ANNUAL REPORT 2002

Canadian Biotechnology Advisory Committee

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Message from the Chair,

Canadian Biotechnology Advisory Committee

On behalf of the Canadian Biotechnology Advisory Committee (CBAC), I am pleased to present CBAC's third Annual Report, covering the calendar year 2002.

This has been a particularly active year for CBAC. Two major projects were completed — namely, on the regulation of genetically modified foods and the patenting of higher life forms — and work on other projects continued. We expanded our outreach efforts considerably and established additional productive liaisons with other bodies engaged in examining the public policy aspects of biotechnology.

CBAC welcomed several new members to its ranks in 2002. I thank all of the members of CBAC who were unstinting in their dedication, in the face of demanding deadlines and heavy workloads to fulfil CBAC's mandate. I also thank the staff of the Canadian Biotechnology Secretariat who so ably supported the committee in its endeavours. I am particularly grateful to Roy Atkinson, who has headed the Secretariat since CBAC's inception in 1999, for his outstanding contributions. Kim Elmslie has been appointed to succeed him as Executive Director. Mr. Atkinson will continue to be associated with CBAC for some months as Special Adviser to provide continuity on certain key initiatives.

As CBAC enters its fourth year, we look forward to building on our achievements and continuing to explore the role of biotechnology in Canadian society as part of the federal government's Innovation Strategy.

Sincerely,

Dr. Arnold Naimark

Chair, CBAC

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General Activities

CBAC significantly increased its communications and outreach activities, particularly with regard to publicizing its reports on the regulation of genetically modified (GM) foods and the patenting of higher life forms. We built on CBAC's citizen engagement plan by expanding its partnership network, augmenting its exhibit program, participating in special forums such as Parliament's Standing Committee on Health, and participating in and making written submissions in connection with major conferences such as the National Summit on Innovation and Learning.

CBAC continued to monitor developments in biotechnology in relation to genomics and proteomics, stem cells and cloning, agricultural biotechnology, patenting, genetic information and privacy, transgenic technologies and xenotransplantation.

Special Projects

Following almost two years of intensive research and consultation, CBAC issued its final reports on the patenting of higher life forms and the regulation of GM foods. CBAC members look forward to receiving the government's responses to the two reports.

The report *Patenting of Higher Life Forms* was released on June 6, 2002. In it, we recommended that patents not be granted on the human body at any stage of development, and that higher life forms meeting the criteria of the *Patent Act* be patentable subject to certain limits. The report discussed pertinent social and ethical issues, made recommendations on improving the patent system, and addressed issues related to the equitable sharing of the benefits of biotechnological inventions and the recognition of traditional knowledge. The CBAC report figured prominently in the Supreme Court's deliberations on the Harvard Mouse case, and there was substantial congruence between the Court's findings and CBAC's report. Although the Court concluded that the Harvard Mouse did not meet the definition of an invention and therefore is not patentable, the Court did not take a position on whether or not higher life forms ought to be patentable, leaving this matter for legislators to decide.

The report *Improving the Regulation of Genetically Modified Foods* was released on August 26, 2002. CBAC concluded that GM foods approved under the current regulatory system do not pose any greater health or environmental risk than their conventional counterparts. The report identified opportunities to improve the management and coordination of the regulatory system, enhance communication with the public, support a voluntary labelling system, strengthen the system's capacity to deal with more complex GM food products, and

CBAC recommended that patents not be granted on the human body at any stage of development, and that higher life forms meeting the criteria of the Patent Act be patentable subject to certain limits.

incorporate scientific and technical advances as they emerge. The report also addressed environmental stewardship, international cooperation and informed dialogue. In a related endeavour, CBAC initiated work on the "Acceptability Spectrum," a tool designed to facilitate discussion on the acceptability of GM foods or other biotechnology-based products.

Developments

In February, the federal government announced Canada's Innovation Strategy. Several aspects of the Strategy directly or indirectly involve biotechnology-based innovations. The Strategy includes regional and sectoral consultations, culminating in a national summit in which the Chair of CBAC participated.

The rapid pace of advances in acquiring and applying knowledge concerning the structure and function of the genomes and proteomes of humans, plants and animals continued throughout the year. These advances expanded the range of potential benefits for human and animal health, the environment and the economy to narrow the public health gap between rich and poor countries. They also extended the range of concerns about potential harms such as the inappropriate use of genetic information to discriminate against individuals relative to employment, credit and insurance or pension eligibility. Calls for stronger legislation concerning privacy of genetic information have been issued in both the United States and the United Kingdom. For example, in a recent Canadian case, it was discovered that DNA samples donated some 20 years ago by members of a British Columbia First Nation for rheumatoid arthritis research had also been used for other types of research without the donors' consent. In Canada, Ontario Human Rights Chief Commissioner Keith Norton stated that genetic information should not be used to deny insurance or invoke exclusionary periods on the basis of a "pre-existing condition."

Research continued into the various uses of embryonic and adult stem cells as well as stem cells derived from primate parthenotes[1] for treating diseases and growing replacement tissues. While research on non-embryonic stem cells continued apace, a number of studies appeared to refute earlier findings suggesting that adult stem cells are multipotent and can be induced to form a variety of cell types. Clearly, additional research is required to resolve the discrepancy.

[1] Parthenotes are embryos grown from unfertilized eggs, which, in mammals, are not capable of developing into viable fetuses.

Claims that a human baby has been produced through cloning captured media headlines around the world. While cloning humans for reproductive purposes is generally deemed to be unacceptable, there is much less consensus on cloning to obtain stem cells for therapeutic purposes. Canada, like Australia and France, appears likely to take an intermediate position, allowing some forms of human embryonic stem cell research but banning cloning. Canada's proposed legislation on reproductive technologies as well as the guidelines issued by the Canadian Institutes for Health Research recommend this approach. Work on an international treaty on human cloning has been delayed by differences in viewpoints: should the treaty immediately ban cloning for any purpose, or should it ban cloning for reproduction only, leaving the issue of cloning for stem cell research for a later step?

The High Court in the United Kingdom ruled that the Human Fertilisation and Embryology Authority does not have the right to license the tissue typing and selection of test tube embryos to save the lives of their siblings. Also in the U.K., where cloning to obtain stem cells is allowed under strict conditions, scientists plan to apply for a licence to experiment on human embryos for medical purposes, and for another to conduct research on parthenogenesis of humans.

There were significant developments on the food labelling front this year. The U.S. issued voluntary country-of-origin information guidelines in October, scheduled to become mandatory in September 2004. Canada's department of Agriculture and Agri-Food will review the guidelines and consult with stakeholders to determine a course of action. The European Parliament backed a proposal to increase labelling requirements for food and to set more stringent rules for testing and identifying the amount of material traceable to genetic modification in foods and animal feed. In Canada, CBAC's report on *Improving the Regulation of Genetically Modified Foods* called for a voluntary labelling regime once an effective standard has been developed. The Canadian Council of Grocery Distributors and the Canadian General Standards Board continued their work on developing a Canadian standard for voluntary labelling, and two parliamentary standing committees examined the issue.

Canada, like Australia and France, appears likely to take an intermediate position, allowing some forms of human embryonic stem cell research but banning cloning.

