



THE CANADIAN COUNCIL ON INTEGRATED HEALTHCARE (CCIH)

Presents
A Discussion Paper on
*The Impact of Genomics
on the Canadian Healthcare System*

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Executive Summary

Canadians will look back on the completion of the mapping of the human genome in June 2000 as a milestone of dramatic change in the manner in which healthcare is delivered in this country. Genomics promises substantial improvements in diagnostic and treatment quality and precision, however, at least initially; it is more likely to be recognised for its disruptive impact on the financing, management, ethical, and accessibility elements of today's healthcare model.

The Canadian Council on Integrated Healthcare (CCIH) is a national, multi-stakeholder health education group with a Mission to help Canadians understand emerging healthcare changes. It used its varied member perspectives to assess the current state of our healthcare system for its readiness to accommodate these challenges. The CCIH found the process of change has hardly begun, and must be started immediately at a very fundamental level. The remedial action must span public, private and professional sectors and include issues identification, mobilization of intellectual and planning resources, and priority setting. Only then can thoughtful, integrated responses become possible.

The CCIH set out to identify the major issues, benefits and risks for key stakeholders, and to help pose the crucial questions. More specifically:

- *How will Canadians enable scientific exploration but also control and regulate the ethical development, use, and sale of these technologies?* Rapidly increasing commercial interest among biotech and pharmaceutical companies presents the potential conflict of science and regulation.
- *Absent a basic level of integration, how can Canadians rationally and effectively plan for the genomic revolution?* A “system-level” approach to managing healthcare in Canada does not exist. Strategic integration of (i) programs and policies; (ii) federal, provincial, regional and local responsibilities; (iii) functional program design; (iv) public and private payer responsibilities; (v) scope of practice and human resource planning for the healthcare professions, (vi) information management technology, to name but a few examples, must become a priority.
- *What communication strategy will ensure educated patients and health professionals, and how can their expectations be managed?* Ethical and practical issues abound, particularly around arming consumers with sufficient, timely, and appropriate information to access testing and treatment, have an effective dialogue with their healthcare professional team, and make good decisions about how to use and pay for genomic technology.
- *How can consumer demand be managed, including fair participation in the costs, given the expense and complexity of these products and services?* Although best guesses place the first true genomic products 3-7 years away, there is already a sense that many of us will immediately consider these to be “magic bullets” – eliminating or dramatically reducing genetic disposition to disease, and obviating the need for personal responsibility for a healthy, active lifestyle.
- *How will patient cost and outcomes data be collected and stored to ensure privacy and confidentiality, and still allow appropriate economic analysis, including quality of life?* A key issue for the payer community (public, corporate and individual) is cost. For example, at this point, it appears new, highly customized products may be many times more expensive than today's broad spectrum drugs. While information technology has developed sufficiently to protect privacy and confidentiality, it is presently inadequate to assure access according to need (determined by whom?), follow the patient through various procedures, and to track outcomes.

- *Are professional associations and regulatory bodies willing to take a leading role to collaborate among themselves, help facilitate equitable access to services, and objectively educate their constituencies?* The health professions will have tremendous challenges, such as expanding the number and role of genetic counselors, keeping up with rapidly expanding scientific knowledge, appropriately prescribing, stocking and dispensing highly individualized products, and communicating among members of the patient's healthcare team.
- *What will ensure governments at all levels create a coordinated legislative, regulatory, and financial framework that allows Canadians to confidently and inclusively plan for the looming impacts of genomics?* With today's issues about rapidly escalating costs, poor access to services, unknown or uneven quality, governments at all levels have suffered (and even started) many attacks on their credibility as health system managers. While many issues are beyond the control of government, e.g., consumer demand, the CCIH expects governments to lead, encourage confidence, engage all relevant stakeholders, and create the conditions for sustainable change.

In essence, there are many organizations, governments, and health professions that must begin immediately to address and communicate the complexities of genomic research, diagnostics, and treatments. Today's system and organizational issues are vexing enough, but they will be multiplied and made much more difficult without a transparent, early, and comprehensive forum to debate these significant challenges. Since genomics issues are international in scope, a "Made in Canada" solution is not totally practical, but an early start can give us the opportunities in health and industrial policy that come with leadership, innovation, and integration.

The CCIH urges the federal Minister of Health, the Honourable Allan Rock, to organize and convene a multi-sectoral, exploratory meeting on the broad impacts of genomics on Canadians and their healthcare system, in the very near future. These issues are tremendously important, and there is a pressing need for Canada to deal with them.

The CCIH hopes this paper helps engage Canadian stakeholders in discussion around the looming impact of genomics. The CCIH would be proud to participate in this important preliminary dialogue.

I.i **Introduction to the Canadian Council on Integrated Healthcare**

The Canadian Council on Integrated Healthcare (CCIH) was founded in 1997, and is driven by the emergence of several key trends in the Canadian health care system. These include:

- the shifting and rapidly escalating need for health care funding;
- advances in information and health care technologies;
- the redefinition of employers' health-related responsibilities, and;
- the need for integration and collaboration within the continuum of care.

The original intent of the CCIH was to bring together key opinion leaders from across the Canadian private health sector to exchange views and develop solutions on the evolving management of health care in Canada. More recently, the Council has broadened its perspective to include membership from labour, consumer health, and politics. A list of members and observers is in [Appendix A](#).

