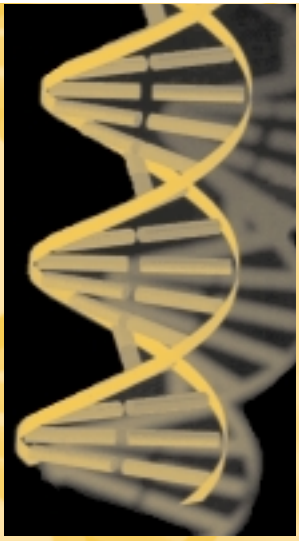
DRAFT REPORT

Genetics, Testing & Gene Patenting:

Charting New Territory in Healthcare Executive Summary



January 2002

Ontario

EXECUTIVE SUMMARY

INTRODUCTION

The multitude of recent and anticipated research developments in the fields of genetic information and genetic technologies hold out the potential to fundamentally re-define medicine within the lifetime of many Canadians.

Even as jurisdictions collectively focus attention on how best to manage healthcare today, we must also retain our focus on the future, on addressing how we modernize and renew. Sustaining healthcare must also be about retaining and strengthening our capacity to innovate and lead. In this regard, the research breakthroughs in human genetics will come to play an increasingly important role, a role, which if appropriately managed, promises much for both healthcare and society in general.

This future role is one for which our jurisdictions can and must take bold steps, in the present, to begin to prepare. In anticipating and attempting to chart the course that genetics will take healthcare and society, Canada would not be alone.

Jurisdictions around the world are currently working to understand and address the social, legal, ethical and policy challenges presented by new genetic breakthroughs.

Canadian researchers have already played significant roles in the international efforts to decode the human genome and bring forward new interventions in the field of medical genetics. So too, in the Canadian biotechnology sector, major breakthroughs are being pursued.

It is estimated that 60% of Canadians will experience a disease with some form of genetic component during their lifetime. Genetic technologies hold out the potential to help a large majority of Canadians.

Governments, at both the federal and provincial/territorial levels, must now match the determination and success of the efforts in science with an equal resolve to begin to understand and address the ethical, legal, social and health-system implications of new developments in genetics. Canada must not lose any more time in putting in place appropriate frameworks to assist both healthcare and society in general to adequately prepare for the changes ahead. As the Saskatchewan Health Services Utilization and Research Commission rightly noted:

> " We have a window of opportunity in which to act while things are still in a manageable scale. By working now to establish the necessary policies and institute the required changes in the health system, we can ensure that the inevitable growth in genetic testing proceeds in accordance with scientific evidence and in a way that enables us to reap its full potential."[1]

This is sound advice, which concurs with the expert opinion that has been provided in Ontario by the Ontario Advisory Committee on New Predictive Genetic Technologies.

For while there is much hope, new breakthroughs in genetics also carry many risks.

1 *Saskatchewan Health Services Utilization and Research Commission. HSURC Brief. Staying ahead of the wave: Preparing for today for genetic testing tomorrow. October 2001. www.hsurc.sk.ca*

HIGHLIGHTS

This report details a range of areas for possible action, on which jurisdictions might choose to act in concert to better prepare both healthcare and society for the impact of genetics. These are:

INTERJURISDICTIONAL FRAMEWORK:

This report is a call for the development of a shared vision across jurisdictions and for the development of shared resources. In short, it is a call for a comprehensive, patient-centred framework to assist jurisdictions in maximizing the benefits offered by new technologies and to set paths for collaborative work to better understand and address the risks.

A comprehensive framework, if developed, could help move Canada and all provinces and territories into the forefront of preparing for the impact of genetics. This preparation will need to take several forms. There is a strong need for greater public engagement, for increased capacity in our health system to incorporate change, and for examining new ways in which we regulate and protect.

PUBLIC EDUCATION AND ENGAGEMENT:

The report outlines the growing need for public engagement and education on matters concerning genetics in healthcare. The report suggests a range of steps to better prepare. These might include reviewing existing school curricula, increasing coordination and intensity of public education activities in genetics and developing multi-sectoral approaches to ensure that accurate and credible information is made available.

PROFESSIONAL EDUCATION:

The report notes the need for increasing training in medical genetics for a range of healthcare providers as an essential preparatory step to meeting the challenges of incorporating new technologies. The report suggests cross-jurisdictional coordination and partnerships with appropriate professional associations to advance health professional education.

GENETIC TECHNOLOGY ASSESSMENT:

The report notes the rising rate of commercial development in genetics and the need for all jurisdictions to have access to high quality, objective health technology assessment and health economic analysis in the genetics field. The report proposes new capacity be added making this information available to all jurisdictions.

SERVICE DELIVERY: QUALITY CONTROL:

The report notes that additional standards and review processes may be required to deal with new testing methodologies and approaches. It is suggested that building on existing capacity and expertise, a framework for quality control be developed for jurisdictions to use where possible, to avoid duplication and divergent standards. The issue of kit and home-based testing through direct-to-consumer advertising is examined and the federal government is called on to examine the existing review process and develop information sharing capacity regarding these developments.

