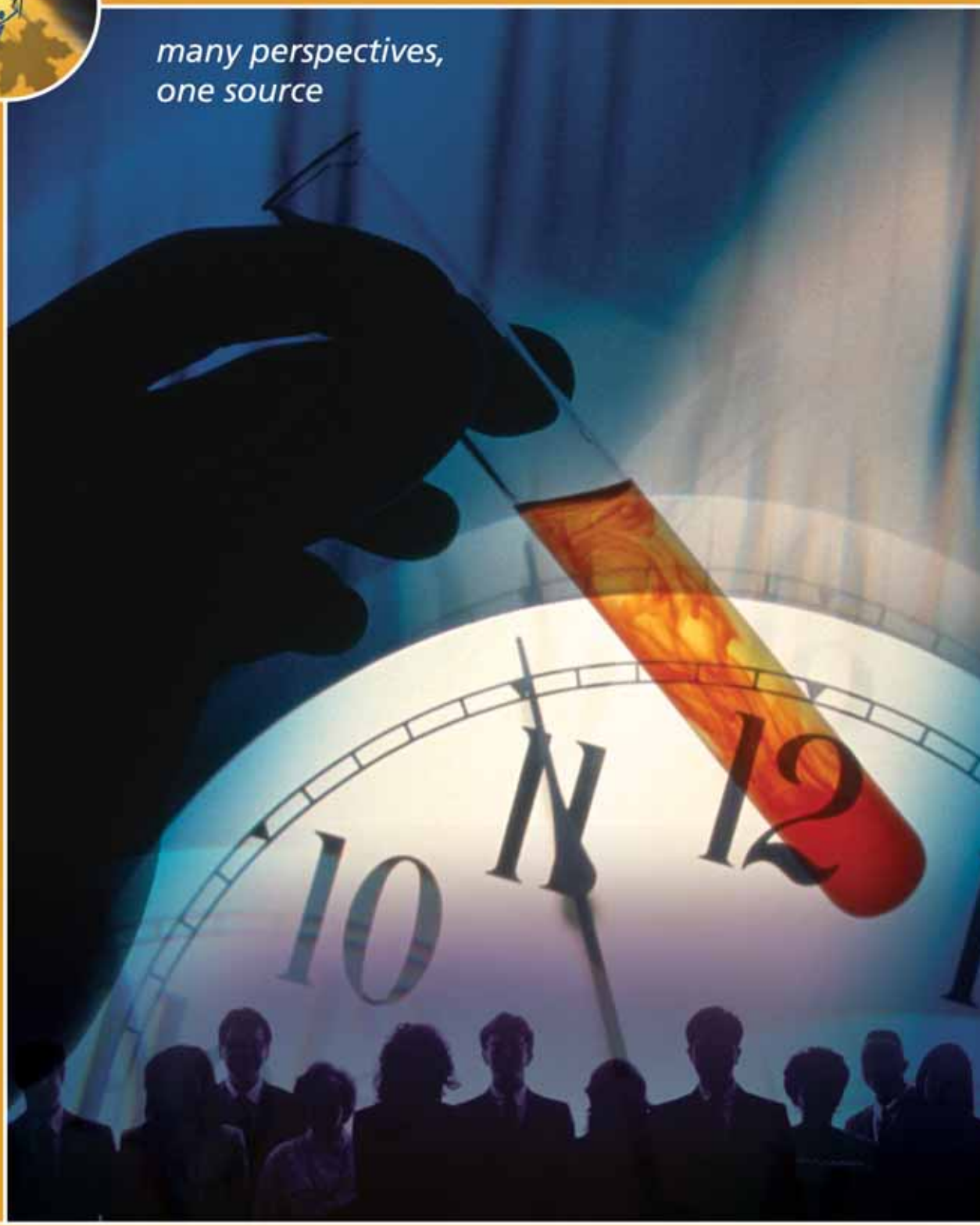
Canadian Biotechnology
Advisory Committee

many perspectives,
one source



2005

Annual Report

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CBAC Annual Report 2005

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Introduction 2005

Message From The Chair

The year 2005 saw a number of accomplishments, notably the completion of a major report entitled *Human Genetic Materials, Intellectual Property and the Health Sector*, and the initiation of an in-depth study on *Biotechnology, Sustainable Development and Canada's Future Economy*. The former investigation was referred to CBAC by the federal departments of Health and Industry; the latter was prompted by CBAC's view that Canada must consider now how biotechnology can be used to advance its sustainable development objectives and develop the policy underpinnings that support our national objectives. In both cases, CBAC adopted an Expert Working Party (EWP) methodology due to the extent of technical expertise required in the consideration of these topics.