The CCIH is the only national, multi-stakeholder professional forum in Canada working to encourage constructive and inclusive dialogue on challenging health-related issues. Its activities are funded through an unrestricted educational grant from Aventis Pharma.

I.ii **Purpose of this Paper**

The mapping of the human genome, completed less than one year ago, will fundamentally and necessarily alter the manner in which healthcare is delivered to Canadians – and our current system is not positioned to benefit from the coming revolution. The CCIH believes that if our society is to capitalize on genomic technology Canadians must begin to prepare their health system now.

The CCIH has issued this paper as a ‘call to action’ for key stakeholders within the Canadian healthcare system to begin a collective discussion on the implications of human genomic research. The CCIH believes that the worldwide scientific community’s progress in the study of human genomics will create new opportunities for better healthcare, but that the technology will be disruptive to our existing healthcare delivery model. The onus is on the key stakeholders to anticipate this disruption and rethink the design of our delivery system today to ensure all Canadians have equal access to the new technologies, processes and treatments that genomics will bring about. Without an immediate, collective effort to identify issues and work towards a truly integrated system, the full potential of this science will not be realized.

I.iii **Distribution of Preliminary Draft**

The Looming Impact of Genomics on the Canadian Healthcare System was sent to individuals and groups whom we perceive to be key stakeholders in the issue at hand. We have invited their comments to help us reach the widest relevant audience, and welcome constructive feedback. We want to thank the following groups for their valued input and suggestions:

II.i Human Genomics Overview

A *genome* is an organism's complete set of genes and chromosomes; the complete set of instructions for the design and function of an organism. The term *genomics* describes the scientific discipline of mapping, sequencing and analysing genomes.

Key to this discussion is the idea that understanding the human genome will lead to a functional knowledge of disease at the molecular level *on an individual basis*. As our understanding of human genomics progresses, a systematic method of finding specific genes of interest and identifying their functions will be developed in order to detect disease or the potential for disease with the ultimate goal of intervening in those functions for prevention or treatment. These specific interventions would be primarily achieved through new diagnostic tests and the engineering of pharmaceutical compounds tailor-made for an individual's genetic profile and specific disease state.

Today, disease is predominantly understood on a symptomatic level, i.e. understanding a disease in terms of *what it does* to the body. Genomics will lead to an understanding of disease in terms of its mechanisms of action, i.e., *how it comes to be*. To date, disease has been studied and understood from a uniform perspective, under broad categories of illness. This perspective of uniformity for both illness and intervention will, in the future, move to one of disease heterogeneity and variability in patient treatment. An example of this can be seen in cancer research which has moved from a view of cancer as 'one disease' to one of many diseases. Researchers and health care practitioners are beginning to tailor treatments for individual patients through genetic screening.

It is clear that progress in this field has to date been rapid. The Human Genome Project (HGP), a consortium of international research groups, began sequencing the human genome in 1990. They completed a working draft covering 90 percent of the genome in 2000, and by 2003, they will finish the sequence with an accuracy greater than 99.99 percent fewer than one mistake every 10,000 letters¹. As science moves ahead with developing an understanding of what has been mapped, we will learn how the estimated 500 to 1,000 genes that cause disease correlate to specific illnesses². These genetic targets will, in turn, drive the development of drugs designed to intervene in this process.

Identifying genes responsible for specific diseases has already yielded positive results in terms of targeting drugs for treatment. One example: in 1993, a drug designed to treat Alzheimer's disease was found to be efficacious in only half of its target population. In the same year, however, a university research team identified a connection between the *apo E* gene and Alzheimer's, while yet another team demonstrated the drug's efficacy in the presence of the *apo E* allele. The result: 83% of Alzheimer's patients without this allele, or 30% of all sufferers, responded positively to the drug³.

From 1990 to 1997, the Boston Consulting Group reported the number of genomic research derived products tripled to over 1,200, the greatest increase being attributed to biotech companies and academic institutions. There were over 125 technology alliances to conduct genomic research by 1997. These numbers illustrate the growing trend to forming technological alliances between pharmaceutical companies, bio-tech research firms and academic research facilities to accommodate

¹ National Institutes of Health, The Human genome Project Exploring our Molecular Selves, 02-12-2001.

² The Pharmaceutical Industry Into Its Second Century: from Serendipity to Strategy, The Boston Consulting Group.

³ Ibid

the organization and cost concerns that are central to genomic research and product development. These alliances are radically changing the process of drug discovery and development within the pharmaceutical industry.

While the timing and form of future developments may be unpredictable, the direction of change is certain: the therapeutics derived from genomics are a square peg in the round hole that is today's healthcare system. How policy makers and healthcare providers can adapt to this new technology is the real issue.

II.ii Key Issues for the Canadian Healthcare System

Overview

- Lack of integration in the Canadian healthcare system
- Mastering new approaches in drug discovery, strategic alliances, and operational efficiencies for pharmaceutical manufacturers.
- Creating coordinated practice models among traditional and emerging healthcare providers.
- Developing an ethical framework to deal with genomic testing and products
- Encouraging realistic expectations among Canadian consumers about choices in therapy, and the necessary balance between cost, quality and access.

The traditional 'silo' structure of the Canadian healthcare system – where individual components of the system (research, funding, regulatory, primary care, health insurance, etc.) operate independently – will not be capable of implementing the practical outcomes of human genomic research.