SERVICE DELIVERY: HUMAN RESOURCES:

Noting the potentially significant increases in genetic testing coming in the near term, the report states that jurisdictions will require improved capabilities to track and project future needs. Given international competition that will exist in the area of human genetics, the report suggests coordinated approaches to health human resource planning in this field.

PRIVACY, DISABILITY AND DISCRIMINATION:

Ensuring the appropriate involvement of the disabled community in decision-making regarding genetic testing and research is presented as an important factor in helping society negotiate the boundaries of ethical treatment. The report also notes growing concern with regard to potential uses of genetic information and proposes jurisdictions work to put in place appropriate protections particularly in the areas of insurance and employment.

PATENT REFORM:

The report notes the recent call by the federal Standing Committee on Health for a complete ban on gene patents. Recognizing the role of the biotechnology sector in promoting innovation, the report does not support a ban, but instead calls for a comprehensive review of the federal *Patent Act* providing a range of concrete proposals such as the introduction of an opposition period, additional infringement protection for healthcare providers, tightening utility requirements and restricting broad-based patents.

OVERSIGHT AND REGULATION: INTERJURISDICTIONAL CO-ORDINATING BODY:

The report urges governments to work together to ensure appropriate and comparable quality standards are in place across all jurisdictions providing genetic testing including; appropriate criteria for deciding when to test, monitoring processes for lab quality, protocols for ensuring appropriate counseling and support, and processes regarding test reviews for accuracy and reliability.

The report notes the need for appropriate capacity to monitor trends in medical genetics and assist all jurisdictions in addressing the ethical, legal and service delivery issues they will face. Stressing the need for a coordinated approach, the report suggests the possible creation of a human genetics commission to assist all jurisdictions.

The report also notes the importance of ensuring comparable quality assurance regimes and standards are in place and urges jurisdictions to cooperate in developing common approaches. In terms of federal review and approval processes, the report stresses the need for vigilance in the review and approval of new kit-based forms of genetic tests.

CO-ORDINATED AVAILABILITY OF TESTING:

Noting the increasing number of tests that will be available and the importance of attempting to develop fair access, the report suggests that jurisdictions examine the creation of protocols to help ensure access to testing for all residents. The report notes that with cooperation and good planning, the range of tests (especially for low-volume, rarer conditions), could be improved by coordinated cross-jurisdictional delivery.

SUPPORT FOR BIOTECH SECTOR:

The report notes the valuable contribution of the biotechnology sector to economic growth and healthcare innovation and suggests that innovative measures taken in the United Kingdom (UK) and the United States of America (USA) to spur biotechnology development may warrant study by jurisdictions.

THE POTENTIAL IMPACT ON COSTS:

The report notes that the growth in genetic-based medicine will necessitate many changes in healthcare and delivery at the individual and system level and that these changes will be associated with costs. The report notes that estimating the economic impacts of genetic technologies is complex and far from straightforward. The cost implications of the test itself is only one component of overall system costs and in many cases is minor compared to the cost for surveillance, prevention and treatment. The report notes that wise policy choices can ensure that savings, where available, are realized, and where cost increases come into play, the most value is obtained for the resources devoted to genetic testing.

THE ROAD AHEAD

By putting in place the components of this framework, the appropriate protections and review mechanisms, by increasing educational efforts and preparing we can begin to achieve two very important goals.

Firstly, we can equip all participants in the healthcare system with the tools and knowledge which will increasingly be required to navigate what will become more complex terrain in various fields.

Secondly, we have the opportunity to build a climate in society where the general understanding and acceptance of genetic innovation is increasingly shaped by reasoned consideration and a balance between the public and private good.

Such a process is, no doubt, a potentially difficult one. It is complex terrain and there are strongly divergent interests. That said, Canadians need to know that action is being taken, that jurisdictions will not simply adopt a wait and see approach. They need to see that opportunities and challenges are being taken seriously and that we are working collectively to address them and prepare for the future.

If sustaining healthcare means, as it must, maintaining and increasing our capacity to integrate new technologies and offering to Canadians the most appropriate and advanced healthcare that we can, then there is an urgent need for the healthcare system to have access to the necessary resources to adapt. The report underlines the need for federal action on a range of fronts, not the least of which must be ensuring that our healthcare system is adequately resourced to keep pace with the benefits of medical science as it continues to evolve.

At the August 2001 Premiers conference in Victoria, Ontario committed to produce a report for Premiers on genetic patenting and the growing importance of genetic medicine for healthcare. This report is an attempt to canvass the critical factors at play and highlight possible viable approaches for jurisdictions to collectively advance.

During development of the steps required to implement a viable framework, traditional notions of health and healthcare will need to be examined, such as the potential of health care to gradually evolve from a schema informed primarily by 'diagnose and treat' to a 'detect and manage' paradigm. A framework will also need to balance the 'right to know' and the 'right not to know' and engage public perceptions of genetic tests as 'definitive proof' of having a condition versus the complex interplay between genes, lifestyle and the environment. Ultimately the major question will be how we balance individual benefit from emerging technologies with public affordability.

