BIOTECHWATCH

CANADIAN BIOTECHNOLOGY ADVISORY COMMITTEE NEWSLETTER

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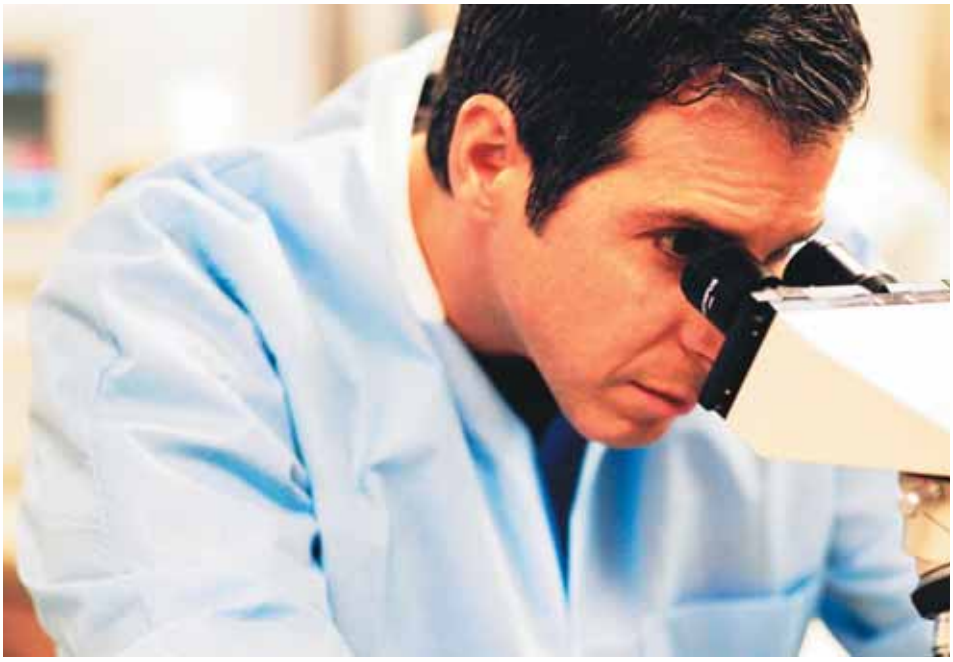
WHAT'S NEW @ CBAC

CBAC RELEASES BIOTECHNOLOGY AND THE HEALTH OF CANADIANS



Few areas of biotechnology have a more direct impact on the daily lives of Canadians than health-related technologies. Vaccines, antibiotics, organ transplantation and genetic testing for diseases like Cystic Fibrosis are just some of the biotechnology-based health innovations (BHIs) already improving Canadians' health, and many more are in development.

Continual advances in molecular biology, chemistry, physics, engineering, and computer and information technologies are leading to discoveries in fields as diverse as genomics, nutraceuticals, nanotechnology and stem cell research. These breakthroughs are translating into tangible health benefits for Canadians.

For example, stem cells can be modified to resist certain infections. Studies are underway to create stem cells resistant to HIV. Once implanted, these stem cells would repopulate the diseased immune system of AIDS patients with cells resistant to the disease. Genetic modification of stem cells can also reduce the risk of organ transplant rejection.

Nanotechnology, the research, development and commercialization of materials and devices on the scale of a billionth of a meter, is opening up new horizons in biomedicine. It is expected that devices that operate at the molecular level or use new materials created through nanotechnology will create powerful clinical tools to detect and treat diseases.

IN THIS ISSUE

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 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:

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Nutraceuticals, composed of phyto-chemicals extracted from edible plants or animal products, are used to enrich foods commonly found in our diet, making healthier foods part of our daily medicine. There are currently 65 products on the market in Canada such as omega-3 fatty acids from fish, probiotics from dairy products, lycopene from tomatoes, and antioxidants from various fruits and vegetables.

Some experts predict these discoveries will revolutionize the practice of medicine in the lifetime of many Canadians, fundamentally changing the way we organize, manage and deliver health services.

