Ethics and Biotechnology:

The Role of the Government of Canada

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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 establishment of an independent advisory commission on biotechnology that would also address ethical

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

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

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).

> 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.

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

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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.

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 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

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).

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

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. . . .
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> 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]

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

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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.

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).

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 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.

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.

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.

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

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.

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.
- *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.

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

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

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

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. . . .
>
> 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.

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.

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.

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.

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.

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*.

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 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

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.

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

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 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

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**).

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**).

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 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:

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**).

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

> **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 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

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.

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.

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."

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

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.

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 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-

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

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 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

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

82. Ibid.

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. 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.

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

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

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.

International Ethics Advisory Committees

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.

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 consensus but at socially acceptable decisions."[102] Agreement on process and forums for

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.

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

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 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

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.

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 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.

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).

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

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

108. See Table A above.

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.

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 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 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

111. See also subsection 1.1.1. above.

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*	1968–	Animal welfare and research ethics guidelines
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.

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

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.

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. 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

114. See Appendix C below.

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.

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

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.

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

CGATBSS/Medical, ethical, legal and social issues:
http://cgat.bch.umontreal.ca/MELSI/melsi.html

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**

U.S. Department of Agriculture, Biotechnology Information Center: **http://www.nal.usda.gov/bic**

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*	Yes – 1
B.1.	*Standing Committees*: Within your Ministry or institution do standing ethics committees exist?	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)