KEY THEMES

INTERJURISDICTIONAL FRAMEWORK

The framework called for in this report is not meant to be a rigidly prescriptive one. It merely offers jurisdictions some markers – possible approaches that provinces, territories and the federal government might choose to take collectively to strengthen our capacity to understand, incorporate and respond to the breakthroughs in genetic technology, while still maintaining the appropriate levers and supports at the provincial and territorial level. The report therefore sets out a series of possible actions for consideration and calls for further collaborative work on the part of governments, providers, educators, patients and industry.

PUBLIC EDUCATION AND ENGAGEMENT

Citing both Canadian and International data, the report suggests that potentially major demand and strong interest exists among the Canadian public for new genetic technologies. This interest is however matched by individuals having a strong sense of not being informed about progress in genetics and related implications (89% of Ontarians polled in 2001 were very or somewhat interested in genetics while 71% indicated however that they felt they knew only a little or nothing at all).

This report notes that without a stronger capacity to engage the public in issues surrounding genetics, there is a high degree of risk that patients may, in the future, be ill-equipped to adequately assess the options available and thereby navigate, with confidence through potentially difficult and complex choices. In particular, circumstances will arise where treatments for conditions are simply not yet available, or where there are complex interactions between genetic predisposition, lifestyle and environment requiring the consumer to make well-informed choices and decisions.

In society at large, without greater public awareness it will also be more challenging for the biotech sector to build the confidence and awareness necessary for a greater, more informed acceptance of the positive contributions that biotechnology can make to Canadian society.

This report notes the role of Genome Canada in promoting education and calls for Industry and Health Ministers to work collaboratively with colleagues on a coordinated strategy for public education across jurisdictions recognizing this as a multisectoral task.

PROFESSIONAL EDUCATION

A knowledge of genetics and the psychosocial aspects of care and treatment will become increasingly important for a broad range of healthcare workers including family physicians, nurses, pharmacists and non-genetic medical specialists. The report calls for jurisdictions to establish a common approach to increasing the training opportunities available at various levels for healthcare professionals in the field of genetics, involving professional associations, industry, educational institutions and bodies such as Human Genome Canada.

The report suggests that this education is an essential preparation for the future and should be coordinated between jurisdictions to ensure greater consistency and to avoid jurisdictions overlapping and duplicating individual efforts.

GENETIC TECHNOLOGY ASSESSMENT

High levels of public interest in new genetic breakthroughs, combined with the rapid commercialization of genetic knowledge will undoubtedly mean that publicly funded health systems will increasingly be required to evaluate claims and counter-claims regarding new genetic technologies and new approaches to treatment.

For all jurisdictions, the capacity to incorporate new genetic technologies in a responsible and effective manner will require improving our collective capacity to assess, evaluate and monitor the relative effectiveness and cost-impact of new genetic technologies relative to existing treatments and procedures.

Without strengthened capacity, there is real risk that misleading, commercial marketing entering Canada from other jurisdictions and via the Internet, combined with the risk of possible premature commercialization could all play a very strong role in influencing the types of tests and interventions which are available or indeed which become publicly funded.

Building on the progress provinces and territories are making in more collaborative pharmaceutical assessment, the report calls for the creation of a new and strengthened capacity for genetic technology assessment, including the potential for the creation of a new agency with specialized capacity to provide all jurisdictions with reliable, timely and objective analysis of new genetic technologies.

The report notes the need to build upon the existing capacity scattered across a number of jurisdictions and the great advantage of avoiding duplication between jurisdictions.

SERVICE DELIVERY: QUALITY CONTROL

There is a need for additional mechanisms and regulations for genetic technologies in order to effectively monitor the quality of services provided. Governments should strive to put in place protections and appropriate testing protocols that jurisdictions need to develop and maintain. As new testing methodologies develop, mechanisms will be required to effectively monitor quality areas such as:

- Testing criteria (under what guidelines and to whom should the test be offered?)
- The accuracy and reliability of the test (should the test be offered?)
- The relative benefit of a new test
- The accuracy and reliability of laboratories conducting the test
- Training of test personnel (are they qualified to perform their duties correctly?)
- The testing process (are patients giving informed consent?)
- The availability or anticipated availability of appropriate treatments or interventions.
- The degree to which patients are receiving a full package of services (are patients receiving adequate pre- and post-test counselling?)

The report notes that Canadians and our healthcare system will be impacted by the possible rise in at-home tests and the availability of such tests over the internet. It is suggested that federal standards for approval for review of such at- home tests be carefully examined and monitored to ensure that they adequately protect Canadians. It is suggested that direct to consumer marketing of genetic testing should be clearly circumscribed if not entirely prohibited for certain forms of testing.