Recognizing the need to assess Canada's health systems' capacity to cope with, and profit from, these innovations, CBAC has analysed our health systems' readiness to assess and adopt beneficial biotechnology-based innovations The Committee's findings are reported in *Biotechnology and the Health of Canadians.*

In the report, CBAC shows how the increase in knowledge about the molecular basis of health and disease can be used for prevention, diagnosis and treatment. It describes the policy initiatives required to ensure these benefits are realized in a socially responsible manner and underlines the need for urgent action. It notes, *"How we respond will be our prerogative, but ignoring the pressures for change will not make them disappear — more likely it will simply compound the costs and complexities of dealing with them later."*

Biotechnology and the Health of Canadians offers Government recommendations to enable Canada's health systems to make biotechnology work for all Canadians. Its proposals strike a balance between capitalizing on economic opportunities generated by bio-based health innovations and respecting Canadians' social values.

The report makes specific recommendations in four key areas: research and development; regulation and commercialization; technology assessment; and, health system adoption. Highlights of the recommendations follow:

RESEARCH AND DEVELOPMENT – WHERE IT ALL BEGINS

Scientific advances are the foundation of innovation in biotechnology. However, the research surrounding these discoveries can sometimes pose ethical challenges, as is the case with genetic research. Even though they recognize the potential health benefits, many people have reservations about possible infringements on their privacy and human rights, and worry about where and how their personal genetic data is stored.

DID YOU KNOW?

- **The Canadian Genetic Diseases Network has been associated with the discovery of more that 50 human disease genes – more than any other non-profit organization in the world (www.cbdn.ca)**
- **Canadian researchers are part of an international interdisciplinary research consortium investigating the ethical, legal and social challenges of biobanks (www.humgen.umontreal.ca)**
- **A Task Force for the Development of an Accreditation System for Human Research Protection Programs is working to establish a mechanism for the development of standards of accreditation (www.ncehr-cnerh.org)**

DID YOU KNOW?

- On March 24, 2005, the Government of Canada announced its strategy to implement "smart" regulation to improve Canada's regulatory system to better meet Canadians' needs in the 21st century. The strategy builds on recommendations in the report of the Government's Expert Advisory Committee on Smart Regulation, as well as studies by the Organization for Economic Cooperation and Development and CBAC's 2002 report to Government on the Regulation of Genetically Modified Foods. The Smart Regulation Strategy is designed to improve and modernize regulation in areas such as food safety, health, environmental protection, natural resources, biotechnology, and transportation. The first in a series of regular updates from Government highlights many of the regulatory initiatives already underway in federal departments and agencies, some of which are directly related to biotechnology.
- Health Canada has developed a Therapeutic Access Strategy that aims to achieve internationally comparable review times – 180 days for priority submissions (300 days for non-priority submissions) on 90 percent of conventional pharmaceuticals within three years. It will take four years to reach similar milestones for biologics and genetic therapies.
- The health sector accounts for more than 80 percent of Canadian and global investment in biotechnology research and development so we can expect to see more products entering the regulatory process.

Biotechnology and the Health of Canadians underscores that an integrated and coherent strategy is essential to guide Canada's ongoing investments in health research, in general, and in BHIs in particular. In addition to ensuring the ethical and safe development and use of biotechnology in the health sector, CBAC recommends establishing a mechanism to set standards and accredit organizations and institutions with responsibilities for research ethics boards, population health databases and banks of biological specimens (sometimes called "biobanks") used for research purposes.

REGULATION AND COMMERCIALIZATION – BRINGING HEALTH INNOVATIONS TO CANADIANS

Bringing biotechnology products to market is a complex, costly and time-consuming process. The challenges to successful commercialization include the need for early stage financing, bio-manufacturing capacity in Canada, better use of public institutions for product testing, and better linkages among universities and business.

Canada currently lacks a comprehensive regulatory regime, which is impeding the development and commercialization of socially beneficial biotechnology. CBAC contends that, just as Canadian industry is a leader in the development of BHIs, so too should Canada lead the way in developing and implementing appropriate regulations.