If each component works without coordination, the delicate balance between the quality, access, and cost of healthcare, will not be optimized. Every aspect of the healthcare delivery system as it impacts Canadians is affected by the relationship between these three factors, each of which can be impacted by the other two. If, for instance, a new technology or treatment is particularly costly, then access to it is likely to be limited by financial constraints. The quality of healthcare for a patient with no access to a needed technology/treatment is thus negatively impacted.

MRI - A Missed Opportunity?

Technology has come a long way since 1946, when Felix M. Bloch and Edward M. Purcell first conceived of using a magnet to take pictures inside living beings. But in the 20 years since the world was first introduced to the "revolutionary" MRI scanner, the machine still has yet to live up to its full potential. The benefits of MRI are astounding: a radiation- and surgery-free way to accurately detect many spine, joint and brain disorders. Of course, the advantage of early detection is earlier treatment, leading to better patient care. So why are thousands of outpatients faced with a wait of up to one year? The high cost of machinery leads to uneven distribution of MRIs in hospitals across Canada. The difference ranges from one scanner per 189,000 residents in New Brunswick to 1:539,000 in Newfoundland. Traveling to private clinics in some provinces, such as Alberta, and in the United States means paying the price for faster care. Last year, Federal Health Minister Allan Rock announced a \$1 billion injection into the health care system for medical equipment, including MRIs, over two years. The results of this still have yet to be seen on the front lines of health care. Extending hours of operation have improved access to existing MRI machines, but there are still no national standards for access to MRI technology.

As previously mentioned, these new technologies, diagnostic tests and drugs that arise from genomic research will be aimed at increasingly specific target populations, resulting in their development costs being borne by ever-smaller populations. However, genetic testing offers the possibility of better treatment accuracy which should result in higher respondent rates and fewer side effects. Ensuring access to and the quality of these treatments in the face of rising costs is an issue that needs to be addressed today. Today's silo planning and budgeting models will not suffice.

The changes within the pharmaceutical industry are significant - as are the stakes for those that succeed or fail in their attempt to adapt to this new environment. The ability to discover and develop specific products for specific indications for specific people is rapidly expanding. In 1998, for example, larger drug companies discovered an average of one new chemical entity (NCE) each. By 2003, the number of NCEs is expected to rise to between five and 10 for each company per year⁴.

The proliferation of new drugs will bring about a paradigm shift in the ways that pharmaceutical companies do business. As the number of drug discoveries and the speed with which they are developed increases, the industry will be forced to evolve from a competitive focus on mass-market therapeutic categories to one that focuses on narrow therapeutic categories and uncertain margins. Pharma companies will have to create drug development system and process efficiencies to replace the economies of scale approaches that have determined their success in the past. 'Blockbuster Drugs' will form an ever-decreasing share of company income and profits.

There are also questions surrounding testing for disease and prescribing genomic research derived medications. Presumably, more accurate predictive tests may create a surge in the demand for genetic testing. If appropriate drugs are available at the point of diagnosis to treat the identified disease, then who will be in the best position to prescribe the drug (GP, specialist, genetic counselor), who will follow up with the patient, who will monitor and record the drug's success rate, and, yes, who will pay for it.

In terms of the scientific community, genomics has created innumerable opportunities for research and discovery. With this constantly growing new body of knowledge comes new abilities to identify and treat disease. These new abilities to intervene in the processes of human biology give rise to complicated ethical, logistical and access issues.

The ability to evaluate genetic risks for diseases such as Alzheimer's or Parkinson's will demand a new evaluation of the risk/benefit ratio of treatment. Medical treatment for patients who already suffer from a disease is one issue with which the medical community is familiar. Managing patients years before the onset of any symptoms is a far more sensitive ethical and financial concern. There is no evidence that genetic tests are 100% accurate in terms of predicting disease, and environmental factors will always play a role in the development of some diseases. Reasonable expectations for genomics must be maintained.

Current ethical, legal and regulatory codes have evolved over the course of many years, as has social acceptance of certain kinds of medical treatments. It could be argued that these policies, formal or otherwise, have to date been reactionary. The speed with which science will make progress in the genome-based future will challenge our ability to adapt, monitor and regulate science and medicine.

⁴ The Pharmaceutical Industry Into Its Second Century: from Serendipity to Strategy, The Boston Consulting Group.

Primary healthcare providers will have an increased ability to focus on individual care, prevention and cure, as opposed to prescribing broad treatment regimens, and encouraging patients to simply cope with acute and chronic diseases. However, their ability to manage the pace of change by keeping up with new knowledge will be a significant challenge. The proliferation of medicines for increasingly specific populations will require a restructuring of continuing medical education to allow primary care practitioners to acquire information and transfer knowledge in a timely manner.

The traditional relationship between primary care practitioners and specialists will undergo significant change as geneticists become key participants in patient care. Genetic counseling as a specialty is virtually non-existent today, and much work needs to be done to define its role in the system, to identify demand, and to prepare the education system to produce enough counselors. Once in place, this new three-way relationship - physician, counselor, patient - will create significant communication and collaboration issues, especially in the absence of an integrated technology infrastructure.