SERVICE DELIVERY: HUMAN RESOURCES

All jurisdictions have faced the significant challenge of ensuring an adequate supply and distribution of physicians, nurses and other health professionals in the midst of an international shortage in many of these professions.

With the anticipated rate of growth of genetic testing we must also face the challenge of beginning to plan now for our human resource needs of the future. Genetics is an international field, highly specialized and qualified, knowledgeable personnel are highly sought after. Geneticists, trained genetic laboratory personnel and genetic counsellors are some of the specialists that are required in delivering services. Genetic counselling to assist patients in making difficult determinations about their care and treatment will unquestionably be a field of increasing importance. All of these specialties are already in relative short supply in jurisdictions currently providing genetic testing.

This report calls for jurisdictions to put in place a shared plan for increasing our capacity to project future needs and to develop a cross-jurisdictional framework to assist jurisdictions in obtaining the appropriate supply and distribution of the skilled personnel that will increasingly be required as healthcare evolves while retaining the valuable expertise that already exists in many jurisdictions. The report notes major investments in genetic expansion that have already been made by jurisdictions such as the United Kingdom and suggests that such advance planning must also be undertaken in Canada.

PRIVACY, DISABILITY AND DISCRIMINATION

Personal health information is some of the most sensitive information about an individual that there is. Genetic information is an obviously important component of personal health information, however, it is a form of information which also raises some unique fears and concerns. Genetic tests reveal information not only about the individual but about families. Technology will allow hundreds of tests to be carried out simultaneously using a drop of blood or hair sample. The capacity to scan hundreds of thousands of samples in minutes will make large-scale screening quite simple. Large databases of genetic information can be created, some of which may exist outside Canada.

The report notes the high levels of concern that exist regarding the possible uses of genetic information by employers and the parallel questions that many Canadians have about how genetic information might be used by insurers. Likewise Canadians need to be assured that data linking and the secondary uses of genetic information are appropriately controlled.

The report outlines the potential for these types of concerns to create a climate which impedes the use of genetic testing in healthcare and therefore the report underlines the need for jurisdictions to take the necessary steps to ensure that appropriate protections are in place.

Many states in the U.S. and across Europe have already taken important steps to put in place specific protections, either legislative or negotiated, to protect the privacy of genetic information and prevent its misuse. Some U.S. law specifies that genetic predisposition will not be considered a pre-existing condition for group health insurance plans. Innovative steps have been taken in the UK to develop voluntary moratoriums on the collection of most forms of genetic information by insurers. Canada, perhaps, has not kept pace.

Similarly, policy principles put forth by the U.K. Human Genetics Commission propose that employees not be required to take genetic tests for employment and that genetic test results should only be used if needed to assess current ability to perform a job safely or assess susceptibility to harm.

The report therefore proposes that Canadian jurisdictions develop common or consistent principles to govern the use of genetic information in employment and insurance and proceed to take steps to appropriately enshrine these protections.

Legislative and policy initiatives are required to protect the interests of children with respect to genetic testing.

Furthermore, genetic breakthroughs carry with them the often exaggerated promise of eliminating certain diseases or conditions. In assessing this promise, the report states that serious consideration must be given to the ethical boundaries of treatment. It is clear that gene technology should be used to assist people rather than to eliminate diversity.

This report stresses the need for the involvement of people living with disabilities and genetic conditions in the discussion of the boundaries of treatment.

PATENT REFORM

Citing the extensive international debate around the practice of the patenting of human genes and DNA, the report examines some of the unique challenges that gene patenting might create. The report recognizes the role of the biotechnology sector in the Canadian economy, the international agreements to which Canada is a party and the important contributions made by the biotech sector to healthcare innovation.

In attempting to think through the potential solutions available to both some of the practical and systemic concerns that exist, this report suggests returning to the fundamental concept of the patent as a contract between society and the inventor. In this regard, while recognizing the important role patents play in protecting innovation, the report suggests that society must also have a role in determining the terms of that contract.

The report notes that there are three main directions Canada can choose to take.

The first approach is that which has been recommended by the Federal Standing Committee on Health. In December 2001, this committee called for a complete ban on gene patenting.

The second is to simply retain the status quo. As Canada already lacks a number of protective measures that exist in other jurisdictions, standing still, may, in effect, amount to simply falling behind, both from the perspective of the biotechnology sector and in terms of meeting the concerns of the public at large.

The third approach called for in the report is the more complex and more challenging but ultimately a more appropriate route to take. Acknowledging the work of the Canadian Biotechnology Advisory Committee and drawing on recent experience in the European community, the report calls for the undertaking of a rigorous review of how and in what form patents should be granted on human genetic material and presents a range of options for putting in place more appropriate balances and protections. This would include an examination of issues associated with stem cell and sub-gene patents.

