Towards a Coherent Ethics Framework for Biotechnology in Canada

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For the Government of Canada Interdepartmental Committee on Ethics in Biotechnology

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Introduction

> ..."*Future research into, and the use of, biotechnology must be based on ethical guidelines. The aims, means, consequences and standards must be ethically assessed and our views must be based on values which are acceptable to the majority of the... population.... Openness and access for the public to all information should ensure confidence that biotechnological and gene technological research....will benefit society.*"
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> Norway, *Biotechnology Related to Human Beings*.[1]

Canada is poised to embark on a critical leg of its journey through the benefits and burdens of 21st century science. The journey reflects the continuing effort of modern society to transform new scientific knowledge and technological developments into wise use. In this instance, the journey is through the biotechnology revolution. The federal government recently unveiled a new policy in this regard. The 1998 Canadian Biotechnology Strategy[2] proposed to establish an independent advisory committee on biotechnology. Amongst other things, the Committee shall advise government on socio-ethical aspects of biotechnology and their implications for policy making. This marks the first time that ethics has been accorded an explicit policy role in the national biotechnology strategy of Canada.

This report maintains that the creation of this new structure is one of three basic steps towards a coherent ethics framework for biotechnology. A coherent ethics framework, it is argued, should consist of structural, procedural and substantive elements. Accordingly, two important remaining steps involve defining public process norms and substantive ethical principles. To explain this argument, Part I below highlights emerging issues before government in the "public policy and regulatory ethics" of biotechnology. Part II examines the roles of government in responding to such ethical challenges, and suggests how a framework fits within governmental responsibilities. Part III outlines the basic elements and functions of a coherent ethics framework. Part IV samples how ethics frameworks work in practice through the experiences of selected countries. Part V offers recommendation to government, to urge it to develop a coherent ethics framework for biotechnology for Canada.

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1 Ministry of Health & Social Services. *Report to the Storting*. Oslo,1992-93:7-9.

2 Government of Canada. *Renewal of the Canadian Biotechnology Strategy*. Ottawa. 1998.

I. Ethics & Biotechnology: Emerging Conundrums for Government

A. Ethical Issues Before Government

The biotechnological revolution has prompted a range of public policy issues to come before society and governments over the years.

- *Transgenics*: Is it wrong to create transgenic animals or plants that do not occur in nature?
- *Research Limits*: Is some biotechnological research or product development so objectionable as to warrant temporary or permanent bans?
- *Labeling*: Should genetically-engineered food products be labeled as such, to promote consumer sovereignty, individual and cultural autonomy and the informed assumption of even minimal risk?[3]
- *Personhood, Privacy & Human Dignity*: Does biotechnology reconstruct our vision or value of the human person? How, for instance, do we implement notions of "genetic ownership, genetic privacy and genetic discrimination"?
- *Intergenerational Justice*: How do we ensure that the production today of genetically-modified organisms is consistent with sustainable development[4] and the needs of future generations?
- *Duties to Nature*: Beyond any duties owed to future generations of humans[5], what ethical duties are owed directly to animals[6] and the ecosystem[7] because of their intrinsic value?
- *Patenting Life*: Is it acceptable to patent microbial, animal or human life forms?[8]
- *Conflicts*: How do we effectively manage the promotion and regulation of biotechnology?

An increasing number of such issues have drawn the attention of the Government of Canada in the 1990s. From 1990-92, for instance, diverse federal institutions produced reports on biotechnology,

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[3] Thompson PB. Food Biotechnology's Challenge to Cultural Integrity and Individual Consent. *Hastings Center Rpt.* 1997;27:34-38.

[4] 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, 1995.

[5] Weis EB. What Obligation Does Our Generation Owe to the Next? An Approach to Global Environmental Responsibility: Our Rights & Obligations to Future Generations for the Environment. *Am. J. Int'l L.* 1990;84: 198.

[6] Feinberg J. The Rights of Animals & Unborn Generations, in Blackstone WT, ed. *Philosophy & Environmental Ethics.* Atlanta: Univ. of Georgia Press, 1974: 43-60.

[7] Rose CM. Given-ness and Gift: Property & the Quest for Environmental Ethics. *Environmental Law* 1994; 24: 1-31.

[8] US Congress, Office of Technology Assessment. *New Developments in Biotechnology: Patenting Life.* Washington, DC: US Gov. Printing Office, 1989.

government policy and associated ethical implications of genetic testing,[9,10] the ownership of human tissue,[11] gene therapy,[12] DNA banks and privacy.[13] In 1993, a Royal Commission outlined an "ethic of care" to advance policy recommendations on reproductive aspects of some biotechnological research and applications.[14] In 1995, the government outlined proposals on the labeling of genetically-engineering foods.[15] The issue has generated ethics opinions[16]and legal standards[17]abroad. In 1997, the cloning of Dolly the sheep[18] in Europe intensified scrutiny of the anti-cloning provisions of reproductive technology legislation that Health Canada had proposed following the Royal Commission Report.[19] In 1998, the Federal Court of Canada agreed to review the denial of a patent claim for a genetically-engineered higher life form -- a transgenic mouse -- for use in cancer research.[20] The case is likely to go to the Supreme Court.

The premise of this report is that such regulatory, legal and policy questions present ethical issues. The ethical issues need to be identified, analyzed and imported into the policy-making duties and roles of government. The issues, roles and responsibilities require new and effective approaches, including the development of an ethics framework for biotechnology.

B. Public Policy & Regulatory Ethics Responsibilities

The need and authority for government to respond to socio-ethical issues of biotechnology arise from its public regulatory and policy responsibilities. As some of the foregoing issues have arisen, many nations have moved to include formal ethical deliberations in developing public policy and laws on biotechnology. They have done so for at least four reasons.

First, as public policy and regulations on biotechnology have posed ethical issues, governments have sought professional expertise in ethics. This is classic analytical problem-solving by recourse to modern ethical reflection. Secondly, and consistent with this, governments have done so because

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

[10] Law Reform Commission of Canada. *Genetic Heritage* (study paper by B.M. Knoppers). Ottawa, 1991.

[11] Law Reform Commission of Canada. *Procurement and Transfer of Human Tissues and Organs*. Ottawa, 1992.

[12] Medical Research Council of Canada. *Guidelines for Research on Somatic Cell Therapy in Humans*. Ottawa, 1990.

[13] Privacy Commissioner of Canada. *Genetic Testing & Privacy*. Ottawa, 1992.

[14] Royal Commission on New Reproductive Technologies. See Table A, below.

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

[16] 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* (safety, consumer choices, cultural/religious considerations, technology assessment, education/information mechanisms, animal welfare, as ethical issues).

[17] See, .e.g.,The Australia New Zealand Food Standards Council Recommendation of August 1999 and the Australia & New Zealand Food Authority. *Standard 18 (of the Food Standards Code): Food Labelling Using Gene Technology*. Dec. 1998, [www. anzfa.gov.au].

[18] Editorial. One Lamb, Much Fuss. *Lancet* 1997;349:661.

[19] *Bill C-47: Human Reproductive & Genetic Technologies Act*, section 41A (1996).

