CANADIAN BIOTECHNOLOGY ADVISORY COMMITTEE

2000–2001 ANNUAL REPORT

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MESSAGE OF THE CHAIR, CANADIAN BIOTECHNOLOGY ADVISORY COMMITTEE

On behalf of the Canadian Biotechnology Advisory Committee (CBAC), I am pleased to present CBAC's second Annual Report, covering the period October 1, 2000, to December 31, 2001.

Many aspects of CBAC's work involve extensive consultations with external experts: people in government departments and agencies, various stakeholder groups and Canadians at large. On behalf of the members of CBAC, I thank all of those who participated in the Committee's consultations or who provided advice and comments on their own initiative for their important contributions. We are also deeply grateful for the hard work and dedication of the Canadian Biotechnology Secretariat staff seconded to CBAC, who often went well beyond the call of duty in achieving highly demanding goals.

Sincerely,

Dr. Arnold Naimark
Chair, CBAC.

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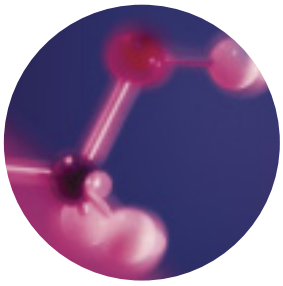
EXECUTIVE SUMMARY

The Canadian Biotechnology Advisory Committee (CBAC) is a body of external experts established in September 1999. The role of CBAC is to advise the Government of Canada on the policy issues associated with the ethical, social, regulatory, economic, scientific, environmental and health aspects of biotechnology. CBAC is also tasked with providing Canadians with easy-to-understand information on biotechnology issues, and providing opportunities for Canadians to voice their views on the matters on which CBAC is offering advice to the government. CBAC reports to government through the Biotechnology Ministerial Coordinating Committee (BMCC).

CBAC's activities fall into two categories: general activities (communication, outreach, liaison, trend and issue monitoring, administration) and special projects on major topical issues. This second Annual Report describes CBAC's activities in the period from October 1, 2000, to December 31, 2001 (referred to as 2001), and presents a brief overview of some of the developments in biotechnology that formed the context for CBAC's work.



General Activities

In the area of communication, CBAC initiated a citizen engagement plan, including development of a partnership network of organizations and associations with interests in public policy related to biotechnology. The network is used to facilitate communication and to encourage participation in CBAC's consultation activities. Communication through the CBAC web site was simplified, and a variety of intensive communication activities were undertaken related to CBAC's special projects. The Chair, members of CBAC, and its secretariat participated in a variety of conferences, symposia and workshops, both as contributors and as part of CBAC's monitoring role.

CBAC continued to maintain liaison with a variety of bodies and agencies involved in biotechnology both inside and outside government. It received briefings on developments within government departments and in interdepartmental working groups, and provided information on the status of CBAC's projects. Its liaison functions not only served to meet communication goals but also assisted in CBAC's trend and issue monitoring role. In the latter connection, CBAC reviewed public policy developments in Canada and abroad and studied major reports published by key advisory bodies in other countries. As part of its mandate to advise the government on emerging issues, CBAC issued an advisory memorandum in January 2001 titled "Stem Cells: Opportunities and Challenges."

Special Projects

Much of CBAC's effort in 2001 was devoted to its major special projects on genetically modified (GM) foods and the patenting of higher life forms. After review and analysis of background studies and initial discussion with stakeholders, CBAC developed consultation documents on each of these subjects. The consultation documents were circulated widely for comment. They also formed the basis of a second round of consultations with stakeholders in five centres across the country. Interim reports containing draft recommendations were published, and reactions and comments to the interim reports invited from all interested parties.

The interim report on GM foods made six main recommendations and 24 supplementary ones aimed at improving the federal regulatory system for GM and other novel foods. It addressed key challenges related to public information, informed choice and environmental stewardship. The interim report on the patenting of higher life forms presented 16 recommendations on the subject including social and ethical matters, the administration of the patent system and limits on patent rights. CBAC will produce final reports on these projects in Spring 2002.

Developments

Rapid development of applications of new knowledge of the structure and function of the genomes of plants, animals and microbes and other advances in biotechnology intensified the challenge of evaluating economic, social, environmental and ethical implications of biotechnology. Concerns about protecting genetic privacy prompted the United Kingdom government to impose a moratorium on the use of genetic tests by insurance companies. The United States House of Representatives held hearings on whether or not federal legislation was required to prevent genetic discrimination by employers and insurers. In Canada, the provinces of Ontario and Saskatchewan issued reports touching on the issue and calling for additional protections.

The effects of gene patents on access to gene-based diagnostic tests came into sharp focus in Canada in 2001 when certain provinces objected to the demands by U.S.-based Myriad Genetics Laboratories that all breast cancer-screening tests based on the BRCA 1 and 2 genes, which the company had patented, must be done through its own laboratories. The plethora of applications for gene patents and their scope reinforced concerns about the constraints that such patents may impose on research.

Stem cells and cloning continued to dominate the headlines on biotechnology. In January 2001, the U.K. passed legislation allowing the cloning of human embryos as a source of stem cells for research purposes. In the U.S., President Bush announced that the government would fund research on human embryonic stem cells only if certain clearly defined criteria were met. The European Parliament maintained its position on allowing

public funding for human embryo research. In Canada, the government introduced draft legislation on reproductive technologies containing several elements pertaining to stem cell research. The government is expected to table a revised bill in the House of Commons in Spring 2002. In the meantime, the Canadian Institutes of Health Research initiated the development of guidelines for research involving embryonic stem cells.

Other notable events included the announcement by a U.S. company that it had cloned the first human embryos for use as a source of stem cells for research. Also noteworthy was the approval granted by the Human Fertilisation and Embryology Authority in the U.K. for the use of pre-implantation genetic diagnosis to guide selection of human embryos for implantation specifically to produce babies who would be suitable as stem cell donors for siblings with genetic defects.

Agricultural biotechnology also figured prominently on the public agenda. In Canada, the Royal Society's Expert Scientific Panel on the Future of Food Biotechnology released its report on the scientific capacity of the system for regulating GM foods. The government's response to the report outlined activities already under way to address the recommendations and those in the planning stages, and noted that the government would continue to address the Panel's recommendations in light of other related work, including CBAC's final report on GM foods.

Labelling of GM foods continued to be an issue that attracted significant public attention. In Canada, the Standing Committee on Health planned to hold public hearings on labelling in 2002. The Canadian General Standards Board and the Canadian Council of Grocery Distributors continued to work on standards for voluntary labelling, and CBAC's interim report on the regulation of GM and other novel foods contained a draft recommendation in favour of voluntary labelling as a first approach, noting that labelling is already mandatory for foods that could pose health risks.

There was considerable diversity in the specific approaches and attitudes within the international community with respect to the regulation of GM foods and crops. However, both in Canada and abroad, there was growing interest in grappling with the challenge of monitoring and evaluating the long-term environmental and health effects of GM crops and foods, respectively. Differences in perspective about the role of biotechnology in the developed and developing parts of the world continued to emerge in various international forums.

Notwithstanding the economic slowdown in 2001, the biotechnology sector of industrial development is still expected to grow significantly in the years ahead. Revenues from Canada's biotechnology sector were forecast to more than double from 1999 to 2002. Canada has more biotechnology companies per capita than any other country and, in absolute terms, ranks third behind the U.S. and the U.K. in revenues, and first in research and development per employee.

Looking Ahead

As Canada moves forward with its Federal Innovation Agenda, it is clear that the development of biotechnology should be an increasingly important contributor to achieving the Agenda's goals. CBAC looks forward to playing its part in providing the Government of Canada with advice that will assist in the formulation of sound public policy in this regard. The range of issues and developments worthy of CBAC's attention will be extremely broad. This will require a selection of feasible projects that optimizes impact.

1. INTRODUCTION

This is the second Annual Report of the Canadian Biotechnology Advisory Committee (CBAC). The report is transitional in nature in that it covers more than a 12-month period (namely, from October 1, 2000, to December 31, 2001), reflecting CBAC's decision to move to a calendar-year basis for its annual reports. It is also transitional in that it marks "the end of the beginning" in the evolution of CBAC. In the little more than two years since its inception, CBAC not only has developed its operational systems and undertaken important projects, but also has gained valuable experience in project planning and execution.

CBAC completed the second year of an ambitious program having made considerable progress in achieving its goals. The Committee issued interim reports arising from its special projects on the regulation of genetically modified (GM) foods and the patenting of higher life forms after consultations with the public and stakeholders. The Committee continued background work on other special projects, monitored domestic and international developments in biotechnology, and expanded its communications and outreach activities.

Although biotechnology, in its broadest sense, embraces a wide array of techniques, much of the world's attention has focussed on applications emanating from advances in molecular biology and genetics. The recent mapping and sequencing of the complete (or near complete) genomes of humans and other organisms was an important milestone in biology. In parallel with this monumental achievement, the old concept of "one gene–one protein–one function" has given way to a more complex picture of how genes operate. This burgeoning complexity is stimulating a search for theoretical constructs and approaches (drawing on physics and computational sciences) that will allow scientists to discern important patterns among the myriad interactions among genes and the proteins they encode, and to move into a new era of integrative biology.

