BioTech WATCH

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Canadian Biotechnology Advisory Committee

many perspectives, one source

WHAT'S INSIDE

Report from CBAC

In March, CBAC released a new report entitled *Human Genetic Materials, Intellectual Property and the Health Sector*. The report builds upon an earlier work, *Human Genetic Materials: Making Canada's Intellectual Property Regime Work for the Health of Canadians*, drafted by an Expert Working Party (EWP) and informed by commissioned research and consultations with expert stakeholders.

Both reports respond to requests from Health Canada and Industry Canada for information about the effects that the protection of intellectual property rights (IP) related to human genetic materials (HGM) could have on the health sector.

IP Rights and HGM

Laws governing IP aim to promote innovation for the good of society and to make valuable knowledge from new inventions available to the public. Although a variety of legal mechanisms can be used to safeguard IP, such as trademarks, copyright or trade secrets, patents are the most common form of protection for HGM-related IP.

About Us

The Canadian Biotechnology Advisory Committee (CBAC) was established in September 1999 by the Government of Canada to provide comprehensive advice on current policy issues associated with the health, ethical, social, regulatory, economic, scientific and environmental aspects of biotechnology.

CBAC is composed of external experts, bringing expertise in such diverse fields as science, business, nutrition, law, environment, philosophy, ethics and public advocacy. At any one time, there are between 12 and 20 CBAC members.

CURRENT MEMBERS:
Dr. Arnold Naimark, Chair (MD, FRCP)
Mary Alton Mackey (Ph.D.)
Gloria Bishop (B.Sc.)
Prabhat D. (Pete) Desai (Ph.D.)
Barry W. Glickman (Ph.D.)
Dr. Pavel Hamet, (M.D., Ph.D.,CSPQ, FRCP(C))
Lyne Létourneau (Ph.D.)
Linda A. Lusby (M.Sc., LLB)
Anne Mitchell (M.A.)
Peter W.B. Phillips (Ph.D.)
Dave Punter (Ph.D.)

For more information, see CBAC's website at:
www.cbac-cccb.ca
Email: info@cbac-cccb.ca

Or contact:
Christine Linden,
CBAC Communications,
(613) 954-7059

Report from CBAC

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The manner in which owners of HGM-related patents exercise their rights has significant implications for the generation, regulation, commercialization, and application of HGM-based health innovations, as demonstrated in the EWP report. Concerns about the effects of patent rights over HGM on the health sector have grown significantly in recent years in the wake of a few high-profile cases involving patent holders who exercised their rights in ways that many regard as detrimental to both innovation and the provision of health services. The concerns about these effects have been particularly prominent in relation to control over access to patented genetic diagnostic tests.

Time for Action

In this era of rapid advances in genetic technologies, both CBAC and the EWP believe that prompt action is needed to enhance Canada's IP regime and better meet the dual objectives of encouraging innovation and making the benefits of such innovation readily accessible to Canadians. Prompt action will foster more effective means of dealing with the undesirable consequences of exercising patent rights when they arise, and will improve the timeliness and transparency of patent processes.

CBAC's Recommendations

CBAC's report strives to balance the need to address impacts to the health system and the need for an efficient, effective and innovative IP regime. In crafting its recommendations, CBAC drew upon the EWP report (supplementing, complementing or modifying its recommendations), feedback on the report from stakeholders and other interested parties, including provincial and territorial ministries of health and industry, and upon earlier CBAC reports.[1]

CBAC proposes a number of *Patent Act* amendments designed to enhance the patent regime's capacity to address unduly restrictive licensing practices. These recommendations include:

- Exemption from claims of infringement for research related to the subject matter of an invention;
- Strengthening of existing provisions regarding abuse of rights under patent and government use of patented inventions (sections 65 and 19 of the Act, respectively);

- Creation of a Patented Inventions Licensing Review Board as a decision-support mechanism for the Commissioner of Patents in exercising his or her discretionary authority with respect to government use of patented inventions and abuse of rights under patent.

In addition, CBAC makes a number of recommendations pertaining to the enhanced and more rigorous application of patentability criteria to genetic inventions (e.g. development of interpretative guidelines), increased opportunities to challenge patents (e.g. creation of an opposition procedure), enhanced voluntary mechanisms to limit unduly restrictive practices (e.g. development of licensing guidelines), and improvements to patent-office operations and services with a view to making them as consistent as possible with the best practices of Canada's major trading partners.