Most of the news concerning agricultural biotechnology and the environment this year emanated from the U.S., much of it concerning GM crops. Traces of StarLink corn were found in an American shipment headed for Tokyo and its food supply. Zambia refused food aid in the form of GM corn from the U.S. The U.S. National Research Council called on the government to review the potential environmental effects of new transgenic plants more rigorously before approving them for commercial use and to monitor transgenic plants after they enter the marketplace. A U.S. poll found that respondents, when given basic information on risks and benefits, were evenly divided over whether GM food and other agricultural biotechnology products hurt or help the environment.

The impact of genetic patents on access to gene-based diagnostic tests was a prominent issue in Canada and the U.K. In Canada, a U.S. company demanded that all screening tests for breast cancer based on two genes on which it holds patents — BRCA 1 and 2 — must be done through its own laboratories and threatened to sue any provincial agency that covered the cost of the tests done in other laboratories. In the U.K., laboratories claimed that the ability to diagnose and study haemochromatosis is being hampered by restrictions caused by the patenting of a key gene, with the result that 30 per cent fewer of them are able to offer the test.

An Ontario report called for a comprehensive review of Canada's *Patent Act* to consider a range of concrete proposals for dealing with problems associated with gene patenting. The U.K. Nuffield Council on Bioethics proposed an ethical framework for gene patenting. It also recommended that patents on DNA sequences be the exception rather than the rule and that the tests of inventiveness and usefulness be more rigorously applied to applications for genetic patents.

Advances in transgenic technologies and xenotransplantation included the development of pigs genetically engineered so the human immune system will not reject a transplanted pig organ. This could result in more successful pig-to-human transplants.

1. Introduction

This is the third Annual Report of the Canadian Biotechnology Advisory Committee (CBAC). The report contains two main sections. The first deals with the committee's activities during the past year. The second presents an overview of biotechnology developments relevant to CBAC's mandate.

In 2002, CBAC reached an important milestone as it completed two major projects and released its final reports on the regulation of GM foods and the patenting of higher life forms. CBAC then turned to the development of its work program for the next three years. The overarching theme for its work program is "Biotechnology in Canadian Society." It has begun to explore projects related to biotechnological innovation and their impacts. CBAC now looks forward to undertaking new special projects, concentrating on biotechnology and innovation. This project more specifically involves examining Canadian institutions to assess how they might be transformed to enable them to better capture the benefits of biotechnology while managing risks and facing social and ethical challenges. This project dovetails with and supports Canada's Innovation Strategy, announced by the Government of Canada in February 2002.

The push for new scientific discoveries and technological innovations continued unabated in 2002. While claims of cloning human babies captured the greatest media attention, a host of lower-profile advances occurred in genomics and proteomics as well as in cell-based technologies such as stem cells and non-human cloning.

Canada, like other countries, continued its efforts to come to grips with the ever-widening horizons created by biotechnological advances and by the social and ethical challenges inherent in them. Substantial additional investments were made in biological sciences and the development of biotechnologies while increasing attention was given to formulating appropriate policies in areas such as patents, health care, privacy of genetic information, GM food labelling, and transgenic technologies such as xenotransplantation and molecular farming.

CBAC, a body of external experts, was established in 1999 to advise the Government of Canada on the policy issues associated with the ethical, social, regulatory, economic, scientific, environmental and health aspects of biotechnology. We also provide Canadians with easy-to-understand information on biotechnology issues as well as opportunities to voice their views on the matters on which we are advising the government. CBAC reports through the Biotechnology Ministerial Coordinating Committee (BMCC). Readers are encouraged to visit our web site at **www.cbac-cccb.ca**

2. CBAC Activities

The year 2002 marked considerable progress for CBAC in both our general activities and our special projects. The committee continued its monitoring and reporting functions, and prepared an advisory memorandum to the Biotechnology Ministerial Coordinating Committee (BMCC) on the *Patent Act* and higher life forms. It also increased its communications and outreach endeavours, particularly with regard to the release of two major reports. The committee also supported work on an "Acceptability Spectrum," a tool designed to facilitate discussion on the acceptability of GM foods or other biotechnology-based products, and developed a new work plan for the next three to five years.

2.A. CBAC Membership

Six new members were appointed to CBAC for three-year terms. Fourteen members were reappointed, seven for one-year terms and seven for two-year terms. The list of CBAC members appears at the beginning of this report, and biographical information about them may be found on the CBAC web site.

2.B. General Activities

i) Monitoring and Reporting Developments

A key aspect of CBAC's mandate is to monitor and report developments in biotechnology and to provide advice to Ministers on emerging issues the committee believes require the government's early attention. Our report on the patenting of higher life forms was quoted extensively in the Supreme Court of Canada's December 5, 2002, decision in the "Harvard Mouse" case. However, the Court concluded that the Harvard Mouse did not meet the definition of an invention and therefore is not patentable. Following the decision, we began preparing an advisory memorandum to Ministers that will recommend how the Government of Canada should respond to the Supreme Court ruling.

ii) Communications and Outreach

CBAC significantly increased its communications and outreach activities in 2002 as part of its mandate to make CBAC and its work more visible by stimulating debate and dialogue among Canadians. These endeavours included issuing news releases, posting items on the web site, participating in regional, national and international forums and major conferences, and expanding the exhibit program. In addition, CBAC members continued to be active in their own right as commentators on major issues of public interest related to biotechnology.

Communications: Much of CBAC's communications effort this past year centred on eliciting views from stakeholders and the public on the committee's two interim reports released in 2001, and on publicizing the release of the final reports last June and August. The reports concerned the two special projects on which CBAC has been focussing its attention since its inception: the regulation of GM Foods, and the patenting of higher life forms.

Comments on Interim Reports: To reach as many people as possible, the interim reports were posted on CBAC's web site. Announcements were placed in specialized journals and magazines, and media releases were issued to tell Canadians about the reports and how to submit their opinions, and copies were also distributed through the partnership network.[2] All interested individuals and organizations were invited to send their views via CBAC's toll-free telephone number or web site as well as by fax or regular mail. In all, 196 submissions were received from organizations, associations and individual Canadians. These inputs were considered by CBAC as it developed the recommendations contained in the final reports.

Wide Publication of Final Reports: The report *Patenting of Higher Life Forms* was released in June. The report *Improving the Regulation of Genetically Modified Foods* followed in August. Both were posted on the web site and distributed through CBAC's partnership network to some 800 recipients, including all Members of Parliament and Senators. The reports were also displayed at several exhibits across the country. Announcements were placed in specialized journals and magazines. News releases advised of their availability. Altogether, some 1,400 GM food reports and 1,200 patenting reports were distributed. As well, several thousand visits were made to the reports on the web site. CBAC responded to several hundred enquiries from the public and the media regarding the two reports and other developments in biotechnology. Media analysis indicated that the GM foods report generated prominent and widespread media coverage following its release.[3]

A key aspect of CBAC's mandate is to monitor and report developments in biotechnology and to provide advice to Ministers on emerging issues the committee believes require the government's early attention.

[2] CBAC's partnership network is a range of groups and individuals who have expressed interest in CBAC's activities and who help distribute the committee's materials to their members and associates.

[3] The media analysis revealed that GM foods dominated the media coverage during the last half of August 2002 due primarily to CBAC's GM foods report. The report garnered prominent coverage over a 24-hour period, but debate concerning the recommendations quickly subsided. Reaction to the recommendations, particularly from editorial writers, was evenly balanced between those urging mandatory labelling and those advocating voluntary labelling. Attention to GM foods during this period was also boosted by Zambia's reluctance to accept food aid that may contain GM material from the U.S.

