Policy Research Initiative
Projet de recherche sur les politiques

Genomics, Health and Society

Emerging Issues for Public Policy

Symposium Report

March 24-25, 2004

Symposium Partners

Canadian Biotechnology Advisory Committee
Canadian Biotechnology Secretariat
Health Canada

Canada

Genomics, Health and Society

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Preface

Genomics gained significant prominence all over the world with the completion of the draft sequence of the human genome in June 2000. This knowledge base, freely available over the Internet, is expected to revolutionize how medicine is practised.

Already, predictions are being made on what we can expect to see in the next 20 years.

- Gene therapy for single-gene diseases will become routine.
- Certain aberrant disease-associated genes will be replaced with normally functioning versions.
- Neonatal genetic testing for certain treatable conditions will become routine.
- Doctors will review individual genetic profiles against panels of drugs available for a specific condition, and then choose the treatment with the greatest potential benefit for the specific individual.
- The number of toxic responses to medications will drop dramatically, eliminating most side effects.

At the same time, societies will face legal, ethical, and social challenges arising from greater knowledge about individual genetic variation. For example, employers might use genetic information to make hiring decisions, or to determine the kind of work that will be done by individual employees. Given these types of challenges, our regulatory instruments need to promote the fact that gene-environment interactions are key in determining outcomes related to genetic variation, that is, genetic susceptibility to a disease does not mean that the disease will develop.

The symposium, *Genomics, Health and Society: Emerging Issues for Public Policy,* held in Ottawa at the Ottawa Congress Centre on March 24 and 25, 2004 was an effort to bring together experts and policy makers to better understand the implications of rapid advances in this human science for individuals, societies, and economies. This report attempts to capture the essence of the presentations and the discussions.

We hope you find this document interesting and informative, and that it whets your appetite for further exploration of the issues emanating from the evolving field of genomics. Comments may be directed to Sushma Barewal at either s.barewal@prs-srp.gc.ca or 613.943.2400 or John Olsthoorn at either olsthoorn.john@biotech.gc.ca or 613.946.8928.

Finally, we gratefully acknowledge the contributions of speakers, chairs, participants, organizers, and partners toward making the symposium a successful event.

Jean-Pierre Voyer
Executive Director
Policy Research Initiative

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Executive Summary

Symposium on genomics, health and society: Emerging issues for public policy

Genomics holds great potential for growth and prosperity, but it also poses significant legal, social and ethical challenges. If Canada is to reap the potential economic and health benefits of advances in this field, a wide range of issues will need to be addressed, including those related to privacy and the use of genetic information, intellectual property protection, innovation, and the evaluation, financing and application of genetic tests to health.

The Government of Canada's Policy Research Initiative (PRI), in partnership with the Canadian Biotechnology Advisory Committee (CBAC), the Canadian Biotechnology Secretariat, and Health Canada, convened a symposium in March 2004 to examine the public policy implications of genomics. Other federal organizations concerned with genomics-related issues were also actively involved in the development of the conference program.

The symposium aimed to:

- further examine the public policy issues raised by papers included in the recent publication, *Genomics, Health and Society: Emerging Issues for Public Policy*
- provide an opportunity for policy discussions among leading researchers, industry representatives, NGOs, and senior government officials
- lay the groundwork for engaging Canadians in a broadened discussion of the public policy issues raised by advances in genomics.

The symposium featured panel sessions on: "Genomics and Health in the 21st Century," "Public Attitudes Towards Genomics in Europe and North America," "Engaging Citizens," "Innovating in the Private and Public Sectors," and "Fairness and Equity in Genomics". Keynote presentations were also given on the United Kingdom's Human Genetics Commission and the Australian Law Reform Commission projects on protection of human genetic information.

The following are some highlights from the symposium.

Genomics and health in the 21st century

A panel discussed the impact of genomics on health care with reference to three key questions.

What is the next significant frontier for genomic science and technology?

How might genomics affect the diagnosis, treatment and prevention of illness in individuals and populations?

What are the broad policy issues for Canada and for other countries?

According to one speaker, the paramount principle for guiding research is that human genome studies must be conducted with the utmost respect. Panel members predicted that in the future, genomics will be used for health protection, health promotion and treating diseases. For example, researchers could apply "reverse population genomics" to determine how genetic variations influence health or disease, and biotech companies could apply genomics to design therapies tailored to individuals. One speaker raised the issue of orphan diseases that affect a small portion of the population and are largely ignored by pharmaceutical companies. Society could address orphan diseases through benefit sharing whereby public sector research receives some benefits from private sector research.

In terms of genomics policy issues, the National Human Genome Research Institute has identified a number of challenges.

- How do we define ethically correct research?
- How do we classify investigations into the genetic basis of personal and group traits, such as race, ethnicity, and sexual orientation?
- How do we spur innovation and protect intellectual property rights without denying medical advances to those who can't afford them?
- How do we promote pharmaceutical investment in rare genetic disorders that don't have great promise for high returns?

- How do we address testing for hereditary disorders that we can't cure in the lifetime of those tested, or of their children?
- How do we protect privacy rights, and the rights of the disabled?
- How does genetic determination interact with non-hereditary factors, such as natural environment, economic conditions, and personal responsibility for a healthy lifestyle?

Public attitudes toward genomics in Europe and North America

This session raised two primary questions.

What are the public's attitudes towards biotechnology and genomics in North America?

Is there a need for more informed public debate?

According to one speaker, idealists view public consultation as part of the democratization of science. But what if the public doesn't speak with one voice? Experts must eventually make the decisions, but their criteria must be transparent. Society needs meaningful consultation, which means people being heard, taken seriously, and, if a viewpoint is not accepted, knowing why.

The following results of public opinion surveys and focus groups conducted by Earnscliffe Research and Communications were considered.

- North Americans generally assess technologies on a case-by-case basis.
- People's perceptions of risk and benefit are the main decision drivers. The exceptions are technologies such as cloning, where there is a moral dimension.
- In general, Americans exhibit more support for and faith in biotechnology than Canadians.
- Americans have a deeper faith in progress and science. Most Canadians cautiously support biotechnology. Most Americans are confidently supportive.

Advising Ministers – the UK experience

Nobel Laureate Dr. John Sulston described the roots, mandate, methods and activities of the Human Genetic Commission (HGC). The Commission's first report–*Inside Information: Balancing Interests in the Use of Personal Genetic Data*–articulated four principles based on the ideal of respect for persons: (i) everybody is entitled to genetic privacy; (ii) personal genetic information should not be obtained without consent; (iii) if personal genetic information is obtained with consent, it should be treated as confidential; and (iv) everybody is entitled to genetic non-discrimination. The HGC recommended that the UK government introduce new legislation making it a criminal offence to deceitfully obtain and analyze another person's genetic data, and to protect people from unfair genetic discrimination.

The Commission's second report–*Genes Direct: Ensuring the Effective Oversight of Genetic Tests Supplied Directly to the Public*–investigated companies that advertise genetic tests using false or misleading claims. The report recommended stricter controls on direct genetic testing, but no statutory ban.

Engaging citizens

Advances in genomics will be widely felt throughout our economy and society. This session asked speakers how citizens can be meaningfully engaged in the public policy issues raised by these advances.

One speaker warned that the merits of genetic prediction and prevention as a national health strategy must be evaluated against health policy objectives. Society needs more public and democratic involvement to assess medical research priorities. Public reaction to genetic testing will determine the success or failure of this strategy.

Other panel members stated that striving for consensus on controversial issues can lead to high levels of abstraction. It is more important to obtain consensus on the nature of the issues, source of disagreement, state of the debate, and quality of the evidence. Careful prioritization of engagement topics is essential. Critical factors for public engagement include:

- having every voice at the table
- providing participants with immediate feedback on the outcomes
- involving decision makers at each step
- ensuring citizens know they were heard, know they were taken seriously, and can see it made a difference.

Innovating in the private and public sectors

A panel identified an appropriate mix of public and private action that would help create and foster the growth of a strong and dynamic genomics sector.

Speakers stressed that while governments can't predict the nature of future genomics inventions and products requiring regulation, appropriate regulatory measures are essential to minimize risks and maximize benefits.

One panel member noted that university labs and industry operate under different rules. Society therefore needs people in academia and industry who understand what rules apply where and how to bridge the gap.

Another issue is the large number of small companies that comprise Canada's biotech sector. These companies lack government support at critical stages, particularly in the gap between proof of concept/seed funds and venture capital. One speaker proposed that Canada could align new discoveries with key receptor companies. That is, we could bring together clusters of scientists and experts to discover and develop promising compounds, fast-track regulatory approval, and provide financing through public/private partnerships.

Fairness and equity in genomics

This session raised three questions.

What do we understand by fairness and equity in genomics?

What are the challenges and opportunities in developing fair and equitable policies and programs?

How could these challenges be addressed and opportunities realized?

One speaker argued that a justice framework limited to questions of fair distribution is too narrow for setting genomics policy. The framework should be expanded to include social justice questions such as how to promote greater equality, respect and status. In addition, those exposed to the greatest risk from new genomics technologies should be invited to participate in discussions concerning the ethical, legal and social implications of genomics, since their role is different than the role of people who stand to benefit from these technologies.

Another panel member discussed India's efforts to benefit from the genomics revolution. The speaker argued that governments of developing countries should provide genetic testing services, especially to the very poor. Private insurance could serve middle-income earners, while the wealthy could pay for gene testing services themselves.

The final speaker questioned whether genomic and other biotechnologies should be treated differently than non-biotechnologies in those cases where the risks, benefits and access are comparable. It was noted that the human population is genetically heterogeneous–i.e., there is no "genetic justice" at birth. Therefore, the likely American response to any attempt to ban the use of bio-enhancements is: "Why can't I give my children advantageous genes and protein levels that other children get naturally?"

Balancing interests in genetic information, materials and technology

David Weisbrot, President of the Australian Law Reform Commission, described the Commission's project on the protection of human genetic information, which examined three basic questions.

- How do we best protect privacy?
- How do we guard against unfair discrimination?
- How do we maintain high ethical standards?

The Commission concluded that it's artificial, unfair and unwise to separate genetic and non-genetic information for policy-making purposes. It would be wiser, instead, to adapt Australia's existing laws, practices, institutions and oversight mechanisms.

The Commission's final report contains 144 recommendations for reform directed at 31 bodies including government, regulators, educators, health professionals, insurers, employers and others. The report makes recommendations on: legislative change; standard setting; community and professional education; how GPs, clinical geneticists and health systems operate; codes of practice in the insurance industry; regulations affecting employment, occupational health and safety; and other issues. Among them, the Commission recommended expanding the *Privacy Act*,

which covers encrypted computer disks and other data sources, to cover identifiable genetic tissue samples; and expanding the *Disability Discrimination Act* to cover discrimination based on real or perceived genetic status.

The Commission also recommended that Australia's National Health and Medical Research Council develop a protocol informing health professionals when to disclose confidential genetic information to genetic relatives in cases where the relative is at serious but non-imminent risk of harm.

Welcome and Introduction

Jean-Pierre Voyer, Policy Research Initiative

The Policy Research Initiative (PRI) organized this symposium in partnership with the Canadian Biotechnology Advisory Committee, the Canadian Biotechnology Secretariat and Health Canada. Several other federal organizations helped to develop the agenda, including the Life Sciences Branch at Industry Canada, Genome Canada and the Canadian Institutes of Health Research.

The PRI works to advance research on emerging policy issues and to ensure that this knowledge reaches policy makers. Currently, the PRI is conducting five research projects related to social and economic policy issues: aging and life-course patterns, poverty and exclusion, social capital as a public policy tool, North American linkages, and sustainable development.

The PRI also stays abreast of emerging policy priorities by organizing events such as this one, as well as workshops, roundtables, and publications programs on specific issues.

In June 2002, the PRI organized a symposium in Toronto on the topic: *Genomics, Health and Society: Emerging Issues for Public Policy.* Based largely on that symposium, a publication of the same title was released in January 2004, which included 14 papers authored by 34 experts addressing the social, ethical, legal, economic and health care implications of genomics. The following important policy questions were raised.

- Will increased public knowledge of the potential of genomics mean excessive use of genomic services?
- What role should governments play in facilitating innovation in new technologies such as genomics?
- How can the developed world engage the developing world in equitable and ethical approaches both in conducting genomics research and in sharing the benefits from advancements in technology?
- How can governments address public concerns and how might citizens be better engaged in policy development?

The goal of this symposium is to delve further into these issues. Our discussions will add new understanding to an already rich base, and will contribute to a broadened dialogue on genomics, its role in health care, and its potential impact on society.

Kimberly Elmslie, Canadian Biotechnology Secretariat

This symposium brings together broad groups of people with various perspectives. We have an opportunity to work together to consider challenges and solutions. We need to consider what advice we should give the Government in order to move forward with advances in science and technology in a way that is socially responsible, engages citizens and promotes understanding.

We are here today for three main reasons.

- The science of genomics is amazing–it captures our interest and forces us to consider what is possible.
- The social and ethical implications of this science are very complicated.
- The public will ultimately decide what's acceptable. We need to work together to provide the analysis needed to move forward.

Science offers us many hopes as well as raising fears. There is hope that science will offer cures for diseases and solve some of the world's major problems. There is fear of loss of privacy, increased discrimination, and possible long-term harmful effects. There is also a fundamental need to understand what the science means for society, for us as Canadians, and for governments exercising their stewardship functions.

This symposium will allow us to consider some of these complex issues, and work together to decide where we want to go.

Genomics and Health in the 21st Century

Genomics has made huge advances in the last two decades and we have reached the point where we know the science and have the technology to identify single-gene health disorders. What is the next significant frontier for genomic science and technology? Will genetic medicine complement or compete with other approaches to health care? How might genomics affect the diagnosis, treatment and prevention of illness in individuals and populations? What are the broad policy issues for Canada and for other countries?

Kevin Keough, Health Canada (Chair)

Genomics and modern genetics began with the publication of Watson and Crick's article on the double helix 51 years ago. Little did they know how rapidly the science would advance. Today, we're studying single-gene conditions. Tomorrow, we'll be studying multi-gene conditions. By the end of the 21st century, who knows where we'll be?

It's impossible to predict the future of genomics. However, as an international community of scientists, clinicians, ethicists, policy makers and human beings, we must agree on the principles that will guide us on our journey. The paramount principle is that the study of the human genome must be conducted with the utmost respect.

Genomics and human health

A genome is the totality of genetic information in an organism. Genomics is the science of obtaining that information, analyzing it and using it to meet various ends. For human health, genomics has several uses:

- protection against threats
- promotion of health
- treatment of disease.

We tend to focus on applications related to the treatment of disease. However, the future of genomics will take us into issues of health promotion and protection.

How little we know

The sequencing of the human genome, which was completed last year, is only the beginning. The genome contains six billion base pairs, or letters. These letters contain coded information to direct activity in cells.

That is an enormous amount of DNA, and we understand the function of only a small portion. It's like a book with six billion letters and very little punctuation. We know there are 23 chapters called chromosomes. We've deciphered a few thousand sentences (genes) at random locations in those 23 chapters. But most of the book remains a series of letters. What does it mean? That's one of the big challenges for genomics in the future.

Also, there isn't just one human genome, there are six billion. In the world of genomics, each of us is a single minority group.

Despite this enormous challenge, there are many areas of promise.

- We share most of the genome with others, but we can identify where there are differences. Given the rapidly evolving technology and information platforms, we'll be able to decode and understand those differences soon.
- We'll see a rapid evolution in our ability to locate parts of the genome and associate them with disease, or with the lack of disease.
- The potential for tailored pharmaceuticals is upon us. However, it's uncertain whether Big Pharma will exploit that potential.

Public policy issues

Last year, Francis Collins and his colleagues at the National Human Genome Research Institute published a series of grand challenges for genomics over the next couple of decades. They found as many policy challenges as technological challenges. That's why we're here today.

Some of the public policy issues include the following.

- How do we define ethically appropriate research?
- How do we classify investigations into the genetic basis of personal and group traits, such as race, ethnicity, and sexual orientation?
- How do we spur innovation and protect intellectual property rights without denying medical advances to those who can't afford them?
- How do we promote pharmaceutical investment in rare genetic disorders that don't have great promise for high returns?
- How do we address testing for hereditary disorders that we can't cure in the lifetime of those tested, or of their children?
- How do we protect privacy rights, and the rights of the disabled?
- How does genetic determination interact with non-hereditary factors, such as natural environment, economic conditions, and personal responsibility for a healthy lifestyle?

There are no simple answers to these questions. However, the sooner we start to address them, the better. And "the sooner" is now.

Claude Laberge, Université Laval

Genomics has made huge advances in the last decade. With the sequencing of the human genome and many other genomes, we have uncovered the complexity of life and are moving towards understanding the determinants of health and disease. Knowledge is coming at the fastest rate ever. We've made significant discoveries about genomics last year, last month and even last week.

All humans are part of the same family. The differences between us may be just in a few nucleotides of the four billion in our genome. We've known for some time there that there are homologous genes between man and mice. It turns out that plants are also made of DNA and have homologous genes with us.

Suddenly, humans are not special–we're part of the co-evolution of life on Earth. Through evolution, we've been sharing what worked, and have eventually developed to where we are now. Paradigms are now becoming more general. It makes the Earth a special place to be, and special for us to have evolved with the rest of the planet.