[20] *President & Fellows of Harvard College* v. *(Canada) Commissioner of Patents* (1997) 79 CPR 3d 98 (Fed. Ct. Trial Div.), appeal granted to Fed. Ct. of Appeal, 1998.

ethical deliberations may help to clarify the values that inspire public policy and law on biotechnology. If it is understood that a legal requirement of informed consent in genetic screening of patients is inspired by the ethical principle of autonomy, the clarity may aid in the administering or reforming of genetic law and policy. Thirdly, then, governments have begun to incorporate ethics analysis due to its dynamic relation with public policy and laws on biotechnology. Because legal and ethical norms may prohibit or regulate conduct, for instance, they help guide policy development. European law thus disallows biotechnology patents on inventions considered contrary to "public order or morality," such as processes for cloning human beings.[21]

Finally, government has also turned to applied ethics to help define ethics frameworks. In the 1970s, the US created by federal statute national commissions to study socio-ethical issues in research and biotechnology. The resulting landmark reports[22] produced by the Commissions helped to frame national biotechnology policy and the subsequent public law regulation of human experimentation. This process has become the prototype for building ethics frameworks to manage socio-ethical issues in national biotechnology policy. In the process, an independent expert ethics advisory committee is created by or under the authority of public law with a mandate to define or deliberate on ethical principles. Once the committee does so, the principles help to structure public policy or law affecting science and biotechnology. Beyond the US, the approach has been relied on in France, Norway, the EU and the UN.

Why has this model of ethical reflection become popular? Its popularity owes to its strengths and relevance compared to other decision-making models involving ethical reflection. Consider some of the alternatives. The standards, technical expertise and ethical duties of scientists and like professionals are relevant to national biotechnology policy. But a focus on the ethical norms of professions proves insufficient to the multiple interests and public values implicated. Turning to the courts to address ethical issues in biotechnology is another relevant, but limited model. When a patient claimed in the 1980s that a physician researcher had -- without his knowledge or consent -- used and transformed his pancreatic cells into a lucrative genetically-engineered anti-cancer drug, the case raised both legal and ethical issues that the California Supreme Court addressed.[23] Impartial court rulings on such matters do resolve narrow biotechnology disputes, remove legal uncertainty, and announce principles to guide future conduct. Still, court rulings are reactive, foster little public participation, and are not well-designed to address questions like the ethics of patenting life. Ethics advisory committees also offer important expertise and reflection on ethical issues, cases or policy.

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[21] See European Union Directive 98/44/EC in Table A, below. Consistent with the procedural and structural elements of a coherent ethics framework urged below, the EU Directive contemplates that the judgement of whether some patent initiatives are "contrary to public morality" will be informed in part by a formal process that includes ethics analysis by independent, interdisciplinary entities or structures. See ,e.g., European Union, Group of Advisers on the Ethical Implications of Biotechnology. *Opinion 8: Ethical Aspects of Patenting Inventions Involving Elements of Human Origin.* Brussels, 1996, and the discussion in sections IV.B.3 & 4, below.

[22] US President's Commission for the Study of Ethical Problems in Medicine. *Splicing Life: The Social and Ethical Issues of Genetic Engineering with Human Beings.* Washington, 1982; Belmont Report, in Table A, below.

[23] *Moore* v. *University of California*, 793 P2d 479 (Cal. 1990).

Their potential contribution to governmental biotechnology policy lies unrealized, however, if they are not structured into the public policy process.

In contrast, the public law model of ethical reflection pertains directly to national biotechnology policy, and helps to harness the strengths of other models. Public law involves the legislative, regulatory and policy process of making, administering or reforming public laws. It provides the foundation for every Ministerial action in the biotechnology domain. In contrast to the reactive role of courts, the public law may help to fix future standards, rights and duties. Its 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."[27] It is intended to foster public participation. When governments create advisory committees on ethics or biotechnology for assistance on its broad legislative responsibilities, then public advisory committees may (a) provide expert, independent advisory opinions on ethical matters; (b) stimulate and channel public and governmental debate and reflection; (c) help to build consensus towards broad ethical norms that help to define socially acceptable policy positions; and (d) thus, inform policy, regulation and law. This is the model adopted by the 1998 Canadian Biotechnology Strategy in its creation of a Canadian Biotechnology Advisory Committee (CBAC).

As the government begins to implement the Strategy, the strengths, limits and challenges of the model may become evident. The independence, composition, mandate and accountability of publicly-created advisory committees like the CBAC are critical elements of their purpose and function. If properly structured, the CBAC may ensure a range of independent and interdisciplinary thought, voices and values. Successful committees effectively perform functions a-d, above, through consensus-building. Thus, a major challenge to the CBAC is to meld legitimate disagreement and value conflicts into coherent analyses and ethically defensible policy options. Some public advisory committees become fractious, politicized or dysfunctional. Some committees recede from public accessibility. Still, the comparative strengths of the model have led Canada and other nations to rely on it to establish a national advisory entity on biotechnology with an ethics mandate. Government has done so to discharge its special responsibilities and roles in managing the benefit and burdens of biotechnology.

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[27] Jones DJ. Artificial Procreation, Societal Reconceptions: Legal Insight France. *Am J. Comparative Law* 1988; 36: 525-540.

II. Government Roles & Responsibilities in Ethics & Biotechnology[28]

The Government of Canada plays 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.

A. Fiduciary of Public Duties, Trust & Monies: The federal government has high duties in the biotechnology domain as a fiduciary of public powers, trust and monies. The citizens of Canada have delegated to the federal government broad societal responsibilities for overseeing such matters as national health and safety, natural resources and the environment, commercialization and economic growth, fostering research and development, etc. Virtually each ministry active in biotechnology is entrusted with public monies to discharge its broad public responsibilities outlined in the relevant Act of Parliament. The government thus stands in a fiduciary relation to the public. As the public's agent, it must act with upmost good faith, loyalty and honesty to promote the public's best interests in the biotechnology domain. Even when those best interests may seem uncertain, the underlying governmental duties always mean that the delegated powers and monies are held in trust for public benefit.

B. Promotion of Research & Development: The government plays a significant role in promoting the research and development (R & D) of biotechnology through the granting of patents and the funding of research, on the view that such research advances the frontiers of knowledge and enhances the quality of life of Canadians.

C. Fostering Ethically Acceptable Conduct: Public credibility and trust in the governmental roles in biotechnology depend 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 in government-conducted research, in regulating biotechnology products, or in government-funded and supported activities. Sometimes fostering ethical conduct means defining and nurturing compliance with ethical norms and standards. This is illustrated by the recent initiatives of the National Research Council and Tri-Council of Canada, as noted in Part IV.D.5, below.

D. Protecting Public Health & Safety: The State has long played a role in protecting those who cannot protect themselves. The role is intended to prevent exploitation of the vulnerable and to protect the public good, on the view that government action protects health and advances human dignity, solidarity and basic notions of fairness. The protective role of government sometimes involves exercising beneficent judgements to minimize harms based on competent risk-benefit assessment. Ethical reflection on these matters helps to identify the implicated values, analyze moral

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[28] Jones DJ. Ethics & Biotechnology: The Role of the Government of Canada. *Renewal of the Canadian Biotechnology Strategy -- Resources Documents: Ethics.* Ottawa: Government of Canada, 1997:1-66 [strategis.ic.gc.ca/SSG/bhoo192e.html], (hereinafter Ethics & Biotechnology).

conflicts, prioritize competing value choices, and evaluate alternative policies for advancing preferred norms.

E. Formal Dispute Resolution: The judicial branch of government plays a leading role in formal dispute resolution of biotechnology conflicts through the courts. Legal issues before the courts sometimes present ethical dimensions. The Moore case from California and the patenting of higher life forms litigation now before the Federal Court of Canada illustrate the point.

F. Promotion & Protection of Human Dignity: For government to promote and protect human dignity in the face of the seemingly inexorable advances of science, government may define substantive norms and orchestrate process models for defining the content of those norms.