In 2002, two years of extensive research and consultation culminated in the release of CBAC's final reports on improving the regulation of GM foods and on the patenting of higher life forms.

Ongoing Communications Endeavours: CBAC also continued its regular communications activities involving the issuing of news releases and posting of web site material regarding committee activities. A significant overhaul of the web site was undertaken to improve its general functionality, including features to encourage Canadians to use the Public Forum more actively. The enhanced web site will be launched in the first half of 2003.

Outreach: CBAC built on the citizen engagement plan it initiated last year to increase awareness of the committee and its work and of biotechnology in general to encourage participation in CBAC activities and to expand the partnership network. We also augmented the exhibit program at selected venues across the country as a means of encouraging debate and dialogue.

Forums and Conferences: On March 12, CBAC Chair Dr. Arnold Naimark and the co-chairs of CBAC's GM foods project, Dr. Peter Phillips and Suzanne Hendricks, appeared before the Standing Committee on Health, which was examining issues related to the labelling of GM foods. Outlines of their comments and a copy of CBAC's written statement to the Standing Committee are available on CBAC's web site.

CBAC attended BIO 2002, the annual conference of the Biotechnology Industry Organization, in Toronto on June 9–12, where Dr. Bartha Maria Knoppers, chair of CBAC's Intellectual Property Project Steering Committee, was a guest speaker. This event is the largest biotechnology gathering in the world, this year attracting more than 15,000 participants from 52 countries.

Dr. Peter Phillips was also a guest speaker at the 2002 Agricultural Biotechnology International Conference (ABIC) in Saskatoon, September 16–18, attended by more than 900 participants from 22 countries. The gathering focussed on the convergence of agricultural biotechnology with life sciences, bioinformatics, health care and nutrition.

Dr. Mary Alton Mackey was a panelist at a public forum co-sponsored by Greenpeace and Council of Canadians at the St. Lawrence Centre in Toronto in October to discuss the GM foods report. The discussion centred primarily on the labelling of GM foods.

CBAC Chair Dr. Arnold Naimark presented a written statement at the Government of Canada's National Summit on Innovation and Learning, held November 18–19 in Toronto. More than 450 decision makers from the private, public and voluntary sectors met to discuss Canada's Innovation Strategy, a long-term vision to make Canada more competitive in a knowledge-based economy. The statement appears in this report as Appendix A.

Other events at which CBAC displayed a booth were BioNorth 2002, a biotechnology and life sciences conference, held November 4–6 in Ottawa, Health Canada's International Conference on Post-Market Surveillance of GM Food on October 18–19 in Ottawa, the National Policy Research Conference on October 23–25 in Ottawa, the Annual Ontario Public Health Association Conference on November 18–20 in Richmond Hill, Ontario, and BioFuture 2002 on November 21–22 in Vancouver.

CBAC interacted with the Institute on Governance as the latter proceeded with its program on governance issues related to biotechnology. Dr. Naimark and other CBAC representatives participated in the Institute's December Forum on patenting of higher life forms.

2.C. Special Projects

In 2002, two years of extensive research and consultation culminated in the release of CBAC's final reports on improving the regulation of GM foods and on the patenting of higher life forms. We hope to receive responses to these reports from the government early in 2003. While the completion of these reports effectively marks the conclusion of these special projects, CBAC undertook to monitor developments in these areas and may provide further advice if the need arises. Following the conclusion of these two projects, CBAC developed a new work plan, which is outlined below in the subsection on Continuing Projects.

i) Completed Projects

Improving the Regulation of GM Foods: CBAC concluded that GM foods approved under the current regulatory system do not pose any greater health or environmental risk than their conventional counterparts in the marketplace. However, the committee did identify important opportunities to improve the management and coordination of the system, to enhance communication with the public, and to strengthen the system's capacity for dealing with the more complex GM food products now in development and for incorporating scientific and technical advances as they emerge. In the report, CBAC recommends ways to improve the management and coordination of Canada's food regulatory system, calls for the introduction of a system of voluntary labelling once a standard has been developed, and advises on creating a centralized information service on GM and other novel foods. The report, available on CBAC's web site, also addresses issues relevant to environmental stewardship, international cooperation and informed dialogue.

Patenting of Higher Life Forms: CBAC recommended that patents should not be granted on the human body at any stage of development, and that non-human higher life forms (seeds, plants and non-human animals) meeting the criteria in the *Patent Act* should only be patentable subject to certain limits. The report discusses the key social and ethical issues involved in deciding whether higher life forms should be patentable in Canada. It discusses and makes recommendations for improving the patent system, sharing the benefits of biotechnological inventions equitably, and respecting traditional knowledge in relation to intellectual property. The recommendations reflect social and ethical concerns related to biotechnology and the need to maintain balance between the rights of patent holders and of those seeking access to the benefits of biotechnology inventions. Now that the Supreme Court of Canada has made its ruling on the patentability of the Harvard Mouse, the federal government is considering its implications. CBAC's report provides advice on policy issues to be addressed by the government.

ii) Continuing Projects

"Acceptability Spectrum" Pilot Project: In 2002, CBAC initiated a three-phase pilot project to examine an "Acceptability Spectrum" for GM food and to assess its viability and usefulness. The Acceptability Spectrum is a tool designed to facilitate discussion among those with divergent views on the acceptability of GM foods and feeds.[4] The first phase of the project involved the creation of an Exploratory Committee, consisting of non-government members who reflect a wide range of interests, to develop and steward the tool through an extensive consultation process. Phase 2 involved six stakeholder sessions, held in March and April in Montréal, Ottawa, Hamilton, Toronto and Vancouver, to review and improve the dialogue tool. The results of the sessions were compiled in a summary report, available on CBAC's web site. Several federal government departments contributed supplementary funding to allow completion of this phase of the project.

Privacy and Genetic Information: The objective of this project is to examine the mechanisms currently in place in Canada to protect the privacy of genetic information. Access to genetic information is a matter of increasing importance to the public and to governments around the world, and CBAC continues to monitor developments. Among the initiatives undertaken in this area in 2002 was the preparation of a session titled *Biobanks: Overview*

[4] The acceptability framework is based on the premise that different kinds of GM foods and feeds can be classified along a four-level spectrum: acceptable, acceptable with certain conditions, unacceptable at present and until more is known or a given standard is met, and not acceptable under any circumstances.

and Issues for a Genome Canada symposium to be held in February 2003. The committee commissioned four papers for the session, each describing current practices in a specific area and identifying any gaps or questions that need to be addressed. The purpose of the papers is to identify and describe the relevant laws, policy and data for future policy analyses and development in Canada concerning large-scale collections of genetic information.

Incorporating Social and Ethical Considerations into Biotechnology: CBAC's original work plan included a special project on incorporating social and ethical considerations into decision making about biotechnology. As a first step, CBAC developed a statement of principles and values. These principles and values were discussed during the consultations surrounding the GM food and the patenting of higher life forms projects. The statement was made available to the public for additional comments. The lessons learned during this initial phase are to be assessed early in 2003, and a decision will be taken on the focus of future work in this area.

Institutional Transformation: CBAC will examine how Canadian institutions, both within and outside government, might be transformed to enable them to best capture the benefits of biotechnology while managing risks and facing social and ethical challenges. These transformations may involve changes in how institutions are organized and perform their functions, the development of new organizations, and/or the cultivation of new partnerships, alliances and networks. The institutional transformations fall into two categories: those that focus on social and economic development (e.g., education, research, knowledge transfer, risk capital) and those that focus on regulatory matters (e.g., risk assessment, management and communication, health, environment and respect for core social values). The exploration of this topic will involve research to determine its parameters, examination of the short-term issues and opportunities associated with biotechnological innovations, and assessment of the pathways for longer-term institutional transformation.