What is health?

Health is a continuum—the standard of health for a fertilized egg is not the same as for an 85-year-old. Here is a traditional social sciences definition of health from the World Health Organization (WHO):

> *Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.*

But in terms of genetics and genomics, health is a dynamic state of maximal personal and temporal adaptation to physical, physiological, mental and social environments confronting the individual. If we want to do population genomics, we must understand all of these elements in order to interpret differences in the genome.

Confines of disease and health

According to the paradigm of genomics, disease has either completely environmental causes (e.g., scurvy caused by a vitamin C deficiency) or has a maximum genetic determinant (e.g., Huntington's disease). But health is more complex–it's a balance of your susceptibility to something. Even monogenic diseases are complex–they can be influenced by variations in other genes.

This complexity in individuals is reflected in the distribution in a given society depending on its history, socioeconomic status, etc. In any given population you can have stratification. This has implications in health promotion and prevention.

The differences between individuals are called SNPs, or single nucleotide polymorphisms. Each of us has about 60 to 80 SNPs. Depending on the environment, our individuality can put us at risk or make us sick.

Society, genomics and health care

The next step in genomics is to understand how our individuality relates to the environment in which we live. This environment is society. We need to develop databases of the genetic variations in large populations. We need to go into preventive medicine knowing the contribution of genetic determinants compared with non-genetic determinants.

We're moving towards individual preventive medicine based on the diversity that puts us at risk differently in different environments.

Reverse population genomics

Much of our current research focuses on finding genes. Eventually, we must do reverse population genomics, where genomic variations associated with health and/or disease through cohort studies are applied to a classical epidemiological sample of the population. Only then can we attain the validation necessary for policy making.

Since such genomic research will deal with human population and societal objectives, this will require new ethical standards. We must consult with the general public to protect participants and the entire population against discrimination. We also have an obligation to share the benefits with society as a whole.

The general involvement of the population in research and the broad dissemination of information may increase public awareness of health factors. This will promote personal responsibility and empowerment regarding health, making public health the result of the individual decisions of citizens.

The Quebec Network of Applied Genetic Medicine has proposed the following principles for conducting population genomics:

- individuality
- diversity
- complexity
- reciprocity
- solidarity
- security
- accountability
- equity
- citizenry
- universality.

CARTaGENE project

CARTaGENE is a cartography of genetic diversity in the Quebec population. The project will map genetic variation in a large reference population of Quebec. This information will allow large-scale medical, pharmacogenomic and public health studies, including association studies of common diseases or "protective" phenotypes, and lead to the discovery of new susceptibility genes.

CARTaGENE is governed by the Institute for Populations and Genetics (IPEG) which is completely independent of the researcher. It's part of a proposal from an international consortium called P3G (Public Population Project in Genomics).

Conclusions

- The heritability we have is hidden and extremely complex.
- We don't know what topologies to use for the complex network that we need.
- There are no simple categories of disease.
- Genetics is a human science, since we are informed by our genome.

We are facing ethical dilemmas (is genomics good or bad?) and challenges of perception. Our current view of the genome is incomplete and blurred.

Implications

- We must conduct more and more research.
- We must involve society if we're going to use population genomics.
- We need international coordination so these projects can benefit all countries.
- The time of "reverse" population genomics has come.

If we want to use genomics for public health, we need a scientific approach, not an ideological approach; not hype or fear, but facts. We have only one planet– if we want to survive as a species, we must understand genomics. Survival is adaptation against selection–it is evolution.

Daryl Pullman, Memorial University of Newfoundland

Early in the human genome project, it was clear that there would be huge ethical, legal and social implications (ELSI). I'd like to look at some of these issues today. Many of my questions are those that the non-specialist public might ask as they try to understand the genohype that we hear every day.

Another acronym in genomics is GE3LS, which stands for genomics: ethics, environment, economics, law and society. The question is, which E will take precedence, the ethical E or the economic E? Will economic priorities set the course of biotechnology? Hence I've titled this presentation: "Anchor or Compass?: ELSI and the Good Ship Biotech." That is, given the current push to take advantage of the economic opportunities presented by the emerging biotech sector, we must wonder if ethical, legal, and social issues will be treated more as an impediment to economic development than as a guide to the direction such development might take.

Economic priorities have possible implications in many areas.

- The university research agenda: Genome Canada dollars are 50-cent dollars, so researchers must seek matching funding from other sources, such as industry. But industry has its own priorities. Researchers are concerned whether they will be able to do basic science, or will the science be driven by someone else's economic agenda.
- Public policy
- Global justice: Will the economic priorities of the large industrialized world take precedence over the social health priorities of the developing world?

Technology, evolution and the evolution of technology

We become so accustomed to technology that we don't realize how it is affecting us. We no longer adapt to nature, but adapt nature to our ends. This is unnatural selection. What took millions of years of evolution can now be changed in a short period of time by manipulating genes. This ability to manipulate nature presents potential unknown risks as we cannot anticipate how almost instantaneous changes will affect other parts of the environment that would otherwise take thousands of years to adjust and adapt. What are our ethical and moral responsibilities as we make those choices?

Unnatural selection assumes that we control the environment through our technological innovations. But another way to think about this is that we are still adapting to the environment, only now the predominant environment is technological rather than natural. This process has been referred to as "autonomous technology": we live in a technological environment and we adapt to that environment. We become totally technologically dependent.

Transformative technologies

Technology has changed how we think about privacy. Before cell phones, people went into phone booths to have conversations. Now, people carry on private conversations in public places. On reality TV shows, people live out their private lives in the public eye.

Although we've given up privacy in many areas, we're still concerned about the question of access to genetic information. In this case, however, the concern is not so much about invasion of privacy per se, but rather with how those who have access to genetic information intend to use it. The point here is that "privacy" and "control of genetic information" are two quite different concerns, and should not be treated as one-and-the-same when it comes to drafting policy.

Implications for medical diagnosis

Technology has implications for medical diagnosis. For example, diagnostic imaging is now considered by some to be a crucial tool for 21st century medicine. However, we have only had this technology for 10 or 15 years.

As we become dependent on technology, doctors have less need to develop diagnostic skills. This affects how we practice medicine. If a test is not available, we can't diagnose a patient and can't provide service. This creates a bottleneck. We can anticipate that such bottlenecks will become more prevalent as we continue to develop various genetically based diagnostic tests.

The known and the unknown

There is a strong economic push to develop genetic interventions. It seems scary to be developing treatments when we still understand so little of the genome. Here we return to the previous point about genetic manipulation of the environment. Instantaneous changes to one part of the genome could have catastrophic consequences for the environment in general, and for individual patients in particular. Early failures in genetic therapy serve as a case in point.

Historically, it has been very difficult to predict the trajectory of new technologies.

- Automobiles versus horses: people thought cars would be an ecological improvement because they would eliminate horse manure.
- Nuclear energy: some thought it would be cheaper to give energy away then to monitor energy usage.
- Paperless office: this is clearly not happening.

What predictions will be inaccurate in genetics and genomics? It's too early in the process, and we still have much to learn.

The technological fix

There is much about genetics that we don't know, but much we do know about health that we don't act upon. Rather than changing our diets or doing exercise, we're looking to genetics to provide a solution. For example, scientists are now looking for the "skinny gene." The drive for this isn't coming from scientists, but from economics. The potential for industry support and profits is directing the research that people are pursuing.

Genetics is exciting, but what does it mean in terms of how we live from day to day? We still have to eat right and exercise. We need to act on what we know already. We shouldn't think there is a technological fix for every problem.

Biotechnology and justice

How do we address gene patents? So many exist already that some say the ship has sailed on this issue. What can we do in light of this?

Orphan diseases are genetic diseases that affect a small portion of the population. There is low economic incentive for Big Pharma to address these diseases. This makes sense from a business perspective, but how do we deal with it from a health and social justice perspective?

One proposal is benefit sharing. We try to ensure research that must be done in the public sector receives some of the benefits from private sector research. However, some companies are very resistant–they say that if we force this on them, they'll go to other countries to do their research.

Governance of research

Governance of research is a long-standing issue. There is a patchwork of oversight in ethical research in this country. We need the political will to put a governance structure in place, especially in light of rapid developments in genetics and the merging of public and private research agendas.

The rocks are right there behind the lighthouse. The good ship biotech is chugging along. If we don't deal with some of those issues, a lack of governance for research ethics in general, and biotech research in particular, could end up scrapping our ship on the rocks.

Discussion

Q: *You've mentioned how hard it is to predict the impact of new technologies. How is genomic research any different from past research on eugenics, with its many obvious implications for social justice?*

Dr. Pullman: Eugenics is always a possible issue. Once we can identify specific genes and polymorphisms that we can select for or against, there might be incentive to start doing so. This raises the question of how we decide what kind of society we want to have. There are ethical implications, such as the cost of health care. We're already facing these implications with issues such as physician-assisted suicide.

Dr. Laberge: Our genetic diversity is the only barrier against evolution and selection. We're currently confronting the greatest environmental barrier that humans have ever faced: the poisonous molecules in our environment and our medications. We know that individuality is the main protection against these molecules. We need to understand the mechanisms at work in our genomes in order to confront this new environment that we're creating for ourselves. Diversity is critical–we need everyone we've got.

Q: *You said paradigms in science are changing rapidly. Public policy making must be based on solid facts. How do we get information on those rapid shifts in paradigms to the risk assessors and policy makers?*

Dr. Laberge: The genome shows us that each individual in society is different. We know that our individuality contains part of our risk for health or disease. People in policy-making and public health must accept that the determinants of health include the innate variations in the determinants of individuals. Within the masses of people in society are individuals, and they have the right to know what to do for themselves in terms of personal health.

Q: *What are some of the key issues in governance of research?*

Dr. Pullman: We need a national body to oversee all human research in Canada. The closest thing we have now is the National Council on Ethics in Human Research (NCEHR). However NCEHR is poorly funded, which makes it difficult to put long-term policies into place.

We need to ensure consistency in standards of ethical review. We need the resources not only to review and approve research, but also to monitor research after the fact. Right now there is virtually no monitoring.

Q: *Dr. Laberge, what are your comments on the need for improved governance of research?*

Dr. Laberge: My interest is in population genomics. There are guidelines from organizations such as UNESCO and HUGO. These guidelines are converging: you must protect individuals against discrimination. You need to secure their information but you must also validate genetic research in the population to ensure social justice before distribution of this knowledge to policy makers.

I would like to see governance of the various population genomics programs in Canada. This could be accomplished, for example, through guidelines from the Canadian Institutes for Health Research (CIHR). There is no national governance right now, so we must deal with international or provincial organizations.

Dr. Pullman: Genetics raises a kind of "privacy paradox." In terms of health information in general, we're moving towards increased privacy of the individual. However, geneticists often state that they don't study individuals, but rather families. Hence it may be inappropriate in some contexts to allow individuals to control access to information that may have been collected through their biological sample, but which has implications for other members of their family. So while we continue to push toward individual privacy regarding health information, genetic research is pushing back in the opposite direction. We have yet to get a grip on the policy implications regarding control of health information in this regard.

This connects with the distinction between research findings and clinical findings. Historically we've tried to keep these separate. That is, we are cautious that information we gain during a research study should not be treated as clinically relevant for individual patients until the study has been completed and the aggregate information is validated. Only when the research study is completed and the results verified should we apply this new knowledge in clinical practice. In genetics, however, the line between clinical findings and research findings is often very vague. That is, we often discover something about an individual patient/research subject that has immediate clinical implications. Yet researchers may feel no clinical responsibility to share such information with patients that comes out of a research study because they continue to conflate genetic research with more standard medical research. The unique nature of genetic research and its potential immediate clinical applications must be emphasized.

Q: *If we had a national body to oversee research in this field, could this body also have the responsibility to create a vision of what we should do? What would this vision be?*

Dr. Pullman: A visioning council is a different role. Clearly, social justice and equity are important for society. How we go about achieving them will vary. Creating a vision for genomics and genetics research may not fall to any particular body, it may be a societal process. However, one current body that does serve part of this function is the Canadian Biotechnology Advisory Committee (CBAC).

Dr. Laberge: Genetics is a human science, not a biological science. The vision should be to give power and freedom to people to decide what to do for themselves. Families should know more about their genetics. We've done research on families in Quebec and found many monogenetic diseases. Why can't these families have access to these tests to decide what they want to do?

Public Attitudes Toward Genomics in Europe and North America

What do the Danish consensus conference model, the Gene-Swiss referendum and the UK "GM Nation" debate tell us about the spectrum of public debate in the European Union? What are the public's attitudes toward biotechnology and genomics in North America? Is there a need for more informed public debate?

George Gaskell, London School of Economics

The "GM Nation" debate, held in the UK in 2002/2003, was a major exercise in public consultation on agricultural biotechnology. For some, it was a watershed moment: the people have spoken. For others, it's a transient tide; the sooner it disappears the better.

I want to provide some background to this debate, discuss some of the surrounding issues, and focus on the relations between technological innovations and civic society.

The years of controversy

During the 1980s and 1990s, surveys showed Europeans were uncomfortable with genetic modification. In 1994, we held the first UK consensus conference. The outcome was surprisingly positive, and raised concerns that would emerge in the late 1990s, such as labelling, consumer choice and patenting of life forms.

In 1995, the first GM tomato puree entered the market, doing well until the introduction of more expensive assessment procedures. At the same time, the BSE (bovine spongiform encephalopathy) crisis raised doubts in the public about science and the policy process.

In 1996, the first shipment of GM Soya came into Britain, followed by the cloning of Dolly the sheep in 1997. The GM furor took off: there were supermarket boycotts and protests. There was a de facto moratorium on the commercial exploitation of GM crops and foods. This led to a crisis in the traditional paradigm for regulation. There was a decline in public trust in science and governance, and a recognition that public opinion matters. Eventually public consultation was written into European regulations.

Views of the public

There are two contrasting views of the public in relation to technology, which I'll call the "traditionalists" and the "progressives."

- Traditionalists: the public is a constraint to innovation to be ignored or overcome with strategic communication.
- Progressives: the public is a signal to guide and channel the direction of technological innovation in socially sustainable directions.

The choice is either to "overcome" the public so that technological innovation can progress, or to bring the public into product design.

Public consultation emerges

The progressives took up the Danish consensus conference model, which tends to provide interesting and unpolarized conclusions. But even the traditionalists were sometimes forced by constitutional mechanism to take note of public opinion.

- The people's initiative in Austria in 1997 collected about 1.2 million signatures and forced the government to reconsider its position on field trials.
- The Swiss referendum in 1998 saw 66% reject the gene protection initiative.

UK: New Labour and new forms of open government

In response to the BSE crisis and continuing problems over GM agriculture, Tony Blair's government overhauled the regulatory system, establishing three new bodies:

- The Human Genetics Commission
- The Food Standards Agency
- The Agricultural and Environmental Biotechnology Committee.

These bodies have been fairly successful in the areas of genes and conventional food, but agri-food biotechnologies are still controversial.

The "GM Nation" debate

This debate, one of a set of inquiries into GM agriculture, set out to find out "what the public really feels and to avoid the polarised positions."

The designers used "innovative" hybrid methodologies: focus groups set the agenda for the debate; meetings were held around the country where volunteers discussed the 13 points on the agenda; these 13 points were put on the web site for feedback. The report characterizes the work as a qualitative assessment of public opinion, but also reports percentages, even for the control sample of 77 persons.

The press reported the percentages: 4-out-of-5 people are opposed to GM foods.

Legitimacy of forms of public consultation

The GM Nation debate raises questions about public consultation.

- The consensus conference model uses ordinary members of the public with little prior knowledge of the topic. There is extensive deliberation– participants learn from the experts, but also question the experts. There are no claims to represent the wider public (procedural legitimacy).
- In referenda, often used in Switzerland, everyone has the chance to vote and issues are widely discussed (constitutional legitimacy).
- The "GM Nation" avoided the problems associated with surveys, but included little discussion or deliberation. Many participants seemed to come from the upper brackets of society and from interest groups.

There were various arguments about the legitimacy of "GM Nation."

- The press saw it as the largest UK social survey on GM food (37,000 completed the questionnaire), hence perfectly legitimate.
- Survey specialists saw methodological flaws: it was not a random survey, but consisted of volunteers.
- Some said it wasn't a survey at all, but a balancing of vested interests. But it failed in this, because industry and regulators were not represented.

Future of public consultation

The idealist position is that public consultation is part of the democratization of science. However, what if the public doesn't speak with the same voice? Someone still needs to make a decision.

Secondly, there are some serious capacity constraints to public consultation. Many members of the public will not turn up to discuss and vote on every policy initiative. This idealized form of public consultation isn't practical in many modern societies.

Do we fall back to the traditionalist position? This poses enormous dangers. Excluding civil society from deliberations has allowed siren voices to dominate the debates. We need to step back and consider social change.

Modernisation theory

Christian Weitzel, a PhD student of Robert Inglehart, wrote a paper characterizing modernization as three interrelated processes:

- socio-economic development
- emergence of more democratic forms in societies
- value change.

The value change is crucial. As people increasingly engage in a "knowledge society," they are expected to make choices and show initiative at work. This change can spread to civil society. The old hierarchical structures of deference and conformity to authority evaporate. People expect to be heard. Emancipatory values emerge.

People are not taking-for-granted what authority figures have to say. We need new platforms: intelligent and adaptive institutions that can accommodate these changes and earn the public's confidence to achieve sustainable technological innovation.