The Committee believes Canada needs a national heath innovation and commercialization strategy and that the strategy should have a specific focus on BHI. It recommends evaluating the current regulatory system to ensure that it works efficiently and incorporates new scientific and technical knowledge into its evaluation and decision-making processes. This will enable it to be more responsive to the rapid rate of innovation and improve Canada's ability to adopt BHIs that enhance Canadians' health. It will also provide a more coherent government-wide approach that ensures high standards of protection for health, safety and the environment.

TECHNOLOGY ASSESSMENT – MAKING SOUND DECISIONS

As public and professional demand for BHIs in the health-care system rises, Canada's health technology assessment (HTA) programs are increasingly called on to make decisions about the value of these new technologies. Given their ethical and social complexity, and economic and health system implications, this becomes an ever more difficult task for decision makers. Canada's capacity to meet this challenge is lagging but it is certainly not alone. All countries are confronting these same issues. International interest in this area presents an opportunity for Canada to play a leading role in this burgeoning sector of the economy.

CBAC recommends a set of priority actions: build on existing models of Canada-wide HTA for drugs to include the assessment of BHIs; develop and incorporate methodologies that examine the broader social, ethical, economic and health systems impact of BHIs; implement field trials on a demonstration basis if more evidence is needed to assess impacts; share HTA capacity both nationally and internationally; and communicate with the public.

HEALTH SYSTEM ADOPTION – FROM PROMISING INNOVATION TO PRACTICAL APPLICATION

The adoption of BHIs is a complicated process influenced by the internal dynamics of health care systems, on the one hand, and health professionals and consumers on the other. There is a constant push and pull between practitioners and patients want to see BHIs adopted because of their health benefits, while health system managers may be resistant because of the technical complexity and potential disruptive effects on costs, organizational structures and professional roles. The social and ethical implications of some BHIs are also an issue.

To smooth the introduction of new technologies and increase Canadians' access to beneficial BHIs, CBAC recommends identifying barriers to their adoption in the health system and finding ways to remove or ameliorate them. In addition, CBAC recommends enabling health systems to adopt BHIs for which assessments and appraisals are incomplete or unavailable, for instance, through conditional approval.

DID YOU KNOW?

- **The Canadian Emerging Technologies Assessment Program alerts decision-makers to upcoming drugs, devices and systems that are likely to have a significant impact on the delivery of health care in Canada. (www.ccohta.ca)**
- **Federal, provincial and territorial governments are working together to develop a comprehensive Canadian Health Technology Strategy that will assess the impact of new technology and provide advice to maximize effective utilization.**

CREATING CONDUCIVE CONDITIONS

No single activity will improve Canada's readiness for BHIs. In *Biotechnology and the Health of Canadians* CBAC argues that action is required on multiple fronts. These include building and sustaining the range of scientific and managerial expertise required to keep pace with the rate of BHI discovery and development; strengthening the communication of clear, reliable information about BHIs; and, facilitating public participation at appropriate points in the development and adoption of these technologies.

By taking action on the recommendations outlined in the report and improving Canada's general readiness for BHIs, CBAC believes Government will take a significant step forward in increasing Canadians access to the health benefits of cost-effective BHIs, while also managing the potential risks and encouraging the ethical use of new technologies. Action in these areas would position Canada as a world leader in one of the fastest-growing industries in the global economy.

The full text of *Biotechnology and the Health of Canadians* is now available at: http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/vwGeneratedInterE/ah00488e.html or e-mail info@cbac-cccb.ca for a paper copy.

BRINGING PATENT LAW IN LINE WITH BIOTECHNOLOGY

It is one thing to patent a gadget that may make a consumer's life more convenient. However, when it comes to applying patent law to potentially life-altering biological inventions, should decisions be made by patent office administrators or the courts, or should the special characteristics of biological inventions be taken into account throughout the *Patent Act?*

Questions surrounding the appropriateness of patenting biotechnology innovations appear, increasingly, to be beyond the scope of Canada's current patent laws. After recent, seemingly contradictory Supreme Court rulings on the patentability of higher life forms, CBAC called on Parliament again in 2004 to determine the application of patent law for biological inventions and clearly articulate it in legislation.