In Canada, the *Patent Act* is under federal jurisdiction. Working with provinces, territories, industry, consumers and other interested stakeholders, the federal government should review the *Patent Act* and the associated processes and supports involved in the patent procedure. In undertaking this review, the federal government should consider the following approaches:

CLEAR PROTECTION FOR RESEARCH AND CLINICAL NON-COMMERCIAL USE

The report notes the need for clear and unambiguous protection from patent infringement liability for healthcare providers and researchers working on genetic materials, which may be patented. The report also notes existing research exclusions in the *Patent Act* but notes the need to strengthen this approach in order to ensure that individuals whose research work may eventually have a commercial application are not effectively blocked by patent from pursuing improved techniques.

IMPLEMENTING CLEAR AND MODERN STANDARDS

The report notes the extensive work undertaken by the U.S. Patent Office to increase utility standards, provide training and interpretive manuals to staff on gene patents and suggests that this step is overdue in Canada. The report also notes that training and interpretive resources are required by both industry and the public as a clear guide to the practices and criteria employed. The report urges immediate action in this regard.

CLARIFY DEFINITION OF PATENTABLE SUBJECT MATTER

Noting that a patent on a gene is unique in that in certain cases genetic materials can be found to have multiple uses in different combinations, the report suggests that the patenting of "concepts" or general, non-specific utilities, is highly problematic and could potentially result in a direct or indirect block to research and development. The report suggests the need for narrowing the subject matter for which genetic material can be patented including the identification of specific uses and the examination of sub-gene and stem cell patents.

METHODS OF MEDICAL TREATMENT

The report cites the fact that methods of medical treatment (e.g. new surgical techniques) are not patentable in Canada and suggests that this exclusion be extended to the use of genetic materials in diagnosis. Different diagnostic technologies themselves would still under this approach be patentable, but the simple use of patented genetic materials in diagnosis per se would not expose a clinician to liability.

ORDRE PUBLIC/ MORALITY

The report notes the presence of an ordre public/morality provision in the patent legislation of a number of countries and its inclusion in the European Directive on Legal Protections for Biotechnology. The report draws upon recent research breakthroughs in stem cell research and human cloning and illustrates that patents in many areas of stem cell manipulation have already been sought. The report therefore suggests that the inclusion of a comparable ordre public/morality provision in Canadian patent law may be a valuable tool to limit patents on processes or procedures, which are deemed contrary to Canadian morality or ethics.

OPPOSITION PERIOD AND APPEALS COURT

The current practice of the European Patent Office is to have a nine month opposition period that can be utilized by individuals or agencies seeking to challenge the scope, content or validity of a newly granted genetic patent. The report also notes that this opposition process is not court based, is inexpensive and co-exists with a patent approval process significantly more expeditious than Canada's. The report notes the value of the opposition procedure in promoting transparency in the patent granting process and suggests the introduction of such a process in Canada be considered. A specialized court to handle the appeals of the Patent Office's decisions and to adjudicate in matters of gene patent validity and infringement should be considered.

COMPULSORY LICENSING

The Ministerial Conference of the World Trade Organization in Doha, Qatar in November, 2001 stated that nations should be able to take measures "to protect public health and in particular, to promote access to medicines for all." The Ministers also stated that countries have the right to determine the grounds upon which they grant compulsory licenses. This concept must include providing access to the diagnostic procedures necessary to determine when and which medicines to provide. The federal government should consider compulsory licensing of patents relating to the provision of genetic diagnostic and screening tests, granted by the Commissioner of Patents in return for a reasonable royalty fee.

The goal of any patent reforms should be to uphold the beneficial aspects of patent law (e.g. encouraging research, invention and innovation) while ensuring a better balance between private and public interests with appropriate transparency and rigour.

INTERJURISDICTIONAL CO-ORDINATING BODY

The greater incorporation of genetic technologies and the breakthroughs of genetic research into both healthcare and society will not be without significant challenges. This report suggests that the changes will not happen overnight, but sporadically and incrementally, leaving jurisdictions with the choice to either simply adopt a reactive role, moving from one challenge to another, in isolation, or to adopt a more co-ordinated forward-looking approach.

In making this assessment, the report examines models that have been adopted in other countries to examine the role of genetics in society and calls upon Canadian jurisdictions to consider the possible creation of a broad-based Human Genetics Commission with the responsibility to co-ordinate expertise from across jurisdictions and sectors and to assist all governments in better tracking and anticipating forthcoming healthcare advances.

Such a body might also be charged with assisting jurisdictions in monitoring the impact of genetic testing and treatments, examining the ethical and legal challenges that may arise unique to healthcare, and reviewing the implications for healthcare delivery from both a patient and system perspective. All provinces and territories would also benefit from the creation of a forum within which capacity can be shared across jurisdictions. This body might also potentially house much needed new capacity in genetic technology assessment which could be available to all jurisdictions.

CO-ORDINATED AVAILABILITY OF TESTING

Beyond the evaluation of emerging genetic technologies, owing to their highly specialized nature, the report suggests that provinces and territories begin to examine how best to more formally co-ordinate the delivery of certain forms of genetic testing.

