Biotechnology and the New Genetics

What it Means for Women's Health

Prepared for the Working Group on Women, Health and the New Genetics

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Preamble

The Working Group on Women, Health and the New Genetics comprises Canadian academics and community activists concerned with the impact of the new genetics and biotechnology on women's health. The Working Group is committed to principles and practices of feminism, equality and social justice.

The Working Group's current focus is the Canadian Biotechnology Strategy (CBS), a policy document of the federal government that promotes the Canadian biotechnology industry. The Group is concerned about the lack of attention to the implications for women's health in the CBS and on the part of the Canadian biotechnology industry as a whole.

In February 2000, we held a workshop in Toronto at which these issues were discussed. This booklet is loosely based on the presentations and discussions at that workshop. A number of documents of the Working Group, including a community mobilizing tool ("If Women Mattered: A Critical View of the Canadian Biotechnology Strategy (CBS) and Alternative Visions for Community Action") and the proceedings from the workshop ("The Gender of Genetic Futures: The Canadian Biotechnology Strategy, Women and Health"), are available on the CWHN website (www.cwhn.ca).

Genetics and biotechnology are changing so rapidly that a booklet such as this can only represent a snapshot in time. So, while some of the technical information may quickly become outdated, we hope that the discussion will contribute to a critical understanding of the ethical and other substantive issues involved in the development and application of these technologies.

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Introduction: What This Booklet is About

The development and growing popularity of biotechnology and new genetics raise fundamental questions about who we are as humans in the 21st century. We are at a moment in time when life forms can be patented and our genes can be sold on the commercial market. At the same time as governments are recognizing that social factors such as poverty and violence influence our health, a persistent view that much can be determined by genetics is quickly becoming "normalized" in the public consciousness. While one trend broadens a view of health, the second medicalizes it further.

Despite the importance of these technologies and their relevance to our health, Canadians know relatively little about them. Recent polls show Canadians as a whole assume that biotechnology is beneficial, and that our governments will regulate it in our best interests.

This booklet re-examines some assumptions about biotechnology and the new genetics for Canadians as a whole and for women in particular. Our principal concern is that, within the federal government, the interests of the biotechnology industry may be a greater consideration than the health of Canadians.

This booklet is intended as a brief overview of "biotechnology" and the "new genetics", and some of their implications for women's health. It is meant to encourage discussion and critical debate. It examines two main areas of concern — agricultural biotechnology, and biotechnology in health care and medicine. Because of the size of the booklet and the scope of the topic, this cannot be a comprehensive study of all the issues. For example, one important topic not addressed here is reproductive technologies since this issue has received broad coverage in women's health literature.

Definitions: A Matter of Interest

Biotechnology is defined by the Canadian Environmental Protection Act as "The use of living organisms, or their parts, for the production of goods and services." Interpretations of the basic definition, as well as views on the safety of these technologies, are far from consistent and vary according to whose interests are being promoted. Included under the term "biotechnology" are such wide-ranging techniques as altering genes through genetic engineering of species, cloning of plants and animals, and xenotransplantation (growing new organs in one species for transplantation into another).

Those who represent the very profitable biotechnology industry or government

departments wishing to promote that industry emphasize the safety and benefits of the technologies to the public and are quick to counter any worries citizens may have. They argue that biotechnology includes such benign and ancient practices as the fermentation of yeast to make bread or beer[1]. However, critics in the environmental and health movements, including both scientists and consumers, argue that it is misleading to put such ancient practices in the same league as these completely new techniques. The potential impact on human health of the more recent technologies, such as xenotransplantation, is of a much greater magnitude, and with far different implications, than these fairly benign older processes.

The term "new genetics" includes specific techniques for intervening in physical and medical processes, but it also reflects a significant world view of human characteristics. Canadian epidemiologist Abby Lippman speaks of the "geneticization" of our bodies and body processes, by which she refers to the gradual and disturbing move towards viewing all aspects of our health primarily in terms of a genetic component, expanding what is called disease and disability and narrowing what is considered normal. She adds that "human biology is incorrectly equated with human genetics".[2] In this booklet, we have included the terms "biotechnology" and "new genetics" together because they raise common concerns. Combined, they represent a disturbing trend towards the medicalization of our health, often at the expense of a more holistic view of the larger, systemic social determinants of health.