The full list of recommendations may be viewed at **http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/en/ah00577e.html**.

To order a copy of the report, please email info@cbac-ccbc.ca or call (613) 954-7059.

1. Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues* (June 2002): **www.cbac-cccb.ca**

With "health" and "sustainable development" identified as two key drivers of biotechnology, a CBAC-appointed Expert Working Party (EWP) is currently studying "Biotechnology, Sustainable Development and Canada's Future Economy" (BSDE). The final EWP report to CBAC is anticipated in late Spring 2006.

The report will be broad-ranging, touching on the major areas brought into focus when considering biotechnology and sustainable development, such as:

- 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 disruptive technologies; and
- Proposing governance solutions to the decision-making challenges associated with biotechnology.

"White" or industrial biotechnology (i.e. bioproducts and processes) will be the predominant focus of the report, along with agriculture, forestry, and aquaculture.

Biotechnology and the Year 2025

The BSDE study, involving an extensive literature review and original research, looks to the year 2025 and examines the role that bioproducts and biorefineries, industrial processing, and bioremediation might play in future sustainable-development initiatives. Of particular importance will be the study's development of a comprehensive sustainability framework for biotechnology applications, which will help guide discussion on this challenging issue.

Project Update

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Aims of the Report

CBAC asked the EWP to prepare a study that satisfies four requirements: first, that it identify opportunities for, and challenges posed by, new biotechnology applications in the future development of the Canadian economy as well as the appropriate regulatory approaches that new applications may require. Second, that it point to those new applications that can contribute to the attainment of national and international sustainable-development goals. Third, that it identify government-policy initiatives that would encourage further innovation in biotechnology applications most likely to contribute to sustainable-development goals; and fourth, that it present a sustainable-development framework for applications of biotechnology.

Influencing Policy

The EWP report, while prepared for CBAC, is principally targeted at policy makers who, over the next five years, will make the critical decisions needed to meet long-term sustainable-development goals. The EWP report will inform CBAC's advice to government.

CBAC anticipates that members of the private sector, academics and non-governmental organizations will also be very interested in the report.

Report's Progress

Progress on the report continues apace; the background in-depth research is complete. The EWP's report to CBAC is anticipated late Spring/early Summer 2006.

DID YOU KNOW?

Under the *Canadian Environmental Protection Act* (CEPA), biotechnology is defined as "the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms."

CEPA acts as a safety net by requiring environmental and health assessments for biotechnology products whose use is not regulated under other federal acts. CEPA's provisions are proactive, and prevent new biotechnology products from being imported or manufactured in Canada until the government has examined their potential risks.

– Health Canada

Biotechnology and Sustainable Forests

The sustainable use of Canada's forests and the maintenance of Canada's share of the world market of wood and wood products greatly depend on our ability to improve the productivity of managed forests. With this in mind, the Canadian Forest Service (CFS) is generating knowledge and exploring biotechnology applications to improve forest regeneration and protection methods, while ensuring that environmental impact considerations are addressed. The biotechnology research supported by the CFS provides promising alternative tools that, in the context of sound forest management practices, will contribute to the ultimate goal of promoting the sustainable development of Canadian forests.