G. Advancing Public Process - Debate, Education & Participation: On the grounds of participatory 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. Agreement on process and forums for reflection may seed constructive public dialogue, trust, an openness to persuasion, and like foundations for consensus-building toward socially acceptable decisions on the merits. Public education on and participation in science policy, moreover, are critical to promoting a modern "culture of science", as the Government of Canada has urged.[29]

H. Norms to Govern Conflicting Roles & Responsibilities:

Identifying Government Conflicts: The people of Canada have delegated to the federal government unique responsibilities and roles. With the duties has come a delegation of power and trust. When the federal government has high responsibilities in the research, testing and product development or diffusion phases of biotechnology, then its roles, responsibilities and accountability in the ethical and social dimensions of these domains should correspondingly be high. Exclusive governmental authority over the *Patent Act*, for instance, means that government has high responsibilities on the ethics of patenting life-forms. Sometimes, in the exercise of its legitimate functions, governmental roles will conflict. Sometimes, they will cast the government in the role as a promoter of biotechnology; sometimes, as regulator; sometimes, as deliberator. When such roles clash, the collisions may lend the appearance that government is in a conflict of interest. Such potential conflicts need to be identified and managed. Otherwise, they may raise concerns about to whom the government owes its duties, whether its judgement has been compromised and whether it has breached the public trust.

Managing Role & Value Conflicts: The potential for conflicts may be addressed by ensuring that substantive norms, policies, and processes are in place to identify, manage or prevent them. Three implementing strategies may prove helpful:(A) establishing the paramount roles and duties of government; (B) adherence to fiduciary duties; and (C) recourse to process mechanisms. Strategy

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[29] Industry Canada. *Science & Technology for the New Century: A Federal Strategy*. Ottawa, 1996:23.

A likely involves consensus-building and addressing underlying values. It demands time, diligence and creativity. Strategy B complements the search for paramount roles and values. Government has a transcendent duty always to act with utmost good faith, honesty and loyalty to advance the best interests of the Canadian public. Even if those best interests are seldom self-evident, the fiduciary duty should nurture all government roles. It infuses every ministry and every file in biotechnology. What the duty specifically commands in particular contexts may not always be clear. Public servants are thus challenged by the duty to apply reasoning and judgment to divine the specific conduct that best serves the public interest in specific cases. In the face of substantive moral uncertainty, Strategy C should help government define its paramount roles and implement its fiduciary duties. Indeed, the continuing integrity and credibility of government in its multiple biotechnology roles may depend on whether it has effective mechanisms to identify, mediate, arbitrate, or resolve underlying value disputes for coherent policy development. The mechanisms may be developed by 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 levels. Institutional and national ethics advisory committees may also help to address underlying value conflicts in the multiplicity of roles that the federal government plays in biotechnology. Indeed, the structures, processes and principles to manage conflicting roles and values should become part of an ethics framework.

III. Towards a Coherent Ethics Framework

> *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.*[30]

This section outlines the basic elements and functions of a coherent ethics framework.

A. A Coherent Ethics Framework: Basic Elements

Whether government commits to developing an ethics framework to ensure that technological development unfolds consistent with societal values, to manage moral uncertainty and policy development, to seek answers to specific ethical questions, or to define better the ethical implications of its roles, a basic questions remains: what is an ethics framework?

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[30] Ethics & Biotechnology, op cited, p.48.

Under the model proposed in this report, a coherent ethics framework consists of substantive, procedural and structural elements. The elements are interactive and complementary.

Guiding Substantive Ethical Principles: To ensure that the research, development, and diffusion of biotechnology unfolds in a manner consistent with fundamental societal values, a leading task in developing an ethics framework is to identify and define substantive guiding principles that reflect and aspire to shared public values. Tables A and B in Section IV, below, profile selected countries that have developed a range of guiding ethical principles for biotechnology such as human dignity, distributive justice, protection of human health, privacy. Where do such principles come from? It will be shown that they typically emerge from formal deliberative processes that draw on a broad spectrum of sources, including theology, philosophy, law, public policy, international doctrines, professional ethical duties. If the breadth of sources attests to ethical pluralism, the pluralism may make the task of defining ethical principles formidable.

When society is able to identify ethical principles, practical challenges greet their implementation. Should the identification of freedom of inquiry as a guiding principle lead to a public policy in favor of human cloning research and easy access to DNA data banks? Or does such research implicate other values and principles? When two principles conflict, do we agree on a hierarchy of public values? Or do we simply outline principles, and leave the resolution of conflict to their application in specific cases or policies? Such questions indicate the strengths and limits of guiding ethical principles. They prove helpful to identifying and expressing values. By themselves, however, they do not resolve specific ethical dilemmas or determine policy outcomes.

Core Process Values & Procedures: For such reasons a coherent ethics framework needs clear process and good procedures: (a) that help define and implement substantive principles; (b) that address disagreement, ethical uncertainty and value conflicts, and (c) that channel ethics deliberations and debate towards policy development. Particular procedures will spring from core process values. To require government advisory bodies on bioethics and biotechnology to be "independent," is a requirement responsive to the values of unbiased and impartial decision-making on the merits of the issues. To enable participants in genetic therapy research to participate only if they have given their free and informed consent, is to commit to a procedural norm premised on substantive ethics principles of respect for the autonomy and dignity of the individual. To require government ethical deliberations to adopt procedures to ensure "transparency,"[31] opens decision-making to scrutiny and advance "accountability", which are fundamental procedural principles of modern deliberative democracy.[32] To insist on fair, publicly inclusive procedures for debating ethical dilemmas is to advance public participation. Indeed, the likelihood that we shall confront ethical dilemmas that will divide opinions, should not disable us from agreeing on good processes

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[31] See The Australian Science, Technology & Engineering Council. *Environmental Research Ethics -- National Principles for the Conduct of Research In Protected & Environmentally Sensitive Areas.* Canberra,1998 ("transparency" as an ethical principle) [www.isr.gov.au/science/astec] [hereinafter ASTEC].

[32] Gutmann A & Thompson D. *Democracy and Disagreement.* Cambridge, Massachusetts: Belknap Press, 1996.

to debate the merits. Such agreement may advance trust and credibility for difficult decisions. The examples indicate that the paths towards our moral choices may be as important as the ultimate choices themselves.

Accountable, Effective Structures: A coherent ethics framework for biotechnology requires publicly accountable, administrative or corporate entities with clear ethics responsibilities. The structural element refers to the institutional mandate and composition of such entities as well as the formal relations they share with policy-making bodies and the public. The structural element thus directly interfaces with the procedural element of the ethics framework for implementation. The precise structure and process of these bodies influence participation in and the dialogue on ethical deliberations through government and society. A commitment to an interdisciplinary and public membership, for instance, helps determines the breadth and content of ethical reflections. Interdisciplinarity presupposes that answers to ethical dilemmas come from no one discipline, school of thought or voice. This advances ethical pluralism. Public membership helps advance citizen participation and public accountability.

B. Goals and Functions of a Coherent Framework

A coherent ethics framework should integrate its substantive, procedural, and structural elements to serve at least five important functions.

1. Accommodating Evolving Ethical Thought

A coherent and effective ethics framework aspires to accommodate and promote evolving ethical thought. Thus, the recent policy statement by the Tri-Council of Canada on norms of ethical conduct for research involving humans recognizes the abundant and pluralistic character of modern ethical thought (See Table B, below, p. i.9). Such sensitivity enhances the likelihood of identifying and addressing ethical issues and value conflicts in Canadian biotechnology policy.

2. Norm Building

Norms in ethics help to determine how we think, what we value, how we process and reconcile conflicts, and what kind of conduct or policies follow from such deliberations. Norms should be substantive, procedural and structural. A commitment to ethical pluralism and evolving thought means that few, if any, substantive guiding principles will be absolute or static.