The opportunities and possibilities of genomics will likely create unrealistic expectations among the public for immediate access to new technologies and treatments. It is important that all Canadians remain abreast of emerging information about genetic medicine and understand the implications, for example, of genetic tests and tailored therapies. However, it is critical that the Canadian consumer plays an active role as a responsible partner to assure that the healthcare system invests in options that are beneficial and sustainable. Even with the proliferation of awareness programs and information resources, consumers often have conflicting opinions about health and disease. Helping them to grasp the reality of new genetic tests and tailored therapies will require more concerted education initiatives in the future. This will be complicated by having many more subjects about which to raise awareness — subjects of increasing complexity — as well as the effects of direct-to-consumer advertising. Timing issues are also a concern: if awareness is raised before these therapies are widely available, then false-hope will be created; if awareness is raised too late, the end-users of the system will be overwhelmed with information, or frustrated with its lack of responsiveness.

II.iii Key Stakeholders in Canada

The CCIH has identified five key stakeholder groups in Canada that will be affected most by developments brought about by human genomics, and that will have significant roles to play in preparing our healthcare system for the changes on the horizon.

- Healthcare Providers: These are the individuals and organizations who provide primary and secondary healthcare to Canadians.
- Consumer/Patients/Advocacy: These are the end-users of healthcare and the groups that represent their interests.
- Industry: These are the organizations that research, develop and manufacture the products and technologies used to test, diagnose, and treat consumers, such as pharmaceutical companies.
- The Payer Community: These are the arms of the government (i.e. Ministries of Health, Veterans' Affairs), private benefit plan sponsors, and insurance companies that ultimately pay for healthcare in Canada and shape decisions on the availability of various technologies and products to consumers.
- Government/Regulatory: These are the arms of the Canadian federal and provincial governments that are responsible for regulating and investing in the infrastructure of the healthcare system.

III.i Key Issues by Stakeholder

In this section, the key micro issues of human genomics that affect each of the five groups outlined in Section II.iii will be examined.

III.ii Healthcare Providers

Key Issues

The impact of genomics on the Canadian healthcare system will likely have a significant impact on the way providers carry out their responsibilities. In terms of genetic testing, for example, it is unclear as to who specifically will be performing the new tests. Coping with unequal geographic access to these tests as they become available will become an important issue, as well. New guidelines for administering tests and interpreting their results will require development, as will guidelines for treatment based on those results. Experience to date has been very poor on both guideline adoption, and guideline quality.

Widespread genetic testing will increase healthcare utilization and at least short-term costs, which will in turn affect case management, mix and budgeting. Currently, the average GP in Canada spends 9.5 minutes per case visit, a figure that is guaranteed to increase with the rise of more complicated diagnostic and treatment procedures. The quality of that communication is also crucial, especially recognising the cultural diversity of Canadians. Almost half of Canadians, and 80% of seniors, had "difficulty with reading materials encountered in everyday life."⁵ If reading and fully understanding medication labels is already beyond the comprehension of a large group of Canadians, how will more complex issues like cost containment and drug utilization reviews be communicated?

⁵ Health Canada, 1998. *How Does Literacy Affect the Health of Canadians?* Viewed June 2001 at: <http://www.hc-sc.gc.ca/hppb/healthpromotiondevelopment/pube/literacy-health/literacy2.htm#situation>. Page 2.

The availability of a specific drug for a specific patient will create control issues about who specifically dispenses the product and where. Pharmacists may face significant difficulties in managing inventory when so many customized products will be available. Formularies as they exist today will be challenged to maintain control – and order – over countless new drugs as they become available. Similarly, patients who receive tailor-made treatment will need detailed follow-up, and just who will be in the best position to do that remains unclear. Researching the outcomes of innumerable treatments will be a major undertaking, if it is possible at all. Tracking outcomes, however, is key to the success of any system that must balance costs and benefits and ensure that certain therapies are available to more than just the largest hospitals, or the small group of patients willing and able to pay.

Possible Benefits to this Group

The possibility of many more breakthrough discoveries leading to real cures for disease must top the list for this group, followed by the creation of more exacting and reliable diagnostic tests. Increased coordination among various types of healthcare providers will be necessary and will require a proactive effort. Once achieved, however, the overall efficiency of the system will likely increase as well.

Possible Risks to this Group

Increasing costs and expenditures, unclear ethical standards and undefined and poorly coordinated standards of practice represent the top three challenges to healthcare providers. As new technologies reach the market, providers will be overwhelmed with information that must be assimilated if it is to be actionable. Treatment guidelines today are often underused or of poor quality, and disregarded by many healthcare professionals. With the proliferation of new medications guidelines will only increase in complexity and importance. The potential expense of new medications will place an additional burden of accountability on those who prescribe them. Uncertainty surrounding the future roles of traditional providers (GPs, specialists, nurses, pharmacists etc.), as well as emerging providers such as genetic counselors, could create 'turf' issues at a time when collaboration will be more important than ever before.

Why Plan Now?

The CCIH believes that Canadian healthcare providers must begin to address these issues today in order to prepare for necessary changes in technology access, database development, more coordinated professional education, cost containment and budgeting, allocation of resources and integration of components of healthcare delivery mechanisms. Defining clear roles for providers is already an urgent matter; identifying new responsibilities and folding new specialties into the provider community will require a significant investment of time and resources.

