountain Declaration's description of biotechnology patenting as an "attack on the value of life."

257. The reader will recognize here an example of the distinction between arguments about intrinsic rightness or wrongness and arguments about consequences that was outlined in Chapter 2.

258. Crespi, *supra* n. 251, p. 434.

259. Scott Altman, "(Com)modifying Experience," *Southern California Law Review* 65 (1991): 293–340.

260. Ibid., p. 308.

261. Ibid., pp. 308–34.

address all the dimensions of commodification, which are discussed in greater detail in Chapter 5. As with the arguments about human genome research, it seems unwise for intellectual property policy to ignore altogether what Margaret Radin calls "the conceptual/social practice nexus."[262] Individual and social attitudes, although intangible, are nevertheless real, and those attitudes are intimately linked to people's experiences and values.

3.5. Summary

Each of the three applications of biotechnology selected for analysis in this chapter raises a range of ethical issues, and involves multiple stakeholders whose ethical commitments may or may not be in conflict. In the next chapter, we describe the way in which similar controversies have unfolded in Canada, and explore some efforts on the part of the federal government to deal with them. As in the introduction to this report, we emphasize that these efforts did not all explicitly deal with ethical issues as such. Indeed, this observation is an important basis for the analysis undertaken in Chapter 5. There, we identify four key ethical tensions that emerge from policy controversies about biotechnology in Canada and elsewhere, as a way of linking the Canadian and international contexts and providing a conceptual basis for further work in this area.

262. Margaret Radin, "Reflections on Objectification," *Southern California Law Review* 65 (1991): 342.

4. Addressing the Ethical Challenges of Biotechnology in Canada

The preceding chapter provides an overview of key ethical questions about biotechnology as they have been raised outside Canada. Because the purpose of this report is to contribute to the constructive resolution of such questions as they arise in Canada, this chapter is structured somewhat differently. It provides an overview of several efforts that have been made within the Canadian government to address policy and ethical issues that are relevant to biotechnology.

We cannot do justice here either to the level of detail characteristic of most of these efforts, or to the complexities of policy analysis and the range of ethical choices within a specific context such as research on human subjects or the protection of biodiversity. Further, it must be emphasized that several of the efforts described here are not intended to address ethical issues, and do not specifically do so. Ethical issues nevertheless arose in the course of the discussion — a point whose importance we return to later in the report. Finally, the efforts in question are different in institutional terms. Some sections of this chapter summarize the results of commissioned research; others describe well-established institutional routines or chronicle regulatory controversies with ethical dimensions, which have been played out in extensive parliamentary hearings and which, so far, remain unresolved.

4.1. The Medical Research Council of Canada, the National Research Council of Canada and Ethical Guidelines for Research

In Canada and elsewhere, scientific research involving human subjects is the area in which explicit and systematic review of ethical issues is most firmly established. Although the Medical Research Council of Canada (MRC) guidelines on this point "are not directly legally binding . . . the duty to observe them exists in legal agreements that the MRC makes with the institutions whose investigators the council funds, and in agreements, often employment contracts, between investigators and their universities or other institutions."[263]

The first set of such guidelines was finalized in 1978, in the same year as the publication of the *Belmont Report* but at a time "when many research institutions had already established Research Ethics Boards (REBs), often in response to U.S. requirements."[264] The MRC guidelines were revised in 1987, and a working group set up by MRC, the Natural Sciences and Engineering Research Council (NSERC) and the Social Sciences and Humanities

263. Summarized comments of Bernard M. Dickens in Proceedings: *Inter-Departmental Workshop on Ethics and Biotechnology, "Moving from Confrontation to Engagement"* (Ottawa: 1994), p. 3.

264. Judith Miller, "What to Do Until the Philosopher Kings Come: Bioethics and Public Policy in Canada," *Politics and the Life Sciences* 13 (1994): 94.

Research Council (SSHRC) now is drafting a code of conduct that will provide a common ethical framework for human subjects research regardless of which of the three participating granting councils is funding it.[265] MRC also maintains a standing committee on ethics in experimentation. Since 1989, the National Council on Bioethics in Human Research (NCBHR), which was established jointly by MRC, Health Canada and the Royal College of Physicians and Surgeons of Canada, has operated as an advisory body whose mandate is to assist local REBs to make the best ethical choices. Consequently, it is fair to say that at least conceptually a well-developed institutional framework exists at both the local and national levels.

The principles underlying the current MRC guidelines, which closely follow those in the *Belmont Report*, are stated in this way:

> The Standing Committee [on ethics in experimentation] believes that the basic ethical principle in research, as in health care, is respect for life. From this principle flow others: the concept of autonomy, the duty to beneficence, and the duty to justice.
>
> Respect for life both justifies and limits research. As for beneficence, mankind may benefit, but individuals place themselves at risk. The benefits and risks of research must always be weighed. Justice must be exercised in allocating the anticipated risks and the hoped-for benefits.
>
> The burden of the enterprise should run with the benefits. Great care must be taken that research risk does not fall unjustly on the infirm, or the racially, economically or otherwise disadvantaged.
>
> The assessment of risk and benefit calls for a most careful study of the relevant data. Both the investigator and the institutional REB must assess the risk to benefit ratio, bearing in mind that risks and benefits may accrue to different people and not be measurable on the same scale. The ratio must be clearly favourable before the proposal can gain ethical approval.
>
> Upon institutional approval of the study, the subjects' participation may be invited, and they too must be able to make their own assessment of the balance between likely benefits and risks to themselves and others, and perhaps to those for whose welfare they are responsible.
>
> The ethical challenge then is to decide in the light of principle what risks are justifiable and for whom, in relation to presumed gain. These dilemmas are the central focus of the Guidelines.[266]

The guidelines elaborate on those principles with reference to a number of issues: special types of research, the nature of informed consent, and confidentiality. Of special interest in the present context is the view taken of gene therapy research. The 1987 guidelines advocate "consideration of human genetic engineering only when there is no reason to believe that the genetic alterations will be inherited"; in other words, restricting the scope of

265. Edward W. Keyserlingk, "Research Ethics in Canada: Revising the Guidelines and Learning from Scandals," *International Journal of Bioethics* 6 (1995): 243–45; Judith Miller, "Research Ethics Boards in Canada: A Time of Review and Renewal," *International Journal of Bioethics* 6 (1995): 246–48.

266. Medical Research Council of Canada, *Guidelines on Research Involving Human Subjects* (Ottawa: Supply and Services Canada, 1987), pp. 12–13

approved activity to somatic cell gene therapy.[267] Within the context of the overall guidelines, a working group subsequently developed a more specific set of guidelines for research on somatic cell gene therapy in humans, once again emphasizing that: "It is not appropriate to approve any protocol where the germ line is foreseen to be altered, even though this is not the primary intention of transfer."[268]

Under the guidelines, the ethical review of research proposals is a matter of process as well as of substance, with the primary responsibility delegated to individual REBs. Composition of these boards should include relevant scientific specialists as well as experts from other disciplines such as bioethics, philosophy, theology and law.[269] REBs should also include members of the community: "The values of the particular community are the matrix of ethical review. The REB must contain members who can reflect community values. Lay members affiliated with a hospital or university board are often suitable, but the board should ideally include non-affiliated individuals."[270] REBs are regarded as having responsibilities both to the institution and to the MRC, and are expected to organize their procedures accordingly, including making provision for continuing review where appropriate.[271]

An informal survey of REBs undertaken early in 1995 identified "monitoring, genetic therapy and other research emerging from the human genome project, and consent issues with vulnerable populations" as major issues of current concern.[272] Also in 1995, NCBHR released the results of a major three-year site visit study of REBs affiliated with 16 Canadian university medical faculties, conducted by NCBHR's Working Group on Evaluation.[273] Among its findings was that of 47 REBs responding to questions about their composition, only five complied with all MRC and (U.S.) National Institutes of Health guidelines. Many did not include lay members not affiliated with the institution, for instance.[274] If we take seriously the importance of deliberation among people with varying perspectives as crucial to the **process** of reaching a decision, and the importance of decisions that reflect community values, this finding emerges as particularly important. Members of surveyed REBs also identified numerous concerns with their operation,

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267. Ibid., p. 17.

268. Medical Research Council of Canada, *Guidelines for Research on Somatic Cell Gene Therapy in Humans* (Ottawa: Supply and Services Canada, 1990), p. 29.

269. MRCC, *supra* n. 266, pp. 45–46.

270. Ibid., p. 45.

271. Ibid., pp. 49–50.

272. Miller, *supra* n. 265, p. 247.

273. "Protecting and Promoting the Human Research Subject: A Review of the Function of Research Ethics Boards in Canadian Faculties of Medicine," *NCBHR Communiqué* 6 (1, Winter 1995): 3–32.

274. Ibid., pp. 11, 20.

including a lack of expertise in ethics[275] and questions about carrying out ethical review for research conducted outside their institutions.[276] The NCBHR working group recommended that REBs cease doing this, although they should review all protocols that may in any way affect patients or employees; at the same time, its report pointed out that "mechanisms for the review of research in non-affiliated institutions are rare, indeed almost non-existent."[277] Given the expansion of privately funded research, this should be an issue of considerable concern, as should a lack of clear policies regarding sanctions for noncompliance with a research protocol once approved.[278] Presumably these issues, as well as the working group's other recommendations, will be addressed in the Tri-Council review that is now under way.

The National Research Council of Canada (NRC) has also adopted a set of guidelines for research involving human subjects, developed by the NRC's Human Subjects Research Ethics Committee, which plays an ongoing administrative role in the implementation of the guidelines. The NRC guidelines, like those of MRC, require demonstration of a favourable risk–benefit ratio.[279] However, they are more demanding in some respects: for instance, they require that research involving "a vulnerable or dependent population can only be justified if it is demonstrated that the research can only be carried out by involving persons from such populations,"[280] and the actual approval of the NRC Management Committee "or its delegate" is required for all protocols except those eligible for expedited review.[281]

4.2. Medical Interventions in Human Reproduction

The preceding discussion deals only with research involving human subjects. However, as noted in Chapter 3, a key area of international controversy involves what may be called the social and scientific ethics, as well as the clinical ethics, of medical interventions in human reproduction. Some such interventions, although by no means all, fall within the realm of biotechnology as defined for purposes of the present report. Recent Canadian policy attention to these issues has been dominated by the history of, findings of and reactions to the Royal Commission on New Reproductive Technology (RCNRT). Established in 1989, the commission issued its final report four years later after a turbulent existence that included the dismissal of four of the original commissioners, the addition of two others, and recurrent criticism from some of the women's organizations that had initially been

275. Ibid., p. 20.

276. Ibid., p. 15.

277. Ibid., p. 17.

278. Ibid., p. 24.

279. National Research Council of Canada, *Research Involving Human Subjects: Guidelines for Institutes* (Ottawa: Supply and Services Canada, March 1995), p. 7.

280. Ibid., p. 8.

281. Ibid., p. 15; for a list of the research practices that preclude eligibility for expedited review, see Ibid., p. 47.

enthusiastic about the commission. The commission's report argued for a set of eight guiding principles (Table 3); it sought to derive those principles from an:

> . . . ethic of care [which] holds, broadly speaking, that moral reasoning is not solely, or even primarily, a matter of finding rules to arbitrate between conflicting interests. Rather, moral wisdom and sensitivity consist, in the first instance, in focussing on how our interests are often interdependent. And moral reasoning involves trying to find creative solutions that can remove or reduce conflict, rather than simply subordinating one person's interests to another.[282]

Table 3. Eight Guiding Principles for Policy on New Reproductive Technology

1. Individual Autonomy	People are free to choose how to lead their lives, particularly with respect to their bodies and their fundamental commitments, such as health, family, sexuality, and work. This principle requires that all members of society be able to make informed decisions, thus requiring that they have information on the range of potential outcomes, risks and benefits.
2. Equality	Every member of the community is entitled to equal concern and respect. This principle precludes any social practice that reflects or perpetuates the assumption that some people's lives are worth less than others, and requires taking into account the interests and concerns of Canadians in all their diversity, including (e.g.) specific attention to the impact of new reproductive technologies on women, racial and ethic minorities, Aboriginal people, people with disabilities, and lesbians. Equitable access to public services such as health care and education is based on this principle.
3. Respect for Human Life and Dignity	All forms of human life (and indeed human tissue in general) should be treated with sensitivity and respect, not callousness or indifference. This includes zygotes, embryos and fetuses; although the law does not treat them as persons, they are connected to the community by virtue of their origins and their possible futures.
4. Protection of the Vulnerable	Vulnerability relates to power imbalances; the welfare of those who are less capable of looking after themselves or who are open to exploitation for various reasons must be given special consideration. The most common example concerns the welfare of children. Society has a responsibility to ensure that vulnerability is reduced where possible and that the vulnerable are not manipulated or controlled by those in positions of power and authority.
5. Non-Commercialization of Reproduction	Commercialization involves the exchange of money or goods with the intent of generating a profit or benefit. Commodification means the treatment of human beings or body tissues and substances as commodities — as means to an end, not as ends themselves. Thus commercialization necessarily includes commodification, but not vice versa. Decisions about human reproduction should not be determined by a profit motive; commodifying human beings and their bodies for commercial gain is unacceptable. However, there may be a legitimate role for commercial interests in certain aspects of reproductive health care, under circumstances that guard against the inappropriate commodification of human tissues.

282. *Proceed with Care*, Final Report of the Royal Commission on New Reproductive Technologies (Ottawa: Supply and Services Canada, 1993), p. 52; the eight guiding principles are found on pp. 52–58. The final report's interpretation of the ethic of care and the eight guiding principles both rely heavily on a paper prepared for the commission by Will Kymlicka; see Kymlicka, *supra* n. 41.

6. Appropriate Use of Resources	Since needs are diverse and resources are finite, resources must be used wisely and effectively, reflecting the fact that resources used to help some people in one way become unavailable to help other people in other ways. Society must establish its health care priorities, for example, and strive to maintain them in difficult political and economic times.
7. Accountability	Those who hold power, whether in government, medicine, technology, or other fields, are responsible for the way they use that power. Although a self-regulating medical profession may be obliged to act in the public interest, it is not necessarily best equipped to assess the social, ethical, and economic implications of new reproductive technologies and may not be accountable enough to those people whose needs they are meant to serve.
8. Balancing Individual and Collective Interests	Both individual and collective interests are worthy of protection; individual interests do not automatically take precedence over collective interests, or vice versa. The individual interests of women or couples seeking assisted conception or prenatal diagnosis services (for instance) must be balanced against the collective interests of society as a whole and of identifiable groups within society, such as women, children, people with disabilities, and members of racial and ethnic minorities. [This principle is explicitly recognized in s. 1 of the *Charter of Rights and Freedoms*.]

Source: Adapted from *Proceed with Care*, Final Report of the Royal Commission on New Reproductive Technologies (Ottawa: Supply and Services Canada, 1993), pp. 52–65.

A key recommendation of the RCNRT was the establishment of a National Reproductive Technologies Commission "charged with the primary responsibility of ensuring that new reproductive technologies are developed and applied in the national public interest."[283] As this statement indicates, the proposed commission was envisioned as having a mandate extending far beyond the ethical review of research, and as much more than just an advisory body. Its statutory powers would include licensing and setting allowable conditions for a variety of medical interventions in human reproduction. It would also set standards and guidelines not only for those activities it was empowered to license and regulate, but also for providers and activities not subject to its authority; and it would collect and store records provided by licence holders.[284] The National Reproductive Technologies Commission would be composed of 12 individuals, with the expectation that at least half of the members would be women[285] and that membership would "always include persons knowledgeable about the interests and perspectives of those with disabilities, those who are infertile, and those who are members of racial minority, Aboriginal and economically disadvantaged communities. A range of expertise should also be represented, including reproductive medicine, ethics, law, and social sciences."[286] It was recommended that the proposed National Commission have six subcommittees, including both commission members and people from outside the commission.[287] The RCNRT further recommended enacting criminal prohibitions on the commercial exchange of human reproductive

283. RCNRT, *supra* n. 282, p. 112.

284. Ibid., pp. 115–19.

285. Ibid., p. 122.

286. Ibid., pp. 122–23.

287. Ibid., p. 123.

materials, on commercial involvement in preconception arrangements (so-called surrogate motherhood), and on certain categories of human embryo research.[288]

In response, Health Canada conducted a consultation with approximately 50 organizations across Canada on the substance of the commission's recommendations. In July 1995, the Minister of Health announced a voluntary moratorium on certain applications of new reproductive technologies, and in January 1996 the Minister announced the membership of an advisory committee that "will advise Health Canada on compliance with the moratorium and on any follow-up action, track the development of emerging new reproductive and genetic technologies and identify other highly questionable practices that warrant inclusion in the moratorium."[289] The membership of the advisory committee in many respects reflects the same criteria of inclusiveness that were evident in the RCNRT's recommendations for the composition of the National Commission. When our report was written [March 1996], a more extensive response to the recommendations of the RCNRT by Health Canada was pending. Subsequently, in June 1996, the Minister of Health introduced legislation to establish a regulatory structure for many of the technologies addressed by the RCNRT.[290]

The reasoning behind the RCNRT's recommendations came in for some thoughtful criticism. Law professor Patrick Healy noted that the ethic of care mandates "the maximization of responsible concern for others not only in personal decision making but also in decision making by public authorities."[291] However, without further elaboration this is little more than a rejection of unbridled self-interest, and an endorsement of the moral point of view. As Healy points out, when so stated, the ethic of care offers "little prescriptive guidance for making practical decisions on specific issues"[292] and its "ambiguity . . . is such that it does not readily explain many of the recommendations made by the commission."[293] Healy also notes that neither the eight guiding principles nor many of the commission's recommendations follow in any kind of unambiguous fashion from the ethic of care. It should be added, and in fact the RCNRT acknowledges, that some of the eight principles are more basic than others: "For example, the principle of non-commercialization . . . is largely a conclusion from the other principles."[294]

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288. Ibid., p. 108.