Our experience with these projects confirms that the unique nature of CBAC — its multidisciplinary membership and its independence — enable the Committee to act as a "meta-advisory body" that can synthesize and reconcile the streams of analysis and advice from a variety of sources in Canada and abroad.

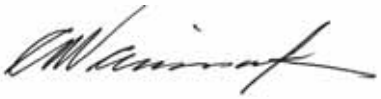
The pace of biotechnology development globally is accelerating, raising new and complex public policy challenges that implicate science and technology policy, trade policy, agricultural policy, developing world issues and economic competitiveness. It is the intersection of these policy areas that benefit from independent analyses so government is equipped to guide the development and applications of biotechnologies in our society.

Government, alone, cannot seize the potential of biotechnology, nor can it singlehandedly manage the risks associated with developments in this field. Canada's success requires the input and support of a broad cross-section of society, including other governments, the scientific community, non-governmental organizations, industry, consumer groups and interested Canadians whose differing views, priorities and expertise collectively bring the necessary balance to the dialogue and ultimately to the policy instruments designed to maximize benefits and minimize risks.

In 2006, CBAC will initiate work to chart the course forward. A series of expert regional roundtables and focus group discussions will assist CBAC in advising government on ways to ensure that Canada's biotechnology strategy is equipped to address the challenges and opportunities ahead.

I would like to thank the members of CBAC for their dedicated service and insights over the past year. On behalf of my colleagues, I also offer sincere thanks to the members of CBAC's Expert Working Parties, who have volunteered their time and expertise to tackle these critical public policy topics.

Sincerely,



Dr. Arnold Naimark
Chair, CBAC

Who We Are

Our mandate, structure, and the ways we work make the Canadian Biotechnology Advisory Committee (CBAC) unique among advisory bodies in Canada and abroad. Membership consists of experts drawn from diverse fields – science, medicine, agriculture, environment, industry, ethics, economics, and communications – and reflects the breadth of areas that biotechnology and its applications affect in our society. Members are appointed on the basis of individual attributes, not as representatives of particular interests. They are appointed by the Government of Canada's Biotechnology Ministerial Coordinating Committee (BMCC). This group of seven Ministers – from Agriculture and Agri-Food, Environment, Fisheries and Oceans, Health, Industry, International Trade and Natural Resources – oversees the Canadian Biotechnology Strategy. As well, their portfolios include a range of biotechnology-related priorities.

Canadian Biotechnology Advisory Committee Membership

CHAIR

Dr. Arnold Naimark
Director
Centre for the Advancement of Medicine
University of Manitoba
Winnipeg, Manitoba

Members*

Ms. Gloria Bishop
Communications Consultant
(specializing in health care)
Toronto, Ontario

Dr. Prabhat D. (Pete) Desai
President
Desai and Desai Inc.
Edmonton, Alberta

Dr. Barry Glickman
Professor of Biology
Centre for Biomedical Research
University of Victoria
Victoria, British Columbia

Dr. Pavel Hamet
Director of Research
Chief, Gene Medicine Services
Director of the Laboratory of Molecular Medicine,
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Montréal, Québec

Dr. Lyne Létourneau
Professor, Department of Animal Sciences
Université Laval
Québec, Québec

Linda A. Lusby
Professor, Environmental Science
Acadia University
Wolfville, Nova Scotia

Dr. Mary Alton Mackey
President
Alton Mackey and Associates
Toronto, Ontario

Ms. Anne Mitchell
Executive Director
Canadian Institute for Environmental Law and Policy
Toronto, Ontario

Dr. Peter W.B. Phillips
Professor of Political Studies
Director of the College of Biotechnology
Associate Member, Department of Management and Marketing and Agricultural Economics
University of Saskatchewan
Regina, Saskatchewan

Dr. David Punter
Professor, Department of Botany
University of Manitoba
Winnipeg, Manitoba

***CBAC members are appointed by the Biotechnology Ministerial Coordinating Committee on the basis of individual attributes, not as representatives of particular interests. All CBAC members serve on a volunteer basis.