Towards a societal debate on sustainable technology

The heart of the debate is not the technology. People aren't concerned about processes of recombinant DNA. People are interested in values. What sort of society will this technology make possible? Is it the sort of society we want?

We must broaden the scope of ethics to create a platform for debate on the social implications of S&T. We need discussions on the values that guide people's lives.

Procedural clarity in science and technology policies

We need procedural clarity in the process of developing and regulating technologies. This includes meaningful consultation–a social contract between the decision taker and the public. This requires dialogue.

Experts must eventually make the decisions. However, the criteria for those decisions must be transparent. Meaningful consultation means being heard, taken seriously, and, if a viewpoint is not accepted, knowing why. The outcome of this process would be transparent and accountable institutions that would become the focus of trust.

Elly Alboim, Earnscliffe Research and Communications

Earnscliffe Research and Communications has conducted nine waves of primary research on biotechnology for the Canadian Biotechnology Secretariat since 1998. Our samples range between 1,200 and 2,000 with more than 60 focus groups. Issues discussed include:

- awareness and familiarity with biotechnology, genomics, applications
- risks and benefits of the technology and specific applications
- assessments of government performance
- ideal roles and priorities for government
- economic policy tools
- GM food and labelling
- stem cell research
- genetic information and privacy
- patenting
- cloning
- public involvement and engagement
- communications and credibility issues.

This presentation will demonstrate contrasts and similarities in public opinion on biotechnology between Canada and the U.S.

Nomenclature

In both countries, the word "biotechnology" has been most consistently used to describe this field. The term "genetic modification" is also recognized, but perceived primarily in terms of food. "Genomics" is not a term many people recognize or use.

Biotechnology

Canadians steadily report slightly less awareness and familiarity with biotechnology. However, actual knowledge and understanding have grown markedly over the past year or two.

Stem cell research: On this topic, recall approaches 60%, which is quite high for such a recent technology. Stem cell research has captured the public's imagination, with one-in-two Canadians believing that it will have a personal impact during their lifetime.

Support or oppose biotechnology: Americans tend to be more supportive of biotechnology than Canadians. In the U.S., about 52% support the use of products and processes that involve biotechnology. In Canada, it is 54%. In the U.S., about 17% expressed strong support, while in Canada it is only 9%.

The levels of strong support in Canada have been relatively consistent and slightly higher than strong opposition. But the number of those who are moderately in favour has been growing slowly over time. Right now, 63% of Canadians express some levels of support for biotechnology.

Critical mass of opposition: Entrenched opposition is quite small, under 10% in both countries. The strong opposition levels in the U.S. are 6%, and in Canada 7%.

These numbers are important. In all of our work on public policy, we try to assess at what point there is a critical mass of strong opposition, where public opinion leads to behaviour that is opposed to that particular issue.

This critical mass develops somewhere between 25% and 30%. People don't protest visibly, and corporations don't suffer problems with customers or the bottom line, until opposition to products reaches these

levels. This is one reason that we haven't had the same level of consumer boycott and opposition in North America.

Attitudes about DNA mapping: Initiatives such as the human genome project are what convince people that the technology has more benefits than drawbacks. This is primarily due to perceived medical and health benefits. The numbers are very large–about 78% or 80% say that the benefits of "mapping" human DNA outweigh the drawbacks.

Genomics

Most Canadians have no firm understanding of genomics, even after hearing a definition. In fact, most people mistakenly believe that genomics is about the application of technologies rather than the basic science of genetic functions. This is one of the reasons that people support biotechnology–they believe that biotechnology is the scientific research and genomics is the development of applications.

Familiarity with genomics: About 2% of Canadians say they are "very familiar" with genomics, while about 30% say they are "somewhat familiar." Of "involved Canadians"–a segmentation of about 30% of the population who are influencers and opinion leaders–about 3% said they were "very familiar" and 40% said they are "somewhat familiar."

Biotechnology applications

In Canada and the U.S., people evaluate applications on a case-by-case basis. The test is the marginal personal benefit. Do the potential benefits (compared with non-GM products already available) outweigh the potential risks to myself or my family?

The U.S. is much more supportive than Canada of all types of applications, particularly generically modified food. The hierarchy of benefits in both countries is the same: health, environment, agriculture and food. Americans are much more supportive of food applications than Canadians.

Medical and health benefits are the primary driver of support. Without these benefits, it is unclear what the levels of support for biotechnology would be.

Purpose versus process: The purpose is the key positive driver to biotechnology applications and the process is the key negative driver. The more intrusive the process, the stronger the benefit must be for people to accept the application. Medical and health benefits, and to a lesser degree environmental benefits, drive support for biotechnology.

Acceptability of cloning applications: There is majority opposition to several applications of cloning in both countries, starting with cloning animals to provide organs for transplantation down to cloning animals to reproduce extinct species. In this area, the moral elements are much more significant than in general biotechnology applications.

Cloning animals for food is strongly opposed in both countries. For most people it's a simple proposition: why eat a cloned cow when regular cows are available?

What drives concern?

Long-range and unknowable risk drives concern about biotechnology in both countries. Long-term risk to human health is the most pervasive concern. This isn't about morality. Moral issues become prominent in cloning, but are absent in more general applications.

Risks in society: Nuclear waste is rated as the No. 1 risk in Canada and the U.S. Violent crime is second in Canada and third in the U.S. Genetically modified food and bioengineered pharmaceuticals are way down the hierarchy of risk. It's really the thalidomide issue that concerns people–what we don't know that might harm us in the future.

Driving concern–GM health: Ethics and morality are not drivers of concern. The primary driver is long-term risk to human health. Ethical concerns are third, concerns that there is something unnatural about these products are fourth. There really is almost no driver of concern other than human risk.

Driving concern–GM food: For GM food, the reasons for concern are a little more widespread, but still focus primarily on long-term risk to human health. Environmental issues and ethical natural issues creep up a bit. This just reflects the widespread concern about GM food as opposed to other applications.

Driving concern–cloning animals: On this topic, ethical concerns suddenly become almost equal to the long-term risk to human health.

Benefits and drawbacks

Most Canadians and Americans believe that the benefits far outweigh the risks in terms of health and the economy. Americans hold these beliefs very strongly.

Overall benefits versus drawbacks: Most Canadians (three-to-one) say that the benefits of knowing more about our genetic information outweigh the drawbacks. This is really a genetic information privacy issue. We don't yet have numbers on this for the U.S.

Major attitudinal drivers

Many people in Canada and the U.S. see biotechnology as the next frontier of science and they want to be part of it as world leaders. There is also a sense of inevitability regarding these technologies. People want governments to manage the risks and take a leadership role.

Addressing long-term risk is a priority in both countries. If there is evidence of ongoing long-term safety research, much of the opposition to biotechnology applications disappears.

Decision making

Scientific evidence and informed choice are the fundamental elements for the preferred decision-making regime on biotechnology. The public sentiment is that experts should make decisions about safety, while citizens should make decisions in the marketplace. The belief in science and experts is even stronger in the U.S. than in Canada.

Best available evidence: In the U.S., 85% agree that a particular use of biotechnology should be allowed if the best available evidence says it is safe. In Canada, 82% agree. Only 2% in either country strongly opposes that proposition, which helps to explain why there has been no real organized opposition to biotechnology products in either country. Most people say the best available scientific evidence is good enough.

Governance issues

There is a notable gap between Canada and the U.S. regarding faith in the two regulatory regimes. Americans have more faith in their regulatory system than Canadians do in theirs. This likely affects attitudes towards risks and benefits as well as applications. It reinforces the importance of a solid stewardship regime.

Government stewardship: In Canada there is a strong majority presumption that government is not doing enough to study and monitor the impact of biotechnology products. In the U.S., it is much closer to a split.

Regulation–work alone or with others: Both countries tend to support international standards. This does not imply that either country will accept approvals by the regulatory authority in the other country. Although people believe in international standards, they want domestic approval.

Conclusions

- In both Canada and the U.S., there is no blanket view of biotechnology. People assess technologies on a case-by-case basis.
- Perceptions of risk and benefit are usually the decision drivers. The exceptions are areas such as cloning, where there is a moral dimension.
- People want to make informed choices. The level of support for mandatory labelling exceeds 90% in both Canada and the U.S.
- In general, Americans exhibit more support for and faith in biotechnology than Canadians. That is most notable in the area of GM foods, but also in areas such as stem cell research.
- Core values are similar in both countries. Americans have a deeper faith in progress and science. The final conclusion is that most Canadians are cautiously supportive of biotechnology, while most Americans are confidently supportive. The gap between the two countries is between 6% and 10%.

Discussion

Q: *There seems to be much more concern for risk to health than to the environment. It seems to me that you can't really separate the two. Would you care to comment?*

Elly Alboim: Where the environment coincides with human health, the level of apprehension is the same. Where there seem to be primarily environmental effects, people have less apprehension.

It's all about what gets into the food chain. For example, there is generally strong resistance to biological remediation of the St. Lawrence River. However, there is strong support for biotechnological remediation of self-contained ponds in pulp and paper sites where people believe, erroneously, that you can restrict the organisms to the self-contained pond so they won't enter the food chain.

George Gaskell: Since the time of the Greeks and writing on food ethics, contamination of food has always been a concern. Many people strongly believe that genetic modification is a form of adulteration. I think that is why it is much more of a pressing concern than environmental issues.

Q: *In Canada, we are at the beginning stages of a discussion on the role of our elected representatives and what has been called the democratic deficit. Could either of you discuss the potential role of elected representatives in public policy in this area?*

George Gaskell: I'm not a constitutional lawyer or a political scientist. But as I understand the British system, advisory committees are crucial. These advisory committees don't make the decisions. Fundamentally, they are advisory to government.

Some of these committees are seen to be very effective in discussing issues in a way that the public, or the elite and interested amongst the public, feel that the various positions have been properly weighed.

What is the role of democratically elected representatives? In many contemporary democracies, as topics such as science and economics become increasingly complex, one sometimes wonders whether one's elected representatives know much more than the ordinary man in the street. But fortunately, they have expert advisors.

However, I really am not competent to talk about constitutional mechanisms. The main question for me is how civil society can be incorporated into policy making in such a way that innovation is channelled in appropriate directions and fits in with the expectations, aspirations and values of the public.

Elly Alboim: Elected representatives are not trusted to deal with expert decision making. Their credibility is quite low. They are really invested with responsibility for making value determinations on behalf of the rest of the population.

For example, we investigated the patenting of higher life forms and whether the final decision should rest with the Supreme Court or the Parliament. Surprisingly, there is a strong preference for those kinds of decisions to be dealt with in Parliament, not in the courts. But when it comes to values, people place their trust in elected representatives.

People recoil from the thought of parliamentarians being responsible for scientific decision making, and not without reason. For example, on the reproductive technology bill, parliamentarians were off public opinion on virtually every issue. They were responding to special interest opinion, not to the general population, particularly on the use of stem cells.

Q: *Based on the last presentation, Canadians seem very willing to devolve risk management to experts in the scientific community. Since some of the people attending this conference are interested in launching some kind of consultation mechanism, I wonder if the European-proposed approach that we heard this morning will really work in a Canadian context.*

Elly Alboim: Our view is that Canadians want to know that there have been consultations. They're not sure they want to personally participate. It divides along levels of interest, obviously, but they are willing to devolve the decision making to others.

But the willingness to devolve decision making also is a willingness to confer legitimacy on processes that appear to be participatory. So importing some of these processes into a Canadian circumstance and running them with willing participants will render them largely legitimate. As long as people believe that they had the option of participating, they can choose not to. To them, the willingness to invite participation shows sufficient transparency and curiosity that they will presume the process has been legitimate.

George Gaskell: During the GM Nation, 37,000 people answered the questionnaire; about 20,000 people came to the meetings. That suggests about one-in-every-2,500 adults participated in some way.

I hear so many people talking about public consultation, and they have a very strange view of the public. This idea that the public are just dying to get into discussions about risk and so forth just doesn't make sense to me. As a social scientist who spends

a lot of time talking to people, I feel this is not going anywhere.

The problem is that it could go nowhere, and we return to the old "Leave it to the technocrats, ignore the public and things will be OK" approach. I don't think things will be OK. I think there will be increasing problems.

People want to know that the issues have been debated extensively. They want to know that the appropriate experts are there, or at least those people who are going to make a fuss if the decision does not go in their preferred direction.

Advising Ministers– The UK Experience

The Human Genetics Commission (HGC) is the UK government body established to consider how new developments in human genetics will impact on people and on health care. Its remit is to give ministers strategic advice on the "big picture" of human genetics, with a particular focus on social and ethical issues. What has been the HGCs advice and how does it formulate its advice? In what ways does this differ from other countries?

Sir John Sulston, Human Genetics Commission, UK

The Human Genetics Commission was formed in 1999 following a regulatory review driven by rising public concerns in the UK, particularly over BSE. The goal was to provide government with advice on the large picture. The Commission works in public and involves the public at all stages. It is chaired by Baroness Helena Kennedy, the Commission's driving force. All 16 members are appointed as individuals to provide their own views. We include representatives with expertise in clinical, research and commercial genetics, law, ethics, and consumer, sociology and disability rights. We also have some ex officio members.

Our remit includes:

- horizon scanning linked with the analysis of developments in human genetics, including their impact on human health, health care, and social, ethical, legal and economic implications
- consulting and informing the public
- promoting dialogue and collaboration
- advising government on strategic priorities.

Since 1999, we have completed three major reports including a survey involving more than 5,000 people on attitudes to human genetics. We have more reports in the pipeline.

We have a genetics services subgroup with a UK-wide focus. We have other subgroups on public involvement, horizon scanning, data bases, gene patents, genetic discrimination and forensic uses of DNA. We hold quarterly plenary meetings that rotate around the country to give people in different places a chance to attend. We also have information gathering meetings, which are organized in an ad hoc way.

Public dialogue

In terms of public dialogue, we have been setting standards for a UK government commission. Openness and two-way communication are important because our purpose is public engagement rather than public education. We don't preach–we dialogue. We experiment constantly. Our web site is improving. It is linked with other groups and media outlets. We believe we need to be flexible and evolve and listen and discuss.

An important part of the HGC is our Consultative Panel. More than 100 people are on the panel, all with direct experience with a genetic condition that leads to a disability or problem. The panel includes directly affected people, family members and caregivers.

Our first report–*Inside Information: Balancing Interests in the Use of Personal Genetic Data*–focuses on the balance between 'respect for persons' and 'genetic solidarity and altruism.' Altruism is an important part of being human. It is often interpreted as care of kin or care of one's own little group. But it also means a sense of duty or care to other people who we don't know. In the genetic sense, we chose to call this 'genetic solidarity.'

Key principles

We cannot collect personal genetic data and use it in research without impinging on people's privacy. We have to find the right balance. People need to feel that researchers are handling their genetic information with transparency. So the HGC drew up four principles based on the overarching idea of respect for persons:

- that everybody is entitled to genetic privacy
- that personal genetic information should not be obtained without consent
- that if personal genetic information is obtained with consent, it should be treated as confidential
- that everybody is entitled to genetic non-discrimination.

Our first recommendation was that the government should legislate a new criminal offence to prevent anyone from deceitfully obtaining and analysing another person's genetic data. Second, we recommended that new legislation is needed to protect people from unfair genetic discrimination. In addition, we need to explore and strike the right balance between those conflicts: an individual's interest in privacy and society's interest in benefiting from the use of personal genetic information in medicine or research.

Genetics and insurance

In 2001, the HGC recommended a moratorium on the use of genetic test results by insurers. Insurance companies agreed to a moratorium on the use of genetic information for policies worth less than £300,000 (£500,000 for life insurance). Our priorities during the moratorium are to:

- review the use of family history information
- look at access to affordable insurance for those affected by a genetic condition–e.g. risk pooling
- promote openness about underwriting decisions and the information given to consumers
- consider wider regulatory and arbitration systems for genetic information and insurance.

The government's response to Inside Information includes commitments to:

- develop a new offence for non-consensual genetic testing
- consider the evidence for unfair discrimination and the appropriate steps to take
- welcome HGC's input to a long-term sustainable policy after the insurance moratorium
- publish a revised code of practice on patient confidentiality
- allow police requests for access to the UK Biobank only "in the most exceptional circumstances."

Genes Direct

HGC's second report is called *Genes Direct: Ensuring the Effective Oversight of Genetic Tests Supplied Directly to the Public*. This issue surfaced when people became aware that some companies were advertising genetic tests with false or misleading claims, so we started investigating what was going on. Some key issues emerged.

- New technology and knowledge may allow cheaper tests for carrier status, metabolism and family relationships (paternity).
- People increasingly want information about their own health and freedom from normal constraints of general practitioner appointments and consultant referrals.
- People also feel strongly that vulnerable people should be properly protected against any commercial misuse of genetics.

As a result of our recommendations, we have been criticized from all sides, which may mean we struck the right balance. We made the following recommendations.

- There should be stricter controls on direct genetic testing, but no statutory ban.
- Predictive genetic tests that rely on home testing or home sampling should be discouraged.
- Genetic tests that provide predictive health information should not be offered as direct genetic tests.
- We need a well-resourced national genetics service that provides access to appropriate genetic tests, interpretation and counselling.