In this case, the report envisages more formalized co-ordinated delivery systems for genetic testing which crosses jurisdictions. Increasing co-ordination would not only allow for greater specialization but would offer a rational approach to addressing rarer genetic conditions, for which the numbers of tests required may be too limited for one jurisdiction to justify putting in place the necessary capacity.

This process in the medium term could potentially allow for Canadians in all parts of the country to benefit from improved access to a broader range of tests at a lower cost than the gradual evolution of disconnected systems. The report suggests Health Ministers examine the availability of testing now and the protocols that might be required to build more co-ordinated systems.

SUPPORT FOR THE BIOTECH SECTOR

Canada's biotechnology sector is a vibrant contributor to the growth of the Canadian economy in terms of jobs, research and investment. The report outlines the capacity for Canada to continue its leadership in biotechnology and suggests approaches worthy of study by the federal government and other jurisdictions to help sustain and promote growth in the biotech sector. Approaches taken by other jurisdictions such as the United Kingdom and a number of U.S. states, including the promotion of research clusters and development zones require consideration for their greater application to biotechnology in Canada.

THE POTENTIAL IMPACT ON COSTS

The growth in genetic-based medicine will necessitate many changes in healthcare and delivery at the individual and system level. Further understanding of genetics will prompt the development of new diagnostic and treatment models. Such services may include population-based or individual screening for specific disorders, presymptomatic medical therapies and ways to meet the challenges of greater precision in diagnostic techniques. Understanding the psychological effects of this knowledge on individual health and appropriate counselling will also become an increasingly important component of medical care and treatment. Canadian healthcare systems will need to offer the possibility of earlier detection of disease and enable doctors to focus on prevention as well as treatment of disease through models developed from genetic discoveries.

The report clearly notes that short term demand for genetic testing will be extremely strong. Noting the increased utilization that has been seen of tests currently available and the considerable number of tests anticipated to become available, the short-to - medium term cost pressures will be potentially significant.

It is also the case that for many of the tests for which there will be strong public demand, predictive genetic tests, by and large the newer forms of testing, will not simply replace existing tests, but will often co-exist with existing tests. Unless carefully controlled, the availability of at-home kits could also indirectly have a major impact on costs for the publicly funded healthcare system.

As such, there is some risk that provinces and territories could see a wide range of new predictive genetic tests emerge for which the costs may be relatively high and the possible impact on health highly variable. While some testing will undoubtedly offer opportunities for more effective interventions and earlier treatment, the positive effects will likely take several years to be felt while the costs will need to be borne in the short-to-medium term. In many cases, the cost of the test itself will only be the 'tip of the iceberg'.

Separate from new genetic tests are the breakthroughs in pharmacogenetics which will see increasingly individualized treatments evolving based upon genotyping (using genetic information to understand the responsiveness of individuals to different forms of medication). This form of drug development has many positive aspects, not the least of which will be the possibility to reduce the high human and financial toll from adverse drug reactions. That said, the costs can be anticipated to be large in the short-to-medium term as the research and development investments that have gone into the creation of so called "smart-drugs" are high and industry will be looking to recoup costs.

Gene therapies, genetics, proteomics and DNA microchip technology also hold significant future promise as well as raising significant potential ethical and financial considerations. Again, the health economic benefits accruing from new and emerging technological contributions may prove to be extremely hard to realize in the short-to-medium term, while the short-to-medium term costs of providing access to these innovations will be high.

Strengthened training and staffing to ensure appropriate genetic expertise in the health system is essential if healthcare is to be equipped to rapidly and effectively incorporate new techniques. This training will require cross-jurisdictional coordination and financial support if it is to have the reach and impact required.

If sustaining healthcare means, as it must, maintaining and increasing our capacity to integrate new technologies and offering to Canadians the most appropriate and advanced healthcare that we can, then there is an urgent need for the healthcare system to have access to the necessary resources to adapt. The report underlines the need for federal action on a range of fronts, not the least of which must be ensuring that our healthcare system is adequately resourced to keep pace with the benefits of medical science as it continues to evolve.

CONCLUSION

The acceleration of genetic research over the past decade has opened up a new realm of possibilities for human health and wellness. Healthcare in Canada and around the world will eventually be transformed in many ways by the breakthroughs that even a decade ago few of us could have foreseen.

Governments have much to contribute to preparing society and preparing healthcare to be positioned to draw upon the best of genetic medicine while putting in place the necessary checks and balances which can assist in limiting the risks that undoubtedly come with this terrain.

Building on the tremendous progress that has been made by Canadian researchers in the decoding of the human genome, Canada must now set a goal of not simply housing groundbreaking science, but preparing society to appropriately harness such innovation.

This report has sought to provide a series of markers to assist all jurisdictions in coming to terms with their own unique challenges and issues in a manner which allows them to draw upon the experience and expertise of others.

We call on the federal government to play a critical role in supporting this process, in recognizing and acting upon areas of change which are required, but also to give full consideration to the enormity of some of the challenges that healthcare will face as we attempt to re-shape the skills, methods and tools required for the most advanced forms of medicine.