The CBAC Chair receives a per diem (to a maximum number of days of work per year) commensurate with the demands of the position.

What We Do

Due to the scope and complexity of our topics, we employ a number of different tools that support our analyses and create ongoing mechanisms for linkage and exchange. For example, CBAC consults with stakeholders, commissions background studies, conducts research and analysis, convenes roundtable discussions, conducts workshops, and establishes expert working parties.

CBAC provides the Government of Canada with comprehensive advice on current and emerging policy issues associated with the health, ethical, social, regulatory, economic, scientific and environmental aspects of biotechnology and its applications. This broad mandate reflects the reality of biotechnology, the challenges and opportunities it presents, and the fact that it cuts across the lines of government departments and, increasingly, demands the integration of diverse perspectives to develop coherent policy.

Various activities are undertaken with a view to providing comprehensive and practical advice to the Government. Our agenda is developed in two ways: based on the policy gaps and emerging issues that members identify, given their expertise in particular fields; and, from direct referrals from federal departments and agencies seeking advice on specific issues.

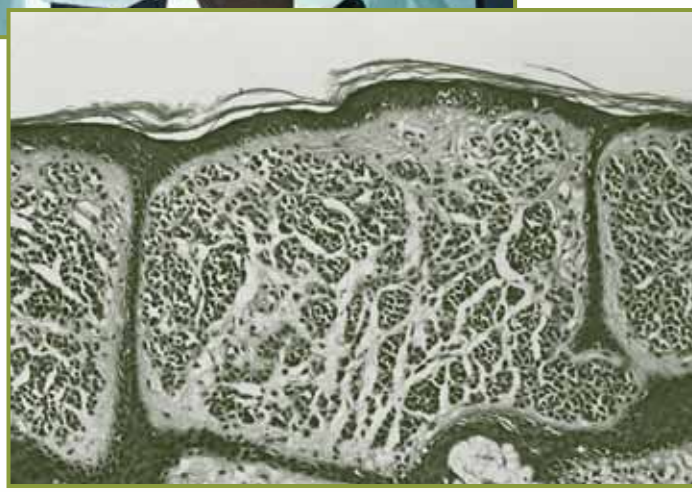
CBAC also uses a variety of mechanisms to advise Ministers and to communicate to stakeholders and the public through comprehensive reports, brief written commentaries, participation in workshops and conferences, our website, meetings with policy-makers, and interviews with the media. CBAC's advice to Government, our reports and background research are all public documents.

Human Genetic Materials, Intellectual Property and the Health Sector

CBAC 2005

Over half of Canada's biotechnology companies focus on human health, producing everything from blood products and vaccines to genetic diagnostic tests. With more than 10,000 biotechnology products or processes in the approval pipeline as of 2003[1], Canada is poised to be a significant participant in this fast-growing field. The research-intensive nature of this sector, combined with typically long product development timelines, make intellectual property (IP) protection essential to business viability. It is the objective of Canada's IP regime to act as an important stimulus for innovation by protecting and nourishing creativity and investment, to the mutual advantage of producers of such innovation, and in a manner conducive to economic and social benefits.

[1] Statistics Canada, "Biotechnology Use and Development," in *Innovation Analysis Bulletin 7, 1,* Cat. No. 88-003-XIE. [online]. (February 2005) **www.statcan.ca/english/freepub/** 88-033-XIE/88-003-SIE2005001.pdf



The manner in which owners of human genetic material-related patents exercise their rights has significant implications for the generation, regulation and application of health innovations. Issues surrounding the patenting of genetic diagnostic tests involving human genetic material, or HGM, garnered national media attention in recent years when some patent holders exercised their patent rights in ways that many regard as detrimental to both innovation and the provision of health services, particularly in regard to access to patented genetic tests.[2] These cases exacerbated existing concerns about gene patents in general and the implications for the health care system of patented genetic technologies in particular. Specific concerns centred around control over access to patented genetic diagnostic tests and their associated costs.