289. Health Canada News Release 1996-09, "Membership of Advisory Committee on Interim Moratorium on Reproductive Technologies Announced," January 24, 1996.

290. Bill C-47, the *Human Reproductive and Genetic Technologies Act*, June 1996.

291. Patrick Healy, "Statutory Prohibitions and the Regulation of New Reproductive Technologies Under Federal Law in Canada," *McGill Law Journal* 40 (1995): 911.

292. Ibid.

293. Ibid., p. 912.

294. RCNRT, *supra* n. 282, vol. 1, p. 53.

It could be argued that, once such derivative principles are taken into account, the RCNRT's principles simply reformulate the four principles of North American biomedical ethics that are briefly discussed in section 2.3 of this report. There are, however, some important variations. For instance, the RCNRT refers not to justice but rather to equality. This is a subtle but important distinction. Although what counts as a transgression of equality requirements is contestable, as illustrated by a number of recent cases involving the so-called equality provisions of Canada's *Charter of Rights and Freedoms,* the principle of equality is not for that reason meaningless. Indeed, the debates about the idea of inequality emphasize the status of equality as a distinctive conception of justice, which in the present context includes such matters as "equitable access to public services,"[295] but also as a concept that can be narrower or broader than justice. It may not apply to some situations where justice would apply, but could be broader in its scope than justice in those situations in which it does apply.

As in the MRC and NRC guidelines, clearly stating protection of vulnerable persons as a guiding principle gives distinctive and important content to the principle of justice. On some versions of justice, the vulnerability of particular individuals simply lacks moral significance.[296] Indeed it is with respect to its implicit conception of justice that the ethic of care may be most clearly distinguishable from, for example, an ethic that emphasizes "getting what you deserve." For these reasons, among others, criticisms of the RCNRT's approach on the basis that it yields indeterminate results in specific cases are misdirected; few ethical approaches that would meet with anything approaching general acceptance as a basis for public policy are capable of doing so.

The guiding principles adopted by the RCNRT do indicate that certain kinds of activities are almost certainly to be regarded as impermissible, even though Healy as well as a number of feminist critics suggest that the RCNRT's interpretation of them may be overly permissive.[297] Perhaps even more importantly, they provide a way in which policy makers can determine **what kinds of questions to ask** when confronted with a particular situation involving medical intervention in human reproduction. When we are uncertain about what principles should be applied, we can seek ethical "answers" through processes. To establish such processes, it is essential that we ask as many of the right questions as possible. Even though there may not be one clearly right answer, this approach will provide us with a range of possible answers, which we can then prioritize, from unacceptable to most acceptable.

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295. Ibid., p. 54.

296. For a critique of such positions see Somerville, *supra* n. 58, pp. 385–94.

297. "[I]t would appear that the Commission has concluded that the 'ethic of care' is best fulfilled by proceeding to the development and implementation of reproductive technologies, subjected to isolated prohibitions and a general licensing scheme. Many will argue that this conclusion evinces a lack of concern for many people, especially women, and affords too much opportunity for the commercialization of genetic research and assisted conception. Indeed, the absence of specific controls on medical practices and scientific research implies tacit approval of them." Healy, *supra* n. 292, p. 914.

A critique of the RCNRT's approach from a different perspective involves issues of implementation. At least a few of the RCNRT's recommendations would seem contraindicated by the ethic of care: "criminal or penal prohibitions are blunt instruments that are often antithetical to anything that might be called the ethic of care."[298] The RCNRT's recommendation of criminal prohibitions on many forms of involvement in commercial preconception contracts,[299] for instance, might lead to a situation in which the testimony of a gestational mother who has entered into such an arrangement as a consequence of her social and economic vulnerability was compelled under threat of prosecution for contempt of court, even if her own conduct in entering into the arrangement were not subject to criminal sanctions. A similar situation might arise in the case of an economically vulnerable woman who had "donated" ova, perhaps in response to one of the advertisements that recently appeared in Canadian university newspapers;[300] here, however, the woman's conduct would itself be criminalized by the recommendations of the RCNRT, which specifically refer to the sale [but not the purchase?] of human eggs, sperm or zygotes. Such outcomes seem inconsistent with the principle of protecting the vulnerable, or even with a distinctive concern for their situations, at least at the level of the individual; for justification within the ethic of care, they require an argument that care for the community, in order to benefit those individuals who constitute the community, demands punitive measures directed at some particular individuals.

This leads to the more general and more fundamental criticism that the report of the RCNRT does not always indicate that the advantages and disadvantages of various legal and institutional ways of achieving a particular policy outcome (policy instruments, in the jargon of political science) were weighed in any systematic or consistent way with reference to the guiding principles themselves.[301] This does not constitute a criticism of the guiding principles outlined by the RCNRT. Instead, it suggests the need for attention to the role of ethics in guiding not only the choice of ends, but also the choice of means. The point is an important one not only with respect to medical interventions in human reproduction: as noted in Chapter 6, the choice of institutional frameworks for regulating biotechnology in general raises important value questions that do not necessarily arise until it is acknowledged that alternative institutional frameworks for making and implementing decisions reflect the relative priority accorded to particular values or principles.

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298. Ibid.; see also pp. 919–43, where this criticism is expanded upon with reference to a number of the commission's specific recommendations including those dealing with embryo research and preconception arrangements

299. RCNRT, *supra* n. 282, vol. 2, p. 690.

300. For a discussion see David Michael Lamb, "Is Egg Donation Exploitation," [University of Toronto] *Varsity*, February 5, 1996, p. 9.

301. The report of the RCNRT is by no means the only report in the field of biomedical ethics against which this criticism has been leveled. See, e.g., Raanan Gillion, "Ethics of genetic screening: the first report of the Nuffield Council on Bioethics," *Journal of Medical Ethics* 20 (1994): 67–68, 92.

4.3. Industry Canada and Biotechnology Patenting

Unlike the situation in Europe and the United States, patenting issues have not had a high public profile in Canada, although human cell lines, for instance, have been considered patentable in Canada for many years. However, more than ten years after the inventors of the Harvard mouse first applied for a Canadian patent, they have appealed to the Federal Court of Canada the final ruling of the Commissioner of Patents on their application. The commissioner held that:

> Since the plasmids and the transgenic unicellular material are produced under the full control of the inventor and are reproducible, I am satisfied that they are a 'manufacture' or a 'composition of matter' under Section 2 of the [Patent] Act. However I cannot extend the meaning of 'manufacture' or 'composition of matter' to include a non-human mammal.[302]

When the case is heard, especially if should end up in the Supreme Court of Canada, it may be that a discussion of the ethical dimensions of patenting will develop along lines similar to those already observed in the United States and in the European Union.

Among federal departments, Industry Canada has extensive responsibilities for promoting the Canadian biotechnology industry. The department's most direct involvement with ethical issues, however, has come through examination of intellectual property (IP) rights under the auspices of the Intellectual Property Policy Directorate. The most direct treatment of ethical issues is a report by some of the authors of the present study, which focusses on patents for higher life forms.[303] Among its key conclusions is the need to distinguish between arguments specific to patenting and arguments about the ethics of the biotechnology enterprise in general, which enter into discussions of patenting because (for instance) of the claim that patent protection provides an important incentive for research and commercialization, and between arguments about the intrinsic rightness or wrongness of particular activities or practices and arguments about their consequences (see Chapter 2). The matrix in Table 4, modified slightly from the earlier report, indicates the policy relevance of this distinction. In addition, because some aspects of that report's discussion of ethical issues are not in fact specific to patenting, and involve issues that come up repeatedly in the biotechnology debate in Canada and elsewhere, we draw on these for the present study where appropriate.

302. Decision of the Commissioner of Patents in the matter of Patent application number 484,723, Ottawa, August 4, 1995, p. 7.

303. The study did not specifically explore the issue of what should be taken to constitute a "higher" life form for the purposes of intellectual property policy.

Table 4. Schematic View of the Ethical Issues Associated with Patenting of Higher Life Forms

Form of argument	Topic of discussion: Biotechnology	Topic of discussion: Patenting
Arguments dealing with inherent or intrinsic rightness or wrongness	**Pro:** Genetic research and its application fulfil humanity's obligation to expand the range of scientific knowledge and technological capability, which are valuable in their own right. **Con:** Inserting genes from one species into another, as in the case of the Onco-Mouse, amounts to "Playing God." Respect for life means that there are some things we can do that we ought not to do.	**Pro:** Patenting higher life forms is required in order to be fair to inventors and investors, who otherwise will not be assured of a return on their time and money. (This is an argument based on principles of justice.) **Con:** "Owning life," in the form of IP rights in portions of the human genome (or, in a different variant of the argument, of any organism's genome), violates a basic ethical duty of respect for life.
Arguments dealing with harmful or beneficial consequences	**Pro:** Biotechnology will make possible new kinds of therapies for debilitating diseases, and increases in crop yields and livestock productivity will enable humanity to produce more food at the same or lower cost. **Con:** New therapies based on understanding the genetic basis of various diseases will be so expensive that they will widen the gap between rich and poor in terms of the quality of health care they can afford, whether or not the therapies in question are afforded IP protection.	**Pro:** Patenting creates a necessary financial incentive for investment in the research and development that will lead to the benefits that can be realized from genetic engineering; without that incentive, those benefits will be delayed or foregone altogether. **Con:** Patenting will lead us to objectify life and living creatures; patenting enables patent holders to reap monopoly profits from lifesaving therapies and diagnostic techniques, thereby driving up cost and limiting access relative to an alternative scenario in which access to the relevant basic research remained in the public domain.

The study argues that the patent system's claim to "neutrality" is at best questionable, and suggests the need for a public debate on the ethical issues associated with patenting higher life forms. Several options are identified: they include a Royal Commission analogous to the RCNRT; a series of informal consultations; and hearings by a parliamentary committee. This last option is identified as the option of choice.[304] One of the outcomes of this process, it is anticipated, would be the identification of principles that would guide the ethical assessment of subsequent patent applications. Those principles could be applied in several

304. Schrecker et al., *supra* n. 82, pp. 99–101.

ways: for instance, by research ethics boards affiliated with research institutions, or by an appointed ethical review board advisory to the patent office.[305] Once again, the last of these options is identified, in a preliminary way, as the option of choice.

The specifics of these recommendations are, in our view, less important than the general finding that issuing patents on higher life forms raises ethical issues broader than those conventionally dealt with in intellectual property law, and requires some form of review based on principles additional to those contained in that body of law itself. More generally, Industry Canada's approach is distinctive and valuable because the department has taken a policy field conventionally viewed as raising few ethical issues and explicitly searched for ethical presuppositions that may be unexceptionable when applied to patents on hair spray, but that take on new and troubling dimensions when they are applied, say, to mammalian organisms or to portions of the human genetic code.

This study is just part of a broader program of research on the economic, ethical and environmental implications of intellectual property rights, which has been carried out by a number of contractors over the past few years. A background study of the Canadian biotechnology industry[306] carried out by James G. Heller Consulting for Industry Canada, Environment Canada and Health Canada finds that, among the problems facing the industry, regulatory barriers "ranked third in importance overall, but they were second in importance for the ag-bio [agricultural biotechnology] sector."[307] If one accepts the argument that "[p]erhaps the most important promise of ag-bio lies in its potential to feed the world,"[308] which many critics of agricultural biotechnology do not,[309] then such barriers may be ethically problematic to the extent that they discourage private investment in basic research.[310]

Intriguingly, "IP protection was not perceived as a barrier [to commercialization] by any respondents" in the study.[311] However, this finding should not lead us to conclude that the economic significance of patenting or alternative forms of IP protection is limited, for at least two reasons.

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305. Ibid., pp. 101–05.

306. James G. Heller Consulting Inc., *Background Economic Study of the Canadian Biotechnology Industry* (Toronto: James G. Heller Consulting, June 1995).

307. Ibid.

308. Ibid., p. 43.

309. See e.g. Rissler and Mellon, *supra* n. 103, pp. 9–10.

310. We make this distinction because in the global frame of reference, it is arguably the overall stock of available knowledge that is important rather than any one country's successful commercial application of that knowledge within its own borders. National economic success or failure on this point is not of course unimportant, but any individual country's performance in this regard may not have a substantial impact on "feeding the world."

311. Heller Consulting, *supra* n. 306, p. 119.

First, the Canadian market is small relative to potential export markets, making IP protection in those markets more important than in Canada.[312] Since most applicants for Canadian biotechnology patents reside in the United States, the report raises the prospect that "strengthening biotechnology IP protection in this country may have significant economic impacts and could lead to an acceleration in the growth of Canada's biotechnology trade deficit."[313]

On the other hand, another study from the University of Guelph's George Morris Centre, which deals specifically with implications of patenting for the animal and agri-food sector,[314] raises the possibility that "Canadian-developed biotechnologies may be available in the U.S. long before they become eavailable in Canada," and further that uncertainties about intellectual property rights could mean that "Canadian bio-engineered products patented in the U.S. may not be available in the Canadian market. This can have significant impacts on the competitiveness of the Canadian agri-food sector."[315] More generally, the study warns that "Canada cannot afford to sit on the fence since the international trade environment is changing quickly to virtually exclude countries without appropriate IP protection from gaining access to emerging biotechnological inventions."[316]

Second, although financing may be the largest single barrier to commercial success, financing and patenting are closely related. The availability of strong patent protection can be a prerequisite for raising capital, whether through market placements or through licensing, joint ventures and strategic alliances.[317]

Debate about the economic implications of intellectual property protection in the biotechnology field will no doubt continue. Suffice it to say here if those economic benefits are presumed in principle to warrant strong or strengthened intellectual property protection, then it makes a great deal of difference not only how large those benefits are but also how they are distributed and what the costs would be of providing a regime of intellectual

312. Ibid., pp. 119, 198–99; see also Vincent Amanor-Boadu, Morris Freeman and Larry Martin, *The Potential Impacts of Patenting Biotechnology on the Animal and Agri-Food Sector*, draft final report (Guelph, ON: George Morris Centre, University of Guelph, March 1995), pp. 89–90. Interestingly, the report suggested that securing IP protection in such major markets might be "beyond the financial reach" of Canadian university-based inventors and their institutions. Heller Consulting, pp. 120–21.

313. Heller Consulting, *supra* n. 306, p. 199.

314. Amanor-Boadu et al., *supra* n. 312.

315. Ibid., p. 90; see also p. 136 on the economic advantages to Canada of taking a leadership role in facilitating farm animal patenting.

316. Ibid., p. 101.

317. Heller Consulting, *supra* n., 306, p. 120; see also Graham Strachan (President and CEO, Allelix Biopharmaceuticals Inc., "Patents: The Lifeblood of the Emerging Canadian Biopharmaceutical Sector," November 27, 1996 (on file with Intellectual Property Policy Directorate, Industry Canada).

property protection less strong than that offered by Canada's major trading partners and competitors. Here is an instance where "getting the facts right" is very important indeed.

The Guelph and Heller Consulting studies both shed some light on a possible tension between the norms of academic research, which emphasize full, open and rapid communication of results, and the requirements of commercialization. Trade journals warn that not only scientific publications, but even private conversations at scientific conferences may involve disclosures that compromise subsequent patent applications.[318] The Heller report notes that:

> Practitioners interviewed for this study recommended that scientists at universities and research institutes learn the importance of IP protection and confidentiality of inventions to assist the universities and research institutes in commercializing their biotechnology inventions.[319]

Because of the potentially adverse effects on the openness and speed of scientific communication, this is precisely the sort of advice about which critics of biotechnology, and of the expanded commercial role of universities in general, are worried. Interestingly, the Guelph study identifies diverging views on this point within the research community:

> Younger [university] faculty and researchers saw the opportunity to patent their animal inventions as a means to advancement. Contrarily, most older faculty . . . saw it as a means to "destroy academic purity by commercializing science." Government researchers, interestingly, responded more like younger faculty, seeing patents as a revenue source for their research activities.[320]

The report does identify at least one instance in which disclosure of research results has been delayed by patenting considerations.[321]

Industry Canada has also supported research on IP and the protection of biodiversity — an area in which Canada has a number of obligations as a signatory to the Biodiversity Cnovention. One extremely detailed study reviews the literature on this topic;[322] a companion report, equally detailed, surveys approaches to the IP/biodiversity linkage in a variety of jurisdictions rich in biological resources including the Andean Pact countries, Costa Rica, Mexico, some African countries, India, Indonesia, Australia and New Zealand,

318. Kathleen M. Williams, "When Is a 'Private' Conversation 'Public' Disclosure?" *Bio/Technology* 12 (May 1994): 523–25; see also Eugene Rzucidlo, "New Year's Resolutions: Ten Dos and Don'ts for Patenting Your Research in the Coming Year," *Bio/Technology* 12 (January 1994): 79–80.