– Natural Resources Canada/CFS

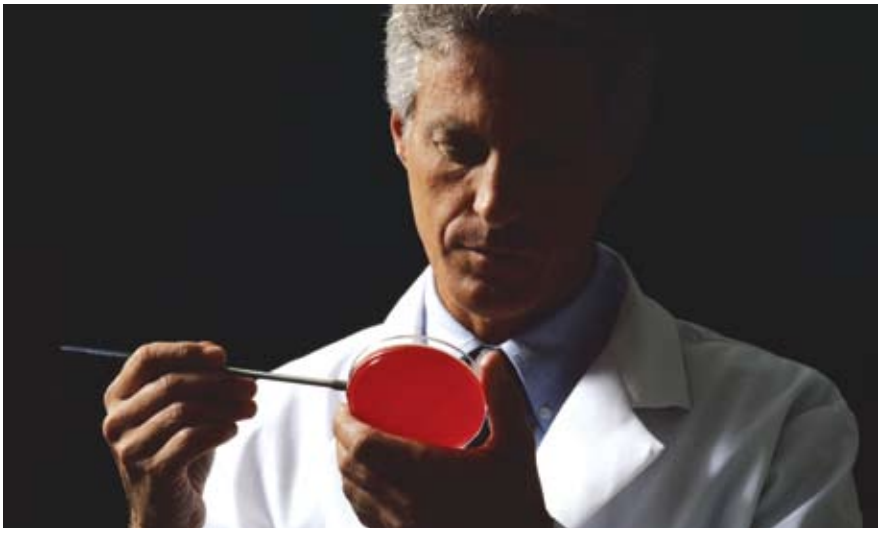
Introduction

From time to time, CBAC will use this newsletter to provide updates on developments in areas in which the Committee has previously advised the Government of Canada. In this issue, we look at recent developments in the governance of research involving human subjects.

Governance of Research Ethics Involving Human Subjects — Developments Since the Release of CBAC's 2004 Biotechnology and the Health of Canadians Report

In its 2004 report entitled *Biotechnology and the Health of Canadians*, CBAC examined the current and emerging opportunities and challenges associated with biotechnology-based health innovation. The report also proposed a series of initiatives to enhance Canada's capabilities and performance in research and development, regulation and commercialization, and technology assessment and uptake — all of which would contribute to Canada's potential as an effective and responsible leader in this important field.

The report proposed several initiatives in the area of governance and oversight of research ethics. CBAC noted that the further development of common standards and transparent methods, along with the promotion of national and international harmonization, and public involvement are critical for maintaining public trust and confidence in health research.



To this end, CBAC recommended that the federal government

> "establish or facilitate the establishment of a body or mechanism both to set standards and to accredit organizations and institutions with responsibilities for: research ethics boards, population health databases, and banks of biological specimens used for research purposes."

The Government of Canada has taken some 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 development used in the U.K., U.S.A. and New Zealand, along with those used in other fields, such as research using animals. The examination will identify elements and practices that could improve human research protection in Canada.

Governance of Research Ethics

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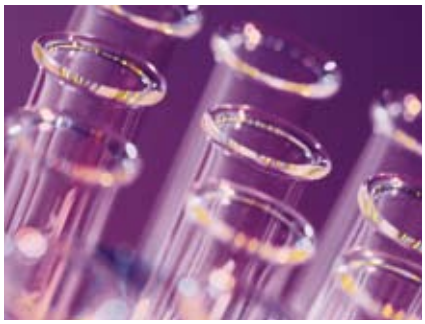
In addition, a task force created by the National Council on Ethics in Human Research (NCEHR), a non-governmental organization co-funded by Health Canada and dedicated to advancing the protection of human-research subjects, is working to develop models for an accreditation system for human research participant protection programs. The Task Force's draft final report has been circulated to stakeholders for comment (see **http://www.ncehr-cnerh.org/english/task_force.php)**. The Task Force expects to submit its report to the NCEHR in late Spring 2006.

In another development, the federal Interagency Advisory Panel on Research Ethics

has begun community consultations that will inform advice to federal research-granting agencies on potential amendments to the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS). The TCPS describes standards and procedures governing research involving human subjects funded by federal research-granting agencies.

Consultation documents may be viewed at **http://pre.ethics.gc.ca/english/consultations.cfm**.

Important progress on ethics has also been made on the international front. In October, the United Nations Educational, Scientific and Cultural Organization (UNESCO) achieved a significant milestone with the adoption of the Universal Declaration on Bioethics and Human Rights. The Declaration addresses ethical issues related to medicine, life sciences and associated technologies as applied to human beings, and takes into account social, legal and environmental dimensions. This is UNESCO's third standard-setting text on bioethics; declarations on the Human Genome and Human Rights, and on Human Genetic Data were adopted in 1999 and 2003, respectively.



CBAC will continue to monitor developments related to the establishment of standards and accreditation programs for research-ethic boards and will provide advice to government on the ethical issues raised by health research in general and by biotechnology applications in particular.

The National Council on Ethics in Human Research

The National Council on Ethics in Human Research (NCEHR) was established by the Royal College of Physicians and Surgeons of Canada at the request of the Medical Research Council of Canada (MRC) and with funding from MRC and Health Canada. In 1995, the Coordinating Committee for NCEHR was established. In part, it is "to serve as a forum for discussion and collaboration of institutional research ethics... particularly as regards NCEHR; in part, it is to provide financial and intellectual support to NCEHR so as to facilitate the discharge of its important responsibilities and the fulfillment of its mission."