In 2004, the federal departments of Health and Industry asked CBAC to study this important and challenging issue. In response, CBAC struck an EWP comprised of experts in various relevant fields to identify systemic incentives and disincentives in Canada's current IP regime with respect to securing financing, establishing strategic alliances, conducting research, developing products, commercializing products and access to, and provision of, health care services. In undertaking this work, the EWP commissioned an analysis comparing Canada's patent system with respect to human genetic and related technologies with those of its major trading partners.

The findings of the EWP, *Human Genetic Materials: Making Canada's Intellectual Property Regime Work for the Health of Canadians*, provided the basis for CBAC's advice to government in its final report, *Human Genetic Materials, Intellectual Property and the Health Sector.*

[2] Health officials expressed concern about the licensing practices and testing costs imposed by Myriad Genetics which holds patents over methods and materials used to isolate and detect mutations in BRCA1 and BRCA2 genes that may indicate predispositions to breast cancer and ovarian cancer.

In developing its recommendations, CBAC balanced the need to address impacts on the health system with the need for an efficient, effective and innovative IP regime.

The EWP's recommendations call for:

- The enhancement, clarification and more rigorous application of patentability criteria;
- Greater opportunities to challenge patents before and after they are granted;
- Increasing the scientific expertise of the Federal Court (consideration of establishing an Intellectual Property Division);
- Amendment of the *Patent Act* to establish an experimental use exemption from claims of infringement in circumstances where the research is related to the subject matter of an invention;
- Enhanced voluntary mechanisms to limit unduly restrictive practices (for example, licensing guidelines);
- Strengthened legislative provisions to limit patent rights in cases of abuse; and,
- Adoption of international best practices by the Canadian Intellectual Property Office.

Most of the concerns about HGM-based patents in relation to the health sector have to do with patent-holders exploiting their rights in ways that are unduly restrictive and that impose constraints on research and provision of health services. Consequently, in complementing the EWP's recommendations, CBAC paid particular attention to matters of health system access and further recommended:

- Clarifying Government use provisions and abuse of patent provisions under the *Patent Act*;
- Establishing, under the *Patent Act*, a Patented Inventions Licensing Review Board to provide advice to the Commissioner of Patents on matters pertaining to the licensing of patented inventions; and,
- Undertaking further monitoring and analysis to determine whether this area merits price control mechanisms, such as those currently applied to patented medicines.

The report underlined that prompt action will foster more effective means of dealing with potentially detrimental consequences of exercising patent rights when they arise and will improve the timeliness and transparency of patent processes, which are crucial to industry. The full list of recommendations may be viewed at http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/en/ah00577e.html.

The way in which IP rights related to HGM are exercised has significant implications for the generation, regulation, commercialization and application of HGM-based health innovations. The number and complexity of these innovations are growing rapidly, making it imperative that steps be taken now to improve Canada's IP regime to achieve public policy objectives — to ensure reasonable access to beneficial health innovations, on the one hand, and to stimulate development of these innovations by granting limited monopoly rights to inventors on the other.

Striking a Balance Today for Tomorrow's Benefit

Given today's realities of a changing climate, increasing pollution and rapidly depleting finite natural resources, Canadians cannot count on an endless supply of clean water, high-quality and affordable food or enough natural resources to continue to fuel Canada's economy and sustain our high quality of life.

Neither can we ignore the growing disparities between wealthy developed countries, like Canada, and impoverished nations elsewhere in the world that require equitable access to these essential services and resources. Innovative approaches are required to find solutions to these complex problems, for Canadians as well as others around the globe.

A Sustainable Future

"We should all be concerned about the future because we will have to spend the rest of our lives there."
Charles Franklin Kettering, Seed for Thought

Biotechnology could play an important role in contributing to solutions for many of these health and environmental challenges in the future. Already, biotechnologies are showing promise by reducing energy pollution and energy needs of industrial processes, helping farmers produce crops in a less environmentally damaging way, and developing ways to extract useable energy from waste products.