319. Heller Consulting, *supra* n. 306, p. 120.

320. Amanor-Boadu et al., *supra* n. 312, p. 114.

321. Ibid., p. 115.

322. Howard Mann, "Intellectual Property Rights, Biotechnology and the Protection of Biodiversity: Literature Review," Industry Canada, Intellectual Property Policy Directorate, Ottawa, January 1996.

as well as reviewing both governmental and non-governmental organization (NGO) activities on a regional and international scale.[323]

Although "[i]t is widely agreed that the Convention itself neither requires nor prohibits the patenting of life forms,"[324] it clearly represents a shift away from a vision of biological resources as the "common heritage" of humankind and toward the control of access to those resources by national governments.[325] Some regime of property rights is thereby implied, although it appears that various kinds of ownership rights and access regimes are allowed for by the Convention.[326] Views are also deeply divided on the implications of alternative IP regimes, and indeed of the Biodiversity Convention itself, for biodiversity conservation especially in the developing world. One perspective is that the patentability of life forms under international trade agreements, the results of whose interaction with the Biodiversity Convention are themselves a topic of legal debate,[327] will be profoundly destructive of biodiversity, and will lead to exploitative transfers of wealth from the developing to the industrialized world that amount to "bio-piracy" as transnational corporations patent and profit from genetic resources originating in the developing countries.[328] Conversely, in the negotiations leading to the Biodiversity Convention, the United States was particularly emphatic in arguing that strong IP protection would have positive implications for conservation of biodiversity.[329] In a limited way, acceptance of this position is implicit in arrangements like the widely cited recent agreement between Merck & Company and Costa Rica's National Biodiversity Institute (INBio).[330]

An issue that is perhaps even harder to resolve is whether it is appropriate to treat life forms in the same way as non-living matter,[331] or whether IP protection will undermine "the ethics of conservation, as the intrinsic value of species is replaced by the instrumental value

323. Barbara Laine Kagedan, "The Biodiversity Convention, Intellectual Property Rights, and Ownership of Genetic Resources: International Developments," Industry Canada, Intellectual Property Policy Directorate, Ottawa, January 1996.

324. Mann, *supra* n. 322, p. 32.

325. Ibid., pp. 24–27; Kagedan, *supra* n. 323, p. 11.

326. Kagedan, *supra* n. 323, pp. 15–23.

327. Ibid., pp. 141–45; Mann, *supra* n. 322, pp. 82–101.

328. Among the most articulate proponents of this view is the Ottawa-based Rural Advancement Foundation International; see the various issues of its *RAFI Communiqué*.

329. Mann, *supra* n. 322, pp. 83–85; Kagedan, *supra* n. 323, pp. 18–19.

330. Mann, *supra* n. 322, pp. 135–41; Kagedan, *supra* n. 323, pp. 69–76.

331. Mann, *supra* n. 322, pp. 90–91.

associated with IPRs."[332] There is clearly room here for considerable debate, linking the specific issue of biodiversity to broader questions in environmental ethics, on the approach Canada should take to meeting its commitments on the international stage.

4.4. Environmental and Consumer Safety Regulation of Biotechnology Products

Regulation of human health and environmental impacts invariably raises ethical issues. The most conspicuous of these have to do with the level of risk (to human health or to the natural environment) that is considered acceptable; with the values that are brought to bear in making this decision, including those involving the distribution of risks and benefits; and with how scientific uncertainties are to be resolved. Concerns about the impacts of bioechnology products on the natural environment (e.g. transgenic plants) and on human health (e.g. rBST) have been a recurring source of conflict. Opponents of the particular products in question argue that scientific assessments of safety have not been comprehensive enough, that the ways in which scientific uncertainty has been dealt with are ethically questionable, or (sometimes) both.

In Canada, the environmental impacts of biotechnology products are regulated pursuant to a variety of statutes by Agriculture and Agri-Food Canada, Environment Canada and Health Canada under a framework approved by Cabinet in December 1992. The framework does not directly state principles and elaborate on them. Instead, it consists of a series of objectives:

1. Maintain Canada's high standards for the protection of human health and the environment.
2. Build on existing legislation and institutions, clarifying jurisdictional responsibilities and avoiding duplication.
3. Develop guidelines, standards, codes of practice and monitoring capabilities for pre-release assessment of the risks associated with release to the environment.
4. Develop a sound scientific database, upon which risk assessments and evaluations of products can be made.
5. Promote development and enforcement of Canadian regulations in an open and consultative manner, in harmony with national priorities and international approaches.
6. Foster a favourable climate for development, accelerating innovation and adoption of sustainable Canadian biotechnology products and processes.[333]

Interestingly, with the exception of a reference to high standards for protecting health and the environment, there is no explicit reference in the framework to ethical issues. Neither is there a mandate to consider the broader social context within which the products of

332. Ibid., p. 94 (summarizing the views of Vandana Shiva, one of the best known critics of IP protection in the context of environmental conservation), pp. 110–12. See also Shiva, "The Seed and the Earth: Biotechnology and the Colonization of Regeneration," *EcoDecision* 10 (1993).

333. As reproduced in KPMG Management Consultants, "Improving Canadian Biotechnology Regulation: A Study of the U.S. Experience," prepared for National Biotechnology Advisory Committee and Chemicals and Bio-Industries Branch, Industry Canada, Ottawa, March 1995, p. 33.

biotechnology will be diffused — for instance, their implications for Canada's commitments to sustainable development (the *Agenda 21* commitments) made at the 1992 United Nations Commission for Environment and Development (UNCED) summit.[334]

There is nothing necessarily wrong with such omissions, but they exemplify a stance toward biotechnology policy that arguably deserves more examination, in keeping with our discussion in Chapter 2 of the importance of being explicit about ethical presumptions and other ethical commitments that are "embedded" in public policy.

Implementing the Canadian regulatory framework involved considerable clarification of jurisdiction among federal departments.[335] For reasons of space, we concentrate here on three issues: approval of genetically modified crop varieties, the regulation of biotechnology products under the *Canadian Environmental Protection Act* (CEPA) and, finally, the controversy surrounding the introduction of recombinant bovine somatotropin (rBST) into the Canadian dairy system. As one might expect from the principles outlined in the regulatory framework, the way in which public policy deals with these aspects of biotechnology differs from the arrangements and inquiries described in the first three sections of this chapter in that there is little routinized or ongoing effort to assess ethical implications. This does not mean that there are no such implications; according to some observers, there are extremely important ones. It does mean, however, that they are not addressed **as ethical issues** in the same way as they are, for instance, in the guidelines for research involving human subjects or even in Industry Canada's research on ethics and patenting.

As noted in Chapter 3, outside Canada and in particular in the United States, there has been ongoing controversy over whether genetically modified crop varieties should be regulated differently from varieties with novel traits introduced by conventional breeding methods. Canada has not opted for a specialized regulatory regime, instead requiring an assessment of environmental safety for all plants with novel traits that are not demonstrably familiar or substantially equivalent to products already on the market, in use and generally regarded as safe, regardless of how the trait was introduced.[336] Assessments of environmental safety, provided by the applicant for regulatory approval, must include consideration of potential for weediness; potential for gene-flow to wild relatives whose hybrid offspring may become

334. On the concept of sustainable development, see World Commission on Environment and Development (WCED), *Our Common Future* (New York: Oxford University Press, 1987). The substantive portions of *Agenda 21* are reproduced in *Earth Summit '92* (London: Regency Press, 1992); see, e.g., Chapter 16 on the environmentally sound management of biotechnology. See also Martha L. Crouch, "Biotechnology Is Not Compatible with Sustainable Agriculture," *Journal of Agricultural and Environmental Ethics* 9 (1995): 98–111; and reply by Donald N. Duvick, "Biotechnology Is Compatible with Sustainable Agriculture," *Journal of Agricultural and Environmental Ethics* 9 (1995): 112–25.

335. KPMG Management Consultants, *supra* n. 333, pp. 41–45.

336. "Assessment Criteria for Determining Environmental Safety of Plants With Novel Traits," Regulatory Directive 94-08 (Ottawa: Agriculture and Agri-Food Canada, 1994), pp. 1–2.

more weedy or more invasive; potential to become a plant pest; potential impacts of the plant or its gene product on non-target species, including humans; and potential impact on biodiversity.[337] Applicants must provide detailed information in support of their claims for environmental safety, including appropriate bibliographic references.[338]

If we adopt for purposes of argument the perspective of a sceptical or critical observer, it appears that following the evaluation of the safety assessment by Agriculture and Agri-Food Canada's Plant Products Division, there is a risk management decision that involves a determination of acceptable risk from the release of the plant with novel trait(s).[339] Indeed this is as it must be, zero risk and zero uncertainty about potential hazards both being unattainable. However, the risk management process itself arguably remains a "black box": since the acceptability of risk is not and cannot be determined on scientific grounds, what non-scientific issues enter into this determination? To use the terminology we adopt in section 2.4 of the report, how was a standard of proof chosen?

Asking this question does not imply a criticism on our part of Agriculture and Agri-Food Canada's handling of regulatory issues. Rather, what we are trying to do is connect the necessarily brief discussion of scientific evidence in Chapter 2 with some existing regulatory practices. Moreover, one use of the term "risk management" relates to minimizing potential legal liability and the likelihood of paying damages. Either a much broader concept of risk management is required to do justice to all the issues at stake, or a concept of ethical acceptability should be used in addition.

A different set of questions is raised by the isolation of the regulatory process from what might be termed "big picture" or macropolicy considerations. It has frequently been pointed out, for instance, that herbicide resistance is the novel trait most frequently introduced or enhanced through genetic engineering. Critics suggest that the resulting potential for increasing the chemical intensity of agriculture is in direct conflict with a model of sustainable agriculture in which reducing the intensity of chemical inputs (both pesticides and fertilizers) would be a primary objective.[340] Some go on to suggest that enhancing the sustainability of agriculture, as of other economic activities, constitutes a form of ethical obligation.

A regulatory approval process for (let us say) canola that has been genetically engineered for resistance to a particular herbicide[341] simply cannot take such considerations into

337. Ibid., p. 3.

338. Ibid., pp. 9–14.

339. Ibid., p. 15.

340. See e.g. Rissler and Mellon, *supra* n. 103, pp. 7–8.

341. Such as Monsanto's Roundup; see "Determination of Environmental Safety of Monsanto Canada Inc.'s Roundup Herbicide-Tolerant *Brassica napus* Canola Line GT73," Decision Document DD95-02 (Ottawa: Agriculture and Agri-Food Canada, 1995).

account if it looks only at the potential of the plant itself for altered environmental interactions. On this point, the argument of critics is really one for including what might be called a system-wide sustainability criterion as part of the regulatory approval process. Indeed, some European jurisdictions have taken a similar step, demanding evidence of positive ecological or socio-economic benefits (rather than just of environmental safety) as a condition for approving the release of genetically modified organisms.[342] Such requirements are sometimes referred to in the European context as a "fourth hurdle," that is, above and beyond regulatory requirements for safety, quality and efficacy.[343]

There is nothing necessarily wrong with a regulatory approach that includes such hurdles. It can be argued that fourth hurdles are required by considerations of social justice, or by governmental commitments to promote sustainable development in all their actions and policies. However, fourth hurdles should be recognized for what they are: distinct additions to the burden of proof applicants for regulatory approval must meet. *An important area for future debate involves the extent to which such hurdles should exist within the Canadian regulatory process.*

Concerns about sustainable development arise, as well, in the context of demands for more extensive regulation of biotechnology products under CEPA. Under the biotechnology regulatory framework, the CEPA New Substances Notification Regulations for micro-organisms and products of micro-organisms prescribe specific environmental and human health information a proponent must provide before importing or manufacturing a new substance as defined by the regulations. However, these requirements come into play only with respect to uses not covered under other federal legislation. Animal feeds and feed supplements, veterinary biologics and plants are regulated by Agriculture and Agri-Food Canada; drugs (including veterinary drugs), cosmetics, medical devices and novel foods are the responsibility of Health Canada.

Both naturally occurring and genetically modified microorganisms and the direct products of micro-organisms would be subject to proposed New Substance Notification Regulations under CEPA if not regulated under other federal legislation.[344] In this respect, Canadian treatment of micro-organisms based on their specific properties rather than on their mode of origin is consistent with its treatment of crop varieties.[345] The report also observes that these proposed regulations "are more stringent than those of most of [Canada's] major trading partners, the United States in particular."[346] Although it quotes Canadian industry

342. Heller Consulting, *supra* n. 306, p. 160.

343. Ibid., p. 161.

344. Ibid., p. 144.

345. Ibid., pp. 160–61; this is the approach recommended by a European Commission spokesperson interviewed for the cited report.

346. Ibid., p. 170.

representatives as arguing that stringent environmental standards will place Canada at a competitive disadvantage, the report is sceptical on this point, identifying the impact of the proposed regulations as "marginal" relative to other factors limiting the expansion of an environmental remediation industry.[347]

In hearings held in 1994 and 1995 by the House of Commons Standing Committee on Environment and Sustainable Development to examine the operations and effectiveness of CEPA, the Industrial Biotechnology Association argued for continuation of a "safety net" role for CEPA, which would apply only to those biotechnology products that would otherwise escape federal regulatory scrutiny.[348] However, the Toxics Caucus of the Canadian Environmental Network (CEN) argued instead for "harmonization" of CEPA standards with other federal statutes: "If different laws continue to be applied to different biotechnology products, all biotechnology products released into the environment should be evaluated with the same criteria, same standards for public participation and available prevention options as in CEPA."[349] The Committee reviewing CEPA accepted this recommendation, arguing for the creation of a new part in CEPA that would "include minimum notification and assessment standards for **all** products of biotechnology released into the environment, including those regulated under federal Acts.[350] Environmental assessment of biotechnology products under those other Acts would be deemed equivalent "only if their notification, assessment and regulatory standards are at least equivalent to those prescribed under CEPA."[351]

It is difficult to see how such regulatory equivalence could be determined given the range of products and product uses subsumed under the definition of biotechnology, although the same consultants' report quoted earlier cites one Canadian regulator as saying "some 20 or so federal acts" do not meet "the standards of human health and environmental safety set by the proposed CEPA legislation."[352] That study, completed in June 1995, indicates that the Department of Justice has directed federal departments to rewrite its regulations under such legislation to conform to the higher proposed CEPA standards.[353] At the end of 1995, the government's response to the Commons Committee report released for purposes of public consultation proposed creating a new part of CEPA to deal "specifically with the **living**

347. Ibid., p. 171.

348. *It's About Our Health! Towards Pollution Prevention*, Report of the House of Commons Standing Committee on Environment and Sustainable Development (Ottawa: Canada Communications Group, June 1995), p. 123,

349. Quoted in Ibid. CEN is a national organization of environmental non-governmental organizations.

350. Ibid.

351. Ibid., p. 124 (emphasis in original).

352. Heller Consulting, *supra* n. 306, p. 161.

353. Ibid.

products of biotechnology;"[354] the qualifier arguably reflects the fact that this is the most salient distinguishing feature in terms of potential environmental impact.

The government rejected the recommendation that CEPA provide a minimum standard of public participation and precautionary intent for the regulatory treatment of all biotechnology products, opting instead (at least for the moment) for the existing "safety net" approach under which CEPA has no role if legislation exists and regulations on notification and safety assessment have already been approved. However, it is emphasized that "views of the public and stakeholders on the application" of this approach "will be sought during the consultation process."[355]

CEN has been sharply critical of this response, arguing that it would actually weaken CEPA by reducing the range of products to which its provisions apply,[356] so controversy seems likely to continue at least over the short run. Although examination of the overall framework provided by CEPA is beyond the scope of this report, it is nevertheless useful to refer briefly to a recent critique of both the existing legislation and the Commons Committee report.[357] Risk management specialist William Leiss argues that the proposed attempt to strengthen CEPA fails to acknowledge the fundamentally flawed nature of the legislative approach it embodies: "The original CEPA has done almost nothing to achieve better environmental protection in Canada, and a CEPA revised along the lines suggested by the Standing Committee Report conceivably might do even less."[358] Leiss's argument that the principles supported by the committee are excessively vague if not meaningless[359] raises the possibility that although there may be a need for extending regulatory regimes to cover, e.g., the open release of microorganisms into the environment,[360] a superficially stronger regulatory approach along the same lines may not be an adequate mechanism for addressing the problem. Indeed it could be argued that it is better to have no legislation or other safeguards than to have ineffective ones. In the former case, we are on our guard; in the latter, we are lulled into a false sense of security.

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354. CEPA Office, Environmental Protection Service, Environment Canada, *Environmental Protection Legislation Designed for the Future: A Renewed CEPA: A Proposal* (Ottawa: Supply and Services Canada, 1995), p. 51 (emphasis added).

355. Ibid., p. 52.

356. A CEN mailing dated March 5, 1996 identifies biotechnology as one of two areas in which the federal government response would weaken CEPA and the environmental control of biotechnology products in general.