III.iii Consumers/Patients/Advocacy Groups

Key Issues

The translation of human genomics research into healthcare products, including tests and treatment, will provide patients with unprecedented opportunities to make truly individualized decisions about their personal healthcare. It is possible that consumers will be able, and even required, to make many healthcare choices at many points along the continuum of healthcare, from prevention to end of life. Arguably, most Canadians are not now ready to deal with these complexities. The challenge will be for consumers to become well informed about options and the implications of these options for

themselves, their children, and others in their family. For example, parents may have the opportunity to decide whether they want their child tested for a gene that would indicate the presence of an inherited condition that may not be expressed until the child is 50 years old. Changes in diet, activity, or environment may reduce the impact of the condition; on the other hand, it may also affect the child's future employment and insurance options.

Moreover, the availability of health resources, including the Internet, will allow the consumer to access to huge amounts of information through a variety of sources. The challenge for the system is to help the consumer to find quality information, allow him or her to distinguish between the myths and realities of medicine, and then, to use the information appropriately to improve their individual health situation.

Consumers will also be faced with new levels of uncertainty and anxiety when faced with the results of genetic diagnostic testing. A 35-year-old who, after a routine genetic test, is told that she has a very high probability of developing a debilitating late-onset disease, will be faced with life-altering decisions much earlier on in life than is presently the case. Individual accountability and choice issues will come to light, particularly as they apply to treatment decisions that affect children or people unable to care for themselves. It is essential that the healthcare system allows the Canadian consumer to participate as a responsible partner in making decisions that are both individually acceptable and affordable for the healthcare system, as a whole.

Privacy and confidentiality of health information will become more contentious with the opportunity for consumers to access to information about potential conditions and disorders that may never become realities. The right of the consumer to sovereignty over his/her health information must be weighed against responsibility to employers and insurers who assume liability for health risks, and system administrators who must allocate health resources fairly among all Canadians. It would be important for all stakeholders to engage in reasoned dialogue over issues such as mandatory genetic testing before they are challenged or tested through another system, such as jurisprudence.

Finally, consumers will face complex issues surrounding access to new healthcare technology and treatments as they are developed and made operational. Access could be impacted by economics, geography (much like MRIs and other high-tech procedures today), employment status, age, awareness and education, and culture/ethnicity, among other factors. Today, each province provides some level of coverage for its citizens, but the degree of coverage varies widely. The need for patients to have access to genomic tests and products, regardless of their province of residence, highlights the void in national standards that must be addressed.

Possible Benefits to this Group

Drugs designed in the very near future will have increased safety and tolerability profiles, and will be more precise and effective in terms of their modes of action. This will increase the ability to cure disease, with fewer side effects and a decreased risk of treatment failure. The viability of pursuing treatments for orphan diseases will increase opportunity to develop more products. This is because patient-specific treatments will become the standard of care as the healthcare system evolves to accommodate genomic therapies. With lower risks of side effects for genetically designed drugs, consumers receiving tailored therapy should expect increased quantity *and* quality of life.

Possible Risks to this Group

The ethical implications of genetic manipulation and genetic selection – for example, choosing whether or not to terminate a pregnancy if genetic tests suggest a probability of the baby developing a disease – will be of immense concern to this group, as well as to regulators. In terms of equity of access and payment for new tests and drugs, consumers already face a multi-tiered healthcare system that does not allow everyone to benefit from equal or equitable access to the services they require. The sheer complexity of the science will create an obstacle for their understanding of the options open to them, possibly limiting the level at which they can effectively participate in their care. Finally, since economics will play a key role in the future in terms of cost/benefit analyses and allocation of new treatments, consumers must learn how to balance a pervasive entitlement mentality, with the necessity of some level of personal financial participation in their care. Consumers will have to pay, either indirectly through their taxes, or directly from their own pockets.

Why Plan Now?

The complexity of these issues demands significant time and planning to identify and address priorities. Education on these issues to achieve a functional level of understanding that will allow consumers to participate in their care will be a major undertaking, but it will be necessary to ensure that decisions about care are not based solely on emotional or uninformed considerations. Industry, employers and labour will need time and significant resources to develop alliances to guarantee the needs of the consumer are adequately represented.

III.iv Pharmaceutical Industry

Key Issues

Genomics is fundamentally disruptive to all aspects of the pharmaceutical industry's value chain—from drug innovation and research, to development and commercialization. Despite this, the pharmaceutical industry has been one of the most significant investors in genomic research, and so has a considerable stake in the adoption of these therapies. In fact, it was the early recognition of the disruptive power of genomics that has driven their investment in genomics to date. In reality, though, many of their business processes are out of alignment with the coming changes that genomics will bring. The most significant of these changes is the change in the number of medication that they will need to create and the number of patients that will take each of these therapies. As genomics allows diseases to be broken down into their sub-diseases, many more medications will be needed to treat smaller and smaller numbers of patients. This change is akin to the transformation in thought that took place in the automobile industry where the Model T Ford, which was sold 'as is', to the cars of today which can be ordered off the Internet with hundreds of different configurations.

In today's drug discovery process, it is often serendipity that isolates drug targets, against which companies test compounds, and screen drug candidates for clinical effect. This has been a major bottleneck in the drug discovery process. The *Human Genome Project* has already provided drug targets for two other critical technologies, combinatorial chemistry and high-throughput screening. *Combinatorial chemistry* allows researchers to generate up to 10,000 times more compounds while reducing the per-compound cost by 1000 times. *High-throughput screening* allows these new compounds to be quickly evaluated against the drug targets. The synergy of these three technologies has the potential to make the process of drug discovery more predictable and economically viable.