In order to examine the potential contribution of biotechnology in a sustainable development context, CBAC has convened an Expert Working Party (EWP) to study *Biotechnology, Sustainable Development and Canada's Future Economy*, charged with:

- Developing sustainable development indicators and progress measures for biotechnology innovation;
- Assessing challenges and opportunities internationally;
- Focusing on potential economic impacts to rural Canada;
- Protecting the environment;
- Involving Canadians in dialogue about these technologies; and,
- Proposing governance solutions to the decision-making challenges associated with biotechnology.

Biotechnology, Sustainable Development and Canada's Future Economy is expected to be completed in Fall 2006.

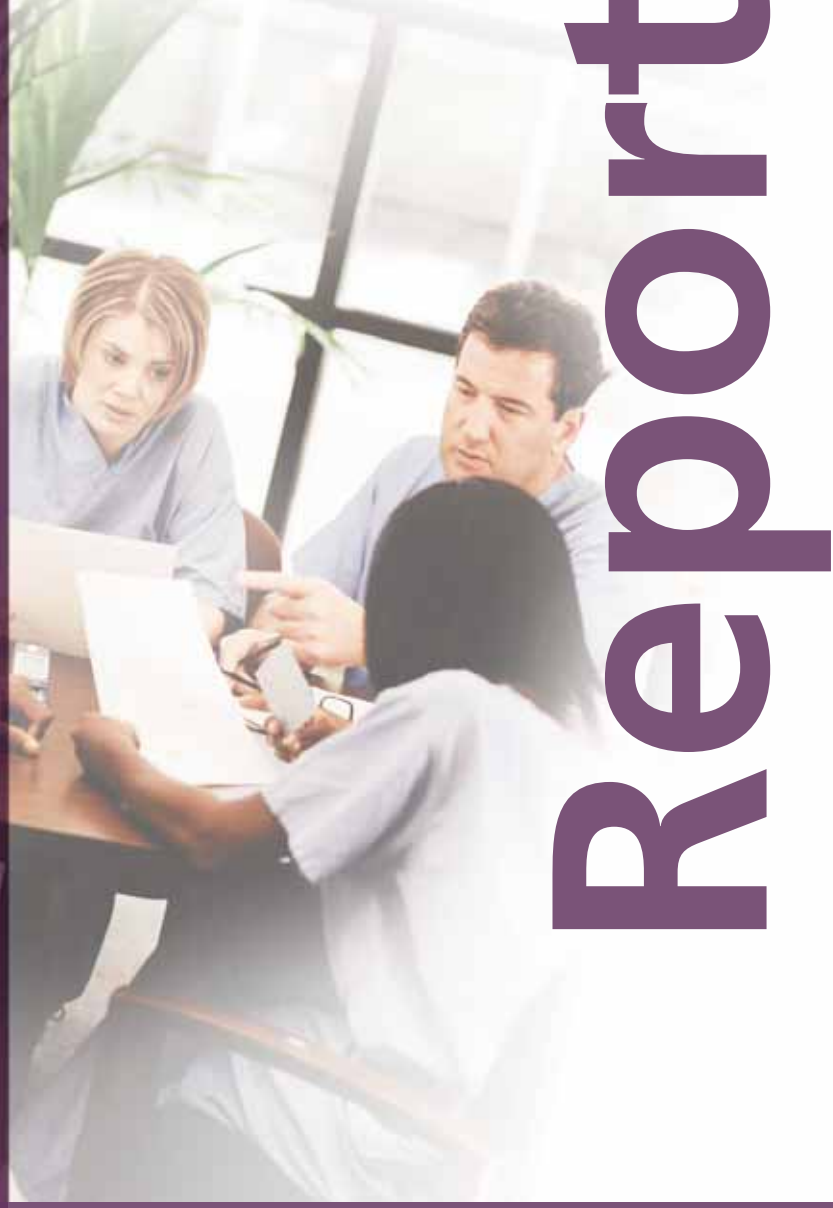
Biotechnology and the Year 2020

What kind of world will a child born on the cusp of the Millennium inherit a quarter century later? By then, the Canadian economy should reflect the efforts of their parents' generation to advance sustainable development solutions to the challenges facing Canada and the world community.