New Work Plan: Following completion of its two special projects in 2002, CBAC developed a new articulation of the general theme of its ongoing work; namely, *Biotechnology in Canadian Society*. As noted earlier, a statement on this matter (see Appendix A) was presented at the Government of Canada's National Summit on Innovation and Learning held November 18–19 in Toronto.

Following completion of its two special projects in 2002, CBAC developed a new articulation of the general theme of its ongoing work; namely, **Biotechnology in Canadian Society.**

3. Recent Developments in Biotechnology

This section briefly summarizes some of the significant developments during the reporting period that are particularly relevant to CBAC's work or that may influence its activities in the future.

3.A. Canada's Innovation Strategy

In February, the federal government announced Canada's Innovation Strategy, which outlines a long-term vision to make Canada more competitive in a knowledge-based economy. Supporting development of Canada's biotechnology sector while protecting the public interest is a key component of the Strategy. Biotechnology has the potential to fundamentally transform innovative economies. In the context of the Strategy, the government reiterated its commitment to achieving the full scope of benefits that biotechnology has to offer and to identifying areas where challenges exist and improvements are required.

Among the Strategy's "early-action" target areas that impact on biotechnology are: the advancement of the target dates for key regulatory reviews from 2010 to 2005, including early action on the drug approval process, an agreement with universities and colleges to double research and triple commercialization, and continued funding for research and development and indirect costs.

(See above subsection 2.C.ii on Institutional Transformation as well as Appendix A for CBAC's statement issued in conjunction with the National Summit on Innovation and Learning.)

3.B. Genomics, Proteomics and Related Developments

Advances in genomics and proteomics are pervading life sciences research. They have the potential not only to expand our understanding of fundamental biological phenomena but also to generate technological innovations with significant economic impact.

Canada has committed itself to being at the forefront of this important field. Genome Canada to date has received $300 million from the government to develop and implement a national strategy in genomics research. The agency has invested more than $293 million in 56 large-scale projects across Canada. With funding from other partners, this amounts to $586 million invested in innovative genomics and proteomics research. Important investments in genomics research have also been made through the National Research Council and the Canadian Institutes of Health Research (CIHR).

The Pan Canadian Proteomics Meeting held in Toronto on November 26–27 attracted more than 100 representatives of the scientific, industry, government and funding agency communities.[5] A decision was made to create the Canadian Proteomics Network. The network will include all Canadian scientists working on proteomics and will be supported through a partnership among Genome Canada, CIHR and industry.

In December, Genome Canada and the Danish Ministry of Science, Technology and Innovation signed a Memorandum of Understanding on Co-operation in Genomics to support initiatives to increase scientific and industrial exchanges and to identify areas of joint research such as population genomics, agriculture and food genomics, and drug discovery. This is the fourth such international agreement for Genome Canada in the last 18 months.[6]

The Canadian Museum of Nature, Genome Canada and CIHR announced in January that the country's first national exhibition on genomics will start a three-year, cross-Canada tour in spring 2003. "Putting the Gee! in Genome" will celebrate Canadian genomic discoveries and encourage public discussion of genomics and its impact.

The Human Genome: A new type of genome map, called the haplotype map, has been developed.[7] Some researchers believe the haplotype map may be a more efficient way to find the genes involved in complex diseases and may offer insight into human evolution and migration. The International Hap Map Project builds on the results of the Human Genome Project. In another development, geneticists at deCODE Genetics in Iceland created a new genome map using their database of genetic information from Icelandic families and the sequence of the Human Genome Project to increase the accuracy of the original genetic map fivefold and correct 104 mistakes in the draft human genome sequence.

Craig Venter, renowned for his role in mapping the human genome, announced plans to offer a service in which a person's entire genetic code would be mapped for about US$621,500. Other researchers say the service would be of little use, because the scientific community can currently test for only a few dozen diseases, and so the client would not

[5] The meeting was sponsored by the Canadian Institutes of Health Research, the Canadian Biotechnology Strategy Fund, and Genome Canada and its centres.

[6] Similar agreements are in place with Sweden, Spain and the Netherlands.

[7] The human genome contains some three billion pairs of DNA. These are organized into sequence variations or "haplotype blocks" comprising about 10,000 or more base pairs. By breaking up the human genome into blocks with known genetic variations, researchers can go directly to those blocks and search for disease genes rather than having to search through all three billion DNA base pairs.

receive substantial information. Dr. Neil Risch, a leading population geneticist, stated in a paper that race can be useful in understanding disease and drug response among different ethnic groups. This statement challenges the emerging view that race is a biologically meaningless concept, as the Human Genome Project has revealed human beings have more than 98 per cent of their genetic makeup in common.

Impact on Human Health: Advances in genomics and proteomics are expected to have highly significant impacts on human health. The sidebar illustrates some of the advances in the field of genetic testing and improved pharmaceuticals. Gene therapy has proven to be more difficult than anticipated. While some limited success has been achieved in certain circumstances, much work remains to be done. Clinical trials conducted on humans continue to be closely monitored and, in some cases, have been cancelled.[8]

Some of the research in gene therapy has focussed on finding ways to deliver genes other than through a viral vector. One method being tested on cystic fibrosis patients involves condensing the DNA molecule into a tiny ball shape that can pass through the nuclear membrane. Another method used in gene therapy aimed at shrinking tumors in mice involves delivering a gene via an injected nanoparticle that targets only new blood vessels that have formed to feed the growing tumor, thus starving the tumor. Another new type of gene therapy, called RNA trans-splicing, has been used to treat mice with a form of haemophilia.

The World Health Organization stated in a major report that developments in genetics could bridge the public health gap between rich and poor countries. It recommended creation of a US$1.5 billion fund for genetic research aimed at ameliorating health problems in poor countries. In response to this report, the University of Toronto's Joint Centre for Bioethics undertook a study that identified the top 10 biotechnologies that could improve global health within the next few years. The list included the development of cheap vaccines, ways to ensure clean drinking water and methods to genetically modify foods to enhance nutritional value.[9]

Non-human Genomic Developments: The genomes of the parasite that causes malaria and the mosquito that transmits it have been sequenced. This means research may now be

Sampling of Gene Discoveries in 2002

- The Health Network in Toronto identified two genes that play a role in heart disease, one that protects against heart disease and one that contributes to it.
- Several projects turned up genes that could lead to better screening and treatment for various types of cancer such as liver, breast and bowel cancer.
- People with a particular genetic pattern tend to develop AIDS more slowly.
- Six genes related to Fanconi anemia, a rare childhood cancer syndrome, were found to be linked also to BRCA 1 and 2.
- People with facioscapulohumeral muscular dystrophy have fewer copies of the DNA sequence D4Z4.

[8] In 2002, two toddlers with Severe Combined Immunodeficiency (SCID) who were treated with gene therapy later developed an apparent leukemia-like side effect. The first sick toddler prompted U.S. and French scientists in October to stop gene therapy experiments for SCID. The second sick child resulted in the temporary halting of 27 more gene therapy experiments other than those for SCID. Scientists have long warned that cancer is a possible risk from gene therapy.