3. Identifying Value Conflicts in Public Policy & Regulatory Ethics

An ethics framework should be designed to identify and mediate effectively the inherent value conflicts in ethical deliberations. Process mechanisms for doing so thus again prove critical. One positive result of affirmatively managing value conflicts and the associated moral uncertainty is to narrow the issues to a range of ethical choices that support different policy options.

4. Fostering Ethical Deliberation, Debate & Public Participation

An effective ethics framework will successfully foster public participation and debate in and towards deliberative fora of decision-making, so as to aid government in addressing controverted ethical matters in biotechnology policy. Sometimes, a pressing need for fuller deliberations may translate into temporary moratoria. The process of deliberation affords government and society the opportunity to identify, assess and debate the ethics of particular initiatives.

5. Preventive Ethics & Education

A coherent framework serves important education, preventive ethics and stewardship functions. Participation in public debate and processes that identify and address ethics issues from interdisciplinary and pluralistic perspectives helps to educate citizens, ministries, companies. Effective education and implementation of the framework should begin to move society from simply reacting to ethics issues in biotechnology, to spotting them on the horizon of societal development. Preventive approaches to managing technology is a prime responsibility of modern governance.[33] A preventive strategy to invest in ethics directly responds to the responsibilities of government as a steward and trustee of public resources.[34]

IV. Ethics Frameworks in Action

This section examines the workings of ethics frameworks internationally. After identifying sample norms that have been relied on in ethics of biotechnology, we examine how some of the ethical norms have worked in selected countries and contexts. Examples of how ethics frameworks discharge their basic functions -- from norm building to fostering public participation -- are also noted. Because the focus is on broad themes, however, the experiences are highlighted and not exhaustively detailed.

A. Sample Ethics Norms & Definitions

Tables A & B, below, outline leading ethical principles and norms that have emerged over the years in statements, policies, laws or practices relevant to biotechnology.

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[33] *Science & Technology*, op. cited, p. 26.
[34] *Ethics & Biotechnology*, op. cited, pp. 35, 48.

Table A: Sample International Ethical Norms

	United States	*Canada*	*Denmark*[e]	*France*[f]	*GAEIB*[g]	*UNESCO*[h]	*Norway*[i]	*United Nations*[j]	*Council of Europe*[k]	*Nuffield Council*[l]
Human Dignity	X[a]	X[c,d]	X	X	X	X	X		X	X
Autonomy/ Informed Choices	X[a]	X[c,d]	X	X	X	X	X		X	X
Equality/Non-discrimination		X[c,d]	X	X	X	X	X	X	X	X
Confidentiality/ Privacy		X[d]		X	X	X	X		X	X
Non-commercialization		X[c]	X	X	X	X			X	
Biological Diversity		X[j]	X[j]	X[j]	X			X		
Distributive Justice	X[a]	X[c,d]	X		X	X		X	X	X
Beneficence	X[a]	X[d]								X
Risk Assessment	X[a]	X[d]		X	X		X	X	X	X
Human Health & Safety	X[a,b]	X[c,d]		X	X		X		X	X
Sustainable Development		X[j]	X[j]	X[j]			X	X		
Protection of the vulnerable/Solidarity	X	X[c,d]		X	X	X	X	X		X
Animal Welfare					X		X			
Ethics Review		X[d]		X	X	X	X		X	X
Transparency					X		X			
Public Participation & Education	X[b]	X	X	X	X		X		X	X

a United States. National Commission for the Protection of Human Subjects. *The Belmont Report: Ethical Principles & Guidelines for the Protection of Human Subjects of Research*. Washington, 1978 [www.med.umich.edu/irbmed/ethics/ethics/html].

b United States. National Bioethics Advisory Commission. *Cloning Human Beings*. Rockville, MD, 1997 [www.bioethics.gov/pubs.htm].

c Canada. Royal Commission on New Reproductive Technologies. *Proceed with Care*. Ottawa, 1993:53-66.

d Canada. Medical Research Council, Natural Sciences & Engineering Research Council, Social Science & Humanities Research Council. *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*. Ottawa, 1998 [www.mrc.gc.ca/ethics.htm].

e Denmark. See,e.g.,Danish Council of Ethics. *Patenting Human Genes: A Report*. Copenhagen,1994: 31-34 [www.etiskraad.dk].

f France. Comité consultatif national d'éthique pour les sciences de la vie et de la santé. *Avis*, 1984-99. Paris [www.ccne-ethique.org].

g European Union. *Opinions of the Group of Advisors on the Ethical Implications of Biotechnology of the European Commission*. Brussels, 1997,[http//europa.eu.int/comm/sg/ethics]; *Directive 98/44/EC of 6 July 1998 on the Legal Protection of Biotechnological Inventions*,[http//europa.eu.int.eur-lex/en/lif/dat/1998/en_398L0044.html].

h UNESCO. *Universal Declaration on the Human Genome & Human Rights*. Paris, 1997 [www.unesco.org/ibc/uk/genome].

i Norway. Ministry of Health & Social Affairs. *Biotechnology Related to Human Beings*. Oslo, 1993; *Gene Technology Act*, 1993 [http//:binas.unido.org.binas/Regulations/full_regs/norway/norway1_html], *Int'l Dig. Hlth Leg*. 1994;45:48-49; *Biotechnology Act of 1994*. Norwegian Biotechnology Advisory Board, *Opinions*, 1991-98 [www.bion.no].

j United Nations. *Convention on Biological Diversity*, 1992, Preamble, arts. 1, 2, 3, 8 [www.biodiv.org].

k Council of Europe. *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology & Medicine: Convention on Human Rights & Biomedicine*, as amended. Oviedo: 1997/1998 [www.coe.fr/eng/legaltxte/e-bio.htm]. See also, Council of Europe. Parliamentary Assembly. Recommendation 934 on Genetic Engineering of 26 January 1982. *Int'l Dig. Hlth Legis.* 1982; 33:382-385; Recommendation 1240 on Protection of Patentability of Material of Human Origin of 14 April 1994. *Int'l Dig. Hlth Leg.* 1994; 45:564-566,[http://stars.coe.fr.ta/ta94/erec1240.htm].

l Great Britain. Nuffield Council on Bioethics: *Animal & Human Transplants*. The Ethics of Xenotransplantation. 1996 [www.nuffield.org].

Table B: Working Definitions of Selected Ethical Norms

Human Dignity: Human dignity refers to the intrinsic worth and identity of humans, giving rise to such dignitary interests as bodily and mental integrity. As a cardinal ethical principle, it is often considered paramount in the hierarchy of public values and ethics norms.

Autonomy & Informed Choice: Autonomy refers to the capacity and exercise of independence or self-determination. It is often protected by procedural requirements that aim to advance informed choice.

Equality/Non-Discrimination: A principle of justice that aims at ensuring the fair and equitable treatment of persons out of respect for human dignity. It proscribes arbitrary classifications and biased treatment.

Distributive Justice: A principle of justice that refers to a fair distribution of the potential good and ills of biotechnology, including benefits and harms. Thus, the inclusion in, or exclusion from, the benefits of life-saving rDNA drugs raises issues about the fair distribution of therapeutic advances.

Beneficence: Regarded in ethics as a duty to do good, this principle implies an obligation to maximize the good and minimize the ills of biotechnology. Practically, it results in reasonable proportionality between benefits and risks of harm.

Risk-Benefits Assessment: An assessment process of the benefits, risks and costs of biotechnological research, development and diffusion.