Once the clinical candidates are ready for human testing another important challenge will emerge. Clinical trials are now designed for relatively large samples of patients, but genomics will be aimed at much smaller sub-groups. This will complicate statistical analysis - as trial size decreases, trial results must show greater treatment benefit in order to reach statistical significance. Evidence-based medicine has become the new standard for practice amongst health professionals, which brings into question how they will interpret and manage the information from smaller studies. Trials will also increase in specificity and complexity for all diseases, increasing the costs associated with clinical trials, however this may be offset by more accurate test populations that result in more effective clinical trials.

Once these new agents are proven to be effective, collaboration with government regulatory and licensing authorities will be required if these new therapies are to reach the market efficiently. Regulatory approval processes in Canada today take longer, on average, than in most Western nations.⁶ As more genomic-derived drugs are brought to market in the future, a larger, more efficient and effective, and transparent regulatory environment will be required to allow access and accountability for Canadians.

Educating healthcare professionals on appropriate prescribing for this massive number of new drugs is a formidable challenge. It is easier to convey information about today's broad spectrum drugs than about many small-segment products. Manufacturers are not currently capable of detailing so many products to physicians, pharmacists, nurse practitioners, and consumers, all of whose product knowledge must be constantly refreshed. Manufacturers will also have to help to enhance distribution channels so pharmacies can dispense patient-tailored therapies.

The cost of these new products makes it unclear if a manufacturer's investment in genomics will be repaid. Many provincial governments and private payers already require pharma companies to establish the cost-effectiveness of a medication before it will be listed. This analysis will become much more difficult in the absence of large clinical trials where health costs can be compared versus alternative standards of care.

The genomics revolution in the pharma industry means the economies of scale that industry has relied upon to date will have to give way to a new business model that capitalizes on the new therapies ability to target subpopulations with a high degree of accuracy+.

Possible Benefits to this Group

The development and use of better genetic testing technologies to screen individuals will allow pharmaceutical companies to stratify test populations more accurately, resulting in more effective therapies. Overall, genomic innovation will help to create better products, and improve patient survival. It should also reward companies who are able to evolve their business models and manage change with higher sales and profits.

⁶ www.canadapharma.org/publications/factsheets/nofactsheet.pdf

Possible Risks to this Group

The changes to the ways drugs are researched, tested, approved, marketed and distributed will destabilize the current business model of pharmaceutical companies. As more drugs reach the market, healthcare providers will be overwhelmed by a mountain of new information, possibly resulting in an increase in prescribing errors. The cost of these products alone is enough to de-rail innovation - if no one is willing or able to pay, why produce them? It will become more important that drug companies create the 'business case' that demonstrates the value and efficacy of these new products to regulators, payers and consumers. Inappropriate use or abuse of drugs designed for other purposes can be expected, as well, as in cases where drugs are used to compensate for unhealthy behaviour. The implications of misusing genetically designed drugs could be severe.

Why Plan Now?

As the business of delivering healthcare to Canadians approaches the \$100 billion⁷ mark it is obvious that the process for evolving that system is complicated and time-consuming. It will be necessary to collaborate with all stakeholders in the healthcare system, particularly regulatory bodies, if pharmaceutical companies are going to be successful in helping Canadians to have access to the best therapies that the genomics revolution will offer. Practically speaking, many of these developments will be available within the next 5-10 years; clearly the time is now to prepare the Canadian health system for these changes.

III.v The Payer Community

Key Issues

For this group, the human genomics issue is to a great extent a financial concern, primarily to locate sufficient funding, and to divide it among those capable of paying. While the true costs of genetic tests and consequential therapies remain to be seen, it can be assumed that genomics-based healthcare will have significant dollar figures attached.

Genetic testing is a new component in healthcare expenditures that may add to the short-term burden of healthcare funding, even if tests and therapies are used appropriately. Theoretically, these costs could be offset by the beneficial effects of disease prevention, by improved, targeted care, and lower care costs in the long-term. Abuse of the new technology, however, would add excessive costs to the system. Tailor made drugs based on an individual's genetic makeup would undoubtedly cost more, which will severely increase health insurance premiums, create more stress for plan sponsors already seeing annual increases of 15-20%, and hitting consumers hard with high out-of-pocket costs. This creates real concern about the sustainability of today's public and private health plans.

Evidence-based models will become the foundation for decisions as to what is covered in a benefit plan. Currently, it is uncertain how this myriad of new genomic tests, medications and treatments will be evaluated, by whom, and under what criteria. New, or at least more refined, economic models to judge the value of therapies will be required. Public and private payers must work together to ensure adequate coverage is available to all Canadians - this is not presently the case, as a recent study showed.⁸

⁷ Health Care in Canada, Canadian Institute for Health Information, 2001.

⁸ Health Transition Fund Project NA202, *Canadians' Access to Insurance for Prescription Medicines*.