Legal and regulatory framework

The UK has rationalized its regulatory process by creating the Medicine and Health Care Products Regulation Agency. There is now one place to go for approval of genetic tests. The UK Genetic Testing Network is introducing arrangements to review tests. There may also be a role for the Human Tissue Authority.

This issue is really about fair trading and fair advertising standards. We need the authorities to examine the validity of advertisements for direct genetic testing. The UK Office of Fair Trading should be

supported by improved professional standards. Other recommendations concern policing the Internet and better consumer education.

The UK government's White Paper on Genetics:

- includes a policy statement on realizing the benefits of genetics via the National Health Service
- recommends a 50 million pound investment in clinical laboratories, training and educating the workforce, information technology and R&D
- recommends safeguards and controls against the inappropriate or unsafe use of developments in genetics
- recommends the prevention of unfair discrimination
- recognizes the importance of the HGC for debate, dialogue and advice.

Future work

We have a group working on genetics and insurance discrimination. We don't want the moratorium on genetics testing by the insurance industry to just fizzle out in a few years. We have a group looking at genetics and reproductive decision-making. We have a short review underway of genetic paternity testing and services.

The HGC will consider the case for offering genetic profiling of children at birth. This is a long-term study. Since the cost of genetic testing is decreasing, genetic profiling will likely happen sometime in the future so we need to discuss the implications.

HGC is now well established and respected. The public and government pay attention to our work. I believe that in future, we need to pursue international agreements that address the ethics of genetic issues on a global-scale.

Discussion

Q: *Consent is a necessary condition, but is it sufficient? To what extent is there full and informed consent, given the public's level of understanding in genetics issues?*

John Sulston: This is an incredibly important point. I would link the issue of consent to the issue of non-discrimination. Consent, however well informed we try to make it, is always imperfect. It should always be obtained because we need to respect people's dignity and privacy as much as possible. But for some reasons, data may be collected without full consent. Then we have to take a second line of defence: we need to use the information in a way that does not disadvantage the individual.

Q: *Could it be that in allowing commercial access to a broad public resource like BioBank, you're just locking up one step back by allowing materials to come out and then be patented?*

John Sulston: In my view, it's not so much patenting as the use and type of patents that are at issue. I don't think that all patenting is bad, just that gene patenting is bad because it creates a monopoly. I think we need to push for narrower patent laws. Once we get past this 'Klondike' phase of biology, patents will once again be granted only for inventions.

Engaging Citizens

Biotechnology is widely believed to be one of the most important new areas of technology for the 21st century. The implications of advances in genomics, in particular, will be widely felt throughout the economy and society. How can citizens be engaged in a meaningful way in the broader discussion of the public policy issues raised by biotechnology, particularly with regard to advances in genomics?

Arnold Naimark, Canadian Biotechnology Advisory Committee (CBAC)

The fundamental public policy challenge of biotechnology is to craft public policy that strikes a sustainable balance between exploiting biotechnology applications that can provide significant economic and social benefits, and the control of other applications that involve profound social and ethical concerns or challenge current approaches to protection of human and animal health and the environment.

The challenge is intensified by several factors:

- the rapid pace of technological innovation
- the lag between the discovery/diffusion of technology and policy formulation
- tension between international obligations and domestic interests
- pervasiveness: biotechnology impacts just about every aspect of public life
- contending political ideologies
- the diversity of interests and needs of constituencies with varying levels of knowledge, sophistication and political orientation
- tensions involved in reconciling scientific, ethical and socio-economic considerations when dealing with the manipulation of living things.

Our mandate

CBAC's mandate is to assist in implementing the Canadian Biotechnology Strategy (CBS). Our purpose is to help policy makers achieve the CBS vision of making Canada a responsible leader in biotechnology. Our Committee consists of up to 21 independent experts who meet in three to four plenary sessions per year and in subcommittees. We undertake research, advise government on a broad range of issues, and report publicly.

A key element of our mandate is to *"enhance public awareness and facilitate an open, transparent, national conversation on key issues around the development and application of biotechnology in Canada."*

When initiating a public engagement process, certain criteria should be considered

- Engagement of whom? Target audiences may include the general public, expert and stakeholder groups; involved versus uninvolved citizens; and the media.
- Engagement in what? A process intended to result in learning, dialogue or advising?
- For what purpose? General edification, political visibility, or crafting public policy?

Public engagement tools

The tools available for public engagement include: public dialogue, town hall meetings, electronic consultations, roundtables, consensus conferences, citizen juries, and deliberative polling.

Implementation issues to consider include: the homogeneity or heterogeneity of the target groups; the value context for discussions; and the expectations of organizers and participants.

Consensus not the goal

During public engagements, CBAC generally does not strive for consensus at all costs. In fact, striving for consensus as an absolute goal can lead to such a high level of abstraction that the outcome is of little use to policy makers. What is useful is to obtain consensus on the nature of the issues, source of disagreement, state of the debate, and quality of the evidence.

You need to be clear about the goal of public engagement. Is it simply to have 'done it' so people have confidence in the system? Or do you want some level of commitment and ongoing engagement from the participants? The engagement process should match

with public expectations regarding: responsibility, accountability, credibility, transparency, clarity, and comprehensiveness.

Project consultation steps

The approach we choose depends partly on our resource availability because we have a relatively small budget. Our project consultation sequence generally follows this course:

- context setting, which involves horizon scanning and engaging experts, and may include deliberative polling and focus groups
- expert panels, roundtables, workshops, which result in a draft consultation document
- reference groups including stakeholder groups and experts, who review the document and provide advice on how to undertake further consultation steps
- multi-stakeholder consultations
- broad public consultations.

CBAC has developed a dialogue tool to help deal with controversial issues involving a high degree of polarization. The dialogue tool allows us to:

- formulate and identify social and economic risks, benefits and trade-offs on a particular technology
- examine ethical issues in the context of Canadian values
- establish a common language for constructive debate by exposing hidden agendas and assumptions, and narrowing the range of dispute.

To be effective, the dialogue tool requires much time and care to develop, and significant leadership and ownership from stakeholders. It cannot simply be taken off the shelf and implemented on any particular issue.

Concluding observations

Lessons from CBAC's experience include the following

- Understanding the context of engagement and establishing clear objectives are prerequisites for the choice of tools and the selection of participants.
- Striving for consensus on controversial issues can lead to high levels of abstraction. Special tools are required to produce a useful and reliable analysis of the state of the debate as input to the policy making process.
- Given resource constraints, careful prioritization of topics for engagement is essential.
- There is a lack of empirical evidence in terms of the influence of engagement tools on policy. For some issues, the use of more than one tool may be desirable or necessary.
- CBAC is committed to engaging citizens or responsible intermediaries in the development of its advice to government, to the extent our resources will allow.
- Collaboration with other bodies could increase our collective reach on subjects of mutual interest.

Helen Wallace, GeneWatch UK

A few years ago, Prime Minister Tony Blair outlined his vision of a genetic future:

> *"…we can now see a future where the doctor will swab a few cells from inside your cheek, put them into a DNA-sequencing machine and a computer will spit out a complete reading of your unique genetic makeup–all 30,000 or so genes that make you who you are. From that, doctors could pinpoint flawed genes and gene products and predict what diseases you are likely to develop years in advance of any symptoms–and how to help you avoid them."*

This vision involves not just genetic disorders, but what the UK Secretary of State for Health calls "the country's biggest killers–cancer and coronary heart disease–as well as diseases such as diabetes that limit people's lives."

Questions to consider

Before we embark on this future, let's ask some hard questions about genetic testing

- Is this a good strategy for health?
- Is this an effective and cost-effective way to reduce the incidence of common diseases?
- What is the predictive value of genetic testing?
- What is the likely public response to genetic tests?
- Are commercial claims independently assessed and regulated?

- Do we have adequate controls to prevent genetic discrimination and maintain privacy and civil liberties?

With our current mechanisms for making decisions about biotechnology, do we already have good signs of evidence-based policy? I would argue not. The UK's latest policy paper, *Our Inheritance, Our Future*, published in June 2003, said some positive things about improving genetic services for people with certain genetic disorders. But it also proposed a vision of the future about expanding genetic testing without providing any evidence or analysis, such as numbers on how many people would benefit. This issue is important because many studies linking a gene with a common disease are later proven wrong or, shown that the risk has been exaggerated. We need to assess the clinical validity and utility of genetic testing. But there is no regulation in the UK to make such assessments happen.

Twin studies

Twin and family studies are often cited to argue that genetic testing must be useful. But high heritability does not necessarily imply a strong genetic component if the results are analysed to take account of gene-environment interactions and complexity. Moreover, twin studies do not demonstrate that genetic testing is always the best approach to health. Genetic tests may wrongly imply that only a minority of people with 'bad genes' need clean environments or a healthy lifestyle–they have a real potential to undermine public health. Few studies exist on people's psychological reactions to genetic tests. The studies completed to date have found that genetic tests do not appear to help people to quit smoking or adopt healthy behaviours. Cost-effectiveness has also not been assessed. The cost of actually making a risk assessment does not simply involve the cost of testing or the cost of genetic counselling. It also involves much time and interaction with health professionals.

The UK White Paper predicted: *"the way external factors and genes interact to cause disease or protect us from disease will be better understood. This information will allow people with certain genetic profiles to avoid foods, chemicals or environmental factors, such as smoking, which are particularly risky for them."* There are many problems in that single sentence. The following are some issues to think about.

Food, nutrition and obesity

The obesity epidemic, particularly in rich countries, is not due to an increase in 'genes for obesity.' It follows that maybe the best way to tackle obesity is not to focus on genes for obesity. Despite press reports about the discovery of susceptibility genes for obesity, a recent critical review identified some 30 candidate genes, none of which had been confirmed or validated as having any predictive value. Yet at least one U.S. company now sells genetic tests for susceptibility to obesity. Other companies sell tests combined with advice on which foods to eat or supplements to take, depending on your test results.

The food industry is promoting scientific solutions to obesity, including 'nutri-genomics' and 'functional foods.' The theory is that a food with advanced properties may reduce your risk of heart disease, for example. Is this really the best way to tackle the obesity-related health problems associated with unhealthy diets?

Hazardous chemicals

Is it wise to test your genetic makeup to see which chemicals you should avoid, as the UK government has suggested? The highest avoidable exposures often occur in the workplace. Genetic testing in the workplace is very controversial. Trade unions in the UK and Europe are strongly opposed to this practice. They see genetic testing as a false option for controlling workplace risks. There is evidence that cleaning up the workplace will likely be a more effective approach than, for example, trying to predict which workers will get cancer from exposure to a particular chemical. Moreover, the resulting genetic exclusion could create a genetic underclass of people who can't get jobs.

Smoking

Genetic tests for susceptibility to lung cancer have often been announced, but further research has always found the claims to be exaggerated or wrong. This is not surprising in the light of twin studies, which show a negligible genetic component to lung cancer. Genetic testing should not, in any case,

change a doctor's advice to quit smoking, since lung cancer is not the biggest cause of premature death in smokers. Heart disease and chronic obstructive pulmonary disease are bigger killers, so it does not make sense to use genetic tests for lung cancer risk to decide which smokers should quit. These tests also do not appear to help smokers to quit. There has been a long history of tobacco industry involvement in this type of research. It is in the industry's interest to (wrongly) imply that only a minority of smokers with 'bad genes' need to worry about the health impacts of smoking.

Medicalization of Risk vs. Lifestyle Changes

Medical interventions are a potential consequence of expanding genetic tests. The danger is that genetic tests could lead to the medicalization of risk, expanding the drug market to include an ever-increasing number of healthy people. Preventive medication can be useful in some circumstances if treatments are effective and reduce the incidence of disease, but where should we draw the line? Some people would rather pop a pill than get exercise, but research suggests that many people dislike preventive medication and prefer lifestyle changes. Pharmaceutical companies would like to see increasing sales of medicines to healthy people and one former Chairman has predicted that by 2020 most medicine in developed countries will be 'pre-symptomatic.' Yet public health measures are often more outcome-effective and cost-effective (e.g., smoking cessation versus statins).

Conclusions

- Genetic prediction and prevention as a health strategy urgently needs evaluation against health policy objectives.
- We need more public and democratic involvement in assessing medical research priorities and health strategies.
- This is particularly important in public health and preventive health, because public reactions and compliance determine success or failure. If people won't take genetic tests–or won't change their behaviour/take the associated medications afterwards–there's no point in pushing this strategy ahead.

Carolyn Lukensmeyer, AmericaSpeaks

I was born in 1945, and grew up in an era when it was very clear that a collective citizen voice could change national policy. But today, most Americans feel it's no longer possible to influence policy on the national level. There is still huge citizen activism in the United States, but it is focused on local government, regional governance structures, and state government.

Most individuals can change and adapt–in their mental map, behaviour, social or family structure–more quickly than the institutional frameworks within which we live. To put it another way: most people believe that the collective wisdom of ordinary people is a better guide about whether to go to war in Iraq than the U.S. government's decision. There is a huge gap between the collective consciousness of individuals and our institutional frameworks.

Public distrust

One reason for public distrust on critical public policy issues is the lack of clarity about what is public and what is private. People often distrust public institutions because they fear those institutions have ceded too much territory to private commercial interests. The context we're living in today is characterized by multi-layered, deep distrust between individuals and institutions. The capacity to formulate public policy options, pass them into laws, and implement them with transparent accountable integrity is a huge challenge.

Regarding trust, people involved in biotechnology policy today are in a good position to engage the public because we're at an early stage in the cycle of public understanding, knowledge and information about biotech issues. This means we're early in the cycle of public distrust about institutions involved in these issues.

To build the credibility and ownership of public engagement processes for citizens, elected officials and parliamentarians, you must include the media. The media's stance on public engagement and the issue you're addressing should be part of your strategy. When AmericaSpeaks holds national dialogues, we run education sessions to help the media cover the complexity of the issues we're discussing.

Success factors

Critical factors for success in public engagement include the following.

- Every voice is at the table: we all have heard stories about demographic groups that won't participate in public processes. But you can get anyone to the table if you do the detail work.
- Scale: in the early stages, you may want to do smaller scale, geographically distributed public engagements to learn the perspective of the whole country.
- Immediacy: the goal is to combine authentic deep deliberation with the capacity to provide instant feedback throughout the process and on the outcomes.
- Decision makers involved at each step: don't do this work if you can't guarantee that the public engagement outcome will have some effect on the decision-making process. If you can't, stick with polls and very low visibility processes.
- Outcomes that make a difference: ensure that citizens know they were heard, know they were taken seriously, and can see it made a difference.

In the meeting we held to discuss the redevelopment of the World Trade Center site, our participants were demographically representative, not a scientific random sample. You don't just want to know what people think. You want them to walk out as an educated public that stays engaged in the process. You want the whole community in the room.

The World Trade Center engagement featured 500 tables with about 10 people at each table. It was important to include Muslim participants. We trained our facilitators to respect Muslim culture and encourage Muslim women to speak up.

You need enough support in the room to ensure the dialogue is authentic, informed and in depth. Experts can be involved as resource persons, but not as participants. Once an expert enters the discussion, it alters the dynamics of public engagement–it is no longer a level playing field.

Capturing ideas

The two primary technologies we used for the World Trade Center discussions were laptop wireless computers and polling keypads. Each table discussed which elements should be part of the new skyline at the World Trade Center site. The laptop kept track of the 'soft' consensus at each table and any strongly held minority ideas. Once this information was fed into a central computer, a team captured the different themes, displaying them for all participants to see. Each table then had time to discuss whether any themes were missing.

Each keypad had a number keyed to the person's demographic. This allowed the policy analysis team and elected officials to do any analysis they wanted on the data. For example, it was important to know how World Trade Center survivors and family members felt about certain discussions, compared to other members of the public. Polling keypads allow you to examine positions by income, race, etc.–and how marginalized people look at an issue.

We analyse our data during the event so we can give each participant a preliminary report of the meeting when they exit. This lets them continue the discussion outside of the room with friends and neighbours. It also gives them the opportunity to monitor media coverage and decision makers' response. Many people use the meeting report to interact with the media as informed citizens, increasing their sense of empowerment and influence.

Conclusions

There are good reasons to do more than just polls and surveys. The point of citizen engagement is to capture the collective wisdom of people who have discussed the issues and begin the process of creating a public constituency for a new law or policy.

But don't do this unless you have thought through what needs to change about your organization to make it more adaptive. If you plan to do citizen engagement on an ongoing basis, how will your organization need to be set up, resourced, interfaced with the public, and linked between bureaucrats and decision makers? This isn't hard work. But don't jump into it unless you have a plan for embedding public engagement within the ongoing processes of the decision-making body.

Do your homework about all the phases of the engagement: what content do people need for legitimacy's sake; and who should be in the room: stakeholders or general citizens?

Target a specific decision maker. How will you fully involve the decision maker in every phase of the work? A public engagement process must be linked to the person who will be accountable to the public for the decision.

Discussion

Q: *Currently, there are some very good genetic tests available for Alzheimer's and other illnesses. As the technology moves forward, the information we get from genetic testing will increase in complexity. It won't be long before we can predict medical outcomes and change the course of treatment by testing for combinations of genes for complex traits. I think genetic testing will be used by practitioners in a very positive way.*

Helen Wallace: I'm not denying that some genetic testing is very useful. For example, there are familial forms of cancer where genetic factors dominate. My concern is that for more complex disorders, we don't have good enough models yet to accurately determine the real health risks to people. There are so many variables that the predictive power of genetic testing may be very low. We need to be clear under what circumstances testing should be done and what kind of assessments we can make. We need more evidence about population attributable fractions. We also need to decide whether applying this strategy to health policy is the right direction in which to head.