The mission of the NCEHR is:

- To advance the protection and promotion of the well-being of human participants in research; and
- To foster high ethical standards for the conduct of research involving humans.

– http://www.ncehr-cnerh.org/english/who_e.php

CBAC Expert Roundtables on the Renewal of the Canadian Biotechnology Strategy

In 1998, the Government of Canada launched the Canadian Biotechnology Strategy (CBS), a government-wide strategy designed to optimize the benefits and manage the risks of biotechnology for Canadians.

Since the launch of the CBS, there have been significant developments in biotechnology, and new opportunities and challenges continue to unfold. These include:

- The implications for regulatory, trade and international development policy associated with new biotechnology products;
- Strategic investments in biotechnology by Canada's competitors;
- Consumers are now more knowledgeable about biotechnology and expect policy processes to be transparent and consultative; and

- The important stewardship role of government to ensure responsible introduction of biotechnology applications in our society, which is increasingly important to the Canadian public.

In light of these and other developments, the federal government intends to consider the next phase of the CBS in 2006.

In order to contribute to this "re-thinking" exercise and provide advice to government, CBAC is convening a series of regional roundtables in Spring 2006. One-day invitational expert stakeholder roundtables will be held in western, central and eastern Canada. CBAC will contribute a brief background paper to the process, intended to be a starting point to elicit views and new perspectives.

The CBAC background paper will be posted on the CBAC website this summer.

DID YOU KNOW?

The Canadian Food Inspection Agency prepares decision documents whenever regulatory decisions are made about plants with novel traits, including those derived through biotechnology. These documents explain what was reviewed to make the decision, and why certain conclusions were reached. They provide background information, describe the plant's novel traits, and discuss the results of the assessment and evaluation of the potential environmental and livestock feed use impacts. Decision documents are available to the public in hard copy and on the Internet, and can be viewed at: **http://www.inspection.gc.ca/**.

Conference on Risk Communications

Delegates from eight federal government departments and several national agencies took part in the first biotechnology-sector conference on risk communication in December 2005. The conference, held in Ottawa, was part of the "Engage the Decision-Makers" series of conferences hosted by the Canadian Biotechnology Secretariat and drew approximately 65 participants eager to learn more about management of risk in government.

Risk communications is a timely issue. Canadians are increasingly concerned about the health, environmental, social and ethical implications of applied biotechnology, a trend accentuated by the public's growing mistrust of public institutions. In light of these challenges, many government departments and agencies are searching for effective ways to engage the public in a dialogue about issues, including biotechnology.

Risk is the product of probability and consequence, but, according to Dr. Stephen Hill of Trent University, few people actually calculate risks in this way. Or, more accurately, few people have the capacity to determine probability effectively and so are limited in their ability to assess real risk.

Part of the solution, Hill propounds, is communication — making the public more aware of probabilities and consequences. During his presentation, though, he emphasized that successful risk communicators build trust and understanding by respecting the opinions and perceptions of the public and by including in the public dialogue, a discussion of values as well as scientific facts.

John Rainford of the Public Health Agency of Canada (PHAC) also spoke at the event. He agrees that risk communications involve more than teaching, telling and marketing — it is more than an ad campaign. Effective risk communications empowers stakeholders and makes them active participants in the public-policy process.

Rainford described PHAC's risk-management model and strategic communications process. Under PHAC's risk-management model, stakeholders are involved during each and every phase, from the identification of issues and contexts to the evaluation of results.

The conference also heard from three other speakers: Brian Biggar of the Treasury Board Secretariat, the Privy Council Office's Ken Moore, and Nora Nishikawa of the Canadian Food Inspection Agency. During the course of the afternoon, the speakers challenged attendees to examine the role of government in managing risk associated with the biotechnology sector. The speakers outlined current communications strategies used in government, highlighted best practices and shared lessons gleaned from selected case studies.

The presentations enabled delegates to appreciate that no single approach to risk communications will work effectively in every situation. In fact, a multitude of valuable models, resources and techniques exist. The speakers encouraged each delegate to adopt the strategy best suited to the culture and structure of a particular department or agency.