The Canadian Biotechnology Strategy: Where are the Women?

In 1998, the Canadian government renewed its commitment to the development of biotechnology in Canada by releasing the policy framework, the Canadian Biotechnology Strategy (CBS)[3] What was renewed in 1998 was a commit-

1 "Biotechnology is an umbrella term that covers a broad spectrum of scientific tools and techniques, ranging from traditional uses of living organisms such as yeast in bread or bacteria in yoghurt to more advanced techniques such as genetic engineering. Biotechnology uses living organisms, or parts of living organisms, to make new products or provide new methods of production." *The 1998 Canadian Biotechnology Strategy: An Ongoing Renewal Process.* Ottawa: Industry Canada, (1998) p. 2.

2 "Prenatal genetic testing and screening: Constructing needs and reinforcing inequities", by Abby Lippman, in *American Journal of Law and Medicine,* Vol. XVII, No 1&2, 1991, pp 15-50.

3 *The 1998 Canadian Biotechnology Strategy: An Ongoing Renewal Process.* Ottawa: Industry Canada, 1998.

ment which had been articulated in policies of the federal government since the early 1980s. The goal of the CBS is "to enhance the quality of life of Canadians in terms of health, safety, the environment, and social and economic development by positioning Canada as a responsible world leader in biotechnology." As such, this framework defines the federal government's role in managing the biotechnology industry, and in managing the development and use of biotechnology in Canada. It also focuses on changing Canada's intellectual property laws in order to facilitate development in biotechnology, and in working to convince the public of its benefits both nationally and internationally.[4]

The Canadian Biotechnology Strategy lacks any attention to the implications of biotechnologies for women. This is despite a commitment by the Canadian government to make all government policies more sensitive to gender by considering the differing implications of policies and programs for women and men (Federal Plan for Gender Equality, 1995). Many women have questions about the genetically modified food we are eating and the genetic testing we are being encouraged to undergo, when proof that these are safe and beneficial has simply not been established.

Why Women's Health?

These new technologies will have a tremendous impact on us all — young and old, men and women, rich and poor, those from developing countries and those from industrialized countries. They have specific implications for women and health[5] for a number of reasons:

1) Women are the primary gatekeepers of health care in the home. Although this role has changed slightly in the past decade, key decisions about health care, food, household products, medical devices, drugs and other pharmaceuticals still remain primarily the domain of women in the home. Therefore, women are a very important group to reach for industries producing new food sources

4 For a critique of the CBS, see "If Women Mattered: A Critical View of the Canadian Biotechnology Strategy (CBS) and Alternative Visions for Community Action" by F. Alice Miller and Marika Morris, 2000, at www.cwhn.ca

5 We use the term "women and health" in a very broad sense referring to three concepts: women's particular relationship to health care systems; women's personal and social interests in health, and the impact of policy and technology on women's health.

and new health technologies. Women are also an important target group for governments attempting to regulate these products and processes and wishing to reassure citizens of safety and efficacy.

2) Part of women's role as gatekeepers of health in the home involves growing, selecting, purchasing and preparing food. Therefore, genetically engineered foods, their labelling and patenting are issues of particular concern to women, as are the safety of the seeds from which these foods derive.
3) Particularly in the area of reproductive health, women receive a disproportionate percentage of medical tests including genetic tests and treatments. Many treatments and technologies once promoted to women as safe and effective were later found to cause harm: the hormone drug DES, the Dalkon Shield IUD, and Meme breast implants, to name but three. Once again, women are being asked to trust and comply with new technologies such as genetic testing and gene therapies about which relatively little is known. One conference participant referred to this as being asked to "take a leap into the genetic darkness".
4) The health of women in Canada could be improved markedly if we could eliminate or at least diminish the structural causes of ill health such as poverty and violence. Efforts to address these larger problems are undermined when health care funds are instead directed to women's individual biology and genetics.

Why Be Concerned as Canadians?

As the largest producer of genetically modified foods after the United States, Canada is an important player in the promotion of biotechnology and the new genetics. Because the federal government sees these technologies as a boon to the Canadian economy, they have been strongly encouraged and promoted. Commercial promotion of the technology, however, is not the government's only mandate. This same government is also responsible for regulating these technologies as part of its moral and legal obligation to protect the health and well-being of Canadians. Therefore, the government has put itself in the position of having to police the very industry it is trying to promote, clearly a conflict of interest.