While developments in genomics and proteomics are at the forefront of fundamental biology, much of the current public debate on the social and ethical implications of biotechnology is being fuelled by the application of cell-based technologies that do not involve manipulating genes *per se*. This is clearly exemplified by recent developments in the use of embryonic stem cells, cloning and xenotransplantation.

The report has two main sections: first, a description of CBAC's activities during the reporting period and, second, an overview of developments in Canada and abroad that are relevant to the Committee's mandate. Readers are encouraged to visit the CBAC web site at http://cbac-cccb.ca for information on current activities.

2. CBAC ACTIVITIES

There are two categories of CBAC activities: general activities and special projects. General activities are those of a broad, ongoing nature such as monitoring biotechnology developments, facilitating public awareness of biotechnology, maintaining a forum for citizen engagement and participating in a variety of outreach activities. Special projects involve the in-depth study of and public consultation on specific subjects as a basis for providing advice to government. Each special project is directed by a project steering committee made up of CBAC members and has a defined end point.

2A) GENERAL ACTIVITIES

i) Monitoring and Reporting Developments

CBAC monitors external activities and developments in biotechnology through linkages with relevant national and international bodies, reviews of major reports published in Canada and abroad, as well as through liaison functions performed by CBAC members and the Canadian Biotechnology Secretariat.

When CBAC concludes that an emerging issue requires early attention by government, CBAC issues an advisory memorandum on the subject to the Biotechnology Ministerial Coordinating Committee (BMCC). In 2001, CBAC issued an advisory memorandum to government on important advances in stem cell research and the policy implications of these developments. The memorandum recommended that Canada should establish a broad, flexible regulatory framework concerning assisted reproductive technologies and, as an interim step, that pertinent guidelines already in place should be revised as necessary to take into account recent and projected advances related to primordial stem cells. The complete advisory memorandum is presented in Appendix B.

ii) Communications and Outreach Activities

Effective communications and efforts to enhance public awareness are central to CBAC's role. To this end, CBAC released several reports, expanded its web site and initiated a number of outreach endeavours.

Communications Activities

Early in the reporting period, CBAC released 32 background papers on key biotechnology issues that the Committee had commissioned to help it shape its advice to government. Eleven papers addressed matters related to the regulation of GM foods; 16 concentrated on intellectual property and the patenting of higher life forms; two examined social and ethical considerations in policy making; one looked at the use of novel genetically based interventions; and two focussed on legal and ethical issues concerning privacy and genetic information.

Outreach Activities

In 2001, CBAC developed a citizen engagement plan to increase awareness of the Committee and its work, and of biotechnology in general; to encourage participation in CBAC activities; and to build a partnership network to amplify its outreach endeavours. The plan addresses youth, communities, stakeholders, the media and the general public through such vehicles as the SchoolNet Partnership initiative, through the Community Access Program and the primary stakeholders initiative.

The Chair and members of CBAC participated in a variety of conferences, symposia and workshops sponsored by voluntary associations, public interest groups and government agencies. The Chair appeared before the 2001 meeting of the G8 Science Ministers.

Gathering Views

Another key CBAC role is to inform the government of what Canadians are thinking concerning biotechnology in general and/or specific subjects. It tracks the views of Canadians through the comments and inquiries it receives via its toll-free telephone line, e-mail, correspondence and web site feedback mechanisms, as well as by evaluating public opinion research. Use of the toll-free number, e-mail access and the web site increased significantly after the release of CBAC's two interim reports. CBAC also monitored public opinion research on topics in biotechnology of interest to the general public. In June 2001, CBAC commissioned a review of several years of public opinion research on the regulation of GM food.

2B) SPECIAL PROJECTS

In its initial work plan, CBAC identified five major topics for in-depth analysis and consultation. During its first year of operation and throughout 2001, CBAC mounted two full-scale projects on two of these topics: the regulation of GM foods and the patenting of higher life forms. Background work was continued on the remaining three projects: incorporating social and ethical considerations into policies for biotechnology; policy implications of the use of novel genetically based interventions; and privacy issues raised by the increasing availability of individuals' genetic information.

The Regulation of GM Foods

The purpose of this special project is to assess the structure and function of Canada's regulatory system as it pertains to GM food. CBAC commissioned background papers, reviewed the relevant literature and, in March 2001, following discussions with a reference group of stakeholder representatives, launched a program of public consultations based on a widely distributed consultation document. In addition to receiving written responses to the consultation document, CBAC held roundtable discussions in five cities across Canada attended by more than 90 members of various stakeholder groups. Some environmental groups decided not to participate in the roundtable discussions, but their

views on various issues were accessible by other means. After deliberating on the input received during these consultation processes, CBAC in August 2001 released an interim report containing draft recommendations and solicited comments from all interested parties. The comment period was scheduled to close on January 31, 2002. By the end of 2001, web site users had made 6,543 visits to the interim report.

The interim report makes six main recommendations and 24 supplementary ones aimed at improving the federal regulatory system for GM and other novel foods. It also addresses the key challenges related to public information, informed choice and environmental stewardship. The interim report recommends a more clear-cut regulatory oversight of GM and other novel foods, and calls for better research and data collection for detecting and monitoring the potential long-term health and environment impacts of GM products. It also recommends the development of labelling standards for GM products to be implemented initially on a voluntary basis to test their adequacy and effectiveness, and a centralized information service on GM and other novel foods for consumers. The complete interim report is available on CBAC's web site at http://cbac-cccb.ca/documents/GMenglish.pdf

Biotechnology and Intellectual Property

The purpose of the special project on Patenting of Higher Life Forms and Related Issues is to consider whether higher life forms (that is, seeds, plants and animals) should be patentable in Canada; to assess various approaches for addressing the inherent social and ethical issues; to ascertain whether particular uses of patented higher life forms should be exempt from patent infringement claims; and to examine other matters related to biotechnology patents. CBAC collected and analyzed information on various aspects of the topic, commissioned research papers and technical reports by experts in pertinent fields, and held meetings with representatives of the research community, non-governmental organizations and industry. A consultation document, accompanied by a summary of the commissioned research, was released in March 2001. In addition to receiving written submissions on the consultation document, CBAC held roundtable discussions in five locations across Canada in April and May, involving a total of 156 participants. After considering the various inputs received, an interim report containing draft recommendations was released in November and was scheduled to remain open for comment until March 15, 2002. By the end of the year, web site users had made 5,336 visits to the interim report.

The interim report makes 16 recommendations on a range of issues concerning the patenting of higher life forms, social and ethical concerns, the administration of the patent system and limits on patent rights. The key issues addressed include whether or not higher life forms should be patentable in Canada, and whether or not certain uses of patented higher life forms should be exempt from claims of patent infringement. The interim report also suggests improvements for the administration of the patent system and recommends a systematic program of research into, among other issues, the balance between the rights of patent holders and those seeking access to

the benefits of biotechnological inventions in health care. The complete interim report is available on CBAC's web site at http://cbac-cccb.ca/documents/IP_biotech_en.pdf

Incorporating Social and Ethical Considerations into Policy Making

In 2001, CBAC decided to modify the project incorporating social and ethical issues into policy making by moving to a two-phase approach. In the first phase, CBAC used its projects on the regulation of GM foods and the patenting of higher life forms as "test beds" to assess the issues involved in the incorporation process. In the second phase, the lessons learned in the first phase will be applied to the articulation of a generic framework for incorporating social and ethical issues into policy development.

As a first step, CBAC identified seven principles and values (see sidebar) to guide its work. The principles and values were included in the two consultation documents for public comment and were examined during the stakeholder discussions. Specifically, CBAC wanted to know if the principles were appropriate and/or if additional ones should be considered. The feedback from these sources was presented in the respective interim reports, and again comments were invited. CBAC also examined the specific social and ethical aspects of both GM food regulation and the patenting of higher life forms.

CBAC noted during the consultation process that the search for common ground between the proponents and the opponents of biotechnology is hindered by a lack of suitable tools to systematically consider and evaluate, on an ongoing basis, the social and ethical factors that influence public knowledge and acceptance of biotechnological innovations. In the latter part of 2001, CBAC initiated a plan with a small group of stakeholders to test a tool for structuring discussion and organizing views on the social and ethical dimensions of GM foods.

Novel Genetically Based Interventions

The objective of this special project is to review the social, ethical, legal, economic, regulatory, health and environmental policy implications of new developments in areas such as human cloning, stem cells, gene therapy and xenotransplantation. Given the speed of new developments in stem cell research, CBAC commissioned a report analysing evolving policies in various jurisdictions concerning the derivation and use of stem cells.[1] In January 2001, CBAC submitted an advisory memorandum to BMCC on developments in stem cell research and policy (see section 2Ai).

In May 2001, CBAC convened a meeting of government departments and agencies that have responsibilities in the field of stem cells to examine areas where further research might be needed and to avoid duplication of effort. Given the activities others were undertaking, CBAC decided not to pursue work in the area of stem cells for the time being. However, given the importance of stem cells to health research and their controversial nature, CBAC continues to monitor developments and may at a later date decide to do further work in this area.