357. William Leiss, "Governance and the Environment," Working Paper 96-1 (Kingston: Environmental Policy Unit, School of Policy Studies, Queen's University, January 1996).

358. Ibid., p. 5.

359. Ibid., p. 14–19.

360. Heller Consulting, *supra* n. 306, pp. 155–58.

Third and finally, there is the rBST controversy. As a result of the level of controversy about rBST in the United States, the House of Commons Standing Committee on Agriculture and Agri-Food asked the Minister of Health in February 1994 for a delay in approval of rBST for use in Canada. After an intensive week of hearings, the committee recommended a one-year moratorium on the use of rBST in Canada, pending further study of "costs and benefits for the Canadian dairy industry; animal health, including the stress placed on target animals; animal genetics; and U.S. consumer reactions and any outstanding human health issues."[361] This moratorium has subsequently been extended *de facto* by the continuation of Health Canada's review of studies on health effects.

Several themes recur throughout the transcripts of the committee's hearings: trust in authorities (or the lack thereof); the perceived need for more openness and accountability in the review process; the divergent mandates of different government departments (in this case, Health Canada and Agriculture and Agri-Food Canada); narrow versus broad conceptions of risk assessment; and consumer sovereignty. A complicating factor was the organization of Canada's milk supply system, in which "everything is basically one pot until such time as it's packaged and sent out for distribution."[362] This means that if rBST is approved, there will be no way to separate milk from treated and untreated cows other than by creating a duplicate system, with significant cost implications. Otherwise, consumers will have no choice but to purchase milk that may come from cows treated with rBST.

The issues of trust and the perceived (un)reliability of scientific experts were closely linked. Several times during the hearings witnesses mentioned instances of products or drugs that were deemed to be safe by experts but later turned out not to be: thalidomide, agent orange, diethylstilbestrol.[363] A witness from the Consumer Policy Institute made specific reference to litigation involving Dow Corning breast implants. As he put it, from the consumer's perspective, "there is a history of products that have gone out on the market and that we found out afterwards were bad, or even that the companies were not honest and forthcoming."[364] Another witness, a veterinarian who had worked at the U.S. Food and Drug Administration during the time that rBST came up for approval, claimed to have observed "things that violate the principles of good science and certainly good regulatory medicine."[365] He contended that many of the problems are in the raw data, but those data are not publicly accessible: "There needs to be some kind of oversight of this [*sic*] data."[366]

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361. *Minutes of Proceedings and Evidence*, House of Commons Standing Committee on Agriculture and Agri-Food (March 24, 1994), [First Report to the House on rBST], p. 13:5.

362. Comments of John Williams, in *Minutes of Proceedings and Evidence* (March 8, 1994), p. 5:17.

363. Ibid., p. 5:39; Dr. Harvey Guyda (Montreal Children's Hospital and McGill University), Ibid.; Dr. Michael Hansen (Consumer Policy Institute), in *Minutes of Proceedings and Evidence* (March 9, 1994), p. 6:48.

364. Hansen, *op. cit.*

365. Comments of Dr. Richard Burroughs, in *Minutes of Proceedings and Evidence* (March 9, 1994), p. 6:15.

366. Ibid., p. 6:24.

Some members of the committee appeared to be surprised to learn that data in support of approval were supplied by the companies in question. Dr. Saul Gunner of Health Canada conceded that "[t]here have been instances in the past when companies have been known — and they've been discovered later — to falsify data."[367] He added that it would be folly for companies to falsify data when so much is at stake, but that ultimately it is a question of trust: "we have to trust the data we get from industry."[368] Consumers, however, may be unwilling to extend that level of trust. Peter Oosterhoff, president of the Dairy Producers' Association, referred to "an environment of fear and mistrust of federal regulators and pharmaceutical companies."[369] The potential for public oversight, however, is constrained by the fact that "information concerning the science, concerning the submission details themselves, is confidential and protected by law."[370]

Concerns about process were arguably fueled by the problem of scientific uncertainty and conflicting scientific evidence. A group of scientists including the executive director of the Canadian Network of Toxicology Centres (and former director of Health Canada's Bureau of Veterinary Drugs) had prepared a joint submission reviewing the scientific literature that is publicly accessible; his conclusion was that "the consensus of global mainstream opinion is that the drug poses no demonstrable risk to human populations."[371] However, both the former U.S. Food and Drug Administration official mentioned earlier and a witness from the Consumer Policy Institute questioned the presumption of consensus on the safety of rBST, especially as regards its impact on the target animal. Wayne Easter eloquently summed up the committee's dilemma as follows: "we're getting people on the one hand saying it's not safe, it causes mastitis, it causes health problems, it causes reproduction problems, and we get others saying the other way."[372] The committee's dilemma is also, of course, the public's dilemma.

Another concern about the process was the restricted basis on which regulatory approval can be withheld. Criteria for approval under the relevant legislation consist of human safety, target animal safety and efficacy; once those criteria are satisfied, approval must be granted. Kent Foster from Health Canada cited a recent Federal Court of Appeal decision to answer the question "whether or not the minister could apply any criteria other than safety and efficacy" to the approval for a prescription drug; the finding of the court was the regulations "restrict the factors to be considered by the minister in the proper exercise of his

367. In *Minutes of Proceedings and Evidence*, March 7, 1994), p. 3:56.

368. Ibid.

369. Ibid., p. 3:7.

370. Kent Foster, Assistant Deputy Minister, Health Protection Branch, Health Canada, in Ibid., p. 3:50.

371. Dr. Leonard Ritter, in *Minutes of Proceedings and Evidence* (March 8, 1994), p. 5:40.

372. *Minutes of Proceedings and Evidence* (March 9, 1994), p. 6:17.

discretion to those concerning a drug's safety and efficacy."[373] However, at least some members of the committee felt that socio-economic factors had to be taken into account in the assessment of the value of rBST, particularly its potential impact on the dairy industry and the possibility of aggregate net income decline for dairy producers as a whole, if gains realized in the form of increased productivity were to be wiped out by a decline in sales in response to continuing concerns about health effects.[374] These factors are outside the mandate of Health Canada; hence the calls for a moratorium.

Members of the committee asked hard questions about who stands to benefit from the adoption of rBST. The response given by Jean Szkotnicki, Executive Director of the Canadian Animal Health Institute, was that milk producers, consumers and taxpayers would all benefit economically, in addition to the producers of rBST.[375] However, it was also admitted that no nutritional value is added to the milk; the product is not improved in any way. As one witness put it: "The only thing this product does is increase the production of a commodity we already have enough of."[376]

The Consumers Association of Canada proposed the following principles to guide federal decision making: the federal government must provide assurances that rBST is safe; accountability for possible injury to human health must be clearly defined; rBST must not harm quality and cost of dairy products; stakeholders must be allowed to participate in the assessment and decision-making process; consumers must be adequately informed about rBST; consumers must share in decisions about labeling; and finally, consumers must participate in a post-approval monitoring program.[377] The other consumer organizations testifying before the Committee made similar points, emphasizing the uncertain nature of the consumer benefits from approval of rBST and the lack of therapeutic benefits associated with the drug. What seemed to be at issue was the asymmetry between potential risks and potential benefits, with the concern being that costs will be borne by small-scale farmers and risks by consumers, whereas benefits were seen as most likely to flow to producers of rBST itself, and perhaps to large-scale farming operators. There is also a potential conflict of rights involved, with the rBST producers' right to market their product coming into conflict with consumers' rights to information and to choice. Normally, this conflict could

373. *Minutes of Proceedings and Evidence* (March 7, 1994), p. 3:59.

374. Many witnesses from consumers' groups and from trade associations were concerned that not only would there be little benefit to farmers or consumers generally but that there might actually be some costs. The Dairy Producers Association expressed great concern about the fact that "consumer reaction has dogged BST since its use in Canada first became public information." (Comments of Peter Oosterhoff in *Minutes of Proceedings and Evidence* (March 7, 1994), pp. 3:7. 7-3-1994) The National Dairy Council of Canada, a trade association of dairy processors, was similarly worried about "potential for consumer backlash."

375. Comments of Jean Szkotnicki, in *Minutes of Proceedings and Evidence* (March 8, 1994).

376. Comments of Dr. Hansen in *Minutes of Proceedings and Evidence* (March 9, 1994), p. 6:48.

377. Comments of Mark Haney in *Minutes of Proceedings and Evidence* (March 8, 1994), pp. 5:6–5:9.

be resolved by labelling but, given the distinctive nature of the Canadian milk supply system, this is very hard to do in the rBST case.

In response to the report of the Standing Committee on Agriculture and Agri-Food, Agriculture and Agri-Food Canada established a multi-stakeholder task force to review the available evidence on costs and benefits to the dairy industry; animal and human health issues; animal genetics and U.S. consumer reaction to rBST. Given the unresolved nature of the rBST controversy, the volume of technical data and the extent to which the hearings illustrated major points of ethical and scientific disagreement, it suffices here to make two points.

First, the composition of the task force was heavily weighted in favour of producer or promoter interests.[378]

Second and more importantly, if we again adopt the perspective of a sceptical or critical observer, here is another case in which the process of health risk assessment itself remains a "black box" with respect to such issues as the choice of a standard of proof. Health Canada's contribution to the efforts of the task force consisted of a five-page memorandum outlining the department's approval process for all new veterinary pharmaceuticals, and a one-page cover letter. Both documents emphasize that all information submitted by the applicant for approval is treated as confidential and that reviews are still pending. The memorandum states that approvals are "based solely upon sound scientific information" and that:

> A demonstration must be made that there is no risk to humans who consume milk or milk products from treated animals and that adequate data is [*sic*] supplied to support efficacy, safety in the dairy cow and product manufacturing. . . .[379]

It may be, of course, that Health Canada's final decision will specify the criteria used to determine the absence of risk and the adequacy of animal safety (in other words, the basis for choosing a standard of proof), will make reference **at least** to the relevant published studies that are in the public domain, and will indicate what aspects of its conclusions rely on studies that cannot be made public. Certainly, it is hard to envision any argument against submitting the scientific review that served as the basis for Canada's decision on rBST for peer-reviewed publication, as the U.S. Food and Drug Administration did with respect to the same regulatory issues. Such publication would go a long way toward improving the transparency of the regulatory process, as well as increasing public confidence in the final regulatory decision, regardless of what it may be.

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378. It included one member named by each of: Agriculture and Agri-Food Canada, Industry Canada, the Consumers' Association of Canada, the Dairy Farmers of Canada, Monsanto Canada Inc., the National Dairy Council of Canada, and Provel, a Division of Eli Lilly Canada Inc. *Review of the Potential Impact of Recombinant Bovine Somatotropin (rBST) in Canada*, Report of the rBST Task Force Presented to the Minister of Agriculture and Agri-Food Canada (Ottawa: Agriculture and Agri-Food Canada, May 1995), p. 2.

379. Ibid., Part 2 (Animal and Human Health Issues).

4.5. Labelling of Novel Foods

As we have seen, the importance of consumer choice (or in a more polemical and problematic version, consumer sovereignty) has been a recurring theme in debates about rBST. Consumer choice can also be expected to emerge as a more significant question about genetically modified crop plant varieties — as indeed it did at an Ottawa workshop on regulating the agricultural products of biotechnology held in November 1993.[380] A subsequent workshop on labelling issues was convened by Agriculture and Agri-Food Canada in cooperation with Health Canada, Industry Canada, and Fisheries and Oceans Canada in November 1994. According to the workshop proceedings, the more than 70 participants reached the following general points of agreement:

- Mandatory labeling of all food products derived from genetic engineering would be meaningless and should not be required.
- Mandatory labeling should be required if there is an identified health and safety risk for certain individuals or population segments, i.e., safety, allergenicity, and significant nutrient or compositional change.
- Novel foods should be considered on a case by case basis to determine if labeling is required.
- Dietary restrictions based on religious requirements could be adequately addressed within the existing infrastructure and no additional procedures are required to satisfy religious dietary restrictions.
- Clear, enforceable criteria should be developed for labeling including voluntary labeling.
- Labels should i) be kept as simple as possible, ii) be relevant and understandable, iii) be truthful, iv) be positive, v) be harmonized with international standards, and vi) provide consumers with the manufacturer's address and 1-800 telephone number.
- A distinction was made between consumer "need to know" and "right to know."
- Consumers have a right to information in order to make informed choices. Labeling is only one option. Consumer information can be made available through a variety of alternate routes. Both governments and companies have an obligation to provide information.
- Canada should develop labeling requirements in step with its trading partners.
- A minority felt that it may not be possible to determine all long-term safety risks during pre-market assessment, and therefore labeling of all foods produced by genetic engineering would be necessary for those who want to avoid these foods. The general consensus [however] was that it is not possible to assure "zero risk" of any product.[381]

As a next step in the process of developing labeling policy, Agriculture and Agri-Food Canada published a set of guidelines for labelling of novel foods derived through genetic engineering, with a deadline for comments of January 31, 1996.[382] The guidelines closely followed the workshop findings, calling for required labelling when potential health or safety risks or significant compositional or nutritional changes were involved. (Health

380. *Proceedings*, Technical Workshop on the Labeling of Novel Foods Derived Through Genetic Engineering, Ottawa, November 1994 (Ottawa: Government of Canada, 1994), p. 1.

381. Ibid., pp. 12–13.

382. *Communiqué*: "Labeling of Novel Foods Derived Through Genetic Engineering" (Ottawa: Agriculture Canada, Food Inspection Directorate, December 1995).

Canada was at that time developing guidelines for such safety assessments.)[383] In the absence of such hazards or changes, the guidelines would not require the labelling of genetically engineered foods.[384] All labels would be required to be "understandable, truthful and not misleading;"[385] both voluntary positive labeling and voluntary negative labeling would be acceptable under this guideline, as long as the claims being made were factual, not misleading, and could be supported.[386] Finally, guideline provisions based on religious dietary requirements were not viewed as required,[387] but concern was expressed about the compatibility of Canada's labelling requirements with those of its major trading partners.[388]

4.6. Privacy Commissioner's Report on Genetic Testing and Privacy

A 1992 report by the Privacy Commissioner of Canada examined the privacy implications of the growth of genetic testing and screening capabilities;[389] it is one of the few formal efforts federal agencies have recently made to do so, apart from consideration of issues specific to clinical and research settings. The report derived from the ethical principle of autonomy a right to a reasonable expectation of genetic privacy, which entails both "the right not to have others know" about one's genetic make-up and "the right not to know about oneself."[390] The report recommended general prohibitions on employer collection of personal genetic information, but did recommend exceptions "if the employees or applicants retain absolute control over the genetic samples and any related personal information."[391] The report also did not clearly recommend separating access to services or benefits from consent to genetic testing; it proposed allowing refusal of testing, "although this may result in the loss of the service or benefit."[392]

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383. Ibid., pp. 4–5.

384. Ibid., p. 6.

385. Ibid., p. 7.

386. Ibid., p. 8. The effect of this provision, if implemented, would be to allow producers of non-genetically engineered foods to indicate that fact, as long as they were telling the truth, but almost certainly not to make any corollary claims, even by implication, about the superior safety or nutritive qualities of their products: were the producers taken to court, the lack of required labeling with respect to safety hazards or changes in nutritive composition associated with their competitors' products would presumably constitute evidence of the deceptive nature of such claims.

387. Ibid.

388. Ibid., p. 9.

389. Privacy Commissioner of Canada, *Genetic Testing and Privacy* (Ottawa: Supply and Services Canada, 1992).

390. Ibid., pp. 30–31.

391. Ibid., p. 32. The effect of this exception would in practice probably be to make the recommendation devoid of effect, since an employer could always negotiate "voluntary" relinquishment of control over samples and their use.