As in today's system, drugs are evaluated for coverage in a health plan according to several factors, not the least of which are evidence-based decisions founded on efficacy and cost. Payer groups may be more willing to pay for evidence-based decisions as the research to support or refuse certain types of treatment becomes clearer and more reliable. This may mean cost-benefit analysis of treatment on an individual basis, raising confidentiality issues, but allowing payers and regulators to direct funds to areas where they would be most effective. Managing the quantity and quality of evidence supporting these numerous new drugs – and the speed with which the information can be processed – is a key issue here. It also presents another area of collaboration between public and private payers, as well as the manufacturers.

No one knows for certain how much employers or plan members would be willing to pay for tailor made genetic tests and therapies, though the likelihood of their success may ensure greater willingness to pay. The cost of genetic tests may be included in plan coverage, meaning higher premium costs for the consumer. Most plans today are designed with no out-of-pocket limit, but to deal with high-priced, highly targeted therapies, plans may have to be re-designed to protect consumers from catastrophic out-of-pocket costs, as is the case in Québec.

Many payers, for whom legislation is a prime driver for making decisions, will feel that regulating costs and access to the new technologies and treatments will be beyond their control. The burden of regulating and legislating a genetically focused healthcare system with the aim of creating workable policy would make today's regulatory framework seem simple by comparison. Payers will be looking to regulatory bodies to more quickly and effectively develop and communicate new regulations.

Possible Benefits to this Group

To the degree the debate on genomics opens the door to innovative and inclusive thinking and greater collaboration between today's multiple payer communities, then more rational, integrated and seamless coverage will be available. The genomic debate may enable payers to force greater dialogue between themselves and manufacturers, physicians, pharmacists and consumer groups to allow more rational marketing, prescribing, dispensing and use of drug therapies.

Providing higher quality of life to Canadian employees and their families will lead to increased societal productivity, benefiting employees and employers, as well as governments. The creation of more targeted therapeutics and their potential cost efficiencies should streamline the system, meaning that Canadians will receive only the tests and treatments they need. The capability for improved assessments of mortality and morbidity risk will allow insurers, governments and medical researchers to better profile our nation's health status.

Possible Risks to this Group

The failure to have significant regulatory and legislative support would severely jeopardize public and private payers' ability to effectively administer their plans, with potentially serious consequences for the people covered by such plans. Adverse risk selection is another possible problem for this group. If, for instance, an individual undergoes genetic testing and discovers a high potential for serious disease and is not required to disclose that information to insurers — or simply does not report it — then life insurers will not be able to match risks and probabilities with costs. This could have an enormous financial and legal impact on the system.

Ethical issues and legal liability exposures are other important issues for this group. The use or misuse of private healthcare information records are a concern today, both for payers and individuals. Clear and consistent national regulations regarding access to genetic information are not yet in place.

Finally, the potential for increased costs beyond the payers' willingness or ability to pay is a significant risk. With a complicated array of genetic tests and therapies, administration and claims costs could increase if use is not well-managed. One key challenge to this group that will be the way in which budgets are forecast and managed to ensure the medical revolution can happen on a practical level — and this will require a willingness on the part of the paying community to budget sufficiently.

Why Plan Now?

The process of identifying, understanding and prioritizing the issues will be a massive undertaking that will demand time and significant resources. Accessibility issues — ensuring that Canadians have equitable access to these new technologies across lines of race, class and geographic location — must be addressed before they are in place. Before Canada can enter the first phase of the paradigm shift that genomics will bring, it must transform its current healthcare infrastructure. Systems must be put into place to enable the efficient management of the healthcare process; this will require the integration of the payer community to achieve a rational division of authority and clear lines of responsibility.

III.vi Government/Regulatory

Key Issues

The complexity of the issues surrounding genomics and the enormity of their impact on the Canadian healthcare system will require a concerted effort from governments at all levels to ensure change strategies are developed and effectively implemented. The Canada Health Act long predates the modern era of genomics, and simplistic reliance on its five principals is not adequate to ensure that access to genomic tests and products will be protected and sustainable. A sizeable infrastructure investment, particularly in information technology⁹ will be necessary to facilitate a transition to an integrated system with many players and many treatment options. Laws and regulations regarding information management are also essential for health researchers as well, who must not be hampered in their ability to study and make recommendations on treatments and our rapidly changing healthcare system.

Having the ability to determine risk for disease through complex, sensitive genetic tests will create the need for facilities, equipment and personnel to administer tests and interpret results. As illustrated in the Canadian MRI access example, the capability to diagnose disease can be easily undermined by a lack of resources. A key issue here centres on whether or not publicly funded institutions could afford to handle the genetic testing burden, or if responsibility would be handled best by the private sector. If the latter occurs, what are appropriate safeguards? Nationally consistent and effective protection for privacy and confidentiality is lacking.

Similarly, meeting the demand for creating new healthcare roles such as genetic counselors and the potential retraining of existing healthcare providers will require a large investment in coordinated continuing education and communication efforts.

⁹ An excellent, and largely ignored, proposal for information management was in the now-defunct Health Services and Restructuring Commission's June 1999 publication; *Ontario Health Information Management Action Plan*.