Q: *Do we have the right models for public engagement? Public debates over scientific issues such as nuclear waste disposal tend to be fairly atomized. It's harder to take a silo approach to public engagement when dealing with new transformative technologies such as nanotechnology, which converges with other technologies on many different levels. Similarly, the issue of genetic testing and privacy converges with information technology and the Internet. How do you meaningfully engage the public in these debates when they are so complex? Or do you simply defer to a technocratic system where you allow the best and brightest scientific minds to deal with these questions?*

Arnold Naimark: We need to establish a common base for the discourse. In the end, what matters to people is how the issue intersects with their lives and values. By moving to a value dimension, we can find a common level for discourse. The question then is a technical one in the sense of how to take complex scientific and technical developments, such as those related to nanoscience, and identify the value implications. If we reach that step, a dialogue can happen. We need to pay attention to the pre-dialogue stage: for complex issues, can we bring in the appropriate people/scientists with social perspectives to help us discern the value dimensions?

Carolyn Lukensmeyer: My experience is that in every one of the issues we've been involved in, the people closest to the issue felt that the interactivity and complexity made it impossible for the public to be engaged in a meaningful way on actual policy options. In fact, it was possible. The challenge is always to get enough expertise in a room so that the public can enter into a discussion of policy options.

Innovating in the Private and Public Sectors

New science and new technologies offer opportunities for entrepreneurs and challenges for public policy makers. Researchers, industry, the public and governments will need to work collaboratively to ensure that genomics improves quality of life for everyone. What mix of public and private action would be conducive to the creation and growth of a strong and dynamic genomics sector?

David Fransen, Industry Canada (Chair)

To set the context for this discussion, some recent policy announcements by the government indicate the importance of this theme. The February 2004 Speech from the Throne emphasized that we must do more to ensure our R&D investment is converted to commercial success. The government has invested $9-10 billion in R&D over the last six or seven years, yet has received little return on that investment. The government will also build on the nation-wide reach of NRC to help small firms bridge the commercialization gap.

The 2004 Budget recognizes the importance of the relationship between knowledge and commercialization. A few examples include: building research foundations, supporting venture capital financing, investing in offshore development, supporting small business and entrepreneurship, and strengthening the Canadian tax advantage. Specific Budget initiatives include: an annual increase of $90 million to Canada's three granting councils; an increase of $20 million to universities to offset the indirect costs of research; another $60 million to Genome Canada; more funding to improve the capacity for commercialization at universities, hospitals and other research facilities; new funding of $270 million to enhance access to venture capital financing for companies turning promising research into new products and services; and so on.

Given the government's S&T commitment and its Budget commitments, this session asks what mix of public and private action would be most conducive to the creation and growth of a strong, dynamic genomics sector. Each speaker will address questions such as the following.

- What, if anything, is unique from an economic and business point of view about genomics and related technologies?
- What are the benefits? What are the risks? Are genomics and proteomics distinctive in this regard?
- Are there specific issues related to genomics and proteomics that require specific regulatory treatment?

John Wallenburg, Office of Technology Transfer, McGill University

I am a scientist whose doctoral degree examined how our genetic material recombines. But I'm also a father. In 1986, my first daughter Marika was diagnosed with cystic fibrosis (CF). In 1988, my family was one of the early beneficiaries of the genomics revolution when Marika's younger sister was diagnosed pre-natally as a CF carrier.

Marika's diagnosis was a pivotal point in my career. I rapidly lost interest in purely academic questions and fundamental research. I wanted to see research results have a real-world impact during my daughter's lifetime. I started trying to understand why some science disappears into the black hole of peer-reviewed research and other results find their way onto pharmacy shelves.

Academia versus corporate culture

In academia there is no 'secret' research; researchers live by the 'publish or perish' rule, and research is conducted for public benefit. In corporations, the rule is 'publish and perish'; the goal is return on investment, and research is conducted for shareholder benefit.

My role at the university encompasses education of the investigators, and my take-home message to them is almost invariably: people don't use technologies, people use products. It is frequently true that the way for society to derive the greatest benefit from a technology is through its commercialization.

Part of a university's objective is to ensure the greatest public benefit is derived from university research. This therefore sometimes involves commercialization of a technology. Converting technologies into products requires a major investment in time and money–especially in the biomedical field. Universities need the means to reassure those potential investors that they have an opportunity to recoup their investment. Academia's interest in patents is largely as an instrument to encourage commercialization. There is however, a large difference in the time to patent versus the time to develop, and it is during this time gap that universities need the ability to invest.

Product development cycle

Traditional pharmaceutical development starts after the identification of a disease target. You look for compounds that may modulate the target. After you identify a candidate molecule, you look for compounds with better and better pharmacological properties before beginning pre-clinical testing, toxicology and animal studies. Product development proceeds through clinical phase I, phase II and phase III testing–before applying for a new drug application. This process can take 6 to 15 years, with cost estimates ranging from US$300-800 million.

The time point after a university files an initial patent application where it incurs the largest expense is the 30-month national phase deadline when it must decide in which countries to seek patent protection. Broad international patent protection costs $50,000 or more. To protect an entire patent portfolio can cost several hundred thousand dollars. This is incurred at a stage when it may still be too early to know how or if the technology will mature sufficiently to attract commercial interest.

Genomics inventions are typically several years ahead of the identification of a 'drugable' disease target, increasing the risk and cost investment required by a university to bring the technology to market.

The CF story – the first 10 years

Let's consider a real-life example of the timelines and benefits that can result from a genomics discovery by examining the first 10-years of development after the identification of the CF gene. In 1985, cystic fibrosis was localized on chromosome 7. In 1989, in a remarkable feat of reverse genetics, a group led by Dr. Lap Chee Tsui in Toronto identified and isolated the CF gene. In 1990, the gene was used to correct the CF defect *in vitro*, confirming its potential use in gene therapy. In 1991, the protein product, cystic fibrosis transmembrane regulator (CFTR), was confirmed as the defective protein in cystic fibrosis. We also started to understand what this molecule does. It serves as a communication point in cell membranes, letting certain molecules in and out of cells. Importantly, this discovery also allowed us to locate which tissues express the CF gene.

In 1992, the CFTR protein was purified, which led to the determination of its three-dimensional structure. In addition, a mouse model of cystic fibrosis was developed, which was necessary for the pre-clinical testing phase. We also found that CF in mice does not reflect the human disease. Although CF is a monogenic disease, different genes impact its level of expression or severity in humans.

In 1993, scientists recognized that in most CF patients, the defective gene doesn't prevent the CFTR protein from being made. Instead, the protein never gets properly transported to the cell membrane. We also obtained the first evidence that gene therapy can correct the basic CF defect in humans. In 1994, the first gene therapy attempts were made using a viral vector, and in 1995 the first attempts were made using non-viral delivery.

Clinical trials

Let's now skip ahead to today and examine the CF-related clinical trials ongoing in the USA. Two gene therapy protocols are underway (one non-viral, one using a virus). Four protocols are trying to rescue the protein by targeting ways of getting CFTR into cell membranes, and five protocols are trying to restore its function. All of these trials can be directly traced to the isolation and identification of the CF gene. They are all the direct result of genomics research.

Other ongoing trials are unrelated to genomics and the CF gene. Six anti-inflammatory protocols are trying to reduce inflammation of lung tissue in CF patients. Five anti-infective protocols are designed to counter chronic bacterial infections, and there are two mucus-regulating protocols and one nutrition-related protocol.

Fully 11 of 25 clinical trials underway today (45%) are the direct result of genomics discoveries made 19 years ago. Importantly, all of these genomics-related protocols address the root cause of CF, whereas non-genomics related trials address the symptoms only.

Conclusions

When scientists identify a gene that's involved in genetic disease, it can lead immediately to a diagnostic test. Thus genetic testing is the very first application that can arise from genomics, but it is only a very small fraction of the overall potential benefit. When I hear that the return on investment in genomics research has been disappointing over the last five years, I get concerned because the window that we're looking at is far too short. The return to investment from genomics research must be examined over a very long period.

Finally, given that we have no idea what 90% of our genome does, it's impossible to imagine or predict the nature of future inventions and the products that must ultimately be regulated. Policy makers will need to create policies broad enough to cover inventions and applications that we can't even imagine today.

David Shindler, Milestone Medica Corporation

There are many reasons why genomics will have a successful impact on our society:

- aging population
- increasing cost of health care
- Big Pharma growth requirements
- need for better and more targeted drugs
- need to improve diagnostics and prevention
- excellent world-class R&D in specific areas in Canada
- advent of Canadian programs: NRC institutes, National Centres of Excellence program, Canadian Institutes for Health Research, Genome Canada, Canadian Foundation of Innovation, university chairs, MaRS in Toronto is incubating facilities and companies
- Biotech Human Resources Council (BHRC).

The future of Canadian health research has never looked as good as it does now. But how will Canada benefit from the life sciences and genomics revolution? My career at Milestone Medica Corporation started when the Royal Bank decided we need new private sector mechanisms to help commercialize technologies. Milestone Medica forms partnerships with universities and hospitals to build the products of tomorrow.

Canada's genomics potential

From the perspective of an early stage seed investment fund:

- we have a growing genetics R&D and infrastructure in Canada
- we have a cohort of competitive emerging companies such as MDS Proteomics and Zenon Genetics–the industry is developing and shows great promise
- key issues include: how to do technology transfer better; how to finance it; how to provide right management, human resources and policy.

Because it takes so much time and money to develop products from genomics research, commercialization must involve a public/private partnership. There is no other way to do it. The dynamics of this partnership are complex, but if it is developed properly it will define the innovative capacity for a nation, and help build whole sectors of our economy.

Bridging the university/industry divide

There is a culture clash between university labs and industry. They operate under different rules, so we must ensure there are people in academia and industry who understand what rules apply where, and how to bridge the gap. For example:

- 'publish or perish' at universities *versus* 'publish *and* perish' in industry

- share with colleagues *versus* non-disclosure agreements
- priority: publish *versus* priority: patent
- competition to be the first to discover *versus* competition to gain market edge
- teach to convey knowledge *versus* learn for competitive advantage
- 'public good' *versus* 'private profit.'

Canada's record in genetic discoveries is second to none. Canadian researchers are pioneers in CF, muscular dystrophy, Alzheimer's, Tay Sachs, and myotonic dystrophy. Our leadership continues today.

Canadian Genetic Diseases Network

The Canadian Genetic Diseases Network brings scientists together on a national basis to do cross-disciplinary work. Its goal is to create a critical mass in human genetics R&D, and to coordinate technology transfer in cooperation with universities and technology transfer offices. Examples of companies that have emerged from this work include: Xenon Genetics in Vancouver, which looks for rare population defects and translates those into drugs; and Apoptogen (now Aegera Therapeutics), which has patented the XIAP (x-linked inhibitor of apoptosis protein) gene. The Network was launched in 1989 and just passed its 15th year. This is a great Canadian experiment and a resounding success. One of its impacts was to support the early Alzheimer's gene research.

Another unique institution is Genome Canada, which has built strength in genomics and proteomics R&D across Canada in agriculture, environment, fisheries, forestry and health. Genome Canada helps make possible large-scale infrastructure and collaborative projects. To date, it has invested more than $300 million, with more funding announced in the 2004 budget. Many things are happening as a result of Genome Canada. There are more new investments in Canadian companies, more core companies, new jobs, new product sales, new users, etc.

Drivers for commercialization

To commercialize genomics discoveries you need to identify a product, you need good management people, you need technology and IP, and you need access to finance. It costs US$500-800 million to commercialize a product from a discovery. To attract these investments, you need stability, you need to know where you're going, and you need a really good plan.

In Canada, we have a lack of critical mass–there are too many small companies. We lack government support at critical stages, particularly the gap between proof of concept/seed funds and venture capital. Milestone Medica tries to fill this gap, but we're not sufficient. Some of the 2004 Budget announcements will help. This gap has to be filled by private-public sector partnerships because the private sector cannot do it alone.

Role of government

To get through our 10 to 15 year genomics development cycles, government must be involved. We also need to build sustainable companies and create regional capabilities. On the policy side, with rapidly emerging fields, guidelines are very important. The original recombinant DNA guidelines set a harmonized framework for R&D.

We need more work on HR development. The fact is people are going to drive this sector, not technology. We need to get the right people, with the right skills, with the right expertise, with the right attitudes in the right places.

Strengthened IP legislation is important to ensure the required investments will be made. Finally, regulatory responsiveness is important. I was worried to learn yesterday that Canadians have little appetite for speeding up regulatory or evaluation processes. Our regulatory agencies have to understand where the danger areas are and work on those. Most genomics activities are quite safe. Slowing down the whole sector is not going to accomplish much.

Recommendations

My prescription is simple:

- public-private risk sharing for the early stages
- continued policy work improvement on intellectual property and regulation.

Make no mistake, the decisions we make now and the things we do today will determine whether we have a viable industry 15 years from now.

Ron Yamada, MDS Inc.

Less than two years ago, a similar symposium was held prior to Bio2002. Many positive changes have occurred since then.

- At Bio2003, President Bush as keynote speaker indicated that biotechnology was "a vital industry"–not important, not emerging, not strategic, but vital.
- 2003-2004 saw the final implementation of seven 'genopoles' in France. These regions combine academic research laboratories, corporate research facilities, incubators, and venture capitalists in order to quickly capture innovation through commercialization. France has also introduced new tax incentives to encourage and accelerate the genomics sector.
- In Sweden, a company called Biovitrium was formed in 2001 mainly as a spin-off from Pharmacia but also with support from the Swedish government. This allowed the clustering in one company of successful scientists, clinicians, product managers, product developers and marketers with a proven record of success in developing drugs. In 2003, Biovitrium announced three different agreements, including a US $300 million agreement with Novartis. This group also provides expertise to biotech companies in the Medicon Valley on the east shore of Denmark/west shore of Sweden. Medicon Valley is the most active bioregion in the world, employing 30,000 people and 4,000 scientists.
- In 2002 Singapore announced it intends to attract biotech companies and scientists. Singapore has been so successful that in 2003, Taiwan introduced a similar NT $29 billion initiative to attract biotech organizations. Japan has also announced a similar strategy.

In Canada, biotech companies such as MDS applaud the federal and provincial governments' continued support of basic research. Without the seeds of R&D there is nothing to harvest. While we have to protect the integrity of academic research, we want to see more emerging companies. But we may have too many companies. Is this the best way to proceed?

MDS at a glance

MDS is headquartered in Ontario. We work in many countries, so we see the impact of both short- and long-term government policies. We provide services and products that enable our customers–pharmaceutical and biotechnology companies–to discover and develop drugs. And as MDS Capital, we provide financial support to emerging life sciences companies.

We notice that some countries have clearly indicated– through their words, legislation, funding and programs– that biotechnology and the creation of a vibrant biotech sector is a priority. We believe Canada is well positioned to build a vibrant sector in which 6 or 7 medium-to large companies are growing rapidly, reinvesting 30% of their revenues in R&D, and providing support, contact and expertise to hundreds of other biotech companies. We believe this is a great nation-building opportunity for Canada. We believe that genomics is a very powerful and important sector with high trade and high health impact.

We also notice that size is important. The average number of employees in a U.S. biotech company is 130, versus 40 in for the rest of the world. Canada now averages about 20 employees per company. How can we expect a fragmented, small set of companies to succeed? From a policy development perspective, how can we offset or mitigate this lack of size and scope?

Policy framework

I believe we need to consider a different framework for policy development. The success of companies will partly depend on ordinary peoples' willingness to use their products. Our experience in other countries shows that a policy framework gives citizens the confidence and willingness to start to accept change. We propose for consideration a social policy framework–one that is built on a solid foundation of excellence in science and sound ethics, and which takes into account intellectual property, regulatory approval, economic trade, and privacy issues. Let's try to integrate these issues and take a more consolidated view.

Our policy framework must be able to adapt to new information, new ideas, new impacts and new issues. We believe that integrating different areas is fundamental to creating a framework that can be continually reviewed and refreshed. This could help Canada take a leading position in its ability to address the movement of science in society in an acceptable manner.

Creating value

To build a sector or industry, we need to focus on what creates value. It is not necessarily true that companies create value, or that the number of companies or employees are the best metrics for assessing whether we're doing well. You create value by moving a product from the pre-clinical through to the drug approval process as quickly and cost-effectively as possible. If you do that, the value of the compound will increase quickly. We need to measure how well our compounds are moving through the value chain, with what speed and with what success.

What if we could align new discoveries with key receptor companies in Canada? For example, should all the vision-related discoveries be evaluated and shepherded by a team from QLT that has the expertise, regulatory knowledge, manufacturing knowledge and clinical experience?

In Canada, Genome Canada is the only major research-granting agency that accepts proposals from corporations. Several years ago, we participated in a research program on mass spectrometry that was half-funded by provincial-federal funds and half-funded by MDS. MDS Sciex is now the leading manufacturer of high-speed sophisticated analytical instruments. In the last three years, we exported over a billion dollars worth of product. If we want to accelerate the technology transfer process, Canada needs to look at different streams of research proposals.