392. Ibid., p. 34. As noted earlier, such exceptions call the entire notion of uncoerced consent into question.

The Privacy Commissioner's recommendation about genetic information collected in the course of ordinary medical care was stronger: such information "should be used only to inform a person's own decisions about medical care" and "must not be used for any other purpose."[393] No principled restrictions on governmental collection of genetic information were proposed; rather it was argued that such collection should occur "only if specific statutory authority exists for the collection;"[394] that people should be told why such information is being collected, even if legislation does not require that they be told;[395] and that various steps be taken to ensure the adequacy and completeness of such information.[396]

The Privacy Commissioner's brief under the *Privacy Act* formally extends, of course, only to institutions under federal jurisdiction, and is primarily concerned with the still smaller subset of governmental institutions. However, as the report noted and as U.S. experience demonstrates, "the private sector has at least as much leeway as government, and likely significantly more, to intrude on personal privacy."[397] For this reason and because of the dramatic expansion in potential applications of knowledge about the human genome since the report was issued, the following recommendation is of special importance:

> Federal and provincial governments and the private sector should work toward the following:
> (a) including explicit privacy protection, in the form of a right to privacy, in the *Charter of Rights*;
> (b) reviewing the [federal] *Privacy Act* and strengthening its provisions;
> (c) legislating to regulate specific aspects of genetic testing, such as forensic DNA analysis;
> (d) legislating, adopting policies, or both, federally and provincially, to regulate private sector intrusions into genetic privacy; and
> (e) fostering respect for genetic privacy.[398]

"Lesser measures," said the Privacy Commissioner, "simply will not stave off abuses of personal genetic information through genetic testing."[399]

393. Ibid., p. 42.

394. Ibid., p. 59.

395. Ibid., p. 61.

396. Ibid., pp. 61–69.

397. Ibid., p. 79.

398. Ibid., p. 85.

399. Ibid.

4.7. Department of Justice Research on Ethics in Government

The Department of Justice plays a distinctive role as a provider of both legal services and legal advice to line departments, including Health Canada. In 1994–95, the department supported two studies on the relation between bioethics and the provision of legal and policy advice on biotechnology issues.[400]

The first of these reports examines the parallels between legal and bioethical analysis and argument. "To a perhaps surprising extent," says author E. W. Keyserlingk, "bioethics has (largely inadvertently) adopted the language and preoccupations of law,"[401] in particular, an emphasis on rights. Although identifying similarities between ethical and legal reasoning, the author nevertheless emphasizes the need to distinguish ethics advice and legal advice in the policy process, which ideally should be carried out by a multidisciplinary team.[402] In a discussion of method in bioethics, the author goes on to argue that:

> [T]he most useful method of bioethical analysis for legal advisors and others contributing legal or policy advice on issues with bioethical implications is one which can accommodate the widest range of values, and at the same time rigorously evaluate all the significant implications of the options under consideration. The method selected here . . . is one which focuses on consequences, but makes its normative criterion that of consistency between the consequences of an option and the value(s) selected as normative in that case.[403]

After exploring some of the limitations of the principles-based approach identified with contemporary bioethics, the study argues for a "consequences-values" method, which begins by "determining the alternative policy options, identifying the ethical dilemma(s) and making a tentative policy choice" that is "framed as a full-flowered ethical position."[404] The process by which the policy options to be considered are identified is of crucial importance to the subsequent analysis, and therefore should be "exhaustive and comprehensive";[405] it must be clearly understood that whatever tentative policy is initially chosen may be modified in light of subsequent comparison of its consequences with the relevant values "to see if they are in accord."[406] Of particular importance in view of the

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400. Edward W. Keyserlingk, "The Relevance of Bioethics in the Provision of Legal and Legal Policy Advice" (Ottawa: Department of Justice, Legal Services, Health Canada, March 1995); Ellen Margolese, "Ethics and Biotechnology: An Examination of the Role of Legal Advisors" (Ottawa: Department of Justice, Legal Services, Health Canada, March 1995).

401. Keyserlingk, *supra* n. 400, p. 4.

402. Ibid., pp. 13–14.

403. Ibid., p. 20.

404. Ibid., pp. 20–27.

405. Ibid., p. 26.

406. Ibid., p. 32. Those values are viewed ultimately as determined by "legislators and the society" (Ibid.), leaving unaddressed the possibility of fundamental and even irreconcilable value conflicts.

approach we take in Chapter 2 is the study's emphasis on values as "warrants" for arguments. In other words, "they are what authorize, legitimate or entitle us to make claims."[407]

The second study, which examines the actual role of legal advisors in providing advice on ethical issues, is based on 23 interviews with both Department of Justice lawyers and officials in the major client departments involved with biotechnology. It is at first disturbing to note that: "Numerous interviewees cited instances where they provided advice on the ethical dimensions of a problem only to have the information deleted at a more senior level."[408] This does not necessarily imply that senior officials are unethical. They may regard ethical issues as outside their mandate, or they may view the ethical dimensions of their work as being dealt with adequately by their existing legislation and administrative brief, leaving them (i.e. the senior officials) to make decisions about the facts of particular cases from which certain policy conclusions follow more or less automatically. Alternatively, they may deal with ethical issues without explicitly identifying them: "One thing that became clear is that, in many instances, people can and do identify policy and ethical issues, but may not label them as such."[409] It would therefore seem especially important to understand the ethical presumptions built into public policy, especially when they do not come neatly labelled as such but are "embedded" in institutions and procedures.

The study provides additional guidance for efforts to develop ethical frameworks for dealing with biotechnology. It stresses that what is needed is not specialized philosophical expertise, but rather "a comfort, familiarity and ability to identify ethical issues."[410] This point is particularly important because the study identifies some discomfort among "people at the technical or scientific level [who] felt that they should not be charged with making ethical evaluations," yet points out that "they do actually make value judgments in the course of their daily work."[411] (As noted in the discussion of evaluating scientific evidence in Chapter 2, an understanding of the nature of such value judgments in the treatment of scientific evidence for policy purposes is essential.)

The study recommends a role for lawyers (specifically Department of Justice lawyers) in ethical analysis in part because of their existing role in the process of policy development, although it cautions that ethics should not be the exclusive domain of the lawyers.[412] Its recommendations on process involve a "coordinated, interdepartmental, interdisciplinary and to some degree public approach . . . to deal with the difficult ethical issues posed by

407. Ibid.

408. Margolese, *supra* n. 400, p. 26.

409. Ibid., p. 35.

410. Ibid., p. 37.

411. Ibid.

412. Ibid., pp. 38–39.

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407. Ibid.

408. Margolese, *supra* n. 400, p. 26.

409. Ibid., p. 35.

410. Ibid., p. 37.

411. Ibid.

412. Ibid., pp. 38–39.

rapid advances in biotechnology."[413] The task is seen as including "development of recommended mechanisms for consultation both with ethical experts and with the public."[414]

The study explores a number of ways in which the coordinating role could be carried out — "ideally, to address some of the broader ethical issues in biotechnology, a multidisciplinary committee" — which would be primarily internal, but which could also involve outside participation and community representation.[415] Whether or not the Department of Justice ended up assuming a coordinating role in the federal government's approach to ethics and biotechnology, the report warns that:

> [T]he present unstructured approach to identify and resolve ethical issues runs the risk that significant public concerns with biotechnology may be missed and/or different departments may reach different conclusions on similar issues.[416]

A more basic potential problem, which we identify in Chapter 2, is that at some important ethical issues will not be recognized and discussed as such at all. They will be considered as administrative or technical issues, with consequences that could be both socially destructive and ethically indefensible.

4.8. Interdepartmental Workshop on Ethics

Finally, mention should be made of an important two-day, interdepartmental workshop held in 1994 on ethics and biotechnology. The workshop was planned by a Steering Committee many of whose members now make up the Working Group for which the present study is being prepared, and combined four presentations by Canadian ethicists, with breakout sessions on intellectual property, human gene therapy and the agricultural products of biotechnology.[417] The record of the group's discussions is itself a useful document. For example, the facilitator's report on one of the three breakout sessions notes that "discussion concluded by confirming the need for many ethical frameworks at many different levels. Pieces of these frameworks are already established in various places, but work will be necessary to ensure that they are adequate to meet the needs of biotechnology."[418]

The results of the present study strongly confirm the validity of this point; they also indicate the importance of recognizing ethical issues as such, and of being explicit about the

413. Ibid., p. 40.

414. Ibid.

415. Ibid., pp. 48–50.

416. Ibid., pp. 40–41.

417. See *Proceedings: Inter-Departmental Workshop on Ethics and Biotechnology*, *supra* n. 257.

418. Ibid., p. 36.

value choices that guide the initial presumptions around which public policy is organized in a variety of areas related to biotechnology. Particularly valuable is the recommendation of the Steering Committee that "a federal framework for ethics should be developed to provide principles in the development of guidelines dealing with specific areas. External consultations on this framework should be conducted and the resulting framework presented in a Memorandum to Cabinet."[419]

4.9. Summary

In the course of discussing the ethical issues associated with biotechnology as they have emerged in Canada, we also identify a variety of existing and proposed frameworks for dealing with such issues. Some of these, notably Research Ethics Boards (REBs), have dealt specifically and exclusively with ethical issues. Others, which may not have been intended to address ethical concerns in the first place, quite understandably do so in a way that does not always recognize the distinctive ethical dimensions of the questions with which they deal. Furthermore, some efforts have been relatively *ad hoc* but directed specifically at biotechnology. Others emerged out of the mandate of a particular institution or agency (such as line regulatory departments or the Privacy Commissioner's office) as it happens to intersect biotechnology-related issues.

We do not consider all the possible ways of dealing with the ethical issues raised by biotechnology. For example, we do not consider the arguments for and against establishing a national advisory council on bioethics, of a type that exists both nationally and supranationally in Europe. Neither do we examine the possible role for ethical codes of practice or conduct as applied to biotechnology research and development.[420]

We do, however, explore a range of approaches to addressing ethical issues that, taken together, have at least two significant shortcomings. The first of these is that ethical issues are not always explicitly addressed as such. We consider this point of sufficient importance that we devote a substantial part of the next chapter to it. The second is that, as noted in the Department of Justice study on the role of legal advisers, existing processes provide no assurance of either comprehensiveness or consistency.

In Chapter 6 of the report, we do not propose a solution to these shortcomings, but we do identify a number of considerations that should be taken into account as the federal government goes about trying to find one. First, however, we combine our review of ethical controversies in Canada and elsewhere to identify ways in which they are conceptually linked.

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419. Ibid., p. vii.

420. On this point see Charles Malone, "Ecology, Ethics, and Professional Environmental Practice: The Yucca Mountain, Nevada, Project as a Case Study," *The Environmental Professional* 17 (1995): 271–84. In the article, Malone argues that many of the stands taken by environmental professionals in the course of debate over the siting of a nuclear waste repository at Yucca Mountain are incompatible with a proposed set of principles of environmental ethics and, by extension, are inappropriate for such professionals.

5. Key Ethical Tensions from the Biotechnology Debate

The terms of reference for this study called for a prioritization of the ethical issues raised by biotechnology. Although the prospect of ranking issues is attractive, doing so presupposes the existence of a comprehensive and uncontroversial framework for biotechnology ethics that links debates such as those about the environmental effects of genetically modified organisms and about the use of genetic information on human beings. However, such a framework has yet to be developed. In its absence, even a strategy as simple as ranking issues based on the number of people affected may not be defensible, or may presuppose the resolution of questions about which some people feel strongly.

For example, what does it mean to be "affected" by medical interventions in human reproduction? Some would argue that all women are affected by the diffusion of such interventions, to the extent that they reflect or reinforce particular attitudes toward women that are viewed as ethically suspect. A ranking of issues is also likely to be inherently fragile given both rapid developments in biotechnology and the volatility of public opinion with respect to a set of technologies about which most people's views are still being formed. For example, while this study was being written the European moratorium on British beef, arising from concerns about links between bovine spongiform encephalopathy and a rare but fatal brain disease in human beings, suggested that a single high-profile event may have far-reaching consequences in terms of what the public regards as important.

Instead, we have adopted a strategy of identifying several sets of key issues or tensions that characterize the debates examined in this report, as well as others. Not each tension will be found with respect to all the debates, but they do have the effect of helping to isolate common elements. The term tensions rather than conflicts has been deliberately selected to reflect the fact that each of the areas described below is characterized by profound disagreement, but also by elements of agreement.

5.1. First Tension: Risk Assessment and Risk Perception

Debates about risk and public policy are by now relatively familiar, because of a long history involving both nuclear energy and toxic environmental contamination.[421] The conventional, and widely accepted, description of how public policy toward such safety hazards is made breaks the process down into risk identification, risk estimation or

421. For an introduction to the debates, which is now somewhat dated but still very useful, see Baruch Fischhoff et al., *Acceptable Risk* (Cambridge: Cambridge University Press, 1981); a more recent and very well-documented critical review is Kristin Shrader-Frechette, *Risk and Rationality* (Berkeley: University of California Press, 1991). The most detailed study of a Canadian controversy involving risk policy is probably Conrad Brunk, Lawrence Haworth and Brenda Lee, *Value Assumptions in Risk Assessment* Waterloo: Wilfrid Laurier University Press, 1991).

assessment, risk evaluation and risk management.[422] Although some terminological confusion surrounds the field, in general risk estimation or assessment refers to a stage of the policy process at which purely factual (or "objective") conclusions about the level of risk are reached, supposedly "free of social and other value judgments" and based on scientific methodology.[423] Risk estimation or assessment is thus distinguished from both risk evaluation (the determination of acceptability), which is admittedly value-driven, and from risk management: the steps taken to control risks, avoid them, or mitigate them to acceptable levels.[424]

Several different types of criticisms can be directed at this conventional model of risk assessment. One is that the risk estimation stage is not as value-free or value-neutral as claimed. Values shape facts,[425] and values play a crucial role in determining how inescapable scientific uncertainties are resolved, at least provisionally, for purposes of the risk assessment process. An extensive study of the Canadian controversy involving the hazards of exposure to the pesticide Alachlor, one of the few recent Canadian instances in which extensive public hearings have been held to examine how a particular risk was assessed by regulators, led its authors to conclude that different risk assessors brought distinctive normative and conceptual assumptions to bear on the whole process of risk assessment. The criteria used to estimate risk levels were not (and could not have been) entirely objective and value-neutral. Instead, "preference for the risk–benefit standard of acceptable risk at the risk management level fed back into and very significantly influenced decisions at the prior risk estimation stage."[426] Like the discussion of standards of proof in Chapter 2, these findings suggest at the very least that values and scientific facts do not come in hermetically sealed compartments.

Another criticism of the conventional model is that it fails to consider a sufficiently broad definition of risk, a line of argument that leads us to the issue of risk perception. One common approach to risk perception research is simply to view people's risk characterizations from the perspective of quantitative risk estimation, and to judge them to be more or less "rational" depending upon how closely they approximate the purportedly objective estimates of risk done by scientists. The literature on risk perception contains ample debate about the significance of the gap between risk estimation and risk perception. A typical response to the gap is to charge that the gap proves the irrationality of public responses to technology, and that if only people were better informed, they could "learn to

422. Shrader-Frechette, *op. cit.*, pp. 55–58.

423. Brunk, Haworth and Lee, *supra* n. 422, p. 4; Shrader-Frechette, *supra* n. 422, pp. 39–44; Emmanuel Somers and Daniel Krewski, "Risks from Environmental Chemicals," in *Risk: A Symposium on the Assessment and Perception of Risk to Human Health in Canada*, edited by J. Rogers and D. Bates (Ottawa: Royal Society of Canada, 1982), pp. 43–52.

424. Shrader-Frechette, *supra* n. 421, pp. 56–58.

425. Fischhoff et al., *supra* n. 421, p. 45.

426. Brunk, Haworth and Lee, *supra* n. 421, p. 4; see generally pp. 42–48.

base their risk aversion on . . . probabilities calculated by experts, rather than on their feelings."[427]

K. S. Shrader-Frechette calls this the probabilistic explanation: "the belief that, for any rational and informed person, there is a linear relationship between a risk, defined as an actual probability of fatality (associated with a particular technological activity) and the value of avoiding the risk posed by that technology."[428] Risk assessors in the scientific community tend to attribute conflicts about technology-related hazards to "intuitive estimates of unreasonably high risk" or to the public's "'emotional' risk evaluations."[429] Although much discussion of the gap between risk estimation and risk perception involves attitudes toward nuclear energy, there are definite parallels with biotechnology. Many experts in risk assessment would probably rank the objective risks of biotechnology, specifically the risks from environmental release of genetically modified organisms or ingestion of genetically engineered food products, fairly low in the roster of health and safety hazards commonly used for such quantitative comparisons.[430] Yet a substantial proportion of members of the public, as seen from opinion polls and attitude survey data, express a high level of fear or at least uncertainty regarding the risks of biotechnology.

In order to explain this apparent anomaly, Shrader-Frechette and others have questioned the probabilistic view of risk. They deny that people's characterizations of risk are simply irrational. Instead, they argue, the "real controversy is over values and over incompatible views over the benefits attributed [for instance] to nuclear power, not over different beliefs about accident probabilities."[431] The probabilistic explanation looks only at a limited notion of harm, corresponding roughly to threats to the health and safety of consumers, members of the public and (occasionally) the natural environment. This is the notion of harm around which the health and safety regulation of biotechnology products and processes is generally oriented. However, it takes into account neither the category of factors defined by Jasanoff as social risks, such as the possibility for increased commodification of life and living

427. K. S. Shrader-Frechette, "Probabilistic Uncertainty and Technological Risks," in *Science, Morality and Politics,* edited by R. Von Schomberg (Dordrecht: Kluwer, 1993), p. 44.

428. Ibid; see also Shrader-Frechette, *supra* n. 421, pp. 90–98.

429. Shrader-Frechette, *supra* n. 427, p. 46, citing among other sources Chauncy Starr and Chris Whipple, "Risks of Risk Decisions," *Science* 208 (June 6, 1980) and Starr, *Current Issues in Energy* (New York: Pergamon Press, 1979), pp. 16–17.

430. A further problem arises because of the difficulties of adapting to such releases the already imperfect quantitative risk estimation techniques used in other environmental contexts. See, for example, H. Miller and D. Gunary, "Serious Flaws in the Horizontal Approach to Biotechnology Risk," *Science* 262 (1993): 1500–01.