In 2002, a 5-4 majority in the "Harvard Onco-Mouse" case ruled that animals do not fall within the definition of "invention" in the *Patent Act* and were, therefore, not patentable in Canada. In 2004, however, a 5-4 majority in the *Monsanto Canada Inc.* v. *Schmeiser* case ruled that, *even though* plants are *not* patentable in Canada, a patent on a plant cell or a modified gene in a cell gives the patent-holder the right to control what others do with the plants because each individual cell in the plant contains the modified gene. Although the court indicated it does not intend to revisit the Harvard case, the ruling in *Monsanto* seems to make the earlier decision meaningless in practice, if not in law.

Canada has an unprecedented opportunity to be the first country to ensure that the special characteristics of biological inventions are taken into account in federal legislation, and not only in the definition of "invention."

Such action would ensure that Canada's patent policies and procedures keep pace with developments in the Canadian biotechnology industry, thereby encouraging greater research and development and commercialization, while also ensuring that the appropriate balance between inventors and citizens is maintained.

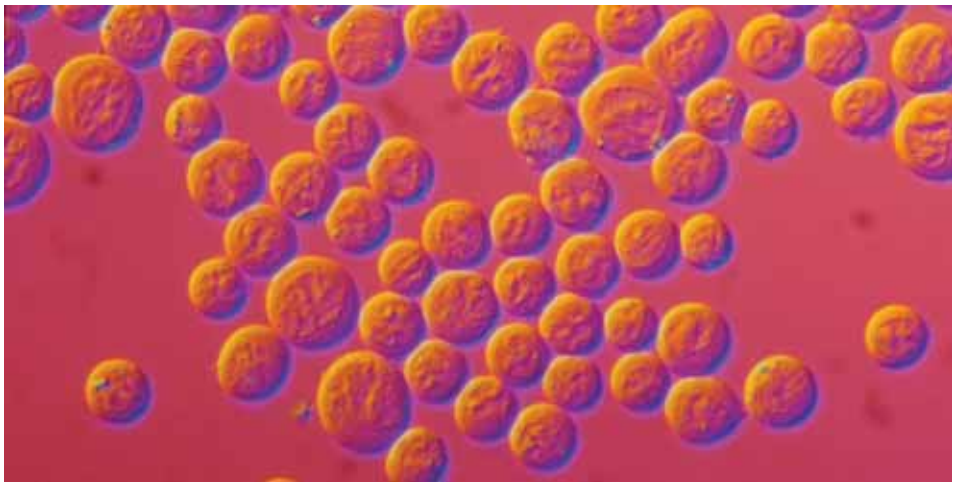
Patent protection of human genetic materials: impacts and implications

In its 2001 Interim Report, "Patenting of Higher Life Forms", CBAC recommended that government examine and address the potential impacts of patenting of genetic-based inventions on the health care system.

Advances in human genetics are expected to be so extensive and powerful in their application that some believe they will eventually change the fundamental nature and direction of the health system and professional practice. These impacts will not be limited to the health sector but will spill over into the economy at large. The rapid progress in the study of genes and their function (genomics) and resulting inventions holds enormous commercial potential. This has given rise to numerous patent applications on most forms of human genetic materials (HGM). Patents on HGM have stimulated intense debate and controversy over ethical, economic, legal and social issues.

A number of advisory bodies in Canada and abroad have examined the issues raised by the patenting of HGM[1]. It is clear from these examinations that devising legislative and regulatory solutions that reflect an optimum balance of interests among various stakeholders is extremely challenging. Arriving at a solution is particularly important in countries with a publicly funded health care system, as Government is responsible for ensuring clinically-useful and medically-necessary innovations are available at reasonable cost, within reasonable time frames, and in a fair way.

In 2004, the federal Departments of Health and Industry asked CBAC to examine the intellectual property regimes as they relate to human genetic materials and their potential implications for the health sector, and to produce a report with recommendations for Government. CBAC's work on this subject is being done through an Expert Working Party (EWP) comprised of experts in intellectual property law, industry, health care, health research, and public policy.