In Canada, 300 to 400 biotech companies are working hard to develop one product. They have other compounds in their pipeline, none of which are being developed and some of which (we estimate between 600 and 1,000) are ready for human trials. But there isn't enough human or financial capital to support those compounds, so their value may disappear. What if we could create the Canadian version of Biovitrium: bring together clusters of scientists and experts with proven experience in drug discovery and development, screen those compounds, fast-track them through the existing infrastructure in Canada, and finance them through a public/private sector fund?

Recommendations

From a policy standpoint, we need a more explicit statement about whether the genomics sector is important. Is it critical or vital? We also need a different framework. We can't afford to look at IP as one form of regulation and drug approval as another–we have to bring them together. We need to focus on creating sustainable value, not just companies and not just employees. And from a policy standpoint, we need to mitigate our lack of size and scope.

Elwyn Griffiths, Health Canada

Twenty-five years ago, biotechnology was called genetic engineering. The quantum jump was our ability to recognize genes and to move them from one organism to another. That caused great concern, and there was a self-imposed moratorium on gene transfer in the early 1970s.

Many conferences were held and the field eventually moved forward in a controlled way through regulation of research. By the early 1980s, the first recombinant DNA products appeared, such as insulin and growth hormone. There were many novel products: safe, effective biological medicines that are now in routine use, such as factor VIII, G-CSF (an anti-cancer treatment), and HepB vaccine. We now have diagnostic tools including highly sensitive nucleic-acid based tests for HIV, Hep C, and West Nile virus.

But biotechnology does not just produce products; it is an enabling technology. Consider the production of the pandemic influenza H5N1 vaccine strain. This flu strain is highly virulent. You cannot grow it in eggs because it kills the cells. But you need a large volume in order to make a vaccine. This is done through reverse genetics. Scientists take the wild-type strain, break it into bits of DNA, cut and insert the bits they need into plasmids, and then construct an attenuated virus. This vaccine is already undergoing safety testing and will be released to manufacturers in mid-April 2004 if they need it.

Biotechnology guidelines

Regulatory measures for biotechnology were put in place early in the development of biotech medicines. In the early 1980s, guidelines were developed on production, quality control, safety issues, and so on. There was a quantum jump in thinking at that time. We tried to set guidelines that would prevent any unforeseen event from happening.

The original guidelines were based on sound science and took a flexible approach. Flexibility is very important. The guidelines were not tablets of stone, because we didn't know how the field would develop. The idea was that their recommendations could be updated or changed in light of experience with production and quality control, and further development of biotechnologies. The Canadian guidelines were developed in concert with regulators in Europe, the UK, and the U.S., who shared information regarding their regulatory approaches.

Benefits of regulation

Why do we want regulatory oversight? Regulations are often called hurdles or barriers by industry. But appropriate regulatory measures are essential to minimize the risks and maximize the benefits:

- to safeguard individual patients and populations against unacceptable adverse events, such as a viral contaminant that spreads throughout a population
- to ensure that patients are given full benefits of scientific innovation and knowledge, because as things move on we want to push the field forward
- to ensure the reliability of diagnostics.

The early development of regulatory oversight and the availability of guidelines have helped to establish the quality, safety and efficacy of rDNA health products and diagnostics. Regulations provide a framework for moving forward with newer, novel technologies. We don't have to reinvent the wheel because we've seen these kinds of products before.

Future challenges

Progress in sequencing genomes and mapping the genes involved in complex multifactorial diseases opens yet further vistas for improving human health. Pharmacogenomics links drug testing and drug usage to genomics–it is the ability to identify individual variability in response to drug efficacy and toxicity, to maximize effectiveness and minimize the risks.

What are the challenges? We need regulatory policies on pharmacogenomics based on the best science to support public confidence. We need to validate lab techniques and test procedures. We need to develop the science framework for interpreting data needs. And we need regulatory guidance.

Harmonizing viewpoints

What is next from a regulatory perspective? Given the speed of scientific and technology development and innovation, we have to keep talking to each other. We need to maintain a dialogue involving regulators, the pharmaceutical industry, academics, public health officials, and the Canadian public.

Science and commerce are international, but public health, social and ethical questions also have a global dimension. Any decisions on the regulation/use of novel technologies increasingly need to be done on an international basis. We won't agree all the time, but we must try to talk with our international counterparts to see where we are all going. International cooperation is high on Health Canada's list of regulatory priorities. Our department is involved with the World Health Organization, the International Conference on Harmonization, and we are making stronger links with major regulatory agencies and laboratories in other countries.

What should our aim be? We need a balanced scientific approach to regulating biotechnology products. Canada has the right framework, but there may be some gaps to fill. The challenge is always to ensure safety and public confidence without inhibiting the development of technologies that could give enormous benefit to society.

Discussion

Q: *Where do the potential conflicts of interest lie with respect to public-private partnerships?*

David Schindler: Conflicts arise mainly in terms of information sharing and public disclosure. Industry wants its information to be proprietary through trade secrets or patent protection. Most conflicts arise over what should be disclosed by a researcher who is funded by the public purse versus what the industry

needs to or wants to disclose. In medicine, new technologies and drugs are primarily developed through a public-private relationship. So the rules have to be very clear. We look long and hard to determine the roles of each party–a professor funded by industry, NIH, CIHR, and other agencies. If you put in the effort, you can establish a rule-based system with guidelines that works. In the majority of cases, things run smoothly.

John Wallenburg: I would like to echo what David said in terms of publication and public disclosure being points of contention. Another issue arises in the private and public sectors whenever they interact: ownership of the intellectual property. Should the university become the owner or do they waive their rights? Who owns what? There is no simple answer.

In general, universities would like to maintain ownership of inventions in order to protect the public interest. If the technology is owned by a company and the company goes bankrupt, the technology tends to disappear. Universities want the opportunity to relaunch their technologies if necessary, whereas companies want the intellectual property because it strengthens their value. It gets even more complicated when large funding consortiums with many players are involved, all of which want a voice in the commercialization.

Q: *What might the regulatory responsibilities and framework look like ten years hence? Will responsibility for regulation shift partially away from government regulators so they have a more strategic load? Will we need some continuously evergreening software applications that keep track of everything, much like an air traffic control system?*

Elwyn Griffiths: To my mind, government regulators should be doing their best to prevent a product from being approved that results in a safety problem. We don't want to wait for this to happen. Regarding software, the European Medicines Evaluation Agency (EMEA) has a good system for tracking decisions. If a new product comes along, EMEA wants to ensure that the regulatory decision is consistent with decisions made two years ago.

By integrating and interacting with other regulatory agencies, we may be able to cope better with the increasing load of work we face. This is a real problem and not just for Canada. It sparked the creation of the EMEA. Canada should be at the table with regulators from other countries, making decisions with them. That is what happened in Europe. The big European countries were all moving forward rapidly in the early 1980s, while smaller countries such as Portugal, Greece and Luxembourg lacked the infrastructure and people to keep up. They now have a seat at the table–their voice is as good as anyone else's.

David Shindler: There is a fundamental issue in terms of human resources. The regulatory agency of tomorrow still needs experts like Elwyn. If we weaken the system by not hiring the right people, then we will not make good regulatory decisions. HR issues such as remuneration are very important in departments with regulatory responsibilities. In Canada, many talented people are not interested in becoming regulators because the salaries are too low. They can become university professors and enjoy a less stressful life.

Q: *Biotechnology, genomics and information technology are begging for public-private partnerships. When you look at the participants list for this conference, we have people from universities and government organizations sitting in the audience and industry representatives sitting on the panel. There is something wrong with this picture. We need more people from industry sitting in the audience. We need to bring in industry during the design stage of public policy. I encourage my colleagues and the Biotechnology Secretariat to actively learn and educate themselves about public-private partnerships.*

Q: *I wish to protest the oversight of not inviting a group of critical individuals to this conference. For the last 20 years, it has been my responsibility to convert genetics and genomics research into diagnostic tests for the public. My colleagues and I are regulated by the Canadian College of Medical Geneticists. Fewer than 20 people in Canada actually do cystic fibrosis tests. I test for about 150 different genetic conditions–only one of these tests is actually regulated by the Medical Devices Bureau of Health Canada. All of the others are home-brewed tests. If you are going to discuss public policy and how to apply the benefits of genomics to society, you need to include this critical group of individuals.*

David Fransen: Thank you for both of these comments, your points are well taken.

Fairness and Equity in Genomics

Issues of privacy, ethics in research, and access to genetic diagnostics and treatment are often quoted as issues for the developed and developing world. What do we understand by fairness and equity in genomics? What are the challenges and opportunities in developing fair and equitable policies and programs? How could the challenges be addressed and opportunities be captured?

Roxanne Mykitiuk, York University

George Gaskell has suggested that determining the kind of society genomics technology makes possible is a question of values. We will inevitably rely on substantive values, norms and principles to help guide the process of policy setting and decision making in genomics. The key values to consider are equity, fairness or justice, and autonomy.

How do we understand these values? Turning first to autonomy, this term literally means self-rule. Autonomy is popularly understood to represent individual liberty or freedom from interference by others, especially the state. The idea is that respect for autonomy is a commitment to recognizing the right of an individual to make informed decisions, free of coercion and interference.

That basic conception of autonomy looms large in debates about genomics policy. Both producers and consumers appeal to the idea of personal choice as the appropriate policy or mechanism for governing genomics. Both groups resist the idea that government might impede their ability to sell, buy or use products and services. There is significant public support that people should be free to buy and sell as they see fit, unless an overriding reason exists for government to limit commerce.

This interpretation of autonomy places the burden of establishing harm on those who argue that potential harms are too large to allow individuals freedom of choice. Within this model, the state has a responsibility to ensure that risks associated with specific products are within acceptable levels. It also has responsibility to ensure that individuals can choose well through access to clear, comprehensive and reliable information.

Consumer model of autonomy

It is important to meet the requirements of the consumer model about autonomy in setting genomics policy. The marketing of genetic tests or services must occur under conditions that ensure consumers can make voluntary informed decisions. However, most criteria aren't straightforward. What constitutes sufficient information to make an autonomous choice? Making sense of genetic information about susceptibility risks, for example, requires an understanding of probability theory and risk calculation, the symptoms associated with the genetic condition, and the safety net efficacy of early intervention.

Even having adequate information might not ensure informed consumer choice if the information is not accessible. If the language of advertising is distorted and incomplete, that information may undermine rather than enhance autonomy.

As a minimum, we need a regulatory system that ensures the assumptions of consumer safety are well founded and helps to promote the understanding necessary for informed consumer choice.

But consumer choice is not the whole story. Autonomy also means the freedom of individuals to pursue fundamental values and interests. Unless producers provide options that allow individuals to pursue their fundamental values and interests, consumer choice will not coincide with individual autonomy. If most farmers plant genetically modified crops or grow transgenic animals, for example, individual consumers may lose the freedom to buy unmodified food products.

The consumer choice interpretation also ignores the fact that individuals have different choices available to them, and different levels of freedom to act according to their means and values. For example, women's ability to make informed choices about using some prescription drugs is limited by research protocols that sometimes investigate only the drugs' impact on male subjects. While all individuals face limits on the

options they can choose, those with less social or economic power will likely face more restrictions than others.

Justice and fairness

On its most basic level, justice means fair, equitable, appropriate treatment. Most discussions of genetic policy and justice focus on how to ensure a fair distribution of the benefits and burdens. Genetic technologies and services, however, raise serious concerns about distributive justice. Who should pay for the tests or products? Should a particular genetic test and counselling services be considered a medical need covered by the Canada Health Act? Should certain tests and services be available on a fee for service basis, such as cosmetic surgery?

If the provinces regard genetic tests as medically necessary for some patients, the costs of providing the tests will have an impact on other services now covered. Genetic tests cost money to administer, as well as the counselling costs and any follow up care. If the provinces declare a test is not medically necessary and decline to absorb the costs under provincial health plans, it will only be accessible to those who can afford to pay. If genetic tests have little value, should the state regulate their availability rather than allow individuals unfettered freedom to purchase them?

Distributive justice questions must also provide guidance on how to apportion health care resources among large-scale categories such as prevention, diagnosis, and chronic care; and how to decide who should have access to a particular procedure and on what basis. If health care budgets are absorbed in response to the expense of biotech innovations, there will likely be less money available to pursue proven public health measures.

Social justice concerns

Important as those questions are, a justice framework limited to questions of fair distribution will be insufficient. The distributive justice paradigm tends to exclude social justice questions. If we address social justice, our focus expands from questions of distribution to include questions of actions, decisions about actions, and how to provide the means to develop and exercise individual capability. Social justice requires us to think about ways to provide greater equality and less tangible benefits.

We need to move away from the naïve view that people act as discrete independent individuals unaffected by their relationship to others. People belong to social groups. Promoting and achieving justice among individuals requires us to identify how institutional structures disadvantage certain groups and privilege others. Thus, paying attention to social justice guides us to ask different questions about genomics policy than focusing on distributive justice. It expands the agenda from questions of payment and access to questions of how to promote greater equality, respect and status. It forces us to look at structural barriers to equality and consider how proposed innovations of genetic testing are likely to affect those features.

From a policy setting view, we also need to pay attention to procedural issues. When structuring bodies for deliberating the ethical, legal and social implications of genomics, it is common to invite stakeholders, interested parties and affected groups to participate in the discussions. It is especially important, however, to attend to the voices most often overlooked–those that bear the greatest risk of a technology being implemented. The role of these representatives is different than the role of representatives who stand to benefit from the technology, and from that of generic citizen participants. The principle of justice or fairness should recognize those procedural as well as substantive questions.

Ishwar Verma, Sir Ganga Ram Hospital, India

We have heard that the Human Genome Project and its implications are going to create a revolution. I believe the expanding horizons of genome research have fuelled people's expectations for finding solutions to all their health problems. I often receive calls from patients or parents with children suffering some genetic disease, asking if the genetic experts have found something to help them.

So far, the major health impact of the Human Genome Project is improved diagnostics. There have been few therapeutics successes. Pharmacogenomics is still in the future. Our diagnostics tests are mainly for purely genetic diseases–monogenic disorders–

although we have also identified some predisposing factors for other diseases.

Ethical issues

About a decade ago, Wertz and Fletcher published a 19-nation study. They asked geneticists to list the major ethical issues confronting them. The first one everyone cited was the fairness and equity of genetic testing. How to make these tests available to everyone? This is as an important issue both in developed and developing countries.

Four players are involved in this issue: the government, which allocates funding; the private sector, which invests for profit; the professionals, who need the skills to apply genomics technology and information; and the public, who must accept the technology.

Thalassemia major is a common disease in India. Thalassemia is the most common single gene disorder in the world. The carrier rate in Mumbai (Bombay) is 4%, in Calcutta it's almost 8%, and in Delhi and the northern states it's about 5%. The total number of carriers is 29.7 million. In India, 10,000 affected infants are born every year.

Treating thalassemia

Treating thalassemia requires repeated blood transfusions. Every month or so, an affected child needs a transfusion. After many transfusions, iron collects in their body. Iron removal requires an expensive drug therapy that costs about US$3,000 per year. Although the Government of India does not provide funds for this treatment, it reduces the customs and excise duties on these drugs. Thalassemia is so devastating that affected families easily accept prenatal diagnosis for their next child. Our policy is to reduce the number of affected children who are born with this disease. At least ten centres in India have a prenatal diagnosis facility for thalassemia.

Consider the plight of a rickshaw puller who earns $50 per month. He spends all his money to treat his child and has no money left for prenatal diagnosis. We can reduce the cost of testing for such people. One alternative is to refer them to a government hospital, which provides almost free health care. But these hospitals are so crowded that there are treatment delays. Another alternative are 'trust hospitals,' which give 30% of their care for free to poor patients. They overcharge the rich to provide free service to the poor.

Causes of inequity

Dilemmas concerning inequity in access to genomic technologies include the following.

- Affected families may not have the knowledge or resources to utilize them.
- Professionals may be unaware of the technologies and fail to inform families. Most professionals know about prenatal diagnosis of thalassemia, but they don't know about other genetic testing available.
- The government may not finance facilities for they feel it is of low priority.
- The private sector provides the service, but only on payment, thus limiting access.

The Government of India did not invest in the Human Genome Project. However, after the Human Genome Project released a draft of the human genome, the Indian government decided to invest in genomics. We hope that, combined with India's strength in bioinformatics, we will come up with some unique products.

Other common genetic diseases in India include Duchenne muscular dystrophy, spinal muscular atrophy, metabolic diseases and fragile X syndrome. Some 20 Indian centres provide molecular diagnoses for genetic diseases. But the issue of equity still remains to be solved.

Addressing inequities

What solutions are possible?

- Money is important, but it isn't everything. There is plenty of money in the U.S. but inequity in health care persists.
- Leaving everything to market forces won't solve the problem.
- Health insurance could be an answer. In India, we have insurance but it does not cover genetic diseases.

In India, the rich could pay for genetic testing themselves. The middle class could be covered through their health insurance. And the very poor, who can't afford health insurance, could be provided genetic testing out of public funds.