This report is intended to generate discussion and dialogue and to offer some suggested routes for us to take – in the end, the final product will be what jurisdictions choose to make it. The hard work lies ahead.

The full list of actions proposed in the report are set out below, more detail on each of the recommendations can, however, be found in the final section of the report.

RECOMMENDATIONS FOR POSSIBLE ACTIONS:

CROSS-JURISDICTIONAL FRAMEWORK

1. **Task Health Ministers in conjunction with appropriate colleagues to develop a comprehensive cross-jurisdictional framework on human genetics and healthcare. The framework should be patient-centred and take into consideration the social, legal, ethical, financial and health system implementation issues raised by the increasing role of genetic breakthroughs in healthcare.**

   The goal of a comprehensive framework would be to undertake in a co-ordinated manner a wide range of specific actions designed to maximize the ability of the Canadian health system to utlilize the breakthroughs offered by new genetic research in an informed and forward looking manner.

   Such a framework should encompass:

   a) **Co-ordinated and intensified public engagement on the role of genetics in healthcare.**

   b) **Increased opportunities for the education and training of health professionals in genetics and new genetic medicine.**

   c) **Strengthened shared capacity in health technology assessment and health economic analysis for genetics.**

   d) **Developing appropriate shared quality control mechanisms (testing protocols, laboratory and test evaluation mechanisms, appropriate consumer protections).**

   e) **Developing common increased capacity in health human resource planning for genetics and putting in place a shared multi-year plan for genetic expertise in the health system.**

   f) **Developing the common principles to underpin privacy, disability and discrimination protections regarding the use of genetic information particularly in the employment and insurance fields.**

   g) **Examining comprehensive patent reform and reform to the patenting processes for human genetic materials.**

   h) **The establishment of a cross-jurisdictional co-ordinating body to provide assistance and expertise to all jurisdictions (Human Genetics Commission).**

   i) **Putting in place the basis for a co-ordinated shared delivery system for genetic testing across jurisdictions.**

   j) **Support for innovative biotechnology sector through continued examination of international best practices for supporting strength and growth in this sector.**

PUBLIC EDUCATION AND ENGAGEMENT

2. Task Health and Industry/Economic Development Ministers in conjunction with other appropriate colleagues to participate in drawing up an interjurisdictional framework for public education in genetics and biotechnology for future consideration. Such a framework might examine contributions that could be made by a variety of sectors and existing agencies and determine the steps best taken to maximise information sharing and coordination.

PROFESSIONAL EDUCATION

3. Provincial and territorial Health Ministers through appropriate channels and drawing upon colleagues from other sectors as required could begin by undertaking a "census" of where we are now and from this point on, with federal cooperation and financial support and in conjunction with appropriate professional agencies, set out a series of key targets for improving the training and educational opportunities available to our healthcare workers. The goal would be to develop a multi-year framework for increasing these skills and training opportunities.

GENETIC TECHNOLOGY ASSESSMENT

4. Building on the progress being made by Health Ministers regarding collaborative pharmaceutical assessments, provincial and territorial Health Ministers could be tasked with establishing a workplan, objectives and timeframe for developing optimum current and future collaborative capacity in genetic technology and testing assessment and evaluation. Such a collaborative process should receive at least partial federal funding and be available to all jurisdictions. Assessment would include economic evidence relative to cost-benefit and medical efficacy studies being conducted both pre and post test approval.

5. Provinces and territories might also wish to task Health Ministers with examining the feasibility of "conditional approvals" on certain testing where sufficient evidence is not yet in place to allow a complete determination of the direct and indirect implications of test coverage.

SERVICE DELIVERY: QUALITY CONTROL

6. Health Ministers could be tasked with establishing a common framework for quality control in genetic testing to be utilized to the extent possible across all jurisdictions. Such a framework which could include testing criteria and standards, should build upon existing capacity and expertise and avoid, to the extent possible, duplication and divergent standards.

7. Provinces and territories could assess with Health Canada and Industry Canada existing review processes and develop an information sharing capacity regarding new developments in kit and at-home based testing in this regard.

8. **Provinces and territories could also call on the federal government to ensure that direct to consumer marketing of genetic testing should at minimum be clearly circumscribed if not entirely prohibited for certain forms of testing.**

SERVICE DELIVERY: HUMAN RESOURCES

9. **Health Ministers could be tasked to use appropriate existing mechanisms such as the Advisory Committee on Health Human Resources (ACHHR), and where, appropriate drawing in Education Ministers to undertake a comprehensive review of existing and projected health human resource needs in the field of medical genetics. Health Ministers could be tasked to develop a medium range plan with the goal of providing an adequate and appropriately distributed supply of genetic expertise to residents of all jurisdictions.**

10. **Health Ministers might also be tasked with ensuring that ongoing independent capacity is in place to deliver independent quantitative analysis on supply, distribution and forecasted requirements of specialized skills in genetics (geneticists, laboratory expertise, counsellors).**