Protecting Human Health & Safety: This fundamental value relates to the well-being of both individuals and communities. It informs such procedural norms as competent risk-benefit analysis, biosafety standards, and public health regulations in biotechnology policy analysis.

Privacy & Confidentiality: A fundamental value expressive of human dignity and autonomy, privacy protects spatial, physical and mental integrity. It also protects access to and control of personal information.

Sustainable Development: Development that meets the needs of the present without compromising the needs of the future. It invokes stewardship duties consistent with the distributive justice principle of fairly distributing the benefits and burdens of biotechnology across generations.

Non-Commercialization: A principle that aims to ensure that the human body or its elements are not regarded or treated as commodities or objects of commerce. To do so impoverishes the intrinsic worth and dignity of the person and humanity.

Protection of the Vulnerable & Solidarity: Out of respect for human dignity, the state has long had special societal responsibilities to those who lack the capacity, autonomy or means to protect and advance their best interests.

Animal Welfare: The analysis of ethical issues in biotechnology that affects the well-being of animals. This involves norms and duties that de(re)fine the moral relationship between human and animals.

Ethics Review: A process norm whereby ethics issues are identified and analysed by an independent, interdisciplinary, expert committee. It has been increasingly adopted to assess, prospectively, the ethics of biotechnological research involving humans, animals, the environment.

***Transparency*:** A process norm for open governance, it ensures that deliberations, decisions and documentation are transparent and accessible.

B. Ethics Norms in Selected Countries & International Contexts

1. France: The Ethics Advisory Opinion Process

France has developed an ethics framework that has significantly contributed to national policy and laws affecting biotechnology. The framework has proved effective, in part, because French society has successfully orchestrated the substantive, procedural and structural elements of a coherent ethics framework. It has done so in four important respects.

First, in 1983 France became one of the first European nations to create a standing, independent, interdisciplinary, national advisory committee with a mandate to advise on ethical issues raised by advances in the biological, health and medical sciences.[35] Some 40 individuals drawn from research, philosophy, theology, government, and university domains comprise the National Advisory Committee on Ethics in Health Sciences. The committee illustrates the structural component of a coherent ethics framework. Secondly, public processes developed to discharge the mandate and work of the French national committee have helped to place it at the centre of national ethical deliberations, public debate and policy formulation. Procedures governing the functioning of the Committee, for example, enable requests for ethics opinions to come from parliament, government or public institutions.[36] The procedure enables various entities in government to contribute to the evolving public agenda of the Committee and enables the Committee to address identified needs. To foster public education, debate and participation, the procedural mandate of the Committee requires it to convene annually a public conference on topical ethics matters.

Thirdly, ethics norms have emerged from formal written opinions of the Committee. It has generated ethical opinions on such matters as gene therapy, the human genome, patenting life forms, biomedical research, DNA testing. In doing so, the Committee has adopted a pragmatic, case-by-case approach to defining and applying substantive ethical principles like respect for human dignity, privacy and equality. (See Table A, above). After initial enunciation in a particular opinion, a principle may be refined and elaborated in a later opinion. This pragmatic approach advances the norm-generating function of a coherent ethics framework, consistent with accommodating new knowledge and evolving ethics perspectives. The approach also allows for the identification of value conflicts and their reconciliation in concrete fact-specific contexts. France has thus innovatively made the formal ethics opinion central to its societal modus operandi to the ethics of modern science, technology and health policy. The French model suggests that to develop credible and effective ethics opinions in a pluralist society requires: (a) formal procedures for requesting them; (b) interdisciplinary expertise to identify ethics issues; (c) inclusive consultations and debate;(d) evolving deliberations to define guiding ethical principles of an opinion; (e) drafting processes that accommodate differing ethics perspectives and that harmonize value conflicts; and (f) processes to diffuse the opinion for policy making, and for public education and reflection. That

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[35] Décret no. 83-132 du 23 février 1983, as modified by art. 23 of Loi no 94-654 du 29 juillet 1994 and Décret no 97-555 du 29 mai 1997. See also Table A, above.

[36] Article 6 of Décret no. 97-555.

few, if any, of the 60 published ethics opinions on the Committee website have divided into majority and minority views likely attests to effective consensus building.

Fourthly, the successful integration of the substantive, procedural and structural elements of the ethics framework of France illustrates the public law model of ethical reflection. Created by the law some 15 years ago, the Committee has advanced public dialogue, responded to government references, educated society, and helped to identify core values and substantive principles through its advisory opinions on issues of public policy and regulatory ethics. Many of the ethics principles now resound in the policies adopted in the so-called bioethics laws of 1994. Amongst other things, the laws address biotechnology patents, genetic testing and medically-assisted procreation.

2. Norway: Codifying National Norms

Norway has built an ethics framework based on substantive, procedural and structural elements that differs in important respects from France. The structural difference is clear. The Norwegian Biotechnology Advisory Board (NBAB) has primary responsibilities for processing ethical deliberations and debate on biotechnology.[37] In contrast to the national bioethics committee model of France, the NBAB ethics mandate is focussed on biotechnology. Its composition thus differs and is arguably more inclusive of the broad spectrum of societal interests affected by biotechnology. Such breadth advances the public participation and accountability functions of a coherent ethics network.

The process of developing substantive ethical principles in Norway has also differed. In France, many ethical principles have emerged from the standing national ethics committee in case-by-case opinions on particular issues. In Norway, many of the leading ethical principles emanated from the work of ad hoc parliamentary and government committees on ethics or biotechnology in the 1980s.[38] The Norwegian Parliament later codified many of them into the public laws that created NBAB and that regulate biotechnology.[39] Thus, many of the ethics norms noted in Table A, above, have emerged from the public law process.

Since the early nineties, the NBAB has thus issued more than 45 pronouncements based on substantive ethical norms like sustainable development, protection of human health and the environment, non-discrimination, informed choice, privacy/confidentiality. The Norwegian framework also functions on process values of public participation, transparency, and accountability.[40] To foster public education and debate, for example, NBAB issues statements, convenes national workshops/international conferences and publishes reports on diverse

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[37] NBAB reports to government through the Ministry of Health. It is composed of 19 members, who are appointed for two to three-year terms from scientific, theological, academic, medical, environmental, philosophical domains and from consumer groups, farmers, environmental organizations, fishermen, industry organizations, trade unions, disabled peoples' organizations. Expertise from governmental ministries comes through observer status in NBAB.

[38] See, e.g., Norway. *Moderne Bioteknologi* (Modern Biotechnology), NOU 1990:1. Oslo,1991.

[39] See Table A, above.

[40] See sections 12-13 (open government and public consultation) of the *Gene Technology Act* in Table A, above.

biotechnology questions that raise issues of environmental ethics, public policy, health ethics and law. Examples include the role of gene technology in agriculture, fetal tissue cells, patenting life, gene therapy, GMOs and sustainable development,[41] genetic testing. In contrast to France, the statutory mandate of NBAB -- to review specific applications of GMOs, for example -- likely implicates it more in the government regulatory process. Indeed, the advisory and regulatory roles of NBAB would seem to create tension between the process values of "accountability" to government and "independence" from it. Yet, the ethical framework that has emerged in Norway to date has done so largely through an open public law and policy process. Continued commitment to such process may enable rigorous monitoring and appropriate reforms to manage the tension.