[9] The survey of 28 leading scientists from around the world focussed on the needs of the developing world and how developments in genomics and biotechnology could benefit the poorer countries. Overall, the experts gave higher ratings to simpler technologies than to high-technology treatments that would likely benefit only those in the western world.

able to develop effective prevention and treatment methods. Dogs and cows joined the high-priority list for genomic sequencing because of their respective medical and agricultural importance. A single-celled organism called *Oxytricha trifallax* also appears on the list because of its compact genome, which could help speed up the search for genes in humans. Already on the list are chickens, chimpanzees, honeybees, sea urchins, *Tetrahymena* and 15 species of fungi. Craig Venter is working on a synthetic chromosome to replace the genetic material of a bacterium. The ultimate goal is to create bacteria that can remove excess carbon dioxide from the air or produce cheap hydrogen fuel.

In April, two research groups published draft sequences of the genome of two different rice varieties. Rice is the first food crop to be sequenced and this significant development could help in the sequencing of other cereal crops. Because rice is the staple food of two-thirds of the world's population, this information could help increase food production and enhance nutrition.

3.C. Stem Cells and Cloning

Stem Cell Research: Researchers are working toward using stem cells as possible new treatments for common diseases such as diabetes and Parkinson's as well as for growing many types of replacement tissues from a patient's own cells. The controversy in this area primarily concerns the fact that the most useful type of stem cells is obtained from human embryos. While research over the past two years has made several advances in non-embryonic stem cells — that is, stem cells from human adults as well as umbilical cords and placentas from live births — a number of studies appeared to refute earlier research demonstrating that adult stem cells are multipotent and can repair other tissues in the body.[10] Research continued in 2002 into the various uses of embryonic and adult stem cells as well as stem cells derived from primate parthenotes.

Cloning Research: Much recent media coverage concerning cloning has focussed on the possibility of cloning humans and claims that this had been accomplished.[11] Meanwhile, research continued on animal cloning as a means of one day treating human disorders and

[10] Some of the debate centres on whether the stem cells are naturally multipotent or whether this is brought on by culturing techniques. While some adult stem cells may indeed be multipotent, more research is required. Many scientists call for more rigorous standards for stem cell research.

[11] The Raelians, a Quebec-based cult, announced in December that a human clone had been born on December 26, 2002, although no proof accompanied the announcement. In terms of media coverage, this was the biggest single biotechnology story since tracking for the Biotechnology Assistant Deputy Minister Coordinating Committee began in September 2000. The extensive coverage raised concerns that such announcements would undermine legitimate research involving cloning to obtain stem cells for therapeutic purposes. Dr. Severino Antinori, an Italian doctor, also announced that a woman was expected to give birth to a cloned boy in January 2003.

While cloning for human reproduction is generally regarded as unacceptable, there is much less consensus on cloning for therapeutic purposes.

illnesses and, in some cases, even protecting against biological warfare.[12] Advances in animal cloning included extending the species to be cloned,[13] developing organs and tissues from cloned cells, and gaining insight into the health status of cloned animals.

Policies Regarding Cloning for Human Reproductive and Therapeutic Purposes: While cloning for human reproduction is generally regarded as unacceptable, there is much less consensus on cloning for therapeutic purposes. Few nations have specific cloning laws. Those that do have chosen to ban cloning for reproductive purposes while their legislation respecting cloning for therapeutic purposes is much less consistent. California,[14] U.K., China and Japan, for example, allow cloning to obtain stem cells. Canada, Australia, France and some U.S. states appear likely to take an intermediate position, allowing some forms of embryonic stem cell research but banning cloning for therapeutic purposes. Canada's draft legislation on reproductive technologies as well as the guidelines issued by the Canadian Institutes of Health Research in March both recommend allowing some forms of embryonic stem cell research but banning cloning for therapeutic purposes.[15] Germany approved strict regulations prohibiting scientists from deriving human embryonic stem cell lines and banning the import of these cells without evidence that no other feasible way exists to conduct the research. The approval of imports would be subject to the establishment of a national commission to review all import proposals.

Work on an international treaty banning human cloning was delayed for at least a year because of differing views among some nations as to the extent of the treaty. The U.S. and the Vatican want the treaty to prohibit all forms of human cloning. France and Germany want a treaty that would immediately ban cloning for reproductive purposes. Given the mixed views on cloning for therapeutic purposes, France and Germany want to proceed now with a ban on cloning for reproductive purposes only, without waiting for a consensus to be reached on cloning for therapeutic purposes.

[12] For example, in one project, scientists cloned cows having functional human antibody genes by using artificial chromosomes to carry the antibody genes into the cows. Being able to isolate human antibodies from cows' milk could someday advance the treatment of hereditary immune deficiencies and viral infections and could be used to protect against biological warfare.

[13] For example, a kitten has been cloned as part of a larger, more difficult project to clone a dog. Plans have been made in Australia to clone an extinct species called the Tasmanian tiger from preserved male and female specimens.

[14] California's new law, adopted in September 2002, permitting embryonic stem cell research, is at odds with the restrictions on federal funds for embryonic stem cell research. The new law enables embryos to be both donated and destroyed for stem cell research but bans the sale of embryos.

[15] Canada's proposed legislation on reproductive technologies was read for the second time in the House of Commons on May 28, 2002, and referred to committee. The bill is expected to be passed in the first half of 2003.

In the U.S., Senator Sam Brownback announced in June that he was abandoning efforts to persuade the Senate to pass a bill banning all human cloning, including cloning for therapeutic purposes, and would instead work on approval of a two-year moratorium on cloning. The U.S. has patchwork legislation among many states. Some people believe this will create confusion over how to regulate cloning, while others believe it could help stimulate national action.

Stanford University stated that it intends to experiment with cloning technology. This has further fuelled the debate over the use of stem cells. Researchers at the university will use cloning to develop stem cell lines for cancer and other health research, which they will share with outside researchers. This could benefit stem cell research in general, as many scientists in the U.S. complain of inadequate access to the currently approved stem cell lines.

The Massachusetts Medical Society, which owns and publishes *The New England Journal of Medicine*, approved a resolution supporting stem cell research. The society favours federal funding for ethically conducted medical research involving embryonic stem cells derived from cloning. It also encourages the state congressional delegation to support federal funding of this research.

The Pew Initiative on Food and Biotechnology released a poll of U.S. citizens in December that found respondents were both fearful and hopeful about the advance in genetic technologies. They tended to distinguish between health and non-health applications of the technologies. For example, two-thirds approved of using genetic testing to help parents avoid producing offspring with genetic diseases, but more than 70 per cent opposed using these technologies to select traits such as intelligence. Seventy-six per cent opposed human cloning and 22 per cent believed that a human has already been cloned.[16] Respondents believed that government needs to regulate genetic technologies, particularly human reproductive cloning.

In the U.K., where cloning for therapeutic purposes is allowed under strict conditions, scientists from the Roslin Institute, where the sheep Dolly was cloned, announced plans to apply for a licence to experiment on human embryos for medical purposes. The Institute's Professor Ian Wilmut has also applied for a licence to conduct research on parthenogenesis[17] of human embryos. Meanwhile, the U.K. Medical Research Council announced in September that the National Institute for Biological Standards and Control will be responsible for setting up the previously announced U.K. Stem Cell Bank.