Statement of Principles and Values Guiding CBAC

Justice
A commitment to ensure a fair distribution of benefits and burdens. A commitment to ensure that policies and practices do not contribute to the oppression of vulnerable groups.

Accountability
A commitment to be transparent and answerable.

Autonomy
A commitment to promote informed choice. A commitment to promote the conditions necessary to allow Canadians to pursue their fundamental values and interests.

Beneficence
A commitment to pursue benefits for Canadians and others throughout the world.

Respect for Diversity
A commitment to ensure respect for diverse ways and forms of life.

Knowledge
A commitment to value both scientific and traditional knowledge.

Caution
A commitment to adopt a precautionary approach when knowledge is incomplete.

[1] L. P. Knowles, *Comparative Primordial Stem Cell Regulation: Canadian Policy Options.* (Ottawa: Canadian Biotechnology Advisory Committee), December 2000.

Genetic Information and Privacy

The purpose of this project is to examine the mechanisms currently in place in Canada to protect the privacy of genetic information. CBAC commissioned reports on genetic testing and related privacy issues. Access to genetic information is a matter of increasing importance to the public and to governments throughout the world. CBAC continued to monitor developments in 2001 and explored the various aspects of the subject to which CBAC might make a useful contribution.

3. RECENT DEVELOPMENTS IN BIOTECHNOLOGY

This section of the report touches on the developments that took place during the reporting period that are particularly relevant to CBAC's work or that may influence its activities in the future. (See Appendix C for a selected list of notable reports and policy developments.)

3A) GENOMICS, PROTEOMICS AND RELATED DEVELOPMENTS

Advances in genomics and proteomics were among the developments likely to have highly significant impacts in health, agriculture, forestry, fisheries, the environment and other important areas of government involvement. Industrial applications of technologies made possible by the advances in genomics and proteomics are expected to be a major economic driver in the decades ahead. Government is faced with the need to invest in building up Canada's capabilities in these scientific fields on the one hand, and the need to craft public policies that respond effectively to the social and ethical implications of the applications on the other.

Developments in Canada

Canada aims to achieve prominence in the area of genomics and, in 2001, the federal government increased its investment in science and technology to help pave the way to achieving this goal.

In February 2001, the Government of Canada announced a $136-million investment in Genome Canada over and above the $160 million contributed the previous year. In April 2001, Genome Canada announced that 22 large-scale research projects and technology platforms in the areas of health, forestry, fisheries, agriculture and the environment would receive funding. The projects at five Genome Centres[2] across the country will involve 2,000 researchers and technicians, and will provide training for more than 700 students and post-doctoral trainees.

Genome Canada's GELS division was created to ensure leadership in addressing ethical, environmental, legal and social issues related to genomics. GELS currently has five research projects under way at four of the Genome Centres across Canada. Some 117 universities, hospitals, non-profit foundations and companies will participate. The federal government expects that its provincial counterparts and the private sector will match the total of $296 million it has provided.

[2] Genome BC, $35 million; Genome Prairies, $15 million; the Ontario Genomics Institute, $36 million; Genome Québec, $40 million; Genome Atlantic, $10 million.

In March, the federal government announced a $750-million investment, to the year 2010, in the Canada Foundation for Innovation to boost the research capacity of Canadian research institutions, including those involved in genomics research.

In May, the Natural Sciences and Engineering Research Council (NSERC) announced an investment of $4.8 million in 11 genomics research projects. The money will go toward endeavours in the areas of evolutionary genetics, gene expression, plant development and growth, physiology of stress, molecular genetics, bioanalytical chemistry and life sciences research related to human health and disease.

The Canada Foundation for Innovation, along with Genome Canada, NSERC, the Canadian Institutes of Health Research (CIHR) and the Social Sciences and Humanities Research Council (SSHRC), held a series of workshops to discuss areas of genomic research in which Canada could be competitive and which would be of benefit to Canadians. Opportunities for Canada to be a leader were identified in proteomics and protein chemistry, in genetics of specific disease and in the cattle industry, where the Canadian industry's breeding data records are among the best in the world.

The Human Genome

The pre-eminent event in genomics in 2001 was the publication of the details of the "working draft" of the human genome. While work continued on the mapping of the genomes of a variety of organisms, increasing effort was being devoted to characterizing the full complement of proteins (the "proteome") in humans and other organisms. This is an enormous task — far greater than the mapping of the human genome, given that the numbers and the various configurations of proteins exceed by orders of magnitude the numbers of genes. The linkage between genes and proteins involves RNA, and the journal *Science* included discoveries involving RNA among the scientific breakthroughs of 2001.

The following developments serve to illustrate the broad range of advances reported in 2001:

- Scientists at the U.S. National Human Genome Research Institute and Lund University in Sweden developed a way to differentiate among several types of childhood cancers, combining for the first time the technology of gene chips with a form of artificial intelligence called an "artificial neural network."[3]
- An international consortium sequenced the genome of the pufferfish, which contains the same genes and regulatory sequences as the human genome but in a smaller molecule, thereby simplifying the study of sequences of relevance to humans.
- Scientists at the National Human Genome Research Institute and the U.S. National Institutes of Health developed a test called "gene-expression profiling" that for the first time can easily distinguish between hereditary and sporadic forms of breast cancer.

[3] The neural network automatically analyses the large amounts of data produced by the gene chip to make highly accurate diagnoses. Gene chip technology analyses the pattern of activity of thousands of genes inside any cell type, including cancer cells.

3B) EMBRYONIC STEM CELLS AND CLONING

As noted in CBAC's advisory memorandum to government, two major recent advances in stem cell research have generated both excitement and concern. These are the demonstration that "pluripotent" stem cells can be isolated and cultured from embryonic or fetal tissue, and that stem cells from adults — taken, for example, from adult skin or bone marrow — can develop into cells with a wider variety of specific characteristics than previously thought.

Much of the current controversy in stem cell research is related to the different moral and ethical perspectives on the use of aborted fetuses and embryos as the source of stem cells.[4] Among some people, this raises profound moral and ethical questions. In late 2001, the controversy took on a new dimension when a U.S. firm, Advanced Cell Technology, announced that it had cloned human embryos for the first time in order to obtain stem cells for research purposes. The announcement raised the fear that this could be an early step toward creating the first cloned human baby.[5] This fear was exacerbated by comments from the Italian doctor Severino Antinori, who indicated that he intended to attempt reproductive human cloning for infertile couples.

In January 2001, the United Kingdom became the first nation to pass regulations allowing the cloning of human embryos as a source of stem cells for research purposes while barring scientists from using cloning techniques for reproduction. The new regulations modified the rules set out in the 1990 *Human Fertilisation and Embryology Act*, which had allowed research on donated embryos only.

Advisory bodies and legislative committees in other countries developed guidelines, or recommendations for legislation, to deal with the issue of cloning in general and the derivation and use of primordial stem cells in particular. An Australian parliamentary committee recommended a total ban on the cloning of humans and on the creation of embryos for research. China announced that it supported stem cell research on human embryos for curing and preventing diseases, but opposed cloning of humans and any cloning experiments aimed at reproduction. Japan passed a law allowing cloning for therapeutic research purposes and forbidding cloning research for reproductive purposes. New Zealand passed legislation to ban human cloning, the genetic engineering of human babies and xenotransplantation. The Swedish Research Council urged the Swedish government to change legislation to allow cloning for therapeutic purposes and to create a law prohibiting cloning for reproductive purposes. The United Nations General Assembly's legal committee supported a resolution calling for a global treaty to ban cloning of humans.

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[4] However, over the past year or two, several advances have involved non-embryonic stem cells — that is, stem cells from human adults and from umbilical cords and placentas from live births.

[5] The controversy may also extend to the patent arena in that another biotechnology firm, Infigen, which clones animals for agricultural and medicinal purposes, alleged that Advanced Cell Technology's experiment may have violated Infigen's cloning technology patent and that it was considering legal action.

In the U.S., the House of Representatives voted to ban both the creation of cloned embryos and their implantation into a woman to produce a child. Meanwhile, President Bush announced that the government would fund research only on existing human embryonic stem cell lines.[6] Within weeks, the National Institutes of Health had developed a registry of 64 cell lines at varying stages of development that met the criteria. This was soon followed by the question of whether or not the quality and quantity of the 64 cell lines would be sufficient for research purposes.

The European Parliament, by contrast, maintained its position allowing public funding for human embryo research. The European Union plans to spend 2.15 billion euros over the next four years on health-related genetic research, about 300 million euros of which will go to research on aborted embryos and those left over from *in vitro* fertilization. The European Commission said the move would not affect its stance on genetic research; it will continue to approve the funding of stem cell research that does not involve the creation of human embryos and will continue to oppose human cloning.