3. European Union: Broadening the Ethics Mandate

The ethics framework developed by the 15 member nations of the European Union (EU) parallels and differs from France and Norway. The Group of Advisors on the Ethical Implications of Biotechnology (GAEIB) was created in 1991 to identify, define, and advise on ethical issues for the European Commission, which is the executive and policy-initiating body of the EU. As an independent and interdisciplinary committee of 7-9 members, GAEIB has outlined substantive ethical principles in formal ethics opinions on subjects like gene therapy, the labeling of genetically-engineered foods, transgenic animals, patents involving elements of human origin. This approach parallels France. To generate its opinions, GAIEIB has developed a working process that relies on initial background and technical reports, consultation of experts, participating in or conducting public hearings, and frequent committee meetings to develop consensus. Table A, above, summarizes some of the ethical principles identified in its opinions.

The mandate of GAEIB has recently evolved, and the change imparts a lesson on the structural elements of an ethics framework: ethics bodies that begin with narrow terms of reference may find their mandates broadening after discharging early assignments. This is due in part to (a) the nature of ethics issues, (b) evolving government needs, and (c) the legitimacy of the particular ethics advisory committee. Under the mandate of GAEIB, government may ask for advice on specific ethics issues or GAEIB may offer opinions of its own initiative. Most of its opinions have come from requests by government. Such process norms heighten committee accountability to evolving government needs, while preserving its independence. An entity that aids government in addressing controversial ethics issues also gains credibility as a contributing analyst and problem-solver.

Within this context, the final opinion of GAEIB examined the 1998-2002 research and technological program of the EU, at the request of the European Commission.[42] In it, GAEIB laid the foundation for changes in the EU ethics framework for biotechnology. GAEIB first noted that in contrast to the narrow issues it had examined in the past, those raised by a scientific research program transcend

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[41] Sandberg P (ed). *Proceedings of an Internaitonal Conference on Release and Use of Genetically Modified Organisms: Sustainable Development & Legal Control.* NBAB, Oslo, 1995.

[42] European Commission, GAEIB. *Ethical Aspects of the 5th Research Framework Programme* (1998-2002). Brussels, December 1997, [http://europa.eu.int/comm/sg/ethics].

biotechnology; they warrant ethical scrutiny on the basis of respecting both national differences and shared "common values". Secondly, it recognized a need to reconcile value conflicts in scientific research. Thus, even as it declared scientific research to be a fundamental human freedom, it argued that EU-funded research should comport with fundamental ethical norms (para. 2.2). It endorsed the procedural requirement of ethics review of proposed research by independent, interdisciplinary ethics committees. Thirdly, for research it referred to duties to minimize the suffering and maximize the welfare of animals, and proposed the following as ethical principles for human research: autonomy, respect for human dignity, non-discrimination, non-exploitation, protection of the vulnerable, risk-benefit proportionality. Fourthly, it noted that informed ethics assessments need to be supported by basic ethics research in the relevant fields. GAEIB called for the establishment of an ethical and legal data-base on life sciences, for concrete public education initiatives, and for broad societal debate on socio-ethical dimensions of the new life sciences.

The views had an effect. In 1998, the European Commission replaced GAEIB with a new entity composed of 12 members with a broader mandate. It is the European Group on Ethics in Science and the New Technologies (EGE). The views GAEIB have also proven influential in other areas of European public policy and law, such as on human cloning.

4. Ethics Frameworks & Human Cloning: Paramount Substantive Principles

While news of advances in genetic research or biotechnological development has become common near the close of this century, the stunning February 1997 announcement of the animal cloning that yielded Dolly the sheep will stand as a marker event in the annals of science, public policy and regulatory ethics. Is it safe? Does it breach impermissible boundaries? Where will it lead? Should it be regulated or prohibited? How should government respond? The questions echo those raised 25 years ago in the first decade of recombinant DNA research.[43]

The responses of some governments to such questions flowed from the work of evolving ethics frameworks. In April 1997, the French National Bioethics Committee deemed human cloning a "grievous assault on human dignity" in an ethics opinion requested by the President of France.[44] In May, the EU ethics advisory group called for strict regulation of animal cloning and for a prohibition of human cloning in a formal written opinion.[45] In July 1997, in response to a Presidential request for its views, the US National Bioethics Advisory Commission proposed a five-year moratorium on federal funding of any human cloning research.[46] In November, based on the work of its International Bioethics Committee, UNESCO adopted a *Universal Declaration on the Human Genome*; it deems human cloning "contrary to human dignity."[47] In January 1998, 21 European

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[43] Ethics & Biotechnology, op cited.

[44] CCNE. Avis N° 54 : Réponse au Président de la République au sujet du clonage reproductif. Paris, 22 avril 1997.

[45] GAEIB. *Ethical Aspects of Cloning Techniques*. Brussels, May 1997; reprinted *Cambridge Qrtly Hlth Care Ethics*, 1998; 7:187-190.

[46] U.S. National Bioethics Advisory Commission. *Cloning Human Beings*. Rockville, Maryland, 1997.

[47] UNESCO. *Universal Declaration on Human Genome and Human Rights*, para. 11. Paris, Nov.1997.

nations signed an international treaty that bans human cloning.[48] The treaty is the first protocol of the Council of Europe *Convention on Human Rights & Biomedicine*.[49] The Convention was drafted by an international advisory group of bioethics experts through the first half of the nineties. In July 1998, the European Union adopted a ban on process patents for cloning human beings in a legal directive on biotechnology that had been debated for years.[50] The policy is consistent with the advise of EU ethics group. Finally, in August 1998, three Canadian research funding Councils declared human cloning ethically unacceptable in their first integrated statement of norms for research involving humans.[51]

These pronouncements on human cloning are telling. They came promptly and forcefully. They did so in part, (a) because they emerged from developing or mature public processes experienced in ethics deliberations; (b) because they came from bodies that had been created and structured into the policy process precisely to deliberate on such issues; and (c) because the relevant ethics body was quickly able to identify ethics issues, to outline implicated principles, to address or resolve value conflicts, and to argue for the pre-eminence of particular principles in public policy. Most of the current prohibitions are based on concerns about human dignity or the protection of human health and safety. Such substantive ethical principles have legitimacy and effect partially because they emerged from interdisciplinary expert bodies, whose independence and advisory role heighten moral credibility, whose structures respond to accountability concerns, and whose prior reflections had won the trust of the public and policy makers.

The pronouncements are also telling in a final respect. The cloning controversy resounds an historic and current theme in ethics and biotechnology: when should the freedom of scientific inquiry and the promise of a biotechnological initiative outweigh the potential ills of particular research. The above responses suggest that deliberations, debate and experience may yield guiding substantive principles that frame or sometimes resolve the value conflicts inherent in such considerations. As a result it would seem that in Europe, for now, concerns for human dignity have paramountcy over the potential benefits from human cloning research. Whether one agrees with the precise weighting of the relevant values or the ultimate policy position, this chapter of the human cloning tale provides a salient example of the workings of the substantive, procedural, and structural elements of coherent and maturing ethics frameworks.

5. Coherent Frameworks: The Evolution of Research Ethics

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[48] Council of Europe. *Additional Protocol to the Convention on Human Rights & Biomedicine: The Prohibition of Cloning Human Beings.* (Jan. 1998).

[49] Council of Europe. *Convention for the Protection of Human Rights & Dignity of the Human Being with regard to the Application of Biology & Medicine: Convention on Human Rights & Biomedicine.* Oviedo: April 1997.

[50] See note 21, above.

[51] Tri-Council, art. 9.5. See Table A, above.

The international development of modern human research ethics norms over the last quarter century has resulted in an ethics model that contributes to national and international biotechnology policy. Canada adheres to the model that functions in many nations.