As major promoters and manufacturers of genetically modified crops, Canada also contributes to potential problems arising from these technologies in the global South. Rather than creating jobs, the livelihood of farmers in a number of the global South countries are being lost because

varieties of seeds that they have planted for centuries have been patented by western corporations and are no longer affordable to them. Biotechnology is a significant factor in the global move towards the industrialization of agriculture and agribusiness.[6] This trend has serious implications for the sustainability of agriculture in developing countries, and will lead to threats to food security through the loss of the diversity of seeds, negative environmental impacts due to pesticides and other forms of pollution and the loss of smallholder farm ownership and of local employment.

The benefits of biotechnology will only accrue to countries of the global South who can afford to pay for the products developed by the industry.[7] As we have seen with drugs for AIDS, many of the countries most in need cannot meet the prices set by the industry. Commercial interests and profits guide corporate priorities and goals, rather than sustainability and human need.

Patents and Intellectual Property: Putting a Price on Life?

All western industrialized countries have patent laws that enable a maker of a product or invention to have exclusive monopoly control over their product. Patent laws recognize the "intellectual property" that belongs to a person or group of persons. Intellectual property means "the legal rights which result from intellectual activity in the industrial, scientific, literary and artistic fields".[8] Patents are awarded by federal governments, and they give the inventor protection so others cannot profit from their invention for a specific period of time — in most countries, twenty years. Because this protection helps cover some of the costs of developing the invention, it acts as an encouragement to innovation.

To be patentable, a product or invention must meet three criteria:

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6 For an elaboration of this issue, see *From Land to Mouth: Understanding the Food System* by Brewster Kneen (Toronto, NC Press Ltd, 1993), or visit the website of RAFI, www.rafi.org.

7 Its close sister, the pharmaceutical industry, is far more likely to develop products for those who are moderately healthy in the developed world (top sellers are for hair growth, impotence and cholesterol lowering drugs) than to create drugs for tropical diseases which kill and cripple millions each year in Asia, South America and Africa. ("Drug companies and Third World: A case study in neglect" by Donald G. McNeil Jr., *New York Times,* May 21, 2000, A1)

8 World Intellectual Property Organization — WIPO Publication No. 476-E, Chapter 1, p. 3 , accessed September 17/2000. The definition goes on to say "Those rights do not apply to the physical object in which the creation may be embodied but instead to the intellectual creation.…"

- it must be novel (i.e., new)
- it must be inventive (i.e., not a discovery)
- it must be capable of industrial application

Patents made sense in the 19th century when they were applied specifically to mechanical inventions. Although the writers of the laws never intended them to be applicable to living organisms, patent law is exploding in this area today, and it is causing concern. Some feel that many of the biotechnological 'inventions' that are being patented today are not really inventions at all but "expropriations from life", or discoveries.

Patent acts are being seriously challenged by those conducting research in biotechnology in order to extend their applicability to living organisms. In Canada, in the summer of 2000, the Canadian Federal Court of Appeal ruled in favour of granting a patent to Harvard Medical School for the "oncomouse", a mouse genetically-engineered to carry a cancer-causing gene. Because this opens up immense possibilities for patenting any non-human life form, and because some feel this could too easily lead to the patenting of human life forms, the federal government currently has appealed this decision to the Supreme Court of Canada.

To date, a number of patents based on human genetic material (specifically single cell life forms) have been granted in Canada. Pat Mooney, Executive Director of Rural Advancement Foundation International (RAFI)[9] cautions, "Once you accept the patenting of life, there is virtually no way to keep the doors shut on the patenting of organs and any other parts of the human body that have commercial application."[10]

Some governments, with encouragement from industry, are working to alter patent laws through international trade agreements. However, not all countries have patent laws, particularly many in the global South where the concern is often less with innovation than with giving citizens access to goods at prices they can afford. Currently the question of patenting life forms (including microorganisms and plants) is on the discussion table of international trade talks at the World Trade

9 RAFI is "a non-government organization dedicated to the conservation and sustainable use of biodiversity, and to the socially responsible development of technologies useful to rural societies".

10 RAFI, "The Mouse that Roared on Animal Pharm: Canadian Courts Rule that Mammals can be a Patented Invention", *Geno-Types,* 10 August 2000.