In Canada, the government's draft legislation on reproductive technologies introduced in Spring 2001, and the Standing Committee on Health's response to it contained several elements pertaining to stem cell research. The bill, to be tabled in the House of Commons in Spring 2002, is expected to state that scientists will be allowed to retrieve stem cells from human embryos, provided that the embryos are left over from fertility treatments, but that human embryos may not be created for the purpose of being destroyed for research. Regulations would be developed for any research involving the use of human embryos and, since only donated embryos could be used for research, regulations would also be needed to ensure that donors have all the information required to give genuinely informed consent to the donation. The draft legislation would not allow human cloning, the sale and purchase of embryos or payment for women to act as surrogate mothers.

In March 2001, the Stem Cell Network received a four-year, $21.1-million grant from the Network of Centres of Excellence program funded by NSERC, CIHR and SSHRC in partnership with Industry Canada. The Stem Cell Network brings together more than 50 scientists, clinicians, engineers and ethicists across Canada to investigate the therapeutic potential of stem cells.

Animal Cloning

Other "firsts" included cloning a cow from cells contained in mammary-gland fluid; using cloning technology to develop bigger chickens that are of consistent weight and taste and come to maturity at the same time; and cloning three healthy calves using a technique that involves manipulating the time at which an egg is fertilized. Critics of animal cloning contend that, of the relatively few cloned animals that actually survive the cloning process and are born, a large proportion are deformed or have other significant abnormalities.

[6] Meanwhile, a private fertility clinic in Norfolk, Virginia, had already announced that it had created more than 100 human embryos for the purpose of harvesting stem cells.

3C) GENETIC INFORMATION AND PRIVACY

As mentioned earlier, the vast new field of genomics promises many benefits but also raises concerns. The inappropriate release or use of genetic information could lead to discrimination in terms of employment, credit, and insurance or pension eligibility. The unwanted sharing of genetic information could also disrupt family relationships. Unless such issues are addressed, the full potential of genetic research for improved health may not be realized. Few countries have legislation dealing specifically with genetic information and discrimination. However, this situation is gradually changing, primarily in the areas of insurance, employment and forensic analysis.[7]

Canada

In Canada, aside from criminal legislation concerning the use of DNA in criminal investigations, most provisions affecting genetic information and discrimination are contained in broader laws — for example, in constitutional and human rights laws — that, while not written with genetics in mind, do provide some legal framework for handling personal genetic information.[8]

A provincial report touching on the issue of confidentiality of genetic information appeared in 2001. Saskatchewan's report *Preparing for Future Possibilities in Genetic Testing* highlighted several ethical matters, and among other things observed that policies and laws must address confidentiality and ownership of genetic material collected through testing.[9]

United Kingdom

In 2001, the U.K. government announced a five-year moratorium on the use of genetic tests by insurance companies except where high-value policies are involved and, in those cases, the tests must be approved by the Genetics and Insurance Committee. The decision was in response to earlier reports by government advisory committees and consultations with the insurance industry.[10] GeneWatch U.K. criticized the new agreement, saying it amounted to a step-by-step approach by the insurance industry to expand its use of genetic tests despite public opposition.

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7 Eugene Oscapella, *Genetics, Privacy and Discrimination*. (Ottawa, CBAC), October 31, 2000.

8 Ibid.

9 The report pointed to a study showing that the principle of informed consent (in this context, the agreement to proceed with a genetic test upon receiving information about its risks and benefits) is not being universally applied. The study, which involved 177 patients undergoing genetic testing, found that only 19 percent had received pre-test counselling and only 17 percent had provided written informed consent. The report noted that, ideally, health policy and law should balance the need for genetic information with individual privacy, and that consent and confidentiality require the individual and the provider to discuss the matter thoroughly and consider realistic planning before the test is done.

10 In the case of the science and technology committee, it recommended that a moratorium should be imposed if the industry did not develop a satisfactory solution on its own within a year.

United States

In December 2000, the U.S. government issued rules to protect the privacy of medical records, and in 2001 both the House of Representatives and the Senate held hearings on banning discrimination on the basis of genetic information. The American Medical Association supported the passage of federal legislation banning genetic discrimination.

In July 2001, the U.S. government issued guidelines covering the privacy rule in the 1996 *Health Insurance Portability and Accountability Act* that provide some protection against genetic discrimination for groups, but do not protect people in the individual or self-employment markets from insurers disclosing or demanding access to genetic information. The guidelines require researchers who use the nation's tissue banks to obtain authorizations when they use patient-specific information such as medical histories.

3D) PATENTING AND HEALTH CARE

The number of gene patent applications in Canada and other countries has risen sharply, accelerated in part by the mapping of the human genome. Several organizations, such as the World Medical Association, the European Parliament and the British Medical Association, have raised concerns about gene patenting. Ontario joined the fray in August 2001 when it called on politicians at home and abroad to work together to find a solution that balances the needs of the biotechnology companies with the needs of society.

While there are several complex issues surrounding gene patenting, the main concerns of the public and government are restrictions on access to testing for predisposition to serious diseases and on the costs to individuals and provincial health plans imposed by patent holders.[11] Particular concern has been expressed about the effects on people in developing countries. In addition, many fear that gene patents, while necessary to help companies recoup their research and development expenses, could stifle research if medical researchers are forced to fight their way through multiple patents and to pay such large fees to use a gene.

In January 2001, the United States Patent and Trademark Office issued new guidelines on gene patenting aimed at preventing companies from making frivolous attempts to patent genes before they have established a particular use for them. Researchers are now required to show a gene's function — that is, its "specific and substantial credible utility" — and its chemical code to get a patent. Previously, utility descriptions could be quite general, which allowed patent holders to claim tenuous connections to an eventual medical use.

The issue of gene patenting came into sharp profile in Canada in 2001 when the U.S.-based Myriad Genetics Laboratories demanded that all breast cancer-screening

[11] In its interim report to government on the patenting of higher life forms, CBAC recommended that a systematic program of research be undertaken on the impact of biotechnology patents on health services.

tests based on two genes on which it holds patents — BRCA 1 and 2 — must be done through its own laboratories. The company threatened to sue any province that covered the cost of the tests done in its own hospitals or laboratories.[12] British Columbia responded by stopping funding of the test. Ontario refused to do so, stating that it is of the opinion that the services it provides do not infringe on a valid claim of Myriad's patent.[13]

In August 2001, Ontario raised the issue of gene patenting at the Annual Premiers' Conference, calling for a national dialogue on several aspects of genetics, including gene patenting and its impact on health care. Ontario was charged with preparing a report on the implications of patenting the human genome. The report should set out recommendations on a range of matters surrounding the human genome, gene patenting and the potential impact on health care, privacy and discrimination.

The cost of drugs and treatments in developing countries also attracted considerable attention in 2001. The United Nations Development Programme addressed the issue in its annual Human Development Report released in July 2001. It noted that low-income countries cannot afford to implement and enforce intellectual property rights and that the high cost of disputes with the world's leading companies discourages developing countries from asserting their legal rights. It urged industrialized nations to help these countries in this regard, including assistance in implementing related aspects of the Agreement on Trade Related Intellectual Property Rights (TRIPs).

The September 11 terrorist attacks in the U.S. also sparked controversy about the enforcement of patents in the face of health care emergencies in general and on Cipro, the Bayer-produced antibiotic used to treat anthrax, in particular. The U.S. government convinced the company to reduce the price of Cipro to allow the government to build a stockpile. Trade ministers at the World Trade Organization talks in Qatar agreed in November to make it somewhat easier for countries to declare the type of national emergency that allows them to ignore patents.

3E) REPRODUCTIVE TECHNOLOGIES

i) Canada's Draft Reproductive Technologies Legislation

In May 2001, Canada's Minister of Health introduced draft legislation concerning reproductive technologies. The draft legislation set out which reproductive technologies would be prohibited (see sidebar) and which would be acceptable, subject to regulations. The regulations would also address matters such as informed consent, counselling, laboratory safety and other items.

Eleven Prohibitions Proposed in the Draft Legislation

- Cloning of human beings
- Germ-line genetic alteration (changing the genetic code such that the modification is passed on to descendants)
- Development of an embryo outside a woman's body beyond the accepted 14-day limit
- Creation of embryos solely for research purposes
- Creating an embryo from another embryo or fetus
- Transplanting reproductive material from animals into humans
- Use of human reproductive material previously transplanted into an animal
- Gender preference (i.e., action taken to increase the probability of a particular sex)
- Sale and purchase of human embryos
- Purchase, barter or exchange of human gametes (sperm or eggs)
- Commercial surrogacy arrangements

[12] The breast and ovarian cancer tests in question cost about $800 in Ontario, compared with Myriad's $3,800.

[13] The Curie Institute and other French research and clinical agencies filed an opposition with the European Patent Office (EPO), challenging what it considers to be the overly broad claims of the BRCA 1 patent. The Institute's position is that the industrial method for direct sequencing proposed by the company does not allow for the detection of all mutations, particularly large alterations of the BRCA 1 gene.

The draft legislation, developed following consultations with Canadians and the provinces and territories, was submitted to the Standing Committee on Health for review and further discussion with Canadians.