Possible Benefits to this Group

With human genome research, federal and provincial regulators have before them a tremendous opportunity to provide sustainable access to all Canadians. Well-designed legislation and clear, consistent regulations will mean Canadians will soon be able to universally reap the benefits at the community level, with particular emphasis on quality. One benefit to governments is to avoid wasting dollars on no-win advertising campaigns over who is doing what with funding that is sourced ultimately from the same taxpayer. Governments can forge ahead with a leadership role, think strategically and inclusively, de-politicize the process as much as possible, and be prepared to act more quickly than in the past. This will undoubtedly translate into increased confidence by Canadians, and greater respect and legitimacy for our beleaguered governments. The opportunity to demonstrate policy and program leadership is before governments now, and brought into clear focus by the tremendous complexity around genomics.

Possible Risks to this Group

Regulators have been traditionally slow to react to the changing face of health care. The progression of human genome research, and the rapid deployment of this technology, will cause a sharp rise in the demand by the Canadian public for genetic testing and treatment. If regulators react too slowly to this emerging need by the public, some dire consequences could result. Ethics could be jeopardized simply because parameters are not properly defined for the use of genomic testing. If access is not addressed, then individuals, whose access is restricted, may choose or be forced to head outside Canada for this technology and treatment, rather than receiving treatment at home. Quality could be compromised without proper regulations to protect individuals from the very technology that presents the opportunity for positive health care outcomes.

Why Plan Now?

Since research on the human genome has progressed swiftly, the time for regulators to prepare the "rules of the game" for genomics is now. In order for the full benefit of genomics to be provided to individuals, legislation and public policy requires immediate attention due to the length of time to consult, develop policy and prepare legislation and regulations. Settling federal, provincial, and regional jurisdictional issues must begin now, and a thoughtful approach must be taken to determining what is public responsibility and what will be private sector opportunity. There is certainly the need for many sectors to be involved in this process, many of which are identified in this paper.

Governments play many roles. Sometimes they create policy and "the rules", but other arms must operationalize and pay for them. For instance, government policymakers will continue to be called upon to balance privacy concerns with the government (and private) plan administrators' need for adequate information to efficiently operate plans and contain costs. In exchange for their funding, public and private payers will demand the treatment they pay for is accessible when needed, of high quality, provided on a timely basis, delivers the purported outcomes, and occurs with the patient's full consent and involvement. Another privacy example is provided is risk selection for private insurance.

IV.i Conclusion

It is clear that fundamental changes to Canada's healthcare system are on the horizon. It is the opinion of the Canadian Council on Integrated Healthcare that Canada needs to develop a clear national strategy on human genomics *before* the science fundamentally impacts the healthcare system. All key constituents must be involved in a collaborative dialogue with the leadership of Canada towards the development of this strategy. Without the implementation of a system designed to address the issues outlined in this paper and elsewhere, there will be no infrastructure to deliver the benefits of genomics to Canadians, and the unlimited potential of the science will be wasted. Finally, it is our opinion that any strategy devised for Canada must be developed in conjunction with other nations. This approach will be necessary both to keep up with progress and to ensure that underprivileged nations with scarce scientific capabilities are not left behind.

The Canadian Council on Integrated Healthcare is eager to act as a catalyst for these discussions, as our membership is drawn from many stakeholder groups having extensive knowledge of their constituents. The CCIH calls upon the leadership of Canada — the federal and provincial governments — and other concerned organizations to join us in identifying and prioritizing the genomic challenges that Canadians face, and to work in a deliberate fashion towards creating a truly integrated, forward-thinking, and effective healthcare system.

V.i Contact Information

For further information on this Discussion Paper, or to learn more about the [Canadian Council on Integrated Healthcare](#), please visit our website at www.ccih.ca, or contact:

Chris Bonnett, MHSc
Chair, Canadian Council on Integrated Healthcare
☎ 416-489-7245
bonnett@sympatico.ca

Editorial review of this paper was provided through many hours of effort by the following:

Chris Bonnett, MHSc
John Elliott
Brad Hussey
Shelley Kee
Durhane Wong-Rieger, Ph.D.

CANADIAN COUNCIL ON INTEGRATED HEALTHCARE

Members

Sharon Blaney, RN, COHN(C)
Telus, Burnaby, BC

Chris Bonnett, MHSc
Chair, Canadian Council on Integrated Healthcare
H3 Consulting, Toronto, ON

Normand Cadieux, MSc
Association québécoise des pharmaciens propriétaires, Montréal, QC

Suzanne Caron, FICA, FSA
la Survivance, Montréal, QC

Wendy Graham, MD
Ontario Medical Association, North Bay, ON

Shelley A. Kee,
Atlantic Blue Cross Care, Moncton, NB

Anthony E. May,
Maritime Life Assurance Company, Vancouver, BC

Barry Noble,
Manulife Financial, Toronto, ON

James Norton,
AON Consulting, Toronto, ON

Dave Patterson,
Ontario Labour Relations Board, Toronto, ON

Steve Semelman, Pharm.D
ESI Canada, Mississauga, ON

Sanjiv Sharma, MBA
Aventis Pharma Inc., Laval, QC

Cyril Theriault,
Government of New Brunswick, Fredericton, NB

Kevin B. West,
Rx Canada, Toronto, ON

Durhane Wong-Rieger, Ph.D
Anemia Institute / Advocare, Toronto, ON

Support

Ginette David (Administration)
Aventis Pharma, Laval, QC

John Elliott (Project Manager)
Aventis Pharma, Aurora, ON

Observers

Russell King, MD
Private Practitioner, Fredericton, NB

Denis Roch,
Canadian Medical Association, Ottawa, ON