Global demographic indicators reveal another kind of inequity: between developed and developing countries. Genomics techniques are expensive and require skilled people. Most genomics research occurs in developed countries. The Human Genome Project appears somewhat irrelevant to developing countries as they battle infectious, nutritional and parasitic diseases. It has widened the gap between rich and poor resource countries

Universal problems

None of the problems belong to only one country. Migration and globalization have universalized our problems. Canada is home to many people with thalassemia who migrated from India, Pakistan and the Middle East. Rich nations could help poorer nations ensure an equitable and fair distribution of the benefits of genomics technologies.

In developing countries, health services have been slow to establish genomic centres. They need to develop their own genomics technologies, appropriate to their level of economy and development. It's actually cheaper to deliver genomics technologies in developing countries because skilled labour is less costly and they have an abundant source of clinical material. This means useful collaborations are possible between developed and developing nations.

Conclusion

Governments need to provide support, especially to the very poor. Private insurance may serve middle-income earners. The wealthy can pay for gene testing services themselves. We need to offer more professional education to physicians. And we need to provide more information and education to women, because in developing countries they remain the key to development and a bright future.

Lee Silver, Princeton University

Why are genomic and other biotechnologies treated differently than non-biotechnologies, in those cases where risks, benefits and access, as far as we can tell, are comparable?

Consider one of the most trivial uses of genomics technology: "glow in the dark" zebra fish. No public funding was involved in their production. If they escaped into our waters, they would die because they are completely unfit for the natural environment. They're fluorescent: they don't suffer from glowing in the dark. They pose no potential harm to the environment. And yet, they have been banned in California and some European countries. If it has nothing to do with health, environment, danger, or animal suffering, why are people so upset by these fish?

The main reason, I believe, is an advertisement that appeared in the New York Times: "Who plays God in the 21st century?" The ad was funded by Jeremy Rifkin and others. The gist is that we shouldn't play with Nature and we shouldn't commercialize living things.

Harper's poll

In 1997, Harper's magazine conducted a poll that asked: who should control the genes given to a child? As a lifelong geneticist, I can tell you that when a mother and a father have a child, the father's and mother's genes both segregate randomly. The U.S. public was asked: who should have the power to control the genetically linked characteristics of a child before birth. They were given four choices: 11% said the parents, 0.7% said the doctor, 16% said "no one," and 70% said "God." So most people believe that God should decide what genes should go into their child.

What is the connection between God/spirits and genes? In western society today, people generally understand the critical role that genes play in development and the proper functioning of plants, animals and human beings. But most people, including 80% of Europeans, believe that spirits animate living things. Consciously or subconsciously, many people put these two ideas together and thus God or Mother Nature becomes the giver of genes. Scientists are therefore accused of hubris (playing God) because they are "going against" God or Nature. Most people believe scientists will be punished, just as Victor Frankenstein was punished by the monster he created. In contrast, most scientists and some humanists have a physicalist view of the world, as opposed to a spiritualist view.

Spiritual beliefs

What is the objection to genetic modification of plants and animals? In America, we are currently ruled by Christian fundamentalists, who believe that only people have souls because the Bible says that God gave souls to people, not plants or animals. I think that explains why they don't worry about genetic modification because they believe there are no spirits in plants and animals that can be harmed.

In Europe and California, spiritual beliefs encompass Mother Nature. If you talk to many well-educated people, they don't have this disconnect between humans and animals. In Switzerland, the 1992 Amendment to the Constitution demands respect for the integrity of living organisms. The German Constitution recognizes the "dignity of living things." Prince Charles has said: "genetic modification takes mankind into realms that belong to God, and to God alone… do we have the right to experiment with, and commercialize, the building blocks of life? We live in an age of rights–it seems to me that it is time our Creator had some rights too."

Early gene control

Most people don't realize that all human civilizations are based on controlling genes. Some examples include the weed that gave rise to corn–corn doesn't exist naturally. French poodles don't exist naturally. And sheep have a coat of wool that sits on them–wool is a human invention. The original animals were basically just hairy goats. Did these genetic modifications violate the integrity or dignity of wolves (where the French poodle came from), weeds (where corn, wheat and rice come from), and hairy goats?

Today, most of Indonesia looks like rice paddies–not what it looked like before people colonized the islands. The worst thing that ever happened to our global environment is agriculture, although without it we would not be able to support six billion people in the world. The rice planted in Java today is not thousands of years old. It was created about 30 years ago by the International Rice Research Institute, which distributed the high-yielding rice.

Engineering the unborn

Returning to the Harper's magazine poll, the first question asked who should control reproduction and 70% said God. In the same poll, the same people were asked: "Eventually, genetic technology may allow a couple to control certain characteristics of their unborn child. If you were expecting a child, would you like to control genes affecting the following four characteristics?"

- disease immunity (84% said yes)
- intelligence (64%)
- sexual orientation (51% said yes)
- gender (19% said yes).

These answers totally contradict the answers to question one.

Consider this real-life story. A British woman was undergoing pre-implantation genetic diagnosis to stop her child from having hemophilia. She was asked if she would consider selecting for athletics and cleverness. At first she said, "I don't like the idea of that!" She then says, "I wouldn't disregard it totally. We'd have to think about it a lot more. I don't like that idea. I think that's messing with Na—. Well, we are messing with Nature, aren't we?"

People not born equal

My final point is one that geneticists tend to ignore: the human population is genetically heterogeneous. People are not born equal. There is no genetic justice at birth. Different populations have different distributions of traits at birth. I'm an asthmatic so I always carry around albuterol, a drug for asthma. A few years ago, someone commented that over 50% of the men on the rowing team at Princeton University are asthmatics who take the same drug. Suddenly, it dawned on me that they aren't asthmatic. They take albuterol to expand their lung capacity. The question is, should people be doing this?

The likely American response to any attempt by the government to ban the use of bio-enhancements is: people won't put weird genes in the children. They will say: "Why can't I give my children advantageous genes and protein levels that other children get naturally?"

Discussion

Q: *How do we address distributive versus social justice issues in policy frameworks and what sort of regime could reconcile those two?*

Roxanne Mykitiuk: Most of us are familiar with distributive justice concerns. But we can't stop with these. We need to recognize the broader questions that a social justice perspective will ask. We need to look at how certain policies might impact those who have been traditionally disadvantaged in our society. In the future, we may create a category of people who are discriminated against on the basis of genetics. Genetic discrimination has the potential to create new categories of oppression or stigma.

Q: *How do you distinguish and control the line between therapy and enhancement? How does the Canadian health care system, with its limited resource base, decide where to draw the line?*

Roxanne Mykitiuk: I would not want to make this decision on the basis of the enhancement/treatment dichotomy, but rather take a look at what health benefits an individual or particular group will receive as a result of some treatment therapy, and what the tradeoffs will be in relation to some other group or individual that lacks certain health benefits.

Q: *Roxanne said we need to be attentive to those who bear the greatest risk from the technology. Don't we really need to be attentive to those who can really benefit from genetic testing and make sure it is delivered to those people?*

Roxanne Mykitiuk: I agree that we need to seek input from those who are going to benefit. If we look at the norms of the consultation process, we tend to find stakeholders who have different things to gain. There is also room for the general public and those with professional expertise. But often missing from the table–because they don't have tremendous power, they don't have a public voice, they don't have information–are those who are at risk. I'm not saying we should only listen to them. But you can't make public policy fairly until you have taken into account the interests of everyone who will be affected by the decision. If that means providing resources to enable some groups to be at the table, that needs to be done as well.

Q: *Regarding Lee Silver's presentation, while questions of justice and equity are very relevant, one of the key dimensions for discussing genomics policy is the level of risk, the spectrum of risks and benefits, that goes beyond what we're used to.*

Lee Silver: All technologies have risks and benefits. The first heart transplant patient was at risk of dying in three weeks and he did die in three weeks. But the benefit was that he was helping research and there was a chance that he would live longer. All medicines go steps forward and one step back. The question is whether to take any steps or just keep things as they are. Human gene therapy has had some failures and forced our regulatory agencies to reconsider and re-evaluate how some trials are going forward. It's unfortunate that some people have to suffer, but as long as you have regulation, you can learn from the mistakes that are made in a way that helps the most people. I'm not denying the risks. But you need a rational point of view when considering risks and benefits.

Q: *The French poet Baudelaire said that learning is to contradict oneself, in the sense that transformational learning involves some form of self-destruction to create a newer self. Throughout the ages, enlightened people–prophets and now psychologists–have attempted to help us become better people. What is the qualitative difference between that and what we're trying to do using genomics to enhance human characteristics?*

Lee Silver: The point I wanted to make is one that most people have tried to ignore for a very long time: we are not born genetically equal in all aspects. Some people are born with a much greater chance of getting cancer or heart disease than others. Some people are born lucky and get all the good genes that give them good health. Some kids are born without anything. Our genetic distribution is unfair. Is there some reason why we must stick with the genes we're born with? Or should parents be allowed to say: "That other child got this gene naturally. Why can't I give the equivalent to my child?" The problem is, you then advantage people who have access and you disadvantage people who don't have access. So in both situations, it's unfair. When an innovation is introduced through the marketplace and competition, more and more people get access over time, at least in developed countries.

Q: *You have suggested that "with good regulation, things would be fine." What is good regulation in this context?*

Lee Silver: I can tell you what bad regulation is. Bad regulation is when society wants to ignore a technology that has great benefits and potential harms, like the United States has done with reproductive technology. That is bad regulation because there is no regulation and so there is no way of controlling what is going on. Good regulation means acknowledging things that are happening. Each society has to decide for itself its values and shape its regulations around those. Obviously, you have to regulate for safety issues.

Q: *There are process regulations. You don't want conflict of interest in the decision-making and there is safety. Is there anything else you would put on the list?*

Lee Silver: The most difficult thing is when you have a technology like biotechnology, which can be used for purposes that are not considered public health needs such as biologically enhancing somebody. What does that mean, to biologically enhance? It means that if you look at the population mean, the technology will allow people to put themselves above the mean. But different populations have different means, so what is a disease in one population becomes normal in another. So what do you do? Do you say: "We're not going to pay for it, therefore nobody can use it?"

Balancing Interests in Genetic Information, Materials and Technology

While there is strong community support for medical research that promises breakthroughs in the diagnosis, treatment and prevention of serious disorders, some understandable anxiety exists over social and ethical issues such as: discrimination and privacy; 'genetic determinism'; access and equity, especially in relation to disadvantaged groups; and the ability of public authorities to effectively regulate this area in the public interest. How are countries beginning to address public concerns and to manage these important issues?

David Weisbrot, Australian Law Reform Commission

The Australian Law Reform Commission (in association with the Australian Health Ethics Committee of the National Health and Medical Research Council) conducted a major national inquiry over several years on the protection of human genetic information. In relation to human genetic information (and the samples from which such information is derived), we had three essential mandates.

- How do we best protect privacy?
- How do we guard against unfair discrimination?
- How do we maintain high ethical standards?

We applied those three issues across many contexts, including: human genetic research; clinical genetics; systemic health care administration; human genetic research databases/biobanks; employment; insurance; constructing kinship and identity (immigration, parentage, Aboriginality); other rights and services (sports, education); and law enforcement uses of DNA testing.

We actively tried to engage the public in our policy-making processes. We set up a broad-based external Reference Group, which included genetic counsellors, people from genetic support groups, clinical geneticists, hospital administrators, insurance industry representatives, trade unionists, etc. We produced consultation documents including an issues paper that raised hundreds of questions, a discussion paper that presented proposals, and a final report. We held 15 public forums across the country, in every capital city and in the major regional centres. We had more than 200 targeted meetings and consultations with the various stakeholders. We received more than 300 written submissions, from individuals and families through to community groups, peak professional associations and government bodies.

Final report

Our final report is available in print, on CD ROM, and on our web site. It contains 144 recommendations for reform directed at 31 bodies, including: government; regulators; educators; health professionals; insurers; employers and others. The report suggests the use of a broad range of strategies, making recommendations aimed at (among other things): legislative change; standard setting; community and professional education; improved performance by GPs, clinical geneticists and health systems; industry codes of practice, especially in the insurance industry; and regulations and practices affecting employment and occupational health and safety.

Our inquiry found a degree of ambivalence in public opinion about the 'New Genetics.' There was much optimism about the potential for improved medical practice in diagnosis, treatment and prevention. We found a high level of support for police uses of DNA testing. But we also found generalized anxiety about genetic research and biotechnology. We heard concerns about commercialization: many people now seem to regard American pharmaceutical companies as the new 'Evil Empire.' Many people were concerned that genomics and its applications (such as pharmacogenomics and stem cell therapies) will intensify the gap between haves and have-nots. Some people in the community (European Jews, Aboriginal people) have had direct experience of tragic eugenics experiments. However, contrary to the experience

elsewhere (especially Europe), we did not find any notable loss of faith in Australia about the government's capacity to regulate biotechnology in the public interest.

A threshold question for the inquiry was: Is genetic information truly exceptional? That is, do we need to develop new and special regimes to deal with this?

There certainly are some unique features about genetic information.

- It is very powerful: a single cell can 'tell all,' unlike other forms of health information, such as x-rays or MRIs.
- It is ubiquitous–we continuously slough off cells that contain DNA, which means there are more pervasive privacy concerns.
- DNA is highly stable–we can test DNA from dinosaurs and it even survived the World Trade Center disaster.
- DNA is uniquely individual–although we also must remember that humans share 99.9% of their DNA.

Our recommendations

The inquiry concluded that it would be artificial, unfair and unwise to separate genetic and non-genetic information for policy-making purposes. Thus, there is no need for a separate Genetic Privacy Act, Genetic Discrimination Act, Genetic Employment Occupational Health and Safety Act, or a specific Genetic Research Act. Instead, we decided it would be more sensible to adapt existing laws, practices, institutions and oversight mechanisms. Some of our recommendations in this respect included:

- extending the Privacy Act to cover identifiable genetic tissue samples (and not only data), in the same way it applies to encrypted computer disks
- amending the Disability Discrimination Act to cover unlawful discrimination based on real or perceived genetic status.

Our central recommendation involved the establishment of an Australian Human Genetics Commission that would operate along similar lines to the UK's Human Genetics Commission. It would not be a regulator, but rather an advisory and standards-setting body.

We tried to address the following public concerns about human genetic research.

- Commercialization and conflicts of research: People get angry when commercial interests are not disclosed fully. They want to know whether a family doctor who donates their tissue to a study is part of a commercial research project, whether a doctor or researcher has shares or options in the company.
- Uncertainty over the benefits for study participants: Researchers need to be clear. Are they promising participants individual results or are they conducting a much broader, double-blinded study? Are they promising personal or community benefits down the road? Are they keeping participants informed on a regular basis?
- Fear about third party disclosures: Will the government be able to see your genetic information? Will your employer? Will members of your family?
- Adequacy of Australia's system for ethical oversight, based on decentralized 'human research ethics committees.'

Ironically, it appeared that some of the community concern stemmed from research being 'over-sold'; that is, scientists and biotech companies tell government and regulators that genetic information is not exceptional, but rather just part of the latest wave of scientific advances. However, in grant applications, public talks and stock prospectuses, they make claims that genomics is exceptional and extraordinary.

Researchers' perspective

Concerns of the research community include the following.

- Researchers don't want bureaucratization or over-regulation of research.
- Capacity of ethics committees to keep up with the volume and complexity of the work.
- Privacy laws may prohibit researchers from identifying linkages and conducting epidemiological work.
- Will the law extend duties of care? If a test reveals that someone is at higher risk, must you inform the person? Can you be sued later if you don't?
- Uncertainty over intellectual property issues.

Clinical genetics

There was considerable criticism from individuals and genetic support groups about the quality of advice received from family doctors and from specialists (apart from medical geneticists). It was said that doctors' communication skills are often poor, particularly their ability to explain concepts of risk and probability. The inquiry recommended more basic and continuing education for doctors about genetics, and the provision of more resources and support for genetic support groups.

We also recommended an increase in genetic counselling services. Genetic counsellors are well trained in communicating risk and probability. When people learn of a genetic condition in their family, it is the counsellors who explain, for example, that their 10% elevated risk may mean 10% of 0.001, and that being a carrier is not the same thing as having the condition. We recommended the recognition and accreditation of genetic counselling as an allied health profession, and that counsellors be better integrated into the health care system.

Legal liability

Members of the medical community expressed uncertainty about issues of confidentiality and shared genetic information. Many said they live in fear of a phone call from someone they've never met saying: "You treated my sister for breast cancer. We haven't been on speaking terms for years. Now I've got breast cancer. If you had just made one phone call or sent me a note, I would have gone for screening and might be okay now." Apart from any legal liability, how do we deal with this ethically? There are difficult issues about patient confidentiality, and individuals also have a right not to know. We recommended that Australia's National Health and Medical Research Council develop a protocol informing doctors and other health professionals the circumstances under which they might lawfully disclose confidential genetic information to genetic relatives in cases where the relative is at serious but non-imminent risk of harm.

We recommended that DNA testing/analysis only be done by fully accredited labs, and that especially 'sensitive' genetic tests be identified and dealt with in a more restricted fashion. In Australia, HIV-AIDS testing is only done in specific hospitals with high levels of quality assurance, counselling mechanisms, and an awareness of privacy/stigmatization issues. We should identify genetic conditions with a similarly high potential for misunderstanding and stigmatization.