The EWP looks to the year 2020 to envision the role that bioproducts and biorefineries, industrial processing and bioremediation might play in future sustainable development initiatives. The EWP will undertake an extensive literature review, as well as conduct original research, to identify actions that need to be taken now, if we are to achieve transformative change within a generation.

The report will focus on applications relevant to agriculture, energy and sustainable resource management, since these are areas of particular interest in Canada. It will attempt to paint a picture of a world in which basic human needs are met, biodiversity destruction has been brought to a halt and greenhouse gas emissions have been reduced to create a healthier environment for people the world over. It will outline the choices that must be made and actions taken to ensure the responsible development and regulation of the biotechnology industry.

Some Progress to Report



Governance and Oversight of Research Ethics

In 2004, CBAC released its analysis and recommendations on *Biotechnology and the Health of Canadians*. In this report, CBAC noted the need for work related to the governance and oversight of research ethics, recommending the development of common standards and transparent methods. Improvements in these areas, along with the promotion of national and international harmonization and citizen involvement, are critical to maintain public trust and confidence in health research.

A particular concern revolves around the rights of individuals who participate in biotechnology research, including the storage and use of genetic information, the design and frequency of clinical trials, and informed consent for people involved in research projects. Among other things, *Biotechnology and the Health of Canadians* recommended the creation of a body to set ethical and safety standards for population health databases. Research projects would have to comply with these standards to quality for federal research funding.

(See http://www.cbac-cccb.ca/epic/internet/incbac-cccb.nsf/en/ah00488e.html for further details about the report's recommendations.)

The Government of Canada has subsequently taken steps toward these goals. Health Canada is working with its partners to investigate issues and options related to standards and accreditation, or comparable systems of "research-participant protection" in Canada. Work includes the examination of accreditation models and standards used in the United Kingdom, United States and New Zealand, as well as those used in other fields, such as research using animals. The study will identify elements and practices that could improve human subject research protection in Canada.

In addition, a task force created by the National Council on Ethics in Human Research (NCEHR) is developing models for an accreditation system for human research participant protection programs. The Task Force's draft final report will be circulated to stakeholders in January 2006 for comment. The Task Force expects to submit its report to the NCEHR later in the year. (For more information visit http://www.ncehr-cnerh.org/english/task_force.php.)

The federal Interagency Advisory Panel on Research Ethics has also begun community consultation that will inform advice to federal research-granting agencies on potential amendments to the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*. The Policy Statement describes standards and procedures governing research involving human subjects, funded by federal research-granting councils. Consultation documents are available at http://pre.ethics.gc.ca/english/consultations.cfm.

Equally encouraging, important progress has been made on the international front. In October 2005, the United Nations Educational, Scientific and Cultural Organization (UNESCO) adopted the *Universal Declaration on Bioethics and Human Rights*. This is UNESCO's third standard-setting text on bioethics. Previous declarations were adopted on the Human Genome and Human Rights (1999) and on Human Genetic Data (2003). For further details, visit http://portal.unesco.org/shs/en/ev.phpURL_ID=1883&URL_DO=DO_TOPIC&URL_SECTION=201.html.

CBAC will continue to monitor developments related to its recommendations and report on these through its newsletter and annual reports.

UNESCO Universal Declaration on Bioethics and Human Rights

October 2005

"The aims of this Declaration are:

I. *to provide a universal framework of principles and procedure to guide States in the formulation of their legislation, policies or other instruments in the field of bioethics;*

II. *to guide the actions of individuals, groups, communities, institutions and corporations, public and private;*

III. *to promote respect for human dignity and protect human rights, by ensuring respect for the life of human beings, and fundamental freedoms, consistent with international human rights law;*

IV. *to recognize the importance of freedom of scientific research and the benefits derived from scientific and technological developments, while stressing the need that such research and developments occur within the framework of ethical principles set out in this Declaration and that they respect human dignity, human rights and fundamental freedoms;*

V. *to foster multidisciplinary and pluralistic dialogue about bioethical issues between all stakeholders and within society as a whole;*