The EWP is co-chaired by Dr. Arnold Naimark, CBAC Chair, and by Mr. Ron Yamada, Executive Vice President (Retired), Global Markets and Corporate Affairs, MDS Incorporated. The EWP program of work includes analysis of existing reports and literature, commissioned research in specific areas (e.g., international comparisons of patent policy and experience with respect to HGM), and stakeholder consultations (with researchers/clinicians, IP experts and economists, industry, financers and developers, health system administrators, and federal/provincial/territorial governments). The final report is anticipated later this year and will be publicly available.

[1] Australian Law Reform Commission Inquiry (2004). *Genes and Ingenuity: Gene Patenting and Human Health;* (U.S.) National Research Council (2004). *A Patent System for the 21st Century;* Canadian Biotechnology Advisory Committee (2002). *Patenting of Higher Life Forms and Related Issues;* Ontario Ministry of Health and Long-Term Care (2002). *Genetics, Testing and Gene Patenting: Charting New Territory in Healthcare;* Nuffield Council on Bioethics (2002). *The Ethics of Patenting DNA: A Discussion Paper;* Organization for Economic Co-operation and Development (2004). *Patents and Innovation: Trends and Policy Challenges.*

Getting the most from taxpayers' investment in health biotechnology R & D

The Canadian government makes a significant investment of public funds in health biotechnology research and development through universities, government agencies and federal departments. CBAC commissioned the study, *"Maximizing Value from the Federal Investment Portfolio in Health Biotechnology Research"*, to discover whether Government is maximizing its investments in these technologies through their commercialization and, ultimately, the production of improved goods and services for Canadians.

According to the study's findings, the lack of focus by researchers on the potential commercial applications of their innovations, coupled with a lack of recognition on the part of the private sector of the value of such innovations, is the greatest impediment to increasing the return on research investments. It recommends that efforts be made to create a "culture of value capture" within federal agencies that recognizes and focuses on the importance of creating marketable products. Only then will federal investments yield dividends for Canadian taxpayers.

The complete research report is available on CBAC's Web site at: www.cbac-cccb.ca

THE BIO-ECONOMY: BIOTECHNOLOGY AND SUSTAINABLE DEVELOPMENT

Biotechnology cuts across all facets of Canadian society but its most profound impacts are felt in the areas of health, the environment and the economy. Since 2002, CBAC has been examining these three areas under an ambitious initiative called *Biotechnology and Canadian Society*. Health was the first issue to be explored by the Committee, which culminated in the publication *Biotechnology and the Health of Canadians*. CBAC's newest project – *Biotechnology, Sustainable Development and Canada's Future Economy* – looks at biotechnology, the environment and the economy in an integrated way.

Interchangeably called the "biological", "bio-based" or "bio-economy", the term refers to using conventional agricultural or other plants in new ways, such as producing ethane from corn or using genetic engineering to modify poplar trees to improve the efficiency of pulp and paper production.

Scientists already know how to produce certain pharmaceutical proteins in plants such as tobacco or industrial chemicals from microbes. Now that entire genomes can be decoded, scientists are turning their attention to protein synthesis and other functional aspects of genomics. It is difficult to anticipate precisely what new products or services, opportunities or challenges, this knowledge will enable,

but their impacts on the economy are expected to be profound.

Due to the broad scope and complexity of this project, CBAC is establishing a panel of experts in various relevant fields to determine how to optimize the contribution of biotechnology to achieve Canada's sustainable development goals. The panel is charged with identifying the opportunities for, and challenges posed by, new biotechnology applications in all relevant sectors and pinpointing appropriate regulatory approaches that may be required to keep pace with new applications. The Expert Panel's report and CBAC's subsequent recommendations to Government will be made public. The project should be completed by March 2006.

CBAC'S 2004 ANNUAL REPORT

For CBAC, 2004 was about change. A change of focus as we turned our attention to the broader impacts of biotechnology on complex systems, such as health care. The fast-paced change of developments in biotechnology. And the change required in Canada's legislative and policy framework to keep up with these developments.