Its principal features include: (1) the identification and definition of national research ethics norms; (2) application of national norms and standards through a process of prospective ethics review of research projects; by (3) independent, multidisciplinary research ethics committees at the local level. In practical terms, it means that research proposed to test new, experimental bio-pharmaceutical agents typically undergoes review by a research ethics committee of a university-affiliated hospital before the research commences. There are hundreds of such local ethics committees across Canada as a result of three generations of national research ethics initiatives since the 1970s. The committees review proposed research involving humans for its conformity with informed choice, confidentiality, proportionality of harms and benefits, and like ethics norms that both the Tri-Council of Canada and GAEIB have recently endorsed. (See Table A, above). While prospective review is mandated by law in many countries, it is generally implemented as a condition of the receipt of federal research monies in Canada.

The model of prospective ethics review proves particularly pertinent to ethics frameworks in biotechnology. First, identifying national research ethics norms, like respect for human dignity and animal welfare, prove relevant to the ethics of biotechnology research. The discussion above on human cloning illustrates how the norm building function of an ethics framework may directly affect biotechnology research. Secondly, as indicated, since therapeutic biotechnology products pass through the research and testing phase towards commercial development and general diffusion, they are likely subject to review by local ethics committees. The increasing universality of this model is indicated by the recent initiative of the US, Japan and Europe, to include it in their effort to harmonize pharmaceutical law governing research.[52] Thirdly, the model provides a concrete example of a preventive ethics mechanism. The procedural requirement of prospective ethics review effectively obliges Canadian health researchers to incorporate guiding national ethics principles into the design of research before it commences, because the local ethics committee may accept, reject or modify the project partially on the basis of those principles. If a genetic therapy research proposal in a local hospital does not adequately address informed consent, for instance, it risks not being approved. Fourthly, the structural requirement of independent, interdisciplinary ethics committees that include public members helps accommodate a range of ethics thought and public accountability into the review process. The public members, health professionals, ethicists and lawyers that often serve on such committees thus must deliberate broadly and reconcile the value conflicts that often accompany ethics review. This advances the basic functions of ethics frameworks outlined above. Finally, these process and structural mechanisms of ethics review are not restricted to human research. In Canada, similar requirements aim to ensure the ethical conduct of research involving

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[52] International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceutical for Human Use. Consolidated Guideline on Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Human Use. *Intl Dig. Hlth Legis.* 1997; 48:231-234.

animals, and the Dutch [53] now require similar review for the licensure of transgenic animal research. Prospective ethics review of research in environmentally sensitive areas has also been proposed in Australia.[54] Such growth is not to suggest that the research ethics model is free from weaknesses. Its implementation requires ongoing and vigilant analysis to harness its strengths. Still, the substantive ethical principles, prospective review process, and the reliance on interdisciplinary ethics committees in the model illustrate the basic elements of a coherent ethics framework.

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[53] Netherlands. *Animal Health & Welfare Act of 1992*, art. 66 (ethics assessment for licensing animal biotechnology).

[54] The Australian Science, Technology & Engineering Council. *Environmental Research Ethics, op cited.*

IV. Prospects & Recommendations for Canada

This section urges government to move towards an ethics framework for biotechnology, as part of a new four point covenant. It recommends concrete initiatives the government may undertake to implement a coherent ethics framework.

A. Government, Science & the Public: A New Covenant

The pace and import of the trends discussed above – that is, the rapidly unfolding promise and perils of the biotechnology revolution; the duties of government and the ethical implications of its diverse and evolving roles; the research, scientific discoveries, and commercial applications that generate novel public policy and regulatory ethics issues; the need for policy coherence on biotechnology files -- all converge to make it an opportune time for the Government of Canada, science, and the public to affirm a new four-point covenant on biotechnology.

1. Fundamental Values & Ethical Pluralism: An Ethics Framework

The 1998 Canadian Biotechnology Strategy now makes explicit what has long been implied in public debates: The research, development and diffusion of biotechnology should proceed in a manner consistent with fundamental values and norms of ethical conduct. To transform this laudable goal to reality, the government should harness pluralistic ethical reflection on evolving societal values to engage stakeholders and the public in a process of building a coherent ethics framework for national biotechnology policy.

2. Stewardship

Leadership in building an ethics framework flows from the paramount role that government plays in biotechnology: to serve as the societal agent to whom Canadians entrust unique powers, special duties and public monies to act in their best interests. The entrustment gives rise to stewardship and fiduciary duties. Government should act with good faith, honesty, diligence and loyalty to its citizens, to husband the benefits and minimize the burdens of biotechnology for current and future generations.

3. Preventive Ethics

Consistent with its stewardship role, government should adopt a preventive strategy to manage socio-ethical issues in biotechnology policy. As a basic function of a coherent ethics framework, a preventive approach involves going beyond reacting to ethical issues to anticipating them for policy analysis and development.

4. Ethics Resources & Structures for the Future

The ethics framework should be built on a new understanding about investing public monies: moral and scientific progress require that resources be concurrently and fairly allocated to both the ethics and science of biotechnology. This advances preventive ethics functions. To implement this consistent with its fiduciary duties, the government should commit new public resources, structures and initiatives to examining the ethical dimensions of biotechnology.

B. Building & Evaluating a Coherent Ethics Framework

1. Towards a Coherent Ethics Framework

By the year 2001, the Government of Canada should have in place the basic substantive, procedural and structural elements of a coherent ethics framework for biotechnology. The framework should effect the basic functions outlined above. This goal presents challenges. Fortunately, analogous foundational elements have already been identified in recent federal initiatives on genetic biotechnologies and federally funded research.[55] The proposal in the 1998 Canadian Biotechnology Strategy to create a CBAC with an ethics mandate begins the process of defining an effective, accountable public structure. Since substantive principles and process values -- like sustainable development -- already infuse Canadian public policy and law and the frameworks of other nations, they provide a foundation to build the ethics norms of Canada (See Tables A & B, above).

2. Programmatic Initiatives: Structures, Processes & Norms

a. Canadian Biotechnology Advisory Committee (CBAC)

Accountability, Mandate & Procedures: The composition, expertise, independence, resources, procedures and mandate of CBAC shall prove critical to its effectiveness and credibility. Part of its mandate should include duties for advising government on means to ensure that biotechnology develops consistent with fundamental Canadian values. This implicates interdisciplinary ethics expertise and the norm-generating function of a coherent ethics framework. Accordingly, in consultation with other relevant national players, CBAC should initiate public processes to identify and define leading ethical principles and values to guide national biotechnology policy. The international experiences highlighted above suggest approaches that might be tailored to Canada. To ensure sufficient accountability and independence, the procedural mandate of the CBAC should include (a) government references: the duty to respond to government requests for analysis, and (b) commission references: the power to bring to the attention of the government socio-ethical analyses that it deems important for federal responsibilities in biotechnology. Accountability

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[55] See Table A, above, for the Royal Commission's "ethic of care" and the Tri-Council's research ethics framework.

may also be enhanced by public membership on CBAC, and by initiatives like ready Internet access to the detailed mandate, composition, working agenda, minutes and reports of the CBAC and its committees. Regular and meaningful public participation in CBAC deliberations should be advanced by such measures as public hearings, workshops, and annual ethics fora.

b. Governmental Ethics -- Expertise, Training & Resources

One function of a coherent ethics framework is to identify ethics issues and value conflicts in biotechnology policy. The function demands ethics expertise and resources. A want of sufficient ethics resources in the lead biotechnology ministries increases the risk that ethical issues will not be internally identified, addressed and managed in a preventive manner. Instead, reactive policies are likely to endure. Some steps have been taken to avert the likelihood. In recent years, some ministries have allocated more financial and human resources to ethics. This preventive trend should be cultivated to flourish across those departments implicated by the public policy and regulatory ethics of biotechnology.

c. Public Participation: Citizen Education, Debate & Oversight

> "Democracy is based upon the conviction that there are extraordinary possibilities in ordinary people."[56]

A basic function and goal of a coherent ethics framework is to foster public participation, deliberation and debate. This flows from a democratic commitment to citizen participation in national science and biotechnology policy. Participation spans a spectrum of citizen involvement: from education, to debate, to shared decision-making, to oversight. The public has a right to help define the new scientific and ethical frontiers of the biotechnological revolution. Government has a corresponding duty to engage its citizens to participate in the public control of science, for several specific reasons.