431. Shrader-Frechette, *supra* n. 427, p. 46.

beings, nor the unquantifiable emotional damage that may go along with biophysical risks.[432]

Even within the realm of physical rather than social risks, several elements in the social context within which risks are experienced or anticipated seem to make them more or less acceptable. These elements include: whether risks produce compensating benefits; whether risks are voluntary or involuntary (imposed); the degree of control over a risk; and the amount of uncertainty associated with a risk.[433] If there are perceived to be compensating benefits, then the risk level will be deemed to be more acceptable, and if the benefits are specific or concrete rather than general or abstract, the degree of acceptance of a particular technological application may increase.[434] (It must be noted that in the biotechnology context the examples of rBST and some forms of medical intervention in human reproduction suggest that benefits as defined by some people will actually constitute elements of social risk for others.) If the risk is voluntarily assumed rather than imposed, it will be deemed to be more acceptable. Risk takers find risks that result from their own actions more acceptable than risks which are the result of the actions of others (the agency issue). The concepts of voluntariness and agency help to explain why people frequently undertake relatively higher risk activities (such as driving cars or smoking) while objecting to having relatively lower risk activities (such as exposure to workplace hazards or industrial emissions) imposed on them. In addition, the more uncertainty surrounds a particular risk, the less acceptable a risk will be deemed.

Another approach to risk acceptability is derived from psychometric studies which have found that individuals' perception of risk could largely be accounted for as a function of two axes of perception, which have been labelled "dread" and "unfamiliarity." Neither of these axes corresponds to probability of death; indeed, this body of research was to a large degree motivated by the attempt to explain why the risk perceptions of lay persons typically fail to correspond to the results of quantitative risk estimation exercises. As between two hazards causing the same number of deaths over a given time period, one producing deaths from a single catastrophe beyond the control of the individual rates higher on the dread dimension than one producing deaths on a chronic basis in circumstances where individuals

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432. On this point, see Diana Dutton, "The Impact of Public Participation in Biomedical Policy: Evidence from Four Case Studies," in *Citizen Participation in Science Policy*, James C. Petersen (Amherst, MA: University of Massachusetts Press, 1984), pp. 157–58.

433. Conrad Brunk, "The Breast Implant Controversy: Did Dow Corning Meet Its Ethical Responsibility to Women?" Paper presented to the Department of Philosophy, York University (Waterloo, ON: Conrad Grebel College, Wilfrid Laurier University, February 1996), pp. 12, 21–25.

434. For instance, in a 1993 Decima poll on Canadian attitudes toward biotechnology, only 17 percent found gene transfers between human beings (what would normally be called human gene therapy) acceptable in the abstract. However, if the transfer were to prevent baldness, the percentage considering the therapy acceptable rose to 30 percent, and if it were to prevent a fatal disease the percentage rose to 61 percent. (It should be noted that the poll did not distinguish between somatic cell and germ-line therapy.) Similar patterns were observed with respect to other hypothetical gene transfers. *Final Report to the Canadian Institute of Biotechnology on Public Attitudes Towards Biotechnology* (Ottawa: Decima Research, December 1993), p. 14.

feel they have more control over the outcome (the classic example of the latter kind of hazard is traffic accidents). Nuclear power is a technology the risks of which tend to fall high on both the dread and unfamiliarity axes, and so tend to be judged unacceptable.[435] Many applications of biotechnology, in particular modification of the genome of living organisms, are perhaps even more unfamiliar in their operations than nuclear fission, and hence are the focus not only of dread but also of remarkably intense resistance.[436]

5.2. Second Tension: Trust and Accountability

Risk perception and risk acceptability are ultimately functions of trust. All risk estimations (whether expert or intuitive, explicit and formal or implicit and tacit) necessarily make at least some assumptions about the honesty and competence of institutions, if only in order to determine the scope of effects to be considered. The range of potential consequences that are to be factored into risk assessment depends upon an evaluation of the competence of governing agents and agencies. As Turner and Wynne put it, "if these agents have a social track record of secrecy, arrogance or incompetence, or if they appear to dominate supposedly independent regulatory bodies and the policy making-process," the effect will be to magnify people's perceptions of the risks.[437] Official procedures of planning and risk assessment may frustrate attempts to bring in as relevant the proponent's (perceived) track record; this may itself become a friction point in social conflicts over technological risk.[438]

Turner and Wynne look to this trust gap for a sociological explanation of at least one aspect of the dimension of dread: people, they suggest, do not dread hazards that they perceive to be within their control as much as other hazards, because they are more likely to trust themselves than they are to trust institutions charged with controlling imposed, impersonal risks.[439] The importance of trust in the particular institution generating the anticipated risk, or making claims about risks and benefits, is also demonstrated by the observation that although both supporters and critics "strongly believe that nuclear power is in the hands of big government or business . . . the pro group evaluates this attribute positively, the con group evaluates it negatively."[440] Further, it has been argued that in addition to scientific

435. Gillian Turner and Brian Wynne, "Risk Communication: A Literature Review and Some Implications for Biotechnology," in Durant, ed., *supra* n. 20.

436. See, e.g., Joachim Radkau, "Learning from Chernobyl for the Fight against Genetics?" in Bauer, ed., *supra* n. 29, pp. 335–55.

437. Turner and Wynne, *supra* n. 435, p. 123.

438. Adrian Pearce, "Environmental Protest, Bureaucratic Closure: The Politics of Discourse in Rural Ireland," in *Environmentalism: The View from Anthropology*, edited by K. Milton (London: Routledge, 1993), pp. 189–204.

439. Turner and Wynne, *supra* n. 435.

440. Harry Otway, "Risk Assessment and the Social Response to Nuclear Power," *Journal of the British Nuclear Engineering Society* 16 (1977): 331.

uncertainty, governments' lack of credibility and their apparent unwillingness "to consider environmental values" also causes controversy over nuclear power.[441]

Qualitative research on biotechnology risk perception in Europe tends to confirm many of these observations. Focus group and workshop participants express concern about the lack of adequate institutional controls and a desire for regulation based on honest and objective information, "free from the interference of commercial or industrial interests."[442] Lemkow found people suspected that biotechnology would offer economic benefits to a few and would impose health and safety risks on the public, and they had little faith that governments were willing or able to act to control those risks. They did not trust that the information available to them was complete and unbiased; there was concern that information was being concealed or manipulated by industry.[443]

In common with the history of debates about rBST and any number of issues in health and safety regulation, these findings suggest that the perceived credibility of sources of information about biotechnology is important. A review of literature on this topic reports that:

> [C]redibility of a communication source is closely linked to the perceived past performance record and its openness for public demands. The more that institutions comply with the expectations of the public, the more confidence people will have in these institutions and the more trust they will assign to their messages.[444]

Whether for this reason or for others, polls have frequently indicated distrust of authorities both in Europe and the United States. As Bud reports:

> According to a recent European Commission poll, industry is trusted as a source of information about biotechnology and genetic engineering by only 6.4% of the European population. . . . Similarly in the United States, the strongest suspicions were about the authenticity of the sources of information.[445]

Particularly concerning large-scale release of genetically modified organisms, respondents expressed "considerable scepticism about both government and companies as sources of information or assurance of safety."[446] In another study of attitudes toward biotechnology and its advocates in the United States, "[s]cientists were seen as the most credible and companies that make genetically engineered products were seen as the least credible

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441. E. Lawless, *Technology and Social Shock* (New Brunswick, NJ: Rutgers University Press, 1977).

442. Lemkow, *supra* n. 25, p. 23.

443. Ibid.

444. Ortwin Renn and Debra Levin, "Credibility and Trust in Risk Communication," in *Communicating Risks to the Public*, edited by Roger E. Kasperson and Pieter Jan M. Stallen (Dordrecht: Kluwer, 1991), p. 212.

445. Bud, *supra* n. 1, p. 211, citing Jennifer Van Brunt, "Environmental Release: A Portrait of Opinion and Opposition", *Bio/Technology* 5 (1987): 559–63.

446. Ibid.

sources of information."[447] Further, "[l]ocal farmers and environmental groups are . . . far more likely to be believed than state or federal government agencies."[448] In a recent Canadian poll doctors and nutritionists were ranked as the most trustworthy stakeholders in the biotechnology debate, closely followed by university scientists, farmers and farm groups, environmental groups and consumer associations; the media and federal government regulators were ranked as least trustworthy.[449]

The flip-side of trust is accountability, which was one of the eight guiding principles enunciated by the RCNRT and which is demanded of governmental institutions and officials with increasing frequency. Issues of trust and accountability link risk acceptability to decision-making processes and the design of institutions. Again, the history of the nuclear power debate provides some useful ideas. In a study of the operation of nuclear safety regulation in Canada, Bruce Doern distinguishes between professionally open and democratically open models of decision making. Nuclear safety regulation in Canada during the late 1970s, when the study was done, corresponded closely to the former model. Private consultation and even controversy among technical experts was extensive. However, participation in those debates by those without scientific or technical expertise directly related to nuclear safety concerns was limited; participation by (or even disclosure of information to) non-expert members of the public was even more limited.[450]

Counterposed against this model is the democratically open model, characterized by "broad participation in regulation-making, licensing and compliance proceedings" as well as extensive information disclosure.[451] Doern views the nuclear reactor licensing process in the United States, which involved open public hearings before a semi-autonomous regulatory agency (the Nuclear Regulatory Commission) as an approximation of this model, although the legalistic nature of such hearings probably does not make them the best models for public involvement in biotechnology policy.[452]

Both these models of regulatory decision making are abstractions, and actual decision-making procedures combine elements of both. The professionally open model fits more readily into a Westminster-style system of government in which lines of accountability are presumed to run through ministers via the legislature to the populace, and it has historically

447. William K. Hallman, "Public Perceptions of Biotechnology: Another Look," *Bio/Technology* 14 (January 1996): 38.

448. Ibid.

449. Decima Research, *supra* n. 434, p. 18.

450. G. Bruce Doern, *The Atomic Energy Control Board,* Administrative Law Series (Ottawa: Law Reform Commission of Canada, 1977), pp. 33–39.

451. Ibid.

452. On the U.S. experience of public hearings in matters related to biomedical policy, see Dutton, *supra* n. 433, pp. 147–81.

provided a relatively accurate description of Canadian health and safety regulation.[453] However, the continued defensibility of such a model presumes a high level of trust in (or faith in the accountability of) government. Reflecting the general shift in contemporary societies away from "blind trust" and toward "earned trust,"[454] the trend in health and safety regulation over the past two decades, despite some resistance, has been in the direction of requirements for information disclosure; at least some formal opportunities for intervention by parties other than the regulated firm, profession or industry; and a growing (if still sometimes uneasy) acknowledgment that decisions in complex science-based policy areas like biotechnology cannot be left to professional expertise or even to "professional conscience and vision." Because science policy decisions are always value driven, a strong argument can be made for maximizing the visibility and accountability associated with those decisions.

The trend toward greater openness and expanded participation has not been confined to health and safety regulation, and as noted earlier the rapidly expanding involvement of "outsiders" (in the sense of people outside the medical or scientific communities) has been a defining feature of modern biomedical ethics. The emphasis in the MRC Guidelines on the involvement not only of non-medical professionals but also of community representatives is a recognition of the role and importance of non-experts. So, too, is the RCNRT's scepticism about the adequacy of continued professional self-regulation to deal with the broader social or community interests and values at stake in decisions about medically assisted reproduction. It is worth emphasizing here that the issue is *not the motives of individual researchers or practitioners*, but rather their ability (a) reliably to assess the value-laden dimensions of their work, and (b) to do so on behalf of a broader community which also has an interest in the outcome of the decision.

Recognition of the public dimensions of decisions about the application of biotechnology is closely tied to increased, if occasionally reluctant, acceptance of the role of public participation in governmental decision making more generally.[455] Such participation may simply involve examining the information on the basis of which decisions were made; it may involve interrogating decision makers or those who supply their information, as in a public hearing; it may extend to active involvement in decisions, as in the case of community representatives on REBs; or it may even involve "public interest" litigation, as with European opponents of biotechnology patenting.

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453. Joseph Castrilli and Clifford C. Lax, "Environmental Regulation in Canada: Towards a More Open Process," in *Environmental Rights in Canada*, edited by J. Swaigen (Toronto: Butterworth, 1981); Schrecker, *Political Economy*, *supra* n. 38, pp. 13–16

454. Somerville, *supra* n. 72, p. 8, referring to a concept developed by Jay Katz, *The Silent World of Doctor and Patient* (New York: Free Press, 1984). Somerville expands on this contrast in a forthcoming publication, with reference as well to the distinction between the "guardian" and "commercial" moral syndromes drawn by Jane Jacobs in *Systems of Survival* (New York: Random House, 1992).

455. Sheldon Krimsky, "Beyond Technocracy: New Routes for Citizen Involvement in Social Risk Assessment," in Petersen, ed., *supra* n. 432, pp. 43–61.

There are arguments against expanded public participation, including the self-selecting nature of participants and the highly specialized nature of the scientific competence needed to understand fully certain kinds of policy decisions.[456] However, there are also compelling arguments in its support, notably that "citizens are capable of learning extraordinary amounts of technical information, and indeed of participating actively in creating relevant new knowledge, when the stakes are high enough."[457] At a minimum, adequate information is a prerequisite for participation in decisions about risks on the part of those who bear them, whether as consumers or as otherwise-uninvolved third parties. Extrapolating from the principle of respect for autonomy in North American bioethics, it is worth proposing the principle that potential risk bearers should be fully informed about the risks they will bear, no matter how small or uncertain the risk is considered to be, by experts or others.

5.3. Third Tension: Distribution, Equity and the Social Control of Technology

This tension emerges in a number of claims about the consequences of biotechnology applications: that they are socially undesirable; that their assessment requires balancing individuals' morally relevant interests against those of the community; or that the likely benefits and burdens are distributed unfairly. A simple example of the conflict between individual and societal interests is that individuals may want access to a variety of options for medically assisted reproduction, but this desire may conflict with collective decisions about the social risks associated with the widespread diffusion of reproductive technologies. More troubling conflicts arise with respect to advances in genetics-based diagnosis and therapy. A working group on the ethical and social aspects of gene transfer, set up as part of a study for Germany's Ministry for Research and Technology, has observed that: "There is a real conflict of goals between individual interest in medical aid at all costs and socio-political interest in controlling the progress of medical technology."[458] Against a background of heightened concern about health care costs, such conflicts have the potential to become increasingly divisive; in the Canadian context, the RCNRT identified a tension between individual access to medical interventions irrespective of cost and a society-wide interest in maintaining equitable access to health care services. Such equity concerns are undermined, it could be argued, **both** by allowing individual access to reproductive interventions on a user-pay basis and by providing public financing for those interventions without attention to competing claims for the same resources.

Arguably, the issues raised in the preceding paragraph reflect a broader set of concerns about the intrinsic (im?)morality of certain technologies and their associated outcomes; equity issues and distributive justice; and, at least in some instances, questions about the

456. Dutton, *supra* n. 432, pp. 169–72.

457. Sheila Jasanoff, "Bridging the Two Cultures of Risk Assessment," *Risk Analysis* 13 (1993): 127.

458. Kurt Bayertz, Rainer Paslack and Kurt W. Schmidt, "Summary of 'Gene Transfer into Human Somatic Cells: State of the Technology, Medical Risks, Social and Ethical Problems,'" *Human Gene Therapy* 5 (1994): 467.

legitimacy of the market as a mechanism for determining society's interests and allocating society's resources.

In the context of environmental policy, some of these concerns have been analyzed with reference to economic analysis and social justice as competing perspectives or frames.[459] To oversimplify considerably, from the perspective of economic analysis the fact that a project will increase the society's wealth or that a regulation will slow the adoption of an economically important new technology, is taken to be of primary ethical importance. Efficiency is regarded as important because in the relatively specialized lexicon of economics, increases in efficiency lead, by definition, to increases in the society's available resources.[460] The perspective of social justice, on the other hand, is primarily concerned with distribution, equity and fairness. One might say that social justice is premised upon every individual's having a right to be treated a certain way, or having a right to a certain outcome.

For example, if one accepts the claim that African-Americans have a right to equal treatment under the law, then a regulatory agency policy that in practice means most hazardous industrial operations will be located in poor, African-American neighbourhoods is likely to be unacceptable on any but the most rigidly formalist definition of equal treatment, even though it may represent the most efficient outcome for the society as a whole (because, for instance, land acquisition costs are lower; the surrounding residents' claims for reduced property values are likely to be minimal because property values were low to start with; and so on). In the international context, this contrast was recently dramatized when a (tongue-in-cheek) proposal by a World Bank economist that the most efficient solution for disposing of hazardous industrial waste would be to ship it to Africa for dumping received widespread publicity, and provoked predictable outrage.

As noted earlier in this chapter, there is a close link between such distributional concerns and the critique of conventional approaches to risk assessment and management. The contrast between the economic analysis and social justice perspectives is conceptually valuable for several other reasons, as well. It demonstrates that "socio-economic" considerations cannot automatically be separated from ethical ones. Presuming the validity of such a separation already takes for granted that the existing distribution of resources within society raises no ethically troublesome issues. Social justice, in particular, directs our attention to hard choices between the good of all and the good of the most vulnerable; between individual interests and obligations to the community. Finally, it focusses attention on the ethical implications of markets as a way of allocating resources and shaping technological development.

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459. A more detailed discussion of these competing perspectives can be found in Alex Wellington and Allan Greenbaum, "Social Conflict and Environmental Law: Editor's Note," in Greenbaum, Wellington and Baar, eds., *supra* n. 81, vol. 1, pp. 15–21.