VI. *to promote equitable access to medical, scientific and technological developments as well as the greatest possible flow and rapid sharing of knowledge concerning these developments and the sharing of benefits, with particular attention to the needs of developing countries;*

VII. *to safeguard and promote the interests of the present and future generations; and,*

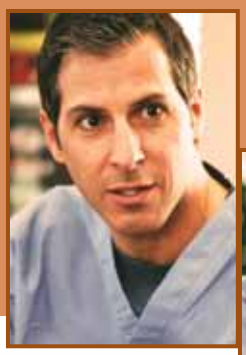
VIII. *to underline the importance of biodiversity and its conservation as a common concern of mankind."*

The Dialogue Tool *provides a way to examine an issue from multiple perspectives. It helps people understand the positions of others, who may hold opposing views. It also helps clarify, balance and reconcile the risks, benefits and trade-offs associated with new technologies, and assess whether a biotechnology development is likely to deliver positive, negative or neutral outcomes.*

Facilitating Constructive Discussion

Dialogue Tool Put to Work

The *Dialogue Tool* was in its final stage of development when CBAC's *2004 Annual Report* was issued. Initially designed to facilitate constructive discussion on contentious issues around genetically modified food and feeds (GMFF), this instrument can be applied more generally to the broad range of issues triggered by the use of biotechnology in our society. The *Dialogue Tool* was formally launched in 2005.



The genesis of the made-in-Canada *Dialogue Tool* dates back to 2001 when, in the course of CBAC consultations with stakeholders about Canada's approach to GMFF, the idea emerged of finding a productive way to debate not only specific concerns about genetic modification, but also the complexities of biotechnology itself. Biotechnology generates social, economic and ethical impacts that may result in polarized views on the use of the technology. Stakeholders identified the need to assess the full spectrum of repercussions to determine whether a new biotechnology product would be acceptable, at least within certain parameters, immediately or in the future, or completely unacceptable under any circumstances.

In 2002, CBAC endorsed the idea and set up an Exploratory Committee composed of people with backgrounds in the consumer movement, environment, food supply chain, public health and industry to design a tool to support constructive dialogue among diverse groups. The Exploratory Committee adopted a three-phase process that included the development of an *Acceptability Spectrum*, a pilot project to test both the tool and process, and subsequent refinements to the initiative.

The Dialogue Tool *consists of a facilitation guide and scenarios for a structured discussion session using an interactive process to deconstruct complex issues around five broad themes:*

- *Health;*
- *Environmental safety;*
- *Social considerations;*
- *Ethical issues; and,*
- *Broader societal repercussions.*

Information is provided in a matrix format, plotting a real or hypothetical case on a grid so concepts can be grasped, different perspectives aired and the dialogue progress charted. Participants create issue profiles and then consider each issue in terms of its acceptability or supportability. Consensus is not the goal; common understanding is. Sometimes, groups agree to meet again to pursue certain issues or extend their discussion.

The resources developed within the *Dialogue Tool* are applicable to a variety of scenarios in which agreement among diverse groups is difficult to achieve. The tool and a user guide are available to policy makers, industry leaders, academics and not-for-profit groups. They are available by contacting CBAC or visiting the Committee's website.

The dynamic nature of biotechnology and its many and diverse applications require an equally dynamic strategy that is nimble enough to take advantage of emerging opportunities and forward-looking enough to anticipate new challenges and adjust accordingly.

Inside the Future

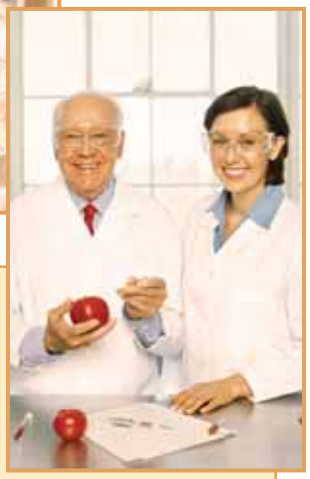
What the Future Holds: The Canadian Biotechnology Strategy: Charting the Course Forward

It has been more than 20 years since the National Biotechnology Strategy (NBS), the predecessor to today's Canadian Biotechnology Strategy (CBS), was rolled out in 1983. As it became apparent the original strategy had started to outlive its usefulness, a Biotechnology Strategy Task Force was struck in 1997 to take a measure of Canadians' values, and to review and build on the work and accomplishments of the original NBS. This led to the 1998 launch of the current CBS, an integrated government-wide strategy designed to optimize the benefits and manage the risks of biotechnology for Canadians.