• *Education & Debate*: Education is fundamental to deliberative democracies.[57] As society becomes more a culture of science, an educated public may most contribute to informed, pluralistic debate on the socio-ethical issues of biotechnology. Debate thus educates government and the citizen; it helps to distill moral choices. Education is central to the profound "societal conversation" that analysts have long deemed critical to shaping the future of genetic engineering.[58] The 1998 Canadian Biotechnology Strategy shares this vision. To implement it, government should develop a biotechnology and ethics education strategy in partnership with centres of learning, NGOs and the private sector. One goal of the strategy should be to cultivate the "extraordinary possibilities in ordinary people" towards the technologically and ethically literate society. Thus, web sites, ethics workshops, public hearings, televised documentaries, electronic town-meetings, and the like should

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[56] Fosdick, Harry Emerson. *Democracy* 19__.
[57] Nussbaum M. *Cultivating Humanity*. Harvard University Press, 1997:1-14.
[58] President's Commission, op cited, pp.81-82.

empower the individual with accurate information and creative fora for participating meaningfully in national science and biotechnology policy.

• *Opportunities to be Heard*: Citizens should have real opportunities to be heard on matters that may affect their health, monies, food choices, values, and lives amid the benefits and burdens of technology. The challenge is to create effective processes to engage the public.

• *Inclusive Problem-Solving:* Inclusiveness is important for "problem-solving" the socio-ethical issues in biotechnology. In the short-term, inclusive dialogue demands more resources, process and inefficiency. Democracy, however, elevates some norms higher in the hierarchy of public values than efficiency. In the long-term, inclusive dialogue may yield broad citizen involvement, public accountability and more enduring results. National brain-storming may nurture ideas and options that prove most constructive to sustainable policy.

• *Transparency Sharing Information, Documentation & Deliberations*: To commit to transparency, is to commit to open and accessible deliberations, decisions and documentation in governance. After all, the relevant information and decision-making power is held by government in trust for public benefit. Transparency encounters difficulty in institutions where a culture of secrecy still prevails. When so, it requires concrete, transformative steps to nurture a culture of open governance.

• *Moral Growth*: Citizen participation helps foster moral growth. For beyond our commitment to representative government lies an ancient democratic ideal: the virtue of citizen participation in governance.[59] Education and discourse on public values may foster moral growth of both individuals and community. This is part of the societal quest for the prudent and just use of biotechnology.

d. Unimpeachable Process: Codes of Conduct, Integrity & Public Accountability

The foregoing has argued that good process shares a dynamic relation with the norm-generating function of a coherent ethics framework. As society continues to works through the uncertainty and conflicts inherent in defining the substantive values of an ethics framework, we shall find ourselves in need of diverse processes: to foster deliberation and debate, to identify ethics norms and policy options, to define the paths of moral choice. To fulfill such needs in a manner consistent with its stewardship and fiduciary duties, the government should develop processes and conduct guides such as the following.

• *Unimpeachable Process:* Unimpeachable, fair and inclusive processes should be developed to identify, analyze and manage the value and ethical conflicts that infuse the development of Canadian public policy on biotechnology and science.

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[59] Held D. *Models of Democracy*. Stanford University Press, 1996:17-69.

• *Avoiding the Appearance of Ethical Lapses*: Government must be vigilant and exercise due diligence to avoid even the appearance of ethical lapses in its diverse biotechnology roles. The mere appearance of venality, misconduct or ethical lapses tarnishes credibility. It discredits government roles and decisions. It corrodes the public trust.

• *Integrity & Conflict of Interest (COI) Norms*: To avoid the ills that attend real, apparent or perceived conflicts of interest on biotechnology files, existing government norms on COI and integrity should be strictly adhered to. (See also section II.H, above).

• *Code of Ethics/Conduct for Biotechnology*: Despite existing ethics norms, reports[60] over the last year have raised issues about the integrity of government process on biotechnology files. Are current norms adequate for managing the ethical process issues raised by the diverse roles the government plays in biotechnology? New academia-industry partnerships have obliged some universities and governments to revise their conflicts of interest norms. Such developments raise a legitimate question: to clarify standards, remove uncertainty and nurture public trust, do we need new norms or a code of government ethics for biotechnology? Or, is broader education about existing norms sufficient? If education is the answer, then the files that have generated concerns might be adopted as teaching tools for formal ethics scrutiny and education in government. CBAC and/or an interministerial working group with broad expertise and public input ought to study such questions. New substantive and procedural norms to better identify and mange the inherent conflicts in the government biotechnology roles advance the goals of a coherent ethics framework.

e. Norm Building: Defining & Adhering to Modern Research Ethics Standards

As part of the norm-building function of a coherent ethics framework, the Government of Canada should ensure that the biotechnological research that it conducts, sponsors or funds conforms to the highest of ethical standards. Incorporating ethics early into the design of research advances another basic function of an ethics framework: preventive ethics. It begins to ensure that the fruits of biotechnology are researched, developed and diffused in a manner consistent with Canadian values and ethics norms. For when a scientist, laboratory or institution engages in research that breaches such norms, otherwise legitimate research may be discredited, seen as morally suspect, or deemed unethical. If government is implicated, the moral insult is compounded. Indeed, the responsibilities that we entrust to government include high duties to foster and adhere to ethical conduct. These roles demand an ethics leadership that regularly earns and cultivates public and moral confidence on the use of public resources in research. The recent work of the Tri-Council and the National Research Council provides a sound basis for continuing, critical and creative review of ethics for biotechnological research associated with the federal government.

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[60] See, e.g., McIlroy A. Approval for Bovine Growth Hormone Hits Roadblocks. *Globe & Mail*, 4 Dec. 1998, A4.

3. Evaluating an Ethics Framework

Since ethics is far from a quantitative enterprise, the evaluation of an ethics framework will largely rely on qualitative criteria. Those criteria should be guided by a purpose-based, a function-based and an experience-based approach. This generates three questions. First, is the framework achieving its general purposes? The question asks analysts to evaluate its evolving purposes and rationales. Secondly, are the substantive, procedural, and structural elements functioning as envisaged? The question asks if the framework works well with regard to such leading functions as (a) accommodating evolving ethical thought; (b) identifying value conflicts; (c) building substantive, process and structural norms; (d) orchestrating ethical debate and deliberation towards policy development; and (e) advancing preventive ethics and public participation. Thirdly, beyond the targeted purpose and functions, has experience yielded collateral benefits or burdens? This question assumes that government and scientific experience are not always linear: unforeseen circumstances, discoveries, experience, sometimes lead to destinations beyond those originally targeted. Lessons from the initial trials and errors will help to evaluate and reform the framework. Finally, process values counsel that evaluations be reasonable regarding priorities, time frames, and growth. Thus, the federal commitment to establishing a CBAC may mean that institutional structure and process norms of an emerging framework take priority in 1999-2000. Within three years of the establishment of the CBAC, internal and external reports should evaluate its contribution to ethics. The evaluation process and its criteria ought to anticipate and accommodate significant evolution in the basic elements of a coherent ethics framework.