The Standing Committee's report called for even stricter controls than did the draft legislation. For example, whereas the original draft legislation allowed licensed individuals to reimburse a sperm or ovum donor only for any expenses they incurred in the course of donating, the Standing Committee recommended prohibiting reimbursement. As well, the Standing Committee's proposals require researchers to obtain a licence to experiment on human embryos left over from fertility treatments and, to get a licence, they would have to show that only human embryos would suffice for their work. The government is reviewing the Standing Committee's proposals and is expected to table a final bill in the House of Commons in Spring 2002.

ii) Pre-implantation Genetic Diagnosis

Pre-implantation genetic diagnosis involves genetic testing of embryos produced by *in vitro* fertilization to allow those who are at significant risk of passing on a serious genetic condition the option of selecting for implantation embryos identified as being free of the undesirable trait. Pre-implantation diagnosis was used in the case of a U.K. couple who wished to have a child that would be free of the Severe Combined Immune Deficiency disorder affecting their six-year-old daughter and therefore could serve as a donor of bone marrow for transplantation. In another case, the Human Fertilisation and Embryology Authority allowed a couple to use the procedure for the first time as a means to select embryos from donors that could result in a child who is immunologically compatible with their son, who is afflicted with a potentially deadly blood disease. While disease prevention or treatment was the primary reason to use the technique in these cases, some are concerned that genetic screening of embryos might be undertaken to create "designer babies" selected for characteristics unrelated to disease avoidance or therapy.[14]

There is, for now at least, general support for the approach taken in the U.K. by the Human Fertilisation and Embryology Authority; namely, licensing centres to test for a limited number of specific and serious conditions. The Human Genetics Commission said that it would consider the wider issue of genetic testing and reproductive issues in 2002.

iii) Other Developments in Reproductive Technologies

- In January 2001, the birth of the first transgenic primate (a rhesus monkey carrying a gene for a luminescent protein) was announced. This was seen as a significant advance in broadening the range of transgenic animals for use in research.

[14] Canada's draft legislation on reproductive technologies prohibits sex selection for other than medical reasons. The U.K. government ordered an investigation into sex-selection techniques due to concern that legal loopholes are allowing private clinics to offer people the chance to select the sex of their baby for social reasons.

- Up to 30 children, 15 of whom were involved in one experimental program in a New Jersey laboratory, have been born through use of a procedure to treat infertility called "ooplasmic transfer." In this procedure, some of the contents of a donor egg from a fertile female are injected into an infertile woman's egg along with fertilizing sperm. Some of the children were found to have genes from three adults, as they received mitochondrial DNA from the egg donor. These children represent the first case of human germline genetic modification resulting in normal children.

- Australian researchers announced they had discovered a way to fertilize human eggs using genetic material from any cell in the body. The group has successfully fertilized mouse eggs in laboratory cultures using somatic cells. This was not previously possible because somatic cells contain two sets of chromosomes, unlike sperm cells, which have only one. The team used chemical techniques to eliminate the extra set of chromosomes. The researchers will not know if the embryos are viable until they are transferred to foster mothers for further development.

3F) HARVARD ONCO-MOUSE, PATENTING OF HIGHER LIFE FORMS

- In 1985, Harvard filed a patent application for the Harvard Onco-mouse in Canada. The Patent Examiner granted Harvard patents on its method of genetic modification, but refused to allow patents on its transgenic mice. The Commissioner affirmed this decision and then Harvard appealed to the Federal Court Trial Division.

- The Federal Court Trial Division upheld the decisions of the Patent Examiner and the Commissioner of Patents. The judge ruled that the definition of invention should not be extended to include higher life forms. Therefore, the judge held that the Harvard Onco-mouse and other similar transgenic, non-human mammals were not patentable subject matter in Canada. The case was then brought to the Federal Court of Appeal.

- In August 2000, Canada's Federal Court of Appeal concluded that a patent ought to be granted to Harvard University for the creation of the onco-mouse. It ruled that the wording of the *Patent Act*, as it currently stands, permits the patentability of genetically altered non-human mammals for use in carcinogenicity studies.

- In September 2000, CBAC issued an advisory memorandum to the Biotechnology Ministerial Coordinating Committee stating that Parliament, not the courts, should determine Canada's policy regarding the patenting of higher life forms.[15]

- In October 2000, government lawyers representing the Commissioner of Patents filed an application seeking leave to appeal the decision to the Supreme Court of Canada. The Supreme Court has agreed to hear the case in Spring 2002.

[15] A majority of CBAC members urged the government to prompt Parliament to amend the *Patent Act* to explicitly forbid, on an interim basis and pending the completion of a Parliamentary review, the patenting of particular classes of higher life forms. Other Committee members favoured advising the government to appeal the Federal Court of Appeal's decision to the Supreme Court of Canada.

- In Europe, where the Harvard Onco-mouse has been patented, an opposition to the patent was filed with the European Patent Office.[16] The opposition division of the European Patent Office confirmed the patent but in amended form, ruling that the patent must be limited to transgenic rodents containing an additional cancer gene.

3G) XENOTRANSPLANTATION

While research continues in the area of xenotransplantation and while some scientific advances were achieved in 2001,[17] most of the developments over the past year were in the public policy arena.

Canada

Consultations in Canada, funded by Health Canada and conducted by the Canadian Public Health Association in 2001, should result in a report to government in 2002 with the central recommendation that Canada should not proceed with clinical trials on xenotransplantation, as critical safety issues remain to be resolved.

United Kingdom

The U.K. Xenotransplantation Interim Regulatory Authority, established by the government to monitor research into animal–human transplantation, released its third report in February 2001. The report stated that xenotransplantation has not lived up to its early promise and that it may never be possible to protect the public from the danger of infection from animal viruses. It stated that safer technologies, such as those based on stem cell research using human embryos, may ultimately yield greater benefits.

United States

The U.S. government issued final guidelines for xenotransplantation researchers to reduce the risk of patients being unwittingly exposed to serious animal diseases. Under the guidelines, researchers are encouraged to reduce the risk of disease by taking special care when raising donor animals,[18] and the health of human participants should be monitored for the rest of their lives to detect diseases of animal origin, even if the transplanted tissue or organ is removed. Research sponsors would have to store tissue specimens from both the human and animal participants for at least 50 years, so that researchers can track the origins of any animal diseases that slowly emerge in humans.

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16 The U.S. and Japan have also granted patents on the onco-mouse.

17 Among the scientific advances reported during the review period were an "antigen-suppression agent," which allowed a British heart doctor to give a patient a transfusion of pig blood. As of four weeks following the procedure, the patient was still reported to be doing well. The doctor said he believes he can use the same technique to make donor bone marrow cells from unmatched donors compatible, but would not elaborate on his discovery because he plans to patent it. Another breakthrough was the creation of transgenic cloned piglets, which the companies said were a significant step in overcoming immunological incompatibility.

18 For example, they should come from "closed" herds, which are not exposed to outside animals, and should be delivered by Caesarean section, when possible, to reduce the transmission of infections to newborns.

The American Medical Association also recommended that patients receiving animal organs or tissues should be monitored for the rest of their lives, even if the organ is eventually removed. In addition, it recommended that children and incompetent adults should not be allowed to participate in clinical trials unless they are terminally ill and have no other options.

The Food and Drug Administration proposed a rule that would make publicly available information on all new or ongoing clinical trials involving either xenotransplantation or gene therapy. Under the proposed rule, the Food and Drug Administration would provide public access to most of the study design and safety information about these types of studies, but would not release confidential business information or personal information related to study participants.[19]

International

Scientists commissioned by the International Society for Heart and Lung Transplantation issued a review in December 2000, which said that clinical xenotransplantation trials involving humans would be justified only if little potential existed for the spread of animal viruses to humans, and that researchers must find a way to overcome the rejection of pig organs by the human body.

3H) AGRICULTURAL AND ENVIRONMENTAL BIOTECHNOLOGY

i) Agricultural Biotechnology

While the proponents and opponents of agricultural biotechnology continued to debate the relative benefits and risks of the enterprise, large and small farmers around the world continued to plant genetically modified crops. The amount of land devoted to such crops was forecast to reach 50 million hectares by the end of 2001, a 10 percent increase over 2000 levels and a 30-fold increase over 1996 levels, when GM crops were first grown.[20]

The initial thrust of recombinant DNA-based agricultural biotechnology was directed mainly to altering crops to make them more resistant to viruses and insects or to increase their tolerance to herbicides. Several advances of this kind were reported in 2001:

- The mapping of the rice genome is expected to lead to the development of crops with higher yields, better pest resistance and greater nutritional value.
- "Gene silencing" was used for the first time to produce a crop plant resistant to a bacterial disease (in this case to modify trees and vines to withstand crown gall, an affliction that affects many perennial fruit and nut crops).
- Aluminum-tolerant wheat strains were created to grow in poor, acidic soils.

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[19] Much of the information that would be disclosed is already publicly discussed or available via various United States meetings.

[20] Preliminary figures from C. James, International Service for the Acquisition of Agri-biotech Applications.

- A six-year study by University of Georgia and Israeli scientists has paved the way for cotton varieties that can grow better in semi-arid climates by using water more efficiently.[21]

The American company, A/F Protein, which is affiliated with Aqua Bounty Farms in Atlantic Canada, has requested approval from the Food and Drug Administration for transgenic salmon with an introduced growth hormone gene. Regulatory approval will depend on rigorous demonstration that the GM salmon are safe to eat. These transgenic salmon reportedly grow up to four to six times faster than non-transgenic salmon.