Organization. The United States has been more aggressive than Canada with patenting life forms and there is pressure on our country to do the same. Changes in international trade agreements could give greater control to transnational corporations largely from the global North who could potentially gain patents for products that belong — and are badly needed — in the global South. In practical terms, this means that "harvesters" from global North countries are patenting seeds, plants and microbials pirated from the global South and making enormous profits from them.[11]

Moreover, patent laws do not always necessarily work to the benefit of a nation's health. In Canada, for example, twenty-year patent laws relating to pharmaceuticals favour the large multinational companies. This patent protection also makes it possible for the brand name pharmaceutical companies to charge whatever they feel the market can bear without having to face competition from lower-priced generic products. Patent protection will serve the biotechnology industry in similar ways.

Biotechnology and our Food: Genetically Modified Organisms

Genetically modified organisms (GMOs) is a term generally used to refer to crop plants which have been altered by means of genetic manipulation; that is, the actual genetic material of the cell is changed, sometimes by splicing a gene from any life form — plant, animal, insect, bacteria, or virus — into another plant or animal.

Genetically modified foods are the latest in a series of new products in food manufacturing and agriculture. Some developments in food production and food handling, such as refrigeration, have been a boon to public health; they have undoubtedly saved lives, and improved our quality of life. Others have simply provided us with healthier alternatives, such as the addition of Vitamin D to milk. By contrast, the health benefits of genetically modified foods, such as vegetables with more appealing colour, are dubious at best. It still remains to be seen whether genetically modified foods benefit anyone but the

11 RAFI estimates that medicinal plants and microbials from the South contribute at least $30 billion a year to the North's pharmaceutical industry. ("Conserving Indigenous Knowledge: Integrating Two Systems of Innovation," UNDP, New York, September, 1994", RAFI)

companies that manufacture them.

Genetic engineering in agriculture in Canada and in most of the industrialized world has usually been aimed at making plants more resistant to pests, or more tolerant of large doses of herbicides. Despite these advantages, many questions remain unanswered:

- What are the short and long term health effects on humans of introducing such plants into our food system?
- How will the ecosystems be affected when these new organisms are introduced?
- How will communities be affected when these new organisms are introduced?
- Are there sustainable alternatives that present lower risks?

The transformation of food sources as a result of these biotechnologies has enormous implications for all of us. To take just one example: genetically engineered foods may cause allergic reactions. DNA from an allergen such as peanuts can now be spliced into a food without the consumer knowing — sometimes not until it is too late. This issue requires much more study as it could have vast implications for the scores of Canadians who have fatal food allergies.[12]

While our most immediate concerns in Canada may be whether or not the food we are eating is safe, there are more far-reaching issues for communities world-wide. We have already mentioned how farmers in many developing countries must now pay royalties and a licencing fee for seeds that corporations have been able to patent as a biotechnological invention.[13] Even more alarming are genetically altered seeds that

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12 There are also concerns about the impact on the environment of the introduction of genetically modified organisms. For example, plants that are genetically engineered to be herbicide tolerant can mix with their wild counterparts to become "superweeds", and genes geared to making insecticides may kill beyond their intended targets. Insects (such as monarch butterflies) that thrive on the pollen of certain crops have been shown to die as a result of ingesting the pollen of crops that have been altered genetically. We also know that genetically engineered plants cross-pollinate once out in the field, so eventually it will become more and more difficult to study the environmental impact of the new breeds as they will all be mixed together.

13 Bringing international agriculture concerns closer to home, the British Columbia-based Basmati Action Group (BAG) is working to raise awareness about a blatant example of "biopiracy" taking place in India and Pakistan. Basmati rice has been grown in parts of India and Pakistan for centuries. In 1997, an American company named Rice Tec managed to secure a patent for certain basmati rice strains in the Western Hemisphere. The Indian and Pakistani farmers now find themselves in a position where they can only continue to grow their rice by buying the seeds from Rice Tec. BAG has launched an international campaign to boycott the purchase of any products of Rice Tec Corporation. Check their website at www.eciad.bc.ca/~lolin/basmati/.

do not produce fertile plants, requiring farmers to buy new seeds every year and/or purchase trademarked chemicals to make them germinate. This practice has been dubbed "Terminator Technology" and the seeds "Suicide Seeds".[14]

Spokespeople for the genetically modified food industry argue that these advances will help to feed the many undernourished people of the world. We would argue that, in fact, the world is quite rich with food. The problem is in the unequal distribution of that food and the poor maintenance of the fertility of the soil. Genetically engineered crops are not the answer to these problems nor the route to sustainable development.