We also addressed the issue of illicit DNA testing. Genetic material is widely available: you can obtain it from the saliva on a person's coffee cup or dental floss, or from a hair sample. Parents, employers, insurers, investigators and the media may seek to obtain a sample and have it tested without the person's knowledge and consent. Should this be allowed? We recommended (as did the UK Human Genetics Commission) that a new criminal offence be created, making it illegal to submit another person's DNA for testing without consent or other lawful authority (such as a court order in a paternity case, a police officer operating under forensics legislation, or a scientists conducting ethics-approved research).

Genetic databases

Unlike the UK (BioBank), Iceland (DeCode), Quebec (CartaGene), Estonia and a number of other places, there are no national or regional human genetic research databases in Australia. (There are state, territory and federal DNA criminal investigation DNA databases, which operate under statute.)

There are, however, thousands of individual human genetic research databases that exist in universities, teaching hospitals and other research organizations. There are also a number of potentially major, but currently inchoate, databases. For example, there are millions of Guthrie cards–neonatal blood spot cards–that exist for every infant born in Australia for at least the last four decades. The tests are for phenylketonuria (PKU), galactosemia, cystic fibrosis and a number of other genetic conditions. The storage, use and disclosure of Guthrie cards are not formally regulated, and potentially could be used as a national database–perhaps on a de-identified basis for epidemiological studies. We need to have an intelligent community conversation about their value and whether such unsystematized collections should be systematized, protected and regulated–or destroyed.

Employment

We found no compelling reasons why employers should use predictive genetic testing. People fear the development of a genetic underclass of individuals with a genetic predisposition (yet no symptoms) that may freeze them out of the workforce. We recommended that there be no use of genetic testing to predict a person's future capacity to work, except in very limited cases where such testing may be necessary to protect a public safety obligation (such as in the case of airline pilots). Even in those rare cases, genetic testing only should be done if the Human Genetics Commission approves the test's use and interpretation as scientifically valid, and there is no alternative. Genetic testing should never be used by employers to avoid their workplace safety responsibilities.

Gene patenting and human health

The Australian Law Reform Commission (ALRC) subsequently was asked by the government to examine the intellectual property (IP) aspects of human genetic information, materials and related technologies–referred to in a shorthand fashion as 'gene patenting and human health.' The terms of reference for the inquiry ask us to negotiate a balance between the known benefits of the IP system–encouraging investment and rewarding innovation and risk-taking–with the risks of harming further research and experimentation or diminishing access to cost-effective clinical genetic services. A discussion paper has been released for community comment. The final report is due by 30 June 2004.

All of the ALRC's publications are available online for free at <www.alrc.gov.au>.

Appendix A: Symposium Agenda

Symposium Day 1 March 24

Welcome and Introduction

Jean-Pierre Voyer, *Policy Research Initiative*

Kimberly Elmslie, *Canadian Biotechnology Secretariat*

Genomics and Health in the 21st Century

Chair — **Kevin Keough**, *Health Canada*

Speakers — **Claude Laberge**, *Faculty of Medicine, Université Laval*

Daryl Pullman, *Memorial University of Newfoundland*

Public Attitudes Toward Genomics in Europe and North America

Chair — **David Zussman**, *EKOS Research*

Speakers — **George Gaskell**, *London School of Economics*

Elly Alboim, *Earnscliffe Research and Communications*

Advising Ministers – The UK Experience

Chair — **Cindy Bell**, *Genome Canada*

Keynote Speaker — **Sir John Sulston**, *Human Genetics Commission, United Kingdom*

Engaging Citizens

Panel and Discussion

Chair — **Kimberly Elmslie**, *Canadian Biotechnology Secretariat*

Speakers — **Arnold Naimark**, *Canadian Biotechnology Advisory Committee*

Helen Wallace, *GeneWatch UK*

Carolyn Lukensmeyer, *AmericaSpeaks*

Symposium Day 2 March 25

Innovating in the Private and Public Sectors

Chair — **David Fransen**, *Industry Canada*

Speakers — **John Wallenburg**, *McGill University*

David Shindler, *Milestone Medica Corporation*

Ron Yamada, *MDS Inc.*

Elwyn Griffiths, *Health Canada*

Fairness and Equity in Genomics

Chair — **Gloria Bishop**, *Canadian Biotechnology Advisory Committee*

Speakers — **Roxanne Mykitiuk**, *York University*

Ishwar Verma, *Sir Ganga Ram Hospital, India*

Lee Silver, *Princeton University*

Balancing Interests in Genetic Information, Materials and Technology

Chair — **Nathalie Des Rosiers**, *Law Commission of Canada*

Keynote Speaker — **David Weisbrot**, *Australian Law Reform Commission*

Closing Remarks

Kimberly Elmslie, *Canadian Biotechnology Secretariat*

Appendix B: Speaker Biographies

Elly Alboim is Principal and Partner, Earnscliffe Research and Communications, leading Earnscliffe's strategic communications practice. He has provided advice on some of the most important and controversial issues in recent Canadian history to a number of federal cabinet ministers and departments. In the private sector, Mr. Alboim has provided strategic communications advice to major Canadian corporations industry associations. He worked as a journalist for the Canadian Broadcasting Corporation from September 1970 to September 1993. Mr. Alboim is, as well, a tenured Associate Professor of Journalism at Carleton University, having taught there since 1980. He is a Member of the Board of the Canadian Journalism Foundation and Vice-Chair of its Professional Development Committee and a member of the CJF's Executive Committee. He is also a member of the Board of the Institute on Governance.

George Gaskell, Professor of Social Psychology, is Director of the Methodology Institute at the London School of Economics. He is a member of BIOS, the Centre for the Study of Bioscience, Biomedicine, Biotechnology and Society and of CARR, the Centre for the Analysis of Risk and Regulation at the LSE. He is coordinator of 'Life Sciences in European Society', a 14 country comparative study of biotechnology in the public sphere funded by the European Commission's 5th Framework Programme. He is a special advisor to the Netherlands Centre for Genomics and Society, a member of the Advisory Board of the Toronto Programme on Bioethics, vice chair of the EC Science and Society Advisory Committee for the 6th Framework Programme and chair of an EC strategy group on Science, Technology and Social Values.

Dr. Elwyn Griffiths joined Health Canada as Associate Director General, Biologics and Genetic Therapies Directorate, in 2003. He holds PhD and DSc degrees from the University of Wales. Following postdoctoral positions at the National Research Council and McMaster University, Canada, he joined the staff of the Medical Research Council, National Institute for Medical Research, London, where he worked for over ten years. In 1980 he became a senior member of staff at the National Institute for Biological Standards and Control, UK, and in 1994 was appointed Chief, Biologicals, at the World Health Organization, Geneva. Here he was responsible for WHO's international programme in biological standardization for assuring the quality and safety of vaccines, blood products and biological therapeutics, including biotechnology-derived and gene transfer medicinal products. Dr. Griffiths is the author of many publications on microbial pathogenicity, vaccines, and standardization and control of biologicals. He has also been a member of numerous UK, European and WHO committees and working groups, such as the British Pharmacopoeia Commission, the vaccines and biological standardization committees of the European Pharmacopoeia Commission, and the European Medicines Evaluation Agency (EMEA) Working Party on Biotechnology.

Dr. Kevin M. W. Keough received his doctoral degree from the University of Toronto in 1971. Before being seconded to his position as Chief Scientist at Health Canada, he was the Vice-President of Research and International Relations at Memorial University of Newfoundland, as well as a professor of biochemistry in its biochemistry and pediatrics departments. Dr. Keough is Deputy Chair of the Council of Science and Technology Advisors, an external national expert advisory council that provides guidance on federal science and technology issues to the Government of Canada. As a former executive member of the Medical Research Council, he was instrumental in the creation of the Canadian Institutes of Health Research, and is now a member of its governing council. He is a founding member of the Board of Directors of Genome Canada.

Claude Laberge received his MD in 1962 from Université Laval in Quebec. He became a Fellow of the Royal College of Physicians of Canada in Pediatrics in 1967 and received Certification in Pediatrics from Quebec in 1968. He is professor of Medicine and Pediatrics at the Faculty of Medicine, Université Laval. From 1969 to 1993 he was director of the Quebec Network of Genetic Medicine, where he was (and still is) in charge of newborn screening. Since 1993 he has been director of the Quebec Network of Applied Genetic Medicine of the FRSQ, the Quebec Health Grant Agency. His basic interest has always been population genetics and the transfer of human genetic

knowledge into public health and health policies. For the last three years, with colleagues of the RMGA he has worked to develop the strategy and the research infrastructure for a "Genetic Map of Quebec," the CARTaGENE Project.

Dr. Carolyn J. Lukensmeyer is the founder and president of AmericaSpeaks. Most recently, she was a central figure in the design and production of Listening to the City, a 21st Century Town Meeting where more than 4,300 citizens gathered to consider plans for the redevelopment of Lower Manhattan after September 11. This day-long event–complemented by two weeks of online deliberation–resulted in the rejection of the six proposed plans, an extension of the timeline for development of a final proposal, and a comprehensive vision for development in the communities surrounding 'ground zero.' Participants at Listening to the City urged planners to develop "soaring" proposals that would bring back the greatness of the Twin Towers and preserve the memory of the tragic events of September 11. From 1997 to 1999, she was the Executive Director of Americans Discuss Social Security, a $12 million project of the Pew Charitable Trust. Its mission was to engage Americans from all walks of life in a nationwide-debate about the future of social security. She holds a doctorate in organizational behavioural and post-graduate training at the internationally known Gestalt Institute of Behaviour.

Roxanne Mykitiuk (BA University of Alberta; LLB University of Toronto; LLM Columbia University, member of the Alberta Bar) is an Associate Professor of Law at Osgoode Hall Law School, York University, where she teaches in the areas of bioethics, children and the law, law and disability and family law. She is the author or co-author of a number of articles and book chapters investigating legal, ethical and social implications of new reproductive technologies and the new genetics, and the legal construction and regulation of embodiment and disability. She is co-editor with Martha Fineman of The Public Nature of Private Violence (Routledge, 1994) and co-editor with Margrit Shildrick of Ethics of the Body: Rethinking the Conventions (MIT Press, forthcoming). During 1990-92 she was Senior Legal Researcher for the Royal Commission on New Reproductive Technologies. During 1996-2000 she was a member of the Clinical Practice Resource Group, Ontario Cancer Genetics Network, Cancer-Care Ontario. She is a member of the Ontario Advisory Committee on Genetics.

Dr. Arnold Naimark is Chair of the Canadian Biotechnology Advisory Committee, a group of experts external to the government that provides advice on a range of biotechnology issues. The Committee's motto is: "many perspectives, one source." A specialist in internal medicine, Dr. Naimark was admitted by examination to the Fellowship in the Royal College of Physicians and Surgeons of Canada in 1964. He had a distinguished career as a Professor of Medicine at the University of Manitoba before becoming Dean of the Faculty of Medicine from 1971 to 1981. He served as the university's President and Vice-Chancellor from 1981 to 1996. Dr. Naimark is currently Professor of Medicine and Physiology at the University of Manitoba,as well as Director of the Centre for the Advancement of Medicine, and founding Chair of the Canadian Health Services Research Foundation.

Daryl Pullman is Associate Professor of Medical Ethics in the Faculty of Medicine at Memorial University, where he teaches ethics and humanities to undergraduate and post-graduate medical students. He is cross-appointed to the School of Nursing and to the Department of Philosophy. In addition to his faculty appointments, he has a clinical appointment with the Health Care Corp of the City of St. John's. He has published widely on a broad range of issues in health care ethics. His current research interests include research ethics, health policy, ethics and aging, end-of-life decision making, issues related to genetic research and therapy, and privacy. He has a continuing philosophical interest in the concept of human dignity and its foundational role in moral epistemology.

Dr. David Shindler has since 1988, served as President and CEO of Milestone Medica Corporation, part of the RBC Technology Ventures group. Milestone provides early-stage funding and management in order to build new ventures and create innovative health care products in partnership with Canada's major universities and biomedical research centres. Previously, Dr. Shindler served for 8 years as Senior Executive and Commercial Director of the Canadian Genetic Diseases Network, a federally funded Network of Centres of Excellence involving Canada's research and medical leaders in genetics. Between

1980 and 1988, Dr. Shindler was an executive in the federal Department of Industry, Science and Technology. During this period he was Manager of Canada's National Biotechnology Strategy, Secretary to the Federal Science Minister's National Biotechnology Advisory Committee, and a Senior Advisor in the field of biotechnology. Dr. Shindler received his PhD from the University of Ottawa with specializations in microbiology and biochemistry, and his undergraduate degree in biology from Temple University in Philadelphia.

Dr. Lee M. Silver is a Professor at Princeton University in the Department of Molecular Biology and the Woodrow Wilson School of Public and International Affairs. He is the author of "Remaking Eden: How Genetic Engineering and Cloning Will Transform the American Family," published in 15 languages. He has also authored a textbook for professionals on mouse genetics, and he is co-author of an undergraduate textbook in genetics. In 1993, he was elected a Fellow of the American Association for the Advancement of Science (AAAS). In 1995, he received an unsolicited 10-year National Institutes of Health MERIT award. He has published over 160 scientific articles in the fields of genetics, evolution, reproduction, embryology, computer modeling, and behavioural science; other scholarly papers on topics at the interface between biotechnology, law, ethics, and religion; and book reviews and op-ed pieces for the New York Times, the Washington Post, Time magazine, and the international science journals, Science and Nature. He has been elected to the governing boards of the Genetics Society of America and the International Mammalian Genome Society.

Sir John Sulston graduated from the University of Cambridge in 1963. He has worked mainly on the nematode, Caenorhabditis elegans , but latterly has been involved with the sequencing of the human genome. A Fellow of the Royal Society, he is acting deputy director of the Human Genetics Commission. He shared the Nobel Prize in Physiology or Medicine in 2002.

Dr. I. C. Verma is currently Head, Department of Genetic Medicine, at Sir Ganga Ram Hospital, New Delhi. He was earlier Professor of Pediatrics and Genetics, at All India Institute of Medical Sciences, New Delhi. He trained in genetics in the UK, USA and Switzerland. He is a Fellow of Royal College of Physicians, London, the American Academy of Pediatrics and the National Academy of Medical Sciences in New Delhi. He has received a number of national awards for research work in genetic medicine: Ranbaxy Science Award, Indian Council of Medical Research, National Academy of Medical Sciences, and BC Roy Medical Council of India award. He is an advisor in genetics to WHO Headquarters in Geneva, and is Vice-Chair of the HUGO Ethics Committee.

Dr. Helen Wallace has been Deputy Director of GeneWatch UK since September 2001. GeneWatch is a not-for-profit group that aims to ensure that genetic technologies are used in the public interest and in a way that promotes human health, protects the environment and respects human rights. Responsible for GeneWatch's work on human genetics, she has a particular interest in genetic testing and its implications for health and human rights. Prior to joining GeneWatch, she was Senior Scientist at Greenpeace UK, working mainly on issues involving environmental risk assessment. She holds a BSc in physics and a PhD in mathematics and spent four years working in industry developing computer models of the marine environment.

Dr. John Wallenburg earned his BSc at McMaster University, and his MSc and PhD in molecular biology from the Université de Sherbrooke. He has held research positions at the Canadian Red Cross R&D facility in Montreal during 1986-1994, and at the Walt Disney Memorial Cancer Institute in Florida during 1994-1996, where he also held a cross appointment at the University of Central Florida. He has served as product manager at Quantum Biotechnologies, Inc. (now QBiogene) and is a co-founder of Morphogenesis, Inc., a biotechnology R&D company in Florida. An Officer of Technology Transfer at McGill University and Health Centre since February 2000, he deals with life science technologies in the Faculty of Medicine and the McGill University and Genome Quebec Innovation Centre. He is also a member of the Intellectual Property and Data Release Group of the International Hap Map Project.

David Weisbrot is President of the Australian Law Reform Commission. He recently conducted a joint inquiry (with the Australian Health Ethics Committee of the NHMRC) into the protection of Human Genetic Information (Essentially Yours, ALRC 96, 2003). The Commission is currently inquiring into "Intellectual

Property Rights over Genetic Materials and Genetic Related Technologies," and the "Use of Classified and Security Sensitive Information in Legal Proceedings," David is an Honorary Professor in the Institute for Molecular Bioscience at the University of Queensland and an elected member of the Human Genome Organization (HUGO). He is the author or co-author of 7 books, and more than 150 official reports, journal articles and conference papers.

Ron Yamada is one of the founders of MDS Inc. and the Executive Vice-President, Global Markets and Corporate Affairs. His responsibilities involve identifying emerging trends in science and technology, government policies and regulations, and new market opportunities. Previously, he was the coordinator of IBM's medical team developing applications for computers in medicine in North America. MDS is a strong proponent of public/private sector partnerships. Involved in a wide range of organizations including HEALNet, an NCE health information research network, and the Centre for Health Evaluation and Policy Analysis (CHEPA) of McMaster University, he currently serves as a member of the Board of the Change Foundation, the Board of Governors of the University of Western Ontario, and the Ontario Science and Innovation Council.

David Zussman has had a varied career in government, the private sector and academia. One of Canada's leading methodologists, he has been closely involved in some of the most exciting developments in governance in Canada over the past 15 years. He has served in a number of positions at the University of Ottawa, where he is a recognized authority on public service management and public policy. In 1995, Dr. Zussman joined the Public Policy Forum, an organization committed to bridging the gap between government business, labour and the voluntary sector. He was appointed President in 1996 and remained in that position until joining EKOS in 2003.