While benefits of advances in agricultural biotechnology to date have been mainly related to food production, the focus of future developments of GM crops may shift toward health applications. This includes genetic modifications to produce plants that have new nutritional characteristics (for example, increased vitamin levels) and crops that can act as biological factories for the production of pharmaceuticals or as delivery vehicles for vaccines. For example, Agriculture and Agri-Food Canada scientists have shown that tobacco can be modified to produce an immune modulator (interleukin-10) currently being tested for efficacy in clinical trials involving patients with Crohn's disease.

Canada and other nations are undertaking studies to evaluate the benefits and risks of advances in agricultural biotechnology. Some of the notable events in 2001 are outlined below.

Canada

Canada announced it would begin field testing genetically altered wheat, the first country to do so. The wheat is intended to provide greater tolerance to herbicides. When commercialized, it is expected to improve yields and reduce costs to farmers. A group of organizations wrote to the Prime Minister asking him to halt the approval of GM wheat unless the concerns of farmers, consumers and buyers were addressed. The call to halt was supported by more than 210 industry associations, local governments and citizen groups across Canada, as well as by 50 Canadian experts and researchers and 60 international organizations, but the reasons for calling for a halt varied significantly among the different interest groups. The ongoing debate on this issue will be facilitated by studies published by the University of Saskatchewan.

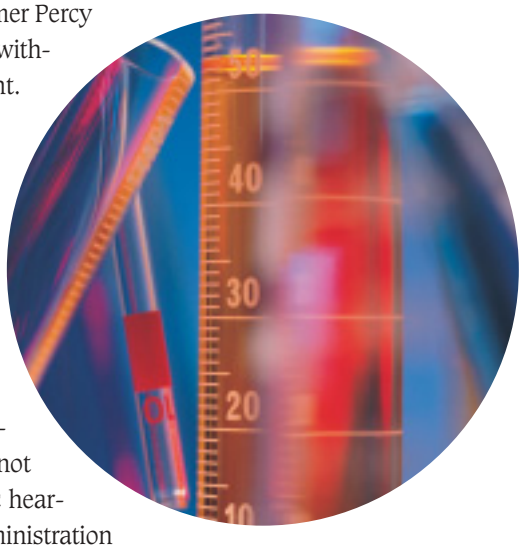
A key issue is the potential loss of market for non-GM wheat. In the United States, some state legislatures have banned GM wheat in their territory; other states are being petitioned or sued to enact similar bans.

[21] The study shows that, at least in principle, researchers can "reassemble" in cultivated cottons the sets of genes that enable wild cottons to survive under semi-arid conditions. Many of these genes were believed lost as cotton was domesticated for higher yields in well-watered conditions.

In February 2001, the Royal Society's Expert Scientific Panel on the Future of Food Biotechnology released its report on the scientific capacity of the Canadian system for regulating GM foods.[22] The report contained an extensive set of recommendations concerning the principles and the scientific and technological processes underlying the current regulation of agricultural biotechnology and the changes necessary to cope with future developments.

The government's response, issued in November 2001, was in the form of an action plan dealing with seven matters.[23] It outlined the various activities that the government had already undertaken to address them and those that were in the planning stages. The government noted that it would combine the Panel's recommendations with other work under way, such as CBAC's final report on GM foods, the endeavours of the Canadian General Standards Board Voluntary Labelling Committee and the related work of the House of Commons Standing Committee on Health. The Sierra Club issued a news release following the publication of the government's action plan stating that the government had "not accepted the full weight of the recommendations." It called for a moratorium on all new approvals of genetically engineered crops and foods, and for a public review of existing products.

In March 2001, the Federal Court of Canada ruled that Saskatchewan farmer Percy Schmeiser knowingly grew a crop of Monsanto's Roundup Ready canola without the company's permission, thus infringing on the company's patent. Schmeiser had argued that the seed had invaded his fields via the wind, bees or passing trucks, and had contaminated the rest of his crop. Monsanto argued that the farmer knew he had Roundup Ready canola in his fields and took advantage of the seeds to grow a full crop of the grain without paying Monsanto the required fee. In June 2001, Schmeiser filed a notice of appeal.



United States

The Food and Drug Administration proposed mandatory rules for genetically engineered crops but left it to manufacturers to decide whether or not to label bioengineered foods. The rules were developed after three public hearings and more than 50,000 written comments. The Food and Drug Administration proposal contains two parts. One part requires companies to show Food and Drug Administration regulators safety data at least 120 days before they bring a new bioengineered food to market. The second part concerns guidelines for voluntary labelling, including which words may and may not be used to describe biotechnology crops.

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22 The Panel was struck by the Royal Society of Canada at the request of Health Canada, Environment Canada and the Canadian Food Inspection Agency to provide advice regarding the safety of new food products being developed through biotechnology.

23 Substantial equivalence, use of precaution, transparency and increasing public confidence, potential human health impacts, environmental safety and GM plants, GM animals (including fish) and GM feeds, and other recommendations.

The Environmental Protection Agency announced it had reauthorized commercial planting of Bt corn varieties, following a year-long review. Bt corn received attention following a 1999 laboratory test finding that monarch butterfly larvae were harmed when fed solely on milkweed leaves heavily dusted with Bt corn pollen. However, based on additional studies, the EPA concluded that Bt corn does not in fact harm monarch populations.[24]

New Zealand

The New Zealand government announced in October 2001 that it would introduce legislation to stop the commercial release of genetically modified organisms into the environment for two more years, but would lift a 16-month ban on field trials of the organisms. The lifting of the ban would be accompanied by new rules to ensure that material used in the research was later destroyed or locked away. The announcement was the government's formal response to a Royal Commission of Inquiry into GMOs, completed in June 2001.

India

A Reuters report quoted an Indian government official as stating that the country would likely allow, by March 2002, the commercial production of a GM crop for the first time. The official said that the first approval would likely concern a GM cotton variety modified to resist the cotton bollworm.

United Nations Development Program (UNDP)

UNDP's annual Human Development Report, released in July 2001, stated that biotechnology and information and communications technologies can help significantly to reduce world poverty. While acknowledging that environmental and health risks need to be addressed, the report stated that developing countries could reap major benefits from GM crops, foods and other organisms, and urged governments to invest more in biotechnology research and development to help meet the agricultural needs of poor nations. The report remarked that problems with biotechnology and food safety are often the result of poor policies, inadequate regulation and lack of transparency — challenges that can be especially great in developing countries — and urged industrialized nations to help their less developed counterparts in this regard. It pointed out that biotechnology debates in the U.S. and Europe mostly ignore the needs and concerns of the developing world. Finally, it called for more research into the long-term effects of GMOs and advocated labelling of GM products.

[24] A separate matter concerning Bt corn, in this case StarLink corn, is not affected by the EPA decision. StarLink corn became controversial because it was bioengineered with a pesticide gene and was approved for animal feed but not for human consumption. When traces of StarLink were found in taco shells, authorities recalled the product.

ii) Labelling

As of August 2001, some 28 countries plus the 15-member European Union had either adopted or announced plans to introduce labelling for GM foods. Other countries, such as Turkey, Ethiopia and Singapore, have expressed interest in or concern about GM foods but, as of August 2001, had not stated whether or not they would impose labelling rules. Four of the nations (Canada, the U.S., Argentina and Hong Kong) have adopted or are considering a voluntary labelling strategy, while 22 countries plus the European Union have adopted or announced plans to implement mandatory labelling systems.

Canada

On October 17, 2001, Parliament defeated a private member's bill that would have made the labelling of all GM foods mandatory in Canada. Senior Cabinet ministers had already asked the Standing Committee on Health to consider the issue and to hold public hearings on it. These hearings were scheduled to begin in February 2002. The Canadian General Standards Board and the Canadian Council of Grocery Distributors have been working on standards for voluntary labelling of GM foods for two years but have not yet made final recommendations. The topic was also addressed by the Royal Society Expert Panel, which concluded that GM foods raised no *scientific* issues that would not be met by the existing requirements for labelling of foods — when an allergen or other safety risk is present, when there has been a significant compositional change in the food, or when there has been a significant nutritional change in the food. CBAC recommended a voluntary system of labelling in its interim report on the regulation of genetically modified foods, noting that labelling is already mandatory for foods containing components posing health risks.

Japan

It was announced in November 2001, that the government of Japan had begun developing a system to numerically label every package of beef to show where the cow had been born and the farm on which it was raised. The introduction of the traceability system is aimed at restoring public confidence following the discovery in September of the country's first case of mad cow disease. The government will launch a task force with scholars and health ministry officials to discuss details.

iii) Environmental Biotechnology

Plants and animals can be engineered to serve as biosensors, detecting or monitoring hazardous material in the environment. For example, bacteria have been modified to be sensitive to TNT, making them potentially useful in tasks such as detecting landmines. On the horizon are GM crops that clean up contaminated and polluted sites such as mines, leading to healthier soil, water and air. The natural ability of some plant species to absorb and store toxic and hazardous substances is being enhanced in the hope of making them useful in cleaning up oil spills and chemical leaks.