In Canada, sections of two federal departments (Agriculture Canada and Health Canada), one agency (the Canadian Food Inspection Agency), and one piece of legislation (the Canadian Environmental Protection Act) are involved in regulating genetically modified foods. Serious questions have been raised about the impartiality of Canada's Food Inspection Agency since it relies heavily on testing done by the manufacturers of genetically modified foods, and supports its claims that these foods are safe to consume. In 1997, a public citizen's conference in Calgary expressed some of these concerns and recommended that "a Code of Ethics reflecting Canadian values must be developed by the Canadian Biotechnology Strategy Advisory Committee with input from all stakeholders to govern Food Biotechnology."[15]

Women as Targets of Promotion

Women tend to be the purchasers and preparers of family meals. Canadian women need to be aware that they are the primary objects of the publicity about genetically modified foods. Manufacturers and at least some sectors of government have determined that it is they who must be convinced of the safety of this new technology.

For example, early in 2000, a booklet called "Food Safety and You" was circulated to households across Canada, at a cost of hundreds of thousands of taxpayers' dollars. In October 2000, the popular Canadian women's magazine, *Canadian Living*, and its French counterpart, *Coup de pouce*, released a supplement devoted entirely to genetically modified foods. Both the booklet and the supplement are produced by

14 From the RAFI website, www.rafi.org.
15 For more on this public citizen's conference, see, www.acs.ucalgary/~pubconf/html/.

the Canadian Food Inspection Agency, an agency that relies heavily on testing done by the manufacturers of genetically modified foods. Both claim that these foods are safe to consume. Groups who have spoken out against genetically modified foods such as Greenpeace and the Council of Canadians expressed concern that their comments, which were part of the first draft of the supplement, did not appear in the final printed version.

In fact, there have been no long-term health studies on genetically modified foods, so we do **not** know if eating these foods is safe. When testing of new products is done predominantly by the very industry that will profit from their promotion, we need to ask whether the health and safety of Canadians is being given the attention it deserves. We also need to ask why these materials are being produced by CFIA, the agency that is supposed to be responsible for protecting our health. Instead of pat reassurances by *Canadian Living* backed by the CFIA, Canadians need solid research about the health effects of these new products. Equally important, we need food inspection and health protection processes which are completely independent of the biotechnology industry.

These are complex issues with strong feelings all around. The economic interests of farmers who make their livelihood by their crops sometimes dictate that they become pitted against environmentalists arguing against the introduction of GMOs into agriculture. Some people lobby for clear and detailed labelling of all foods so that consumers can choose genetically modified or unmodified foods (currently this is not required in Canada). But labelling does not address the deeper implications of GMOs in foods. Many consumers, producers and scientists want a broader social evaluation of the impacts of genetically modified foods. They want to ensure that scientific research not be influenced by the industries that could profit from the outcomes. Others want 'substantial equivalence' to be the benchmark for the approval of genetically modified foods, that is, a genetically modified crop or other product must be shown to be just as safe as its non-genetically-modified equivalent before it is introduced onto the market.

While environmentalists, health activists and a range of other concerned parties attempt to put on the brakes with the proliferation of genetically modified organisms, it is clear that the tide is now moving at a pace which will require greater systemic measures to quell its momentum. To sustain the pressure towards maintaining public health and safety as the highest standard, lobbying efforts must be continuous at all levels of government involved in this issue.

FOCUS: Bovine Growth Hormone

Bovine Growth Hormone — BGH — (also known as Bovine Somatotropin — BST) is a hormone that increases milk production in cows. Those who advocate using the hormone claim that cows injected with the engineered version of the natural hormone (called recombinant BGH or rBGH) produce 10 to 25% more milk.

Considerable controversy surrounds the use of this hormone in every country where it is used. Its supporters argue that more milk from fewer cows leads to lower costs to the consumer as farmers will need less animal feed and grazing land. The manufacturers of rBGH, particularly the Monsanto Company, maintain that the milk and the meat from the cows injected with the hormone are both safe for human consumption. Opponents, however, point to a growing body of evidence of