PRIVACY, DISCRIMINATION AND DISABILITY

11. **Health Ministers could be tasked in collaboration with appropriate colleagues with developing a set of principles to govern the use of genetic information in the insurance and employment fields. These principles might then be used to either inform appropriate provincial activities or form the basis of legislation or alternate action if such a measure is deemed to be required.**

12. **Health Ministers might also be tasked with determining appropriate mechanisms to ensure the involvement of people with disabilities in discussing the establishment of future parameters for genetic testing in healthcare.**

PATENT REFORMS

13. Working with governments, industry, researchers, patient groups and other stakeholders, the federal government should review the *Patent Act* as it pertains to gene patents. It is important to stress, that with appropriate balance a framework can be created that honours Canada's international agreements, protects healthcare institutions and providers while preserving the spur to innovation that the patent system is seen as offering in genetic research. The goal of the review should be modernization of the Act to achieve the objective of a fair and transparent patent review and approval process. This process should recognize the role of gene patents in supporting industry, but put in place appropriate safeguards and protections for healthcare, medical practitioners and researchers. Possible goals to direct the review would include:

a) Ensuring that appropriate protections are put in place to protect healthcare professionals and institutions, when using genetic materials in research or the provision of care, from legal action or the threat of legal action pertaining to patented genes or DNA sequences. This approach would therefore allow the continued use of different forms of testing (and their patenting) and different interventions each using some or all of the same gene or DNA sequence, but would not allow one gene patent to, in effect, control future subsequent medical use of that gene sequence or portion thereof.

b) Developing new patent office guidelines, procedures and training materials with regards to genetic patents, clear guidelines must be spelled out providing direction regarding novelty, non-obviousness and utility as they pertain to the issuing of genetic patents. Particular attention must be paid in this regard to Single Nucleotide Polymorphisms (SNP) and Expressed Sequence Tags (EST) patenting and include a determination as to whether and under what conditions these sub-gene patents might be granted.

c) Clearly defining the patentable subject matter to exclude broad-based genetic patents covering multiple potential uses and limit patents to clear and well-defined specific uses.

d) Clarifying the "experimental use" and "clinical non-commercial use" exceptions in the *Patent Act* to clearly indicate that non-commercial clinical use of patented genetic material and general research use of patented material are excluded.

e) Expanding the "methods of medical treatment" exclusion in the *Patent Act* to put in place explicit liability protections for medical practitioners and institutions for providing publicly funded medical services in the field of genetics including diagnostic genetic services using patented materials.

f) In light of recent developments in human cloning and moves in other jurisdictions to patent stem cell processes pertaining to the production of human organs, we would urge the federal government to consider adopting a public ordre morality clause within the Canadian *Patent Act*. Such a mechanism appropriately modified from the European experience would grant the Commissioner of Patents the ability to reject patents on processes, products and techniques which are deemed to violate Canadian morals and ethics. Such a power does not currently exist.

g) **Introducing an opposition period of nine months upon issuance of a new gene patent, based on the current European Patent Office model, to allow interested and affected parties to bring forward reasons for which the content, scope or validity of the patent should be reviewed.**

h) **Revising the compulsory licensing provisions in the *Patent Act* to cover genetic diagnostic and screening tests in the public healthcare system, thereby allowing the Commissioner the power to grant a compulsory license and to set an appropriate royalty rate after engaging appropriate industry and health sector expertise, if required, but without prior negotiation with the patentee.**

i) **Examining the creation of a specialized court to handle appeals of the Commissioner's decisions and to adjudicate in matters of patent validity and infringement.**

INTERJURISDICTIONAL CO-ORDINATING BODY

14. **Task Health Ministers with developing a draft terms of reference for a possible genetics Commission, setting out reporting relationships, core goals and objectives and role and responsibility vis-à-vis provincial resources and committees. The Ministers might also be tasked with determining appropriate funding sources for such an initiative, including federal resourcing as an option. This information could be brought forward to Premiers at a later date for decision.**

15. **Task Health Ministers with undertaking the groundwork required to promote a coordinated cross-jurisdictional approach to genetic testing. This task could begin with a detailed review of the types and forms of testing that are currently being undertaken by different jurisdictions and the setting out of some key principles and objectives that might form a future framework.**

SUPPORT FOR BIOTECHNOLOGY SECTOR

16. **Task Industry Ministers to explore priority areas to strengthen the biotechnology sector through a number of innovative means such as:**

- **Examining the support to companies in the area of life sciences to encourage research, development and innovation. Such support could include increased funding for research and development, tax and investment incentives.**
- **Continuing the practice of providing special federal funding for the regulation of biotechnology after 2002-2003 to provide resources for the anticipated 500 fold increase in biotechnology applications over the next decade.**
- **Adapting the delivery of intellectual property services provided by the Canadian Intellectual Property Office (CIPO) to provide a sound, predictable intellectual property environment.**
- **Involving the biotechnology industry representatives in discussions to ensure that CIPO provides globally competitve services for biotechnology patenting.**