Researchers at the University of Guelph have developed a line of transgenic pigs trademarked Enviropig™ that use plant phosphorus more efficiently. This novel trait of the Enviropig™ reduces the phosphorus content of their manure by as much as 75 percent. As this manure has less phosphate, it is better suited for long-term repetitive application to agricultural land, and there is less potential for pollution of the environment to occur as a result of the application of this manure.

Some experts point out that biotechnology can help to mitigate climate change. Participants at a U.S. Department of Energy workshop in June 2001 determined three ways in which biotechnology applications could help to reduce greenhouse gases: carbon sequestration using microbes and plants, use of biomass for fuel production, and use of biological processes to make cleaner fuels with higher energy content.

4. CANADA'S BIOTECHNOLOGY SECTOR[25]

In 1999, Canada's biotechnology sector generated almost $2 billion in revenues, including $718 million in exports. These revenues are expected to exceed $5 billion in 2002. Every region of Canada shares in the growth of the biotechnology sector, which employs almost 7,700 people, typically in high-quality jobs.

With some 358 firms, most of which are small companies, Canada has more biotechnology companies per capita than any other country. It is also second behind the U.S. in terms of number of companies, third behind the U.S. and the U.K. in revenues, and first in research and development (R&D) per employee.[26]

The health sector continues to dominate the biotechnology landscape with 42 percent of the companies in that sector, followed by agriculture (25 percent), environment (10 percent), food processing (8 percent), bioinformatics (5 percent), natural resources (5 percent) and aquaculture (4 percent).

Growth in Canada's Biotechnology Sector, 1997–99

	1997	1999	Percentage increase
Employment	9,824	7,695	–22%
Revenues	$813 million	$1,948 million	140%
R&D expenditures	$494 million	$827 million	67%
Number of companies	282	358	27%
Exports	$413 million	$718 million	74%
Imports	N/A	$234 million	

Over this same time period, the federal government substantially increased its expenditures on biotechnology research and development to reach $380 million in 1999–2000.

Science-based organizations and core biotechnology companies are broadly distributed across the country. Québec, Ontario, Alberta and British Columbia are particularly strong in the health care sector. Saskatchewan is a global leader in agricultural biotechnology. Atlantic Canada excels in aquaculture, forestry and biodiversity.

[25] Unless otherwise stated, the figures in this section derive from *Biotechnology Use and Development Survey — 1999*, Statistics Canada.

[26] The numbers in this paragraph are taken from *Statistics Canada 1999* and *Ernst & Young European Life Sciences Report 2000*.

5. LOOKING AHEAD

CBAC conducted considerable work during the reporting period to advance its general activities and to make progress on its two priority special projects. The work built on the foundation forged the previous year when CBAC members first met and formulated their Program Plan.

In the coming months, the Committee expects to issue its final reports and recommendations concerning the regulation of GM food and other novel foods, and the patenting of higher life forms. Both reports will be submitted to BMCC in Spring 2002. As these two special projects draw to a close, CBAC will assess other topics that require special consideration and decide which to pursue as special projects. CBAC will also continue its work with stakeholders to test the Acceptability Spectrum as a means of facilitating public dialogue around the acceptability of various GM (and other novel) foods.

CBAC will continue to track scientific, policy and other events in Canada and around the world to keep government informed of the latest advances in biotechnology and the implications that they may have for Canada and Canadians. It will also continue its communications and outreach endeavours with a view to expanding its partnerships and reaching as many Canadians as possible.

While the biotechnology world experienced remarkable developments in 2001 and while nations made significant strides to address the ramifications implicit in them, most of the issues are still evolving. In Canada, these include the labelling of GM foods, the effects of impending reproductive technologies legislation, the impact of biotechnology patents on the health care system, privacy issues, the upcoming decision by the Supreme Court of Canada concerning the patenting of the Harvard Onco-mouse, and a host of issues in the area of agricultural biotechnology and its impacts on human and animal health and the environment.

Since biotechnology is widely held to be among the main technological drivers of economic and industrial innovation, the continuing evolution of the government's Innovation Agenda is bound to have either a direct or contextual effect on the biotechnology sector. This indicates the years ahead will be replete with interesting and important issues for CBAC's future agendas.

APPENDIXES

A. GLOSSARY

Biotechnology: A body of technical knowledge about living organisms or their constituent parts. The term "applied biotechnology" refers to those aspects of biotechnology used to make products and drive processes that serve social, scientific or economic purposes. Much of modern biotechnology is concerned with techniques involving the manipulation of tissues, cells and their internal structures, and biological molecules (including DNA).

Clone: A group of genes, cells or organisms derived from a common ancestor. Because there is no combining of genetic material (as in sexual reproduction), the clone is genetically identical to the parent.

Gene: A segment of the DNA molecule, made up of linear sequences of four molecules (bases), that carries the structural information for the assembly of a protein. The human genome contains more than three billion such bases.

Gene therapy: Gene therapy is an experimental form of treatment that involves substituting normal genes for abnormal or missing genes. The genetic insertion can be performed either inside the living body or in extracted cells that are then returned to the body.

Genetic engineering (GE): The insertion, deletion or alteration of a gene or DNA sequence in an animal, plant, bacterium or other organism in order to create organisms with specific characteristics.

Genetic modification (GM): Includes GE and methods to cause mutations, such as exposure to chemicals or radiation.

Genome: The entire set of genes of an organism.

Genome map: A description of the order of genes and the spacing between them in all chromosomes of an organism.

Genomics: The study of how genetic information is structured, stored, expressed and altered.

Harvard Onco-mouse: An animal that has been genetically modified to exhibit highly increased susceptibility to the development of cancer and that is therefore of great value for cancer research.

Higher life forms: All living organisms that have more than one cell including plants, seeds, animals and human beings.

Human Genome Project: A public consortium of international researchers established in the 1990s to map the human genome.

Novel food: Any plant or animal product intended for use as a food that does not have a history of use as a food sufficient to evaluate its safety, or has been manufactured, preserved or packaged in a way not previously applied to that food and which causes a significant change in the properties of the food, or a food derived from a plant, animal or micro-organism that has been genetically modified to differ significantly from the unmodified form.

Patent: A patent is the right to exclude others from making, constructing, using or selling a new, useful and "non-obvious" invention for 20 years from the date the application for the patent is filed.

Pluripotent: Not fixed as to developmental potentialities; having developmental plasticity.

Primordial stem cells: The stem cells present in human embryos and the germ cells present in the fetus.

Proteomics: The field of study concerned with the structural and functional relationships between proteins and the genes governing them.

Ribonucleic acid (RNA): A long chain, usually single-stranded nucleic acid. The primary function of RNA is related to the process of protein synthesis within the cell and more generally to the processes of expression and repression of hereditary information.

Somatic cells: Cells of the body that compose the tissues and organs other than the germ cells (sperm cell or egg or their antecedent cells) involved in reproduction.

Transgenic organism: A plant, seed or animal into which has been inserted genetic material from an unrelated plant, seed or animal, often across species boundaries.

Xenotransplantation: The transplantation of cells, tissues and organs from one species into another.

B. ADVISORY MEMORANDUM ON STEM CELLS

January 15, 2001

Canadian Biotechnology Advisory Committee Advisory Memorandum

Stem Cells: Opportunities and Challenges

Background

The term "stem cells" refers to cells found in animal and human tissues that are non-specific or "undifferentiated" but are capable of developing into "differentiated" cell types with specific structural and functional characteristics (e.g., bone cells, muscle cells, nerve cells). While the undifferentiated cells of the early embryo are the most commonly recognized examples of stem cells, such cells also exist in adult tissues and some differentiated adult cells can be made to behave like stem cells.[27]

Two major recent advances in stem cell biology have generated both excitement and concern. They are the demonstration that "pluripotent" stem cells can be successfully isolated and cultured from embryonic or fetal tissue, and the reports that stem cells from adult tissues have the potential to develop into cells with a wider variety of specific characteristics than previously believed. Both of these discoveries may lead to a variety of clinical applications. These may include tissue replacement therapies where none have been available in the past and more effective approaches where existing methods are of limited use because of complications such as tissue rejection.

The public policy implications of these advances are more salient in the case of primordial stem cells than adult stem cells because of the source of primordial stem cells and explicit or implicit prohibitions on research involving human embryos and fetal tissue now in existence in many countries. The overarching question is whether these advances should lead to a reconsideration of current prohibitions and, in particular, whether new policies and guidelines are needed pertaining to research on primordial stem cells.[28] The answer to this question may well vary among different jurisdictions, depending on current policies and practices.

Recent Policy Developments

In light of the impressive potential of stem cell research and its ethical implications, expert groups in the United States and the United Kingdom have examined this issue and produced reports to guide policy development. Both groups recommended, subject

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[27] Sources of stem cells: early embryos created by *in vitro* fertilization; early embryos created by cell nuclear replacement (inserting the nucleus of an adult cell into an egg from which the nucleus has been removed); from the germ cells or organs of an aborted fetus; from umbilical cord blood; from some adult tissues such as bone marrow or skin; from mature adult cells programmed to behave like stem cells. Adapted from the report of Chief Medical Officer, United Kingdom: *Stem Cell Research: Medical Progress with Responsibility. June 2000*.