460. Ibid., pp. 18–19.

Questions about the proper role of the market emerged when the isolation of the BRCA1 gene, mutations in which confer high hereditary susceptibility to breast cancer, was described as typical of "life in the fast lane of genetics research."[461] The gene was isolated by a team of more than 40 researchers at the University of Utah Medical Centre, the National Institutes of Health, McGill University, and two pharmaceutical firms, who were competing with a number of other researchers including Francis Collins, the director of the National Center for Human Genome Research (NCHGR), one of the key institutions in the Human Genome Project. The successful team's leader (Mark Skolnick) founded a private sector sponsor (Myriad Genetics Inc.) while continuing to hold a University of Utah appointment; in return for financial backing, Myriad had entered into advance agreements covering the commercialization of products based on the gene with both the university and Eli Lilly and Company. More contentiously, the researchers immediately filed for a patent on the gene as part of Myriad's corporate strategy[462] — suggesting a potential for tension among scientific, humanitarian and commercial goals.

Such tensions often pit the interests of individuals as consumers or employees against the commercial imperatives guiding biotechnology firms, insurance companies and various employers. Producers of diagnostic tests based on the BRCA1 gene may have an interest in seeing markets for the test grow as rapidly as possible, but health care consumers' interests might be better served by slower growth — for instance, through use of the tests only in the context of research into viable treatment options.[463] More generally, medical and life insurers in a competitive market, and to a lesser degree employers, may perceive themselves as driven to seek the advantages provided by the most comprehensive possible package of genetic information about prospective policyholders and employers. However, consumers' interests might be better served by the diffusion of genetic screening only in tandem with the enactment of privacy safeguards strong enough to guard against medically (and we would say ethically) perverse outcomes. As an example of such outcomes, patients may refuse tests that might be medically valuable because they fear that the results, if made available to third parties, could make them unemployable and/or uninsurable.[464]

The distributive issues are more complex in the rBST debate, both in Canada and elsewhere, because they involve more than just a potential conflict between business and consumers. The introduction of rBST is defended on the basis that it will improve the productive efficiency of individual farm operators and, at least by implication, of the economy as a whole. For rBST opponents, these aggregate-level economic gains are less

461. Rachel Nowak, "Breast Cancer Gene Offers Surprises," *Science* 265 (September 23, 1994): 1796.

462. Ibid., pp. 1796–99; Declan Butler and Diane Gershon, "Breast Cancer Discovery Sparks New Debate on Patenting Human Genes," *Nature* 371 (September 22, 1994): 271–72.

463. For a review of recent developments in this area, see Tim Beardsley, "Vital Data," *Scientific American* 274 (March 1996): 102–03.

464. Ibid., pp. 100–03.

ethically relevant than unresolved concerns about safety and animal welfare,[465] and less ethically relevant than negative impacts both on individual operators (some small, perhaps undercapitalized operators will go under) and on the social fabric. Claims about the social fabric presume that the preservation of family farms is a social value of some significance. Some people would not make this assumption, but that disagreement only highlights the tension we are trying to illustrate.

As noted in Chapter 4, the phrase "fourth hurdle" is used to describe regulatory demands that must be met in some European countries, above and beyond demonstrations of safety, quality and efficacy, before approval is granted for release of genetically modified microorganisms. Thus, for instance, Norwegian legislation requires "significant emphasis" on considerations of sustainability and benefit to the community in decisions approving genetically modified organisms for release, although such benefit need not be demonstrated in every individual case.[466] The exclusions from patentability on ethical grounds contained in the EPC present a fourth hurdle of a similar kind: in addition to meeting the standard criteria for patentability, applicants must at least be prepared to rebut the claim that patenting their invention would be contrary to *ordre public* or morality.

It may be worthwhile to start using "fourth hurdles" as a generic term for policy interventions and proposals that reflect explicit concern for distribution, equity or community interests. Those community interests need not be explicitly defined in terms of the distribution of likely benefits and burdens. Concern for the sustainability of agricultural practices reflects a conception of those interests that does not have a distributional component except, perhaps, one involving the competing interests of present and future generations. People who argue (for example) against regulatory approval of rBST for use in Canada based on socio-economic concerns are saying that a fourth hurdle is needed: even if particular technologies meet both the test of safety and the test of the market, that is not enough. Social benefit (or, at a minimum, consistency with certain principles of equity or distributive justice) ought to be demonstrated as well, whatever the gains in economic terms to society as a whole.

As another instance of how fourth hurdles and the underlying principles might be applied, it has been suggested in the United States that rather than just meeting environmental impact assessment requirements, new development projects should be required to undergo an

465. For many rBST opponents, these concerns loom especially large because there is not seen to be any social benefit at all from the introduction of rBST, but merely private economic benefit. In other words, there appears to them to be no reason to accept any prospective hazards at all associated with safety or animal welfare, however small those hazards may be.

466. Inge Lorange Backer, "'Sustainability' and 'Benefits to the Community' Concerning the Release and Use of Genetically Modified Organisms in the Norwegian Gene Technology Act," in *Release and Use of Genetically Modified Organisms: Sustainable Development and Legal Control,* edited by A. Sandberg, Proceedings of an International Conference (Oslo: Norwegian Biotechnology Advisory Board, 1995), pp. 42–43.

ecological benefits assessment.[467] The effect of such a requirement would be to shift the underlying presumptions of development policy in a fundamental way, amounting (critics would argue) to a presumption against the projects in question rather than in their favour. To return to a formulation of such issues used in Chapter 2, proponents of ecological benefits assessment argue that it is not enough to allow projects to proceed only if environmental damage can be reduced to acceptable levels ("yes, but"). Instead, projects would only be allowed to proceed if the complete absence of ecological harm, or even the generation of ecological benefit, could be demonstrated ("no, unless"). This shift reflects, in turn, profound disagreements about the severity and scope of current ecological impacts and the urgency of their reduction.

The argument that social, ecological or community benefits should be demonstrated as a condition for regulatory approval of biotechnology products and processes (or for other new technologies) is philosophically and politically challenging, because it implies that at least in some contexts neither the operations of the market nor existing health and safety regulations can be relied upon to ensure that technological innovation proceeds along ethically defensible and socially worthwhile lines. Such claims can be read as calls for comprehensively reassessing a model of social and economic organization in which the operation of markets has been implicitly presumed to yield overall outcomes that are on balance benign, if not always without unpleasant or even dangerous consequences,[468] and have sometimes been explicitly rejected on that basis. For example, it has been claimed that "no other products [i.e., other than those involving biotechnology] have to demonstrate socio-economic efficacy" in addition to meeting the conventional criteria for regulatory approval.[469]

How should governments deal with such issues as they occur either during debates about specific biotechnology applications or in the course of efforts to establish a general framework for dealing with the ethical issues raised by biotechnology? A critical point is that choices about how to deal with fourth hurdle issues are likely to have what might be called **asymmetrical consequences**. In other words, a decision to reject the claim that any such controls are necessary presupposes the ethical defensibility of a generic policy mix of markets-plus-regulation, and effectively dismisses as irrelevant claims about broader social goods, issues of distributive justice or community interests. (These phrases do not, of

467. Mary H. O'Brien, "Ecological Alternatives Assessment Rather Than Ecological Risk Assessment," *Human and Ecological Risk Assessment* 1 (1995): 357–66; Peter Principe, "Ecological Benefits Assessment: A Policy-Oriented Alternative to Regional Ecological Benefits Assessment," *Human and Ecological Risk Assessment* 1 (1995): 423–35.

468. Cf., the comment of Robert Collier of Monsanto Canada, in a discussion of the fourth hurdle concept during the rBST hearings, to the effect that: "If you subject every technology to the same standards [of social benefit], then you could make a strong case that we really don't need a new model car every year, or several of the other things that society expects on a regular basis. . . ." *Minutes of Proceedings and Evidence*, House of Commons Standing Committee on Agriculture and Agri-Food, March 10, 1994, 7:33.

469. KPMG Management Consultants, *supra* n. 333, p. 33.

course, mean the same thing, but all can be and have been invoked in debates about biotechnology.) However, a decision at least to consider some of these issues does not imply accepting the need for controlling or restricting the biotechnology application at issue **in any particular case.**

Within a discussion of how to resolve such issues, it is important to note that a more limited distributive principle, that of special concern for vulnerable persons, has achieved considerable acceptance. It was stated as one of the RCNRT's guiding principles, and is also reflected in the MRC guidelines (with specific reference to issues of risk and benefit) as they address the issue of research risks borne by "the infirm, or the racially, economically or otherwise disadvantaged." As noted in Chapter 4, the NRC guidelines go further in some respects, requiring that research must not involve "persons from a vulnerable or dependent population" unless the research "can only be carried out by involving persons from such populations."[470] In the form of the criterion that the best interests of the child should be considered as paramount, concern for the vulnerable is well established in family law: children are, after all, normally the most vulnerable parties (and those least able to speak for themselves) in disputes about custody and distribution of assets.

This principle so far has been most widely accepted with respect to the conduct of research in clinical settings. In those settings, an understanding is now emerging that the relevant issue is not only the assumption of risks by vulnerable populations, but also the extent to which members of vulnerable population are also the beneficiaries of the risks taken — or, conversely, whether the sole or principal beneficiaries are individuals or members of populations not exposed to the risks. There is some evidence that similar principles are being applied more broadly to environmental risks. In 1994, for instance, the Clinton administration issued an executive order requiring federal agencies to take issues of environmental justice into account in their decision making, and establishing an Interagency Working Group on Environmental Justice.[471] Concern for the vulnerable could be extended or extrapolated into the area of health and safety regulation by way of, for instance, a requirement that all determinations of risk acceptability for regulatory purposes should include explicit consideration of the equity dimensions, and should pay special attention to risks borne by vulnerable populations.

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470. NRC, *supra* n. 279, p. 8.

471. "Federal Actions to Address Environmental Justice in Minority Populations and Low-income Populations," Executive Order 12,898, February 11, 1994; reproduced in *Environmental Justice: Issues, Policies, and Solutions*, edited by Bunyan Bryant (Washington DC: Island Press, 1995), pp. 221–26. This collection as a whole provides a valuable introduction to the application of this principle of special concern in environmental policy.

5.4. Fourth Tension: Commodification and Respect for Life

An important range of concerns about the applications of biotechnology involves the concept of respect for life. These concerns are most acute when they involve human biological material; for many observers, they are brought into the foreground of the debate by efforts to patent human genetic material and products derived from it. However, they involve not only human beings but also (for example) the possible corrosive effects on an "ethic of conservation" of an approach to biodiversity that emphasizes IP rights and commercial potential.

One way of analyzing these concerns holds that "there are two irreconcilable world views competing for recognition . . . the 'pure science' view and the 'science-spirit' view."[472] The pure science view "is that our science, especially the new genetics, has in effect explained everything that there is to know about us as humans."[473] Typical of this world view is the comment of one molecular biologist to the effect that:

> The development of a human being is guided by just 750 megabytes of digital information. In vivo, this information is stored as DNA molecules in an egg or sperm cell. In a biologist's personal computer, it could be stored on a single CD-ROM.[474]

The science-spirit view, on the other hand, combines enthusiasm about scientific achievements, "the wonder of what this science reveals,"[475] with awe at the scope of the mystery of the unknown that it further opens ut. It incorporates the idea that increased scientific understanding of the common genetic heritage shared by humankind with other species enhances our respect for life, including human life, and its complexity. This view is reflected in the comment of a molecular biologist that:

> We all knew that evolution was true, but now, every time I pick up a cell, I have the same amazement. These genes really are there, and they are the same genes across species. . . . We really are connected to all these organisms.[476]

Scientific knowledge can thus lead either to reductionism or to reverence.

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472. Margaret A. Somerville, "Are We Just 'Gene Machines' or Also 'Secular Sacred'? From New Science to a New Societal Paradigm," *Policy Options* 16 (March 1996): 5.

473. Ibid., p. 3.

474. Maynard V. Olson, "A Time to Sequence," *Science* 270 (20 October 1995): 396.

475. Ibid., p. 4.

476. Quoted in James Levine and David Suzuki, *The Secret of Life: Redesigning the Living World* (Toronto: Stoddart, 1993), pp. 10–11; see generally Chapters 1–2. For an elaboration of this point with specific reference to the relatively minor genetic differences between human beings and the so-called great apes, see as well Richard Dawkins, "Gaps in the Mind," in *The Great Ape Project*, edited by P. Cavalieri and P. Singer (New York: St. Martin's, 1993), pp. 80–87.

Another element in such concerns about maintaining respect for life involves the idea of commodification, which generally refers to the association of something or some practice with attitudes that ordinarily accompany a certain subset of commercial transactions.[477] Commodification

> . . . has many meanings; it can refer to actions that (1) violate a duty of respect for persons by treating the person as a thing that can be sold; (2) alter a person's moral status so that the person becomes a thing without a will; (3) alter the sensibilities of people directly involved in market transactions by causing them to regard each other as objects with prices rather than as persons; and (4) alter the sensibilities of people who learn about or live in a society that permits the sale of persons but who do not participate in such transactions themselves.[478]

The phrase "a certain subset" is important because employment contracts, for instance, are commercial transactions but may not lead to commodification. More disturbing are transactions or legal institutions[479] that involve seeing the entity in question as property. A concept closely related to commodification, which captures the disturbing nature of some commercial transactions, is objectification.[480] To objectify something (or someone) is related to treating it as a market commodity, but what is disturbing about objectifying a person or organism is not so much the exchange of money as it is the notion that a subject, a moral agent with autonomy and dignity, is being treated as if it can be used as an instrument for the needs or desires of others without giving rise to ethical objections.[481] This can mean equating the "worth" of the subject with his, her or its market value; it can also mean treating or thinking of the person or creature as the kind of entity which can be acquired or traded by way of market exchanges **or** transactions that look like market exchanges (in other words, they are governed primarily by the norms of reciprocity), even if no money changes hands.

As suggested by the increasing political salience of animal rights and animal welfare, concerns about objectification or commodification are not restricted to the human organism. These concerns may arise with respect to other forms of life, or indeed with respect to life itself. They are likely to become more intense (for some people) in the event of a major future expansion of the use of genetically engineered mammals in agriculture, laboratory research or xenotransplant surgery, and as the capability to clone adult mammals becomes routine.

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477. Altman, *supra* n. 259; Radin, *supra* n. 262 and Radin, "Justice and the Market Domain," in *Markets and Justice*, edited by Roland Pennock and John Chapman (New York: New York University Press, 1989), pp. 165–97.

478. Altman, *supra* n. 259, pp. 295–96.

479. Such as slavery, or (more recently) the legal status of women and children as property of the husband in some jurisdictions until well into the twentieth century.

480. Shapiro, *supra* n. 213, pp. 351 (citations omitted).

481. Radin, *supra* n. 262, p. 345.

Both commodification and objectification involve change or reinforcement of the ways we think about living things of all sorts. New technologies like genetic engineering can lead to commodification either because they result in "dramatic changes in the sensibilities of participants and observers," or because such technologies "entrench, reinforce, or make seem more natural and inevitable, attitudes or beliefs that are already widely held." Scott Altman refers to these as modified-experience and attitude-reinforcement arguments, respectively.[482]

Concerns about commodification and objectification are frequently expressed by feminist philosophers and social scientists who criticize new reproductive technologies on the grounds that they introduce financial considerations into the social relationships of reproduction.[483] By treating reproduction as an activity that can be purchased, manipulated and contracted for, these technologies encourage the attitude that women are instruments for reproduction, and that children are commercial products. The discourse associated with assisted human reproduction also provides illustrations of objectification: the success of in vitro fertilization (IVF) clinics is often assessed in terms of their "take-home baby rate."

Arguments from commodification or objectification would appear to have particular force with respect to the failure of patent law to distinguish between living and non-living things. Through this failure, it can be argued, patent law reduces living organisms to the level of things to which no respect is due, thus subtly embodying the Cartesian view of all non-human organisms as automata devoid of consciousness or the ability to suffer. The concern that patenting higher life forms will modify our experience — change our attitudes and sensibilities toward life — in unwelcome ways gains credence from the language of manufacture and production used to describe the genetic alteration of animals for commercial purposes. Says one report on animal patenting: "The farm animal is becoming a 'collection of its genes' instead of a whole animal because of increasing scientists' ability to alter genetic compositions."[484] This is the kind of thinking abhorred by critics of patenting, and like the reference to take-home baby rates, this example illustrates that language is significant not only because of the attitudes it might engender, but also because of the attitudes it might reinforce. "Language is not neutral. . . . We form our narratives and our narratives form us — we are, at least in part, the stories we tell."[485]

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482. Altman, *supra* n. 259, pp. 294–95.

483. Christine Overall, *Ethics and Human Reproduction: A Feminist Analysis* (Boston: Allen and Unwin, 1987), especially Chapter 3; Barbara Katz Rothman, *Recreating Motherhood: Ideology and Technology in a Patriarchal Society* (New York: Norton, 1989).

484. Amanor-Boadu et al., *supra* n. 312, p. 127; see also J. Hodgson, "Whole Animals for Wholesale Protein Production," *Bio/Technology* 10 (August 1992): 866.