Pre-implantation Genetic Diagnosis (PGD)

In the U.K., the Human Fertilisation and Embryology Authority (HFEA) decided in February that a British couple could use the embryo screening technique called PGD to test for an embryo that matches their two-year-old son, Zain. Zain has a rare inherited blood condition, thalassaemia, and needs a bone marrow transplant to survive. The parents planned to use cells from the umbilical cord of the new baby for the bone marrow transplant. However, in December, Britain's High Court ruled that the HFEA does not have the right to license the tissue typing and selection of test tube embryos to save the lives of their siblings. The HFEA may appeal the Court's decision. The court case was initiated by a pro-life campaigner on behalf of a group called Comment on Reproductive Ethics.

[16] This survey took place before the Raelian announcement.

[17] Parthenogenesis is a special type of sexual reproduction in which an egg develops into an embryo without the involvement of a sperm.

3.D. Agricultural Biotechnology

Labelling of GM Food: Many countries either have introduced labelling requirements for GM foods or are in the process of doing so. Several nations including Canada are working within the Codex Alimentarius Commission to develop an international voluntary standard for labelling. Developments in this area continued to unfold in 2002, notably in Canada, the U.S. and Europe.

CBAC's report *Improving the Regulation of Genetically Modified Foods*, issued in August, recommended introducing a voluntary labelling regime but only after an effective standard with broad support has been developed. It also recommended that Canada enhance its efforts, in concert with other nations, to develop a harmonized approach to labelling with special emphasis on developing an internationally accepted labelling standard.

The Canadian Council of Grocery Distributors and the Canadian General Standards Board (CGSB) continued their work on developing a standard for the voluntary labelling of GM foods. The most recent draft of the standard was published in December 2001. Through 2002, this draft was being revised before going to final ballot. Two parliamentary standing committees also addressed the issue. The Standing Committee on Health, whose mandate includes consideration of the best ways to meet consumers' needs for food information, suspended its hearings in April 2002 and may resume in the first half of 2003. The Standing Committee on Agriculture studied the impact of voluntary and mandatory labelling on agricultural producers and the agri-food industry. It issued its report in June. Among its recommendations, it called on the government to continue developing a voluntary standard for labelling foods according to whether or not they were derived from biotechnology; the standard would apply only to genetically engineered organisms, as proposed in the CGSB draft standard.[18]

In October, the U.S. issued voluntary guidelines, scheduled to become mandatory in September 2004, requiring U.S. retailers to display country-of-origin information to consumers at the final point of sale for imported and domestic fresh beef, pork and lamb, fish and seafood, and fruit and vegetables. Exemptions are granted if the item is an ingredient in a processed food item or sold in a food service establishment. Canadian and American food companies, packers and processors protested the guidelines, calling them costly and unnecessary. Agriculture and Agri-Food Minister Lyle Vanclief called U.S. guidelines flawed and unworkable, and said they run counter to the long-term interests of both

NGO Consumer Information Initiatives

- The Canadian Institute for Environmental Law and Policy released a report in March 2002 titled *A Citizens' Guide to Biotechnology: Helping Citizens Have a Real Say in the Development of Biotechnology in Canada.*
- In October, Greenpeace released its Shoppers Guide telling consumers which of some 1,000 products commonly found in Canadian supermarkets do or do not contain genetically engineered ingredients.

[18] This "narrow definition" would include only organisms produced through recombinant DNA technology and would exclude products derived from chemical or radiation mutagenesis.

countries. The Minister said his department would review the guidelines and consult with stakeholders to determine an appropriate course of action.

In the U.S. in November, Oregon voters roundly rejected an initiative that would have required labels on food containing genetically engineered material. The measure was defeated by 73 per cent of those voting in a state plebiscite.

The European Parliament backed a proposal that would increase labelling requirements for food and lead to more stringent rules for testing and identifying foods and animal feed for genetically engineered (GE) content. The proposal would decrease the threshold for GE content from 1 per cent to 0.5 per cent and require manufacturers to trace foods to their place of origin.

Agricultural Biotechnology and the Environment: Most of the news concerning agricultural biotechnology and the environment in 2002 emanated from the U.S. Much of it concerned unapproved mixing of GM with non-GM crops. Traces of StarLink corn were found in an American shipment headed for Tokyo and its food supply, and Zambia refused food aid in the form of GM corn from the U.S.

Two teams of government researchers confirmed University of California–Berkeley biologist Ignacio Chapela's findings that GM corn was growing in Mexico. The alleged presence of transgenic corn in traditional strains of maize has caused much controversy. Some scientists claim that Chapela's methodology was flawed and that the results are therefore not conclusive. It is still unclear whether transgenic corn has actually invaded Mexico. In June, the Secretariat of the Commission for Environmental Cooperation (CEC), part of NAFTA, announced that it would prepare a special report on the potential effects of transgenic corn on traditional maize varieties in Mexico. An international advisory group was named in October, which included two CBAC members, Dr. Conrad Brunk and Dr. Peter Phillips. The report is expected to be released early in 2004.

Three companies were fined for not following proper procedures. Two did not follow proper isolation procedures for their experimental crops. A third was fined under the *Plant Protection Act*, 2000 and ordered to pay approximately $2.8 million to buy and destroy soybeans grown on land previously used to grow GM corn.

The U.S. National Research Council called on the government to review the potential environmental effects of new transgenic plants more rigorously before approving them for commercial use, and to monitor GM plants after they enter the marketplace to confirm pre-market assessments. A U.S. poll found that respondents were evenly divided over whether

CBAC's report* Improving the Regulation of Genetically Modified Foods, *issued in August, recommended introducing a voluntary labelling regime but only after an effective standard with broad support has been developed.

GM crops and other agricultural biotechnology products hurt or help the environment when given basic information on risks and benefits.

In another development, Australian researchers found that the pollen from non-GM oilseed rape (canola) can spread long distances but only in small amounts. The same would likely be true of GM canola pollen, which will make it difficult to achieve perfect isolation between GM and non-GM crops involving plants such as canola.

Scientific Developments: Among the scientific developments in 2002 were several concerning rice, the staple food of two-thirds of the world's population. In April, two research groups published draft sequences of the genome of two different rice varieties. Other advances included rice plants that require less water and others that carry a gene for a human breast milk protein. Japanese scientists developed a technique that allows them to more efficiently render specific genes in rice inactive. This could help scientists discover the function of plant genes and result in more accurate genetic modification.[19] These developments and others could help to increase global food production and enhance nutrition.

The Food and Agriculture Organization and the Consultative Group on International Agricultural Research requested donations from national governments, foundations and corporate sponsors to establish a fund to help secure the genetic information contained in the world's major crops.

3.E. Patents and Access to Health Care

The issue of gene patents came to the fore in Canada in 2001 and 2002 when an American company invoked a patent claim to block laboratories in Canada from using a test for detecting a genetic predisposition to the development of certain types of inherited breast cancer. The U.S.-based Myriad Genetics Laboratories demanded that all breast cancer screening tests based on two genes on which it holds patents — BRCA 1 and 2 — must be done through its own laboratories.[20] The company threatened to sue any provincial agency that permitted the tests to be done in any other laboratories. British Columbia stopped funding of the test. Ontario has refused to do so. Meanwhile, Ontario released a report titled *Genetics, Testing and Gene Patenting: Charting New Territory in Healthcare*, which

[19] With regard to rendering specific genes inactive, U.S. researchers knocked out the gene in soybeans that is responsible for many of the allergic reactions that people have to soya.