One of the distinguishing features of the new strategy was the decision to establish the Canadian Biotechnology Advisory Committee (CBAC). During the Task Force consultations, Canadians called for an independent advisory body that would operate at arm's-length from government to provide impartial and comprehensive advice on crucial policy questions surrounding biotechnology to government, and to keep Canadians abreast of these developments.

The role of CBAC has evolved in the years since its inception. Early in its mandate, the focus was on the adequacy of existing policies and instruments, such as regulatory systems and patent policy. More recently, the Committee has also considered the broader impacts of biotechnology on complex and dynamic systems under the theme *Biotechnology and Society*. Within this theme, CBAC has completed and published its studies on *Biotechnology and the Health of Canadians*, and *Human Genetic Materials, Intellectual Property and the Health Sector*. Work is currently underway on *Biotechnology, Sustainable Development and Canada's Future Economy*.

CBAC will contribute its advice to a rethinking of the 1998 Canadian Biotechnology Strategy and will be informed in this process through a series of three invitational regional expert roundtables and public focus groups discussions in western, central and eastern Canada. CBAC will provide its analysis and recommendations to the Government of Canada in early Fall 2006 to assist government in charting the path forward.



The one constant in biotechnology is change. New opportunities and challenges emerge at a fast pace. Among the pressing issues on the horizon that will need to be dealt with are the following:

- *The implications for regulatory, trade and international development policy associated with new biotechnology products;*
- *Strategic investments in biotechnology by Canada's competitors;*
- *Increased expectations of the public, which is now more knowledgeable about biotechnology and expects the policy process to be more transparent and consultative; and,*
- *The important stewardship role of government to ensure the responsible development and commercialization of biotechnology applications in our society, which play an increasingly vital role in the everyday lives of Canadians.*

Since its inception in 1999, CBAC has:

- *published six major reports with recommendations to government:*
  - Patenting of Higher Life Forms
  - The Regulation of Genetically Modified Foods
  - Biotechnology and Health Innovation
  - Protecting Privacy in the Age of Genetic Information
  - *CBAC's Expert Working Party Report on* Human Genetic Materials: Making Canada's Intellectual Property Regime Work for the Health of Canadians
  - Human Genetic Material Intellectual Property and the Health Sector;
- *submitted eight advisory briefs on the topics of: patent protection for higher life forms (two advisory briefs), privacy issues associated with genetic research gaps in Canada's regulatory framework for products of biotechnology, stem cells, biotechnology and Canadian innovation, the Harvard Onco-Mouse case, and CBAC's views on the renewal of the Canadian Biotechnology Strategy;*
- *provided commentary on various initiatives at the request of federal department's including Environment Canada's research plan for long-term effects, Health Canada's biotechnology strategy, interdepartmental analysis of issues around genetic information and privacy, Agriculture Canada's initiative on responsible introduction of new products of agricultural innovation, and commissioned research for Industry Canada on maximizing value in health biotechnology research;*
- *released 50 research papers commissioned to support CBAC's analyses and to contribute to the international evidence base in important topic areas;*
- *hosted over 20 consultations and roundtable discussions to seek broader input and expert advice as part of CBAC's commitment to comprehensive analysis of biotechnology issues and impacts; and*
- *sponsored the development of the* Dialogue Tool to *support constructive discussion on complex issues triggered by biotechnology applications.*

***Sign up to receive CBAC's newsletter* – Biotech Watch**

Biotech Watch *provides brief overviews of CBAC's projects, highlights new developments and indicates upcoming topics. The current issue is available at http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/en/h_ah00361e.html. You can subscribe to receive email notification about new CBAC publications, including* Biotech Watch*, on the CBAC website at http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/en/ah00145e.htm*