485. Margaret A. Somerville, "The Song of Death: The Lyrics of Euthanasia," *Journal of Contemporary Health Law and Policy* 9 (1993): 45.

How should we evaluate the potential hazards of commodification and objectification? They are unlike the physical risks associated with the use of new therapeutic agents, or with the release of genetically modified organisms, in that few established institutional frameworks are available. However, they are like the socioeconomic concerns on which proposals for fourth hurdles are based in that the absence of existing institutional frameworks does not mean that the issues are unimportant. Indeed, they may be especially important precisely because they have not been explicitly or systematically addressed. Failing to do so, and relying instead on precedents in existing social practices and relations, "encourages us to take the status quo as given *morally*, not just empirically."[486] Like arguments about the need for more thoughtful social control of technology, arguments about commodification and objectification have the salutary effect of forcing us to consider the possibility that the ways we do things now really are just no longer good enough.

5.5. Summary

This chapter identifies four key ethical tensions associated with biotechnology and its applications, in Canada and elsewhere. As the development of an ethical framework for biotechnology in Canada is pursued, it may be useful to keep in mind the extent to which whatever institutions and principles are proposed will help in the resolution of these tensions.

486. Radin, *supra* n. 262, p. 343.

6. The Way Forward

Developing an ethical framework for biotechnology in Canada means undertaking two different kinds of tasks. The first of these involves developing principles for resolving ethical questions related to biotechnology. Such principles might, for example, involve specific statements of the initial presumptions that should guide decision makers. The second task involves considerations of process or institutional design.

In this chapter, we begin by arguing that the two are related, and identifying three distinct ways in which the institutions for making and implementing public policy can become involved with ethical issues. In this discussion, we emphasize that ethical commitments can be "embedded" in institutions whose orientation toward public policy appears at first to be primarily technical or instrumental.[487] Second, we emphasize the importance of considerations of process in resolving ethical issues. Both sets of observations provide useful starting points for further work on helping government to deal creatively and constructively with the ethical tensions identified in Chapter 5, and others.

6.1. Ethics in Public Policy: Three Dimensions

The institutions of public policy can become involved with ethical issues and conflicts in at least three distinct ways.

First, a particular institution can have an explicit mandate to make decisions that are clearly acknowledged as ethical, or to investigate ethical issues in a search for solutions. Institutions which have actual decision-making authority can make their decisions by applying particular ethical principles to cases and trying to resolve conflicts among competing principles, or by using ethically defensible procedures. The work of clinical ethics committees and REBs, two examples of such decision-making bodies, reveals the need to interpret principles and formulate criteria for their application. When that need is met by devising defensible procedures for arriving at decisions, ethics becomes an amalgam of substance and procedure. (Here, as elsewhere, we recall the observation of one of the members of the Interdepartmental Working Group for which this report was prepared: "Ethics is a *process* one goes through in order to arrive at a decision.") Moreover, often, although not always, the structure and composition of these committees embodies a commitment to resolving the issues they deal with on the basis of a perspective that is not primarily that of medical professionals or scientists acting in their professional capacity.

Both these features are also reflected in the establishment of a variety of advisory bodies which address ethical issues in ways that are not binding. The conclusions of such bodies rely for whatever authority they command on the strength of the arguments they make, the

487. On the limits of instrumental approaches to public policy, and the commitments they may embody, see Laurence Tribe, "Policy Science: Analysis or Ideology?" *Philosophy and Public Affairs* 2 (1, Fall 1972): 66–110.

transparency of those arguments (for instance, with respect to the way particular principles have been applied and the way moral relevance has been established) and the credibility of their members.

In Europe, such bodies have been established both at the national and international levels. An example at the national level is Norway's Biotechnology Advisory Board, set up in 1991 with a mandate involving biotechnology and gene technology in relation to humans, animals, plants and micro-organisms. The membership of the board is interesting in that it apparently reflects an effort to combine diverse expertise with stakeholder representation. In addition to senior officials from six government ministries, the board includes representatives from national organizations of handicapped people, farmers, fisherpeople, and businesses, as well as representatives from the national conservation society, the national confederation of trade unions and the Research Council of Norway. In addition, eight members were appointed for their professional expertise; they include scientists as well as a theologian and a bishop.[488] Among its recent activities, the board organized a major international conference held in September 1995 on sustainable development and the release and use of genetically modified organisms.[489]

At the international level, the Group of Advisers on the Ethical Implications of Biotechnology to the European Commission was set up in 1991, as the result of an effort to promote "the competitive environment for industrial activities based on biotechnology within the [European] Community." It was expanded in 1993, partly in response to a commission white paper on growth and competitiveness that emphasized the importance of biotechnology[490] while recognizing that: "Technology hostility and social inertia in respect of biotechnology have been more pronounced in the Community in general than in the United States or Japan. It has become clear that these issues should be examined in greater detail in order to properly address these concerns."[491] Thus whatever scepticism may be in order about some of the motivations behind the group's establishment and expansion, it is clear that governmental concern with biotechnology's economic potential is not incompatible with serious and systematic concern for its ethical dimensions. This point is of special importance in the Canadian context because of the commitments to economic development underlying both the National Biotechnology Strategy and the regulatory framework for biotechnology.

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488. "The Norwegian Biotechnology Advisory Board," publication of the board.

489. Sandberg, ed., *supra* n. 466. Interestingly, and in contrast to the lack of reference to sustainable development in the Canadian regulatory framework for biotechnology, it is explicitly incorporated into the Norwegian body's frame of reference.

490. "Ethics and Biotechnology," Press Release for Press Conference by President Delors and Mrs. Lenoir [Chair of the Group], Secretariat General of the European Commission, May 24, 1994.

491. "Growth, Competitiveness and Employment," White Paper of the European Commission (Brussels, December 1993), p. 117.

Second, frameworks for making decisions that are not explicitly or avowedly ethical can be set up in ways that reflect particular values, or the primacy assigned to a particular ethical principle. Various kinds of health and safety regulation involve making decisions based on scientific evidence, but doing so within a framework that has to be policy- or value-driven. Choices must be made about how the burden of proof is to be assigned, and about how much evidence is enough in situations where there are factual uncertainties.

Decision makers may not be aware of the ethical commitments that are implicit in the criteria they use for making decisions, or of the potential for conflict with other commitments that are also of importance. Alternatively, they may be aware of these ethical commitments and conflicts, but have no mandate to do anything about them or even to disclose them to the parties who are potentially affected. In keeping with our emphasis on procedure and transparency, we would stress the importance of bringing those values into the open, for instance, by creating procedures that make it easier to examine or challenge the initial presumptions that currently structure decision making in particular cases.

Third, ethical commitments may be "embedded" in policies, institutions and procedures, often in ways that policy makers and the public alike tend not to think about because they are taken for granted. An example already provided is the criminal trial process. Another involves the way access to health care is provided. In the United States, where health care is provided primarily through the private marketplace, over 35 million people are without health insurance, and millions more have incomplete or inadequate coverage.[492] As a result, scenarios like one which occurred in Texas in 1985 are possible: suffering from third-degree burns as the result of an accident at work, a man without health insurance was turned away from three hospital emergency rooms, each of which, after discovering he could not make an up-front payment against the costs of his care, decided that his was not an emergency case. Seven hours after the accident, he was finally admitted at a teaching hospital, the fourth from which he had sought treatment.[493]

Health policy in Canada embodies quite a different conception of justice; the Texas case is incompatible with the common values of concern and respect for the welfare of others that form the basis for Canada's system of publicly funded, universal, comprehensive, accessible health care. Health care is a special case in Canada because those principles have been codified in the *Canada Health Act*; no comparable statement of principles exists south of the border. It is important to understand that the Canadian and the U.S. health care systems rest on sharply contrasting values, reflected in quite distinct initial presumptions. Despite add-ons like the Medicaid program, which provides publicly funded health insurance for some poor Americans, the initial presumption of U.S. health policy allocates health care through the market, like cars or condos. Anything more than a minor change in

492. David Himmelstein and Steffie Woolhandler, *The National Health Program Chartbook* (Cambridge, MA: Center for National Health Program Studies, 1992), pp. 4, 13.

493. Beauchamp and Childress, *supra* n. 48, p. 350. For a description of another, similar case see Himmelstein and Woolhandler, *supra* n. 492, p. 27.

this state of affairs is an intervention that demands justification. In Canada, conversely, the initial presumption is the desirability of universal access to more than just a bare minimum of health care, largely if not entirely independent of ability to pay. Justification is demanded, instead, for actions that might undermine that state of affairs.

Intellectual property policy, an area of considerable importance for biotechnology, likewise involves important embedded ethical principles. At least in North America, the basic principles of patent law can be traced historically to an equation of the public interest with the furtherance of commercial and industrial innovation. If we concede the possibility that advances in biotechnology might create serious tensions between the public interest and the furtherance of commercial and industrial innovation, then the patent system's claim to moral neutrality can be called into question, if only because accepting that claim predisposes future public policy choices toward accepting the status quo.[494]

The supposed neutrality of decisions about patenting, and of the framework within which they are made, leads to an important further point. Because social life is riddled with competing ethical claims, it is tempting to argue that governments exist precisely to maintain social stability in the face of such incompatibilities, and should therefore adopt the approach of "not taking a stand." Sometimes this is a thoroughly defensible approach; there may be very good reasons for governments not to try resolving competing ethical claims, but they should be able to offer a principled defence of such an approach, and to explain why they consider it to be neutral. Otherwise, they are open to the criticism that their policies take "the status quo as given *morally*, not just empirically,"[495] with implied ethical and political commitments that may not have been adequately examined.

6.2. The Importance of Process in Resolving Ethical Issues

Ethics can in many respects best be understood as a process of developing, understanding, testing and refining the principles by which decisions are reached. Sometimes this process goes on inside our heads. At other times, this process goes on by way of a dialogue among stakeholders in any one of a number of institutional settings.

To the extent that consensus or acceptance of a particular principle, reasoning process or outcome appears to increase over time, it may be because: "Ethical issues . . . evolve generally in four stages: threshold, open conflict, extended debate, and adaptation."[496] The cynical view is that adaptation simply reflects acquiescence or resignation. A more sanguine view is that ethical reasoning is a learning process that leads (over time, and sometimes erratically) to a genuine increase in understanding. Principles like those of

494. See Schrecker et al., *supra* n. 82, p. 98–100.

495. Radin, *supra* n. 262, p. 343.

496. John Fletcher, "Evolution of Ethical Debate About Human Gene Therapy," *Human Gene Therapy* 1 (1990): 56.

beneficence, respect for autonomy and justice did not just happen; they are the product of an extended and continuing process, and (ideally at least) they are constantly being refined, modified and adapted in ways that reflect sensitivity to new issues and perspectives.[497]

This view of ethics as process has important consequences in terms of the design of decision-making procedures. For instance, it strongly suggests that, other things being equal, more public participation is better than less — not only because of the pragmatic connections between trust and the acceptance of risk, but also because opportunities for learning are maximized. In addition, patience is in order with respect to procedures the outcome of which may seem frustratingly vague and indeterminate, at least in the short run.

There is another dimension to the issue of process. The nature of democratic societies and institutions is that process is important for reasons that are independent of the outcome of decisions in particular cases. In fact, the "social contract" (to invoke an admittedly overused concept) that keeps democratic societies relatively stable has to do less with specific outcomes than with the institutions and processes used to arrive at them.

With this insight in mind, it is worth looking briefly at a range of possible explanations for dissatisfaction with the outcomes of decisions about biotechnology.

One explanation is simply that a minority of the population is irrational, unwilling to accept scientific facts or insistent on confusing debates about safety and efficacy with broader macropolicy concerns about the direction of society or the economy. For reasons outlined in the preceding chapter's discussion of risk, scepticism about the claim of irrationality is in order. The suggestion that critics of biotechnology sometimes present their critiques in contexts where they are perceived as misdirected is more apt. However, this may be due less to the critics' irrationality or perversity than to the absence of alternative ways of raising the ethical issues they view as extremely important: if you view the introduction of a particular technology as ethically suspect, and the only regulatory "handle" involves issues of safety and efficacy, that may be the handle you try to grasp even though you would much prefer another one.

A second potential explanation cites the limited degree of openness and information disclosure associated with the health and safety regulatory framework. In the case of the rBST hearings, for instance, Health Canada's non-disclosure of scientific data provided in support of the application for regulatory approval was criticized repeatedly. In this instance it appears to have been mandated by statute, as part of a balancing of commercial interests against the interests of potential risk-bearers that clearly is unsatisfactory to some. Given both the factual links that can be observed among trust, openness and accountability and the

497. Some observers have identified this process quite explicitly through a comparison of successive editions of Beauchamp and Childress's *Principles of Biomedical Ethics* and the critiques made during the intervening periods. See also Weijer, *supra* n. 47.

substantive arguments that can be made in support of greater disclosure, the time for re-examining such statutory provisions may have come.

The third potential explanation is, in our view, the most plausible as well as the most promising with respect to procedural and institutional change. A key difference between regulation of the health and safety of consumer products and industrial processes and the resolution of ethical issues in medical treatment and research is that for the latter, but not the former, an institutional mechanism is in place that facilitates (and to some extent requires) dealing with ethical issues openly and explicitly **as ethical issues**, within a set of general principles that are widely agreed upon but at the same time subject to interpretation in specific situations. This characteristic of debates about clinical and research ethics is the reason for the amount of time devoted in Chapter 2 to what must have seemed to some readers, at least, an excessively abstract account of mid-level principles and moral relevance.

When they are working properly, REBs and clinical ethics committees provide a forum or a context in which ethical issues are discussed in those terms. No analogous mechanism exists in cases where, for example, concerns are raised about the potential environmental hazards associated with biotechnology applications; safety issues are discussed, although not in explicitly ethical terms. Another way of saying this is that ethical debates can and do happen, but not within an institutional framework where there is a direct connection between the policy outcome amd the reasons for resolving the underlying ethical issues in one way rather than in another. This is partly because, as noted above, ethical issues and embedded ethical commitments are often not acknowledged as such.

The absence of any "permanent and effective venue for formal bioethical review of federal policies" dealing with issues such as genetic research and biotechnology patenting led the environment writer for the trade journal *Bio/Technology* (now *Nature Biotechnology*) to call in 1995 for the establishment of a national advisory body to deal with such issues.

> With a handful of exceptions, neither Congressional or industry leaders have given the changing bioethical issues that underlie the development of law . . . anything approaching thoughtful consideration, despite legitimate ethical and legal questions raised by industry insiders and outsiders alike.[498]

This state of affairs stands in direct contrast to the appreciation of the need to "do ethics," and the expressed engagement with ethics, that has characterized many professional and public activities over the past decades. This engagement can be regarded as a revolution in consciousness.[499]

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498. Russ Hoyle, "Biotech is still searching for a bioethics forum," *Bio/Technology* 13 (August 1995): 735–36.

499. Margaret A. Somerville, "A Generation's Revolution in Consciousness: The Search for Ethics," Falconbridge Lecture, Laurentian University, Sudbury, Ontario, 1990.

6.3. Concluding Remarks

Douglas Amy argues that policy analysis and ethics are ultimately incompatible, because of the inconvenient nature of the questions raised by ethical analysis and because of political decision makers' tendency to portray their day-to-day activities as primarily, if not exclusively, technical in nature.[500] However, the discussion in the preceding paragraphs, and perhaps in particular the need to identify and justify initial presumptions, suggest that an ethical perspective on public policy is crucially important. Indeed, policy analysis and policy decision making without an explicit ethical component may ultimately be irresponsible, when the ethical dimensions of the issues at stake fail to receive adequate attention. Only by chance will good public policy result from initial presumptions that are left unexamined and commitments to particular values (perhaps at the expense of others) that are left unacknowledged. Excluding ethics from policy analysis ultimately means deferring to whatever judgments emerge from the workings of power and influence within the political process. This approach may be politically expedient, but it is not ethically defensible.

Finally, we need to recognize that "doing ethics"[501] in any venue but particularly in government, is not simply an abstract or academic inquiry. It is also an exercise of power because what is determined to be ethical will be permitted, and what is determined to be unethical will, in one form or another, be discouraged or prohibited.[502] Questions about **who** decides ethical issues, what **processes** are used to arrive at those decisions, on what **basis** (that is, in terms of what values and principles) those decisions are justified, and what the **purpose** of raising ethical issues is, must therefore be addressed not only because they are intrinsically important, but also because they are central to how the power inherent in "doing ethics" is distributed. "Doing ethics" must, in other words, be undertaken responsibly.[503] That requirement is most stringent when both what is at stake and the power that can be wielded are substantial. The principal aims of this report are to vindicate the need for government to respond to the manifold ethical issues raised by biotechnology, and to direct that response in ways that are likely to produce responsible procedures and responsible outcomes.

500. Amy, *supra* n. 33, pp. 578–84.

501. See Margaret A. Somerville, "Labels versus Contents: Variance between Philosophy, Psychiatry and Law in Concepts Governing Decision Making", *McGill Law Journal* 39 (1994): 181–82, for discussion of the differences between talking about ethics and "doing ethics," the latter of which is in the nature of a verbal act.

502. See Margaret A. Somerville, "How (Bio)ethical are Bioethicists?" *Eubios Ethics Institute Newsletter* 3 (1993): 58.

503. Ibid.