[20] New research reported in August demonstrates that the risk of developing breast cancer due to BRCA 1 and 2 is much lower than originally thought. The previous estimate was 70–85 per cent of those carrying the mutation by age 70; the current estimate is 26 per cent.

calls for a comprehensive review of Canada's *Patent Act* and provides a range of concrete proposals to deal with the problems associated with gene patents. This report was discussed at the January meeting of the provincial and territorial premiers.

In the U.K., the ability to diagnose and study haemochromatosis, a debilitating disease caused by iron overload in the body, is being hampered by the patenting of a key gene. The patent gives the holder a monopoly on testing for the mutations that cause haemochromatosis. According to a study in the February edition of *Nature*, this monopoly on testing has resulted in 30 per cent fewer laboratories being able to offer the test.

On July 23, the Nuffield Council on Bioethics released *The Ethics of Patenting DNA*, which proposed an ethical framework for gene patenting. It recommended that granting patents on DNA sequences should be the exception rather than the rule. It suggested that the tests of inventiveness and usefulness should be more rigorously applied to applications for genetic patents and that patents for a DNA sequence as a diagnostic test or gene therapy should rarely be granted.

The U.S. is attempting to create a legal framework for the regulation of biotechnologically based medications produced by generic drug manufacturers. Several such medicines no longer have patent protection. It is unclear what procedures the new generic versions of these medicines will be required to undergo to be approved by the Food and Drug Administration. These products, which are typically composed of proteins, enzymes or antibodies, are much more complex to replicate than drugs that are merely chemical compounds. It is not known if their safety can be assured using the same standard. The Biotechnology Industry Organization believes such products are so complex that generics would have to undergo the same approval process that the medication originally did in order to prove their safety and efficacy.

The European Patent Office (EPO) decided in July that the "Edinburgh"[21] patent should be maintained in an amended form so that it does not include human or animal embryonic stem cells. The Opposition Division of the EPO decided that the previously granted patent did not comply with the requirements of the European Patent Convention.

GM Animals and the Environment

- At the University of Guelph, the carcasses of 11 genetically engineered "enviropigs" were mistakenly taken to a rendering plant and made into animal feed. Environmental groups felt the animal feed should have been recalled, but government officials decided the risk was minuscule.
- The U.K. Agriculture and Environment Biotechnology Commission issued a report stating that GM fish should not be farmed in offshore aquatic net pens due to the potential for escape. It called for creation of an advisory body on GM and cloned animals to monitor developments and advise the government.

[21] The Edinburgh patent describes a method of using genetic engineering to isolate stem cells, including embryonic stem cells, from more differentiated cells in order to obtain pure stem cell cultures. The granting of the patent led to protests and triggered a major public debate on the patenting of stem cell technology. The debate centred on whether the patent extended to humans. The EPO determined that the previously granted patent violated Article 83, which stipulates that the invention be disclosed in a manner that allows it to be carried out by an expert, and Rule 23d(c), which excludes the use of human embryos for industrial or commercial purposes.

3.F. Privacy and Genetic Information

There are two areas of particular concern related to the inappropriate use or release of genetic information. One is whether stored samples of biological materials should be the property of the research institution, the researcher or the person from whose body they came. The other is the potential use of genetic information to discriminate against individuals in matters such as employment, credit, insurance or pension eligibility. Both of these areas manifested themselves this year, the first one most notably in Canada and the second primarily in the U.S. and U.K. While few countries have legislation dealing specifically with genetic information and discrimination, this situation is gradually changing.

Members of the Nuu-chah-nulth (Nootka) First Nation on Vancouver Island discovered that DNA samples they had donated almost 20 years ago for rheumatoid arthritis research have been used for other types of research without their consent. The geneticist who originally collected the samples moved from the University of British Columbia to the University of Utah and then to Oxford, taking the samples with him and using them for other research projects. The geneticist acknowledges that he did not obtain renewed consent, and UBC officials acknowledge that the participants consented only to arthritis research. The situation has led to the introduction of policies at the British Columbia and Utah universities that researchers must obtain consent for each new use of a stored sample for research. The University of Utah also introduced the policy that study samples are university property.

With regard to genetic testing and possible discrimination, the Ontario Human Rights Commission released a report in February on consultations it had conducted concerning human rights issues in insurance. In announcing the report, Ontario Human Rights Chief Commissioner Keith Norton stated that genetic testing and related information should not be used to deny insurance or invoke exclusionary periods on the basis of a "pre-existing condition."

In the U.S., senior officials of the Bush administration called on Congress to pass legislation to bar employment and insurance discrimination based on genetic information, as the current laws are seen to offer insufficient protection. Meanwhile, a U.S. railroad company, Burlington Northern Santa Fe Corp., agreed to pay $2.2 million to workers it had tested for genetic defects in order to settle charges that it had illegally tested these workers. While the information was not actually used to screen out employees, the collection of the information was seen as discriminatory. In the end, the DNA test that was performed (to determine a genetic predisposition to carpal tunnel syndrome) was found not to provide any useful information about the employees.

Federal Funding for Plant Research

In October, the Government of Canada announced funding totalling $10 million over the next five years to the National Research Council's Plant Biotechnology Institute in Saskatoon for a program aimed at developing crops for enhanced human health. The project aims to develop and improve plants that produce natural health products as well as to produce pharmaceutical products in plants through molecular farming technologies.

In the U.K., the Human Genetics Commission issued two documents regarding genetic information and privacy. In May, it released a report recommending that stricter controls should be placed on the use of DNA data, and that independent bodies should oversee the management of DNA collections. The commission also issued a consultation document concerning the supply of genetic tests directly to the public. Because genetic testing does not offer simple yes or no answers, some believe the test results need to be interpreted by qualified individuals. Others argue that home tests should be available over the counter so that people who would not go to the doctor can get tested. Also in the U.K., GeneWatch warned doctors that they should be sure the necessary safeguards are in place before their patients submit samples to the new, national genetic collection, Biobank UK.

In August, after 18 months of investigation and wide public consultation, the Australian Law Reform Commission (ALRC) and the Australian Health Ethics Committee (AHEC) released a wide range of recommendations that would allow employers to fulfil their legal obligations while protecting Australian employees from potential misuse of genetic testing and information. The Nuffield Council report mentioned earlier also touched on these issues.

3.G. Transgenic Technologies and Xenotransplantation

A new method was developed to increase the efficiency of creating transgenic mammals. Tosk, a biotechnology company in San Francisco, said it is able to add genes to mammalian cells with unprecedented efficiency because of the use of transposons.[22] This finding could also have implications for conducting gene therapy on humans.

Researchers are planning to genetically modify an invasive European species of carp in order to eradicate it from several Australian rivers and streams where it has taken over. Multiple copies of a gene called "daughterless" will be introduced into the carp, which will then be released into the waterways. The genetic modification will prevent the fish from producing female offspring. The process has not yet been approved.

Scientists are adding a gene to mosquitoes in the hopes of halting the transmission of malaria. The added gene prevents the malaria parasite from moving into the mosquito's salivary gland and therefore from entering any humans that the mosquito bites. It is hoped that GM mosquitoes would gradually replace wild mosquitoes, thus reducing malaria in developing countries.

[22] Transposons are units of DNA that can move from one position to another in the same or a different genome. They trigger changes in gene expression by shutting off genes or causing insertion mutations.

Nexia Biotechnologies Inc. and the U.S. Army Soldier Biological Chemical Command reported that they have produced spider silk proteins via cell culture techniques. This recombinant spider silk may have medical, military and industrial applications, as spider silk has a unique combination of high-performance properties including toughness, strength, lightness and biodegradability.