CBAC's 2004 Annual Report details our work over the past year, including our recommendations to the Government of Canada and its partners on current policy challenges associated with biotechnology. In addition, it describes our outreach and communication activities throughout the year, as well as our efforts to engage stakeholders on current and emerging issues in biotechnology.

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best practices

RISK COMMUNICATION

In the past 20 years, there has been a significant change in the way governments and citizens interact - called the "democratic revolution" in 1993 by the former Clerk of the Privy Council of Canada, Marcel Massé.

People today want to play an active role in the decisions that affect their lives, particularly those that affect their health. They are better informed and better educated, but they have also become increasingly disillusioned about governments and distrustful of information provided by them.

As governments work to enhance public trust and confidence, the field of risk communication* is increasingly important. The following are two examples of effective approaches to risk communication on the particularly sensitive issue of food. Canadians feel strongly about having access to credible information as it relates to foods available in the marketplace, a point reinforced by public pressure for nutrition labelling.

TWO-WAY COMMUNICATION AT EVERY LEVEL OF DECISION-MAKING

Good communication equals openness, responsiveness, trust and participation. This is the formula for risk communication used throughout the Canadian Food Inspection Agency (CFIA) and outlined in *Communication and Government: Theory and Application for the Canadian Food Inspection Agency.* It remains the same in all situations, from single food recalls to policy decisions to controversial issues management.

RISK COMMUNICATION

Risk/'risk/ n. communication/kemjuini'k(e)n/ n. LME [f. as prec.: see – ATION}

1. The exchange of information and opinions on the chance or possibility of danger, loss, injury or other adverse consequences. It occurs among individuals, groups, and institutions with the primary goal of reaching a better understanding of actual and perceived risks, possible solutions, and related issues and concerns. Such communication can range from simple warning labels to communications advisories to public hearings.

It is estimated that approximately 20% of processed foods and beverages are generated as a result of biotechnology, particularly fermentation technology. As processes and products become more integrated, an even higher proportion of food products will employ a biotechnology process such as fermentation, enzymatic processing or incorporation of genetically modified raw materials into the manufacturing process. Opportunities and Challenges for Application of Biotechnology in the Canadian Agri-Food Sector (April 1998)

CFIA believes that successful risk communication is not simply about giving out information or making stakeholders understand an issue. Rather, it's a two-way process that recognizes the importance of public perception and determines the public's tolerance for risk. It also recognizes the need to gain public trust to maintain credibility.

CFIA has found that the result of this open approach to communication is increased confidence and trust. In addition, it has found that openness improves the level of debate on issues among government, the food industry and the public. If citizens are engaged and feel they are being heard, they are much more likely to listen, and risk communication messages are more likely to reach their audience. CFIA attributes much of the effectiveness of the Agency's food risk communication to its alliances with its many partners.

RESPECT FOR THE AUDIENCE'S INTELLIGENCE AND INSIGHTS

Respect is key to the risk communication approach outlined in *Communicating About Agricultural Biotechnology in APEC Economies: A Best Practices Guide*. It contends that engaging interested consumers and stakeholders in a way that respects their intelligence helps to satisfy them that they are being given adequate information. The guide goes through each step of an effective risk communication campaign to help communicators in APEC countries achieve this goal.

Before beginning any risk communication task, organizations must assume responsibility for communicating and devote sufficient resources to the task. They must understand the audience and provide them with accurate, balanced information, as well as additional sources to reinforce it. When the information provided is scientific, it is important to consult the best research available and to use a range of expertise, including experts from as many of the technical, social, economic, political and ethical sides of the issue as possible.

In addition, organizations must work closely with other partners to ensure that risk messages are clear, accurate and consistent. Clear, consistent messaging reduces the likelihood of confusion and mistrust, and helps increase confidence in the information. In cases of scientific doubt, the public should be made aware of these doubts, as well as any other unknown factors or assumptions.

Perhaps most important, however, risk communication must be timely, accessible and interactive. Including ways in which the public can participate, for example by providing feedback or requesting more detailed information, is a good idea, as is using a range of media to deliver messages, including the Internet, brochures and videos. Distributing information at locations frequented by target audiences makes information even more convenient to access.