[28] The term primordial stem cell is used to denote the stem cells present in human embryos (ES) and the germ cells present in the fetus (EG).

to conditions that reflect the differences in the social and ethical considerations applicable to the various ways in which stem cells are derived, that stem cell research not be prohibited. However, the specific policy initiatives resulting from these reports differ significantly between the U.S. and the U.K. These initiatives and those in other jurisdictions are described in a paper, prepared for CBAC by Ms. Lori Knowles of the Hastings Centre, appended to this Memorandum.[29]

In Canada, the recommendations on assisted reproductive technology (ART) contained in the Report of the Royal Commission on New Reproductive Technologies (1993) may be interpreted as being relevant to stem cell research. However, neither those recommendations nor the voluntary moratorium on certain reproductive technologies called for by the Minister of Health in 1995 have legal regulatory force. Bill C-47 (the *Human Reproductive and Genetic Technologies Act*), which died on the Order Paper in April 1997, included provisions related to embryo research. However, the bill antedated recent discoveries related to stem cells — as did the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* published in 1998. The question remains whether current Canadian guidelines on embryo research and fetal research require revision or amplification in the light of recent scientific developments.

CBAC and Stem Cells

CBAC's program plan includes a special project on *Novel Genetically Based Interventions*. This project includes topics such as human cloning, stem cells, xenotransplantation and gene therapy. Given the speed of new developments, the potential therapeutic benefits that may flow from them and the profound ethical issues to which certain applications of stem cell research give rise, CBAC is in the process of advancing some of its planned work in this important area. This may include studies of the ethical, legal and developmental aspects of stem cell research in the context of the situation in other jurisdictions, but with special emphasis on the legal, regulatory and political circumstances of Canada.

CBAC has members with special interest and expertise in certain key aspects of stem cell research and its potential applications. These members also have connections with other groups undertaking or contemplating work in this area, thereby enhancing the potential for productive collaboration. In addition, CBAC will be involving other experts either to undertake specific studies or to join CBAC's Project Steering Committee. To begin this process, CBAC commissioned Ms. Lori P. Knowles, Director, Research and Outreach of the Hastings Centre, to prepare an analysis of evolving policies, in various jurisdictions, on the derivation and use of stem cells.[30]

One of CBAC's most important roles, and a key element of its mandate, is to provide a forum for Canadians to become informed about and engage in discussion of important developments in biotechnology such as those represented by advances related to stem cells. In fulfilling this role, CBAC will synthesize the outcome of its own studies

[29] L. P. Knowles, *Comparative Primordial Stem Cell Regulation: Canadian Policy Options.* Canadian Biotechnology Advisory Committee, December 2000.
[30] Ibid.

and deliberations with those of other groups in order to provide Canadians with a comprehensive view of the context for public policy development.

The Canadian Institutes of Health Research has established a working group on stem cell research, and it may well be that other groups will be taking up this issue. For this reason, it is desirable to alert interested parties to the work CBAC has planned in this area so that appropriate information exchange and liaison mechanisms may be developed to avoid undesirable duplication of effort and to promote effective use of limited resources, including the relatively small pool of Canadian experts.

Recommendations

In the light of the foregoing, CBAC recommends that:

1. ***BMCC take note of recent discoveries pertaining to stem cells and the international trends in policy development arising from them.***

2. ***Canada establish a broad framework of regulation pertaining to ARTs, including embryo research, that addresses the scientific, ethical and social issues raised by primordial stem cell research and that it is readily adaptable to new discoveries and to experience gained in the application of the new technologies.***

3. ***As an interim step, current guidelines pertaining to research involving embryos and fetuses be reviewed and revised as necessary or desirable to take account of recent and projected scientific and technological advances related to primordial stem cells.***

CBAC looks forward to participating in the processes that are involved in the implementation of either or both of the latter two recommendations.

C. REPORTS AND PUBLIC POLICY DEVELOPMENTS

International Developments

January — *Breeding Distrust: An Assessment and Recommendations for Improving the Regulation of Plant-derived Genetically Modified Foods.* Prepared for the Food Policy Institute of the Consumer Federation of America.

April

UNESCO — International Bioethics Committee (IBC), *The Use of Embryonic Stem Cells in Therapeutic Research.*

UNESCO — International Bioethics Committee (IBC), *Report of the IBC on Solidarity and International Co-operation between Developed and Developing Countries concerning the Human Genome.*

World Intellectual Property Organization (WIPO) — *Intellectual Property Needs and Expectations of Traditional Knowledge Holders,* Report on Fact-finding Missions on Intellectual Property and Traditional Knowledge (1998–99).

May

Europe — Greenpeace and Misereor (the development agency of the German Catholic Church) filed a legal objection with the European Patent Office against an application by du Pont for a very wide-reaching patent claim on maize with specified properties.

June

United States — *Stem Cells: Scientific Progress and Future Research Directions.* National Institutes of Health, Office of Science Policy.

July

New Zealand — *Report of the Royal Commission on Genetic Modification.*

New Zealand — *Embryonic Stem Cells and Human Therapeutic and Reproductive Cloning.* Discussion document prepared by Prof. R. Stewart Gilmour for The Royal Society of New Zealand.

OECD — Conference on New Biotechnology Foods and Crops: Science, Safety and Society, Bangkok.

August

UNESCO — International Bioethics Committee (IBC), *Draft Report on the Follow-up to the International Symposium on Ethics, Intellectual Property and Genomics.*

WIPO — *Agenda for the Development of the International Patent System* — open for comments until January 2002.

September

European Commission, Consultation Document: *Toward a Strategic Vision of Life Sciences and Biotechnology*.

UNESCO — International Bioethics Committee, *Draft Report on Collection, Treatment, Storage and Use of Genetic Data.*

United States — Memorandum of Understanding between WiCell Research Institute, Inc. and Public Health Service United States Department of Health and Human Services concerning access to stem cells.

United States — *Stem Cells and the Future of Regenerative Medicine*. National Research Council and Institute of Medicine.

October

European Union — The challenge by the Netherlands against European Directive 98/44/EC, Legal Protection of Biotechnological Inventions was dismissed by the European Court of Justice.

UNESCO — *Bioethics: International Implications,* a roundtable of science ministers.

November

Europe — The European patent on the Harvard mouse, which had been opposed by Greenpeace and other organizations, was upheld.

European Parliament, Temporary Committee on Human Genetics and Other New Technologies in Modern Medicine, *Report on the Ethical, Legal, Economic and Social Implications of Human Genetics.*

Farmers Legal Action Group, Inc. (FLAG), *GMO Liability Threats for Farmers: Legal Issues Surrounding the Planting of Genetically Modified Crops.*

OECD — GMOs and the Environment: An International Conference, Raleigh-Durham, North Carolina.

United Nations Food and Agriculture Organization (FAO) — *International Treaty on Plant Genetic Resources for Food and Agriculture* approved by FAO Conference, by 116-0, with two abstentions. The Treaty is intended to preserve the diversity of food and agriculture and the "fair and equitable sharing of the benefits" and is the outcome of seven years of negotiations to revise the International Undertaking on Plant Genetic Resources to bring it into harmony with the Convention on Biological Diversity.

December

Sweden — *The Swedish Research Council's guidelines for research-ethical review of human stem-cell research.*

United States — Supreme Court ruled that the *Plant Variety Protection Act* of 1970 does not prevent plants from being patented. *J.E.M. Ag Supply dba Farm Advantage v. Pioneer Hi-Bred International,* Dec. 10.

World Commission on the Ethics of Scientific Knowledge and Technology (COMEST), Second Session, including a Youth Forum on the Ethics of Science and Technology.

In Progress During 2001

World Intellectual Property Organization (WIPO) — *Inter-Governmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore.* The first session was held in the Spring and determined an agenda for the work of the committee. A December meeting was to consider a patent-related paper, *Progress Report on the Status of Traditional Knowledge as Prior Art*. IGC members were also invited to take note that the *International Treaty on Plant Genetic Resources for Food and Agriculture* was adopted by the FAO Conference in November (see above).

National Developments

February — Royal Society of Canada Expert Scientific Panel, *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada.*

March — Canadian Institutes of Health Research, *Human Stem Cell Research: Opportunities for Health and Ethical Perspectives (Discussion Paper)*.

October — Woodley, *The Impact of Transformative Technologies on Governance: Some Lessons from History.* Scoping paper sponsored by the Institute on Governance/ Law Commission of Canada.

October — Blair Consulting, *Biotechnology Patents and Product Approval Processes: Challenges and Opportunities.* Presented to the Ontario Ministry of Energy, Science and Technology.

November — Report of the Provincial Advisory Committee on New Predictive Genetic Technologies, *Genetic Services in Ontario: Mapping the Future.*

December — *Assisted Human Reproduction: Building Families.* Second Report of the Standing Committee of Health.