PPL Therapeutics, the Scottish firm that owns the Roslin Institute where Dolly was cloned, announced it has cloned pigs that have been genetically engineered so that the human immune system would not reject a transplanted pig organ. It has been suggested that pig-to-human transplants may be feasible within four years.

4. Canada's Biotechnology Sector[23]

Canada's biotechnology sector consists of more than 400 companies, employing 62,000 individuals. Canada ranks second in the world, after the U.S., in terms of number of firms, and third after the U.S. and the U.K. in generating revenues.

The greatest concentration of biotechnology companies in Canada lies in the therapeutics sector (57 per cent), followed by agriculture (15 per cent), diagnostics (10 per cent), genomics (9 per cent), environment (8 per cent) and medical devices (1 per cent).

Canada's biotechnology sector is distributed across the country. The dominant players are Quebec with 133 biotechnology firms (32 per cent), Ontario with 119 firms (29 per cent) and British Columbia with 81 firms (20 per cent). Quebec, 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.

In 2001, annual revenues reported by Canada's publicly traded biotechnology firms exceeded $1.5 billion, a 300-per cent increase over 1997 levels. More than 400 biotechnology products are in the research pipeline. Canada's growing R&D capacity in biopharmaceuticals is a natural evolution from a research base that has won an international reputation in fields such as genomics, proteomics, bio-informatics, immunotherapies, protein engineering and new drug delivery systems. Canada has established the fastest rate of growth in the number of workers devoted to R&D, in external patent applications and in business expenditures on R&D among G7 countries.

Factors believed to be essential to continued growth of Canada's biotechnology sector include the country's strong base of scientific expertise, its continuous investment in research and development, access to early-stage capital, a supportive tax environment and government leadership in economic and innovation policy.

[23] Information in this section derives from *Beyond Borders: The Canadian Biotechnology Report 2002*, Ernst & Young.

Appendix A. Biotechnology and Canadian Innovation

Statement on the Occasion of the National Summit on Innovation and Learning

November 18–19, 2002

The Institutional Transformation Imperative

Transformative technologies like biotechnology bring fundamental changes to societies and thus hold important implications for all Canadian regions, communities and sectors. Through its capacity to provide important benefits for health, the environment and our quality of life, biotechnology is bringing change, as well as challenging existing institutions and beliefs. Its effects will be even more profound in the future. The development and beneficial application of biotechnological innovation must therefore be a central element in the articulation and implementation of Canada's Innovation Strategy.

Complex transformative technologies like biotechnology also carry with them risks, pressures on existing regulatory and decision-making institutions, and create tensions and trade-offs that cut across personal and social values. As Canada moves forward to capture the benefits of biotechnological developments, we must ensure that these risks and tension are addressed and managed through institutional changes in and outside all levels of government in Canada.

The work of the Canadian Biotechnology Advisory Committee (CBAC) to date has clearly demonstrated that policies and programs seeking to promote successful and sustainable innovation in the broadest sense must focus not only on the technical aspects of innovation but also on fostering the social and institutional transformations necessary to realize the full social and economic benefits of technological advances and to manage the challenges, pressures and uncertainties.

CBAC is embarking on a major analysis of this institutional transformation imperative and, by next autumn, intends to provide strategic advice to federal Ministers on the more immediate issues and opportunities. CBAC will also inform Ministers of the major topics, background analysis, consultation processes and partnerships it intends to pursue in developing advice on the longer-term institutional transformations required to achieve the goals of:

- ensuring Canadians capture the economic, social, health care, environmental, and quality of life benefits from biotechnology; and
- addressing and managing the potential challenges, risks, hazards, tensions and trade-offs associated with this transformative technology.

Innovation Is Everybody's Business

CBAC will be approaching the foregoing task with the realization that there is a need for a much broader and deeper understanding of the individual and institutional factors that facilitate or hinder responsible and effective development and assimilation of biotechnological advances so that innovative ways can be found to:

- address the development of biotechnology in a manner that reflects the values of Canadians, protects the environment, ensures sustainability, and builds social cohesion and consensus;
- achieve a fair distribution of benefits including greater equality of access to useful products and services for all Canadians and for the citizens of developing countries; and also to achieve a fair distribution of exposure to risks; and
- nurture our intellectual and entrepreneurial resources, thereby strengthening our economic independence and sovereignty, boosting employment, stimulating greater productivity and increasing our standard of living.

Identifying and successfully introducing innovations requires involvement of all sectors of Canadian society in the process of institutional transformation. The transformations may involve changes in how existing institutions, both within and outside government, are organized and perform their functions, the development of new organizations or the development of partnerships, alliances and networks among institutions and organizations. The institutional transformations can be considered to fall into two categories. The first is those that focus on social and economic development (e.g., education, training, research, knowledge transfer, the search for best practices, risk capital supply, staying abreast of scientific and technological advances, new approaches to enhancing access to benefits). The second is those that focus on regulation (e.g., risk assessment, management and communication, protection of human and animal health, the environment, and respect for core social values). In implementing institutional transformation, it will be necessary to strike a sustainable balance between competing objectives and social values.

Canada seeks to be a responsible world leader in the development, application, stewardship and governance of biotechnology and has a firm basis for pursuing that goal. With the impetus provided by the Innovation Strategy and sustained commitment, there is every reason to be confident that we can capitalize on these strengths for the benefit of all Canadians by matching scientific and technological ingenuity with social ingenuity.

CBAC supports a strategy for innovation that is more than simply the invention of new products and processes and establishing ways of getting them into the hands of Canadians. It must be seen as creative activity that takes place within a broader context and that embraces an imperative to transform our institutions. Our members look forward to contributing to such a strategy and to an expanded understanding of both the benefits and unintended consequences of biotechnological innovation.

Appendix B. Reports and Public Policy Developments

January

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Ontario Human Rights Commission, *Human Rights Issues in Insurance: Consultation Report*, February 2002, **http://www.ohrc.on.ca/english/consultations/insurance-consultation-report.shtml**

United Kingdom, House of Lords, *Select Committee on Stem Cell Research Report*, London, February 13, 2002, **http://www.parliament.the-stationery-office.co.uk/pa/ld200102/ldselect/ldstem/83/8301.htm**

March

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Canadian Institutes of Health Research (CIHR), *Human Pluripotent Stem Cell Research: Guidelines for CIHR-funded Research*, Ottawa, March 4, 2002, **http://www.cihr.ca/about_cihr/ethics/stem_cell/stem_cell_intro_e.shtml**

National Research Council, *Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation*, Washington, DC, March 2002, **http://www.nap.edu/books/0309082633/html/**

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South African Medical Research Council, *Guidelines on Ethics for Medical Research: Reproductive Biology and Genetic Research*, Tygerberg, April 2002, **http://www.sahealthinfo.org/ethics/ethicsbook2.pdf**

World Health Organization, *Genomics and World Health*, Geneva, May 2002, **http://www3.who.int/whosis/genomics/pdf/genomics_report.pdf**

May

An *Act Respecting Assisted Human Genetic Reproduction* was tabled in the House of Commons on May 9 and had its second reading on May 28 and was referred to committee. The text can be found at **http://www.parl.gc.ca/37/1/parlbus/chambus/house/bills/government/C-56/C-56_1/C-56_cover-E.html**

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Australian Government, Research Involving Embryos and Prohibition of Human Cloning Bill 2002, Canberra, June 27, 2002, **http://www.aph.gov.au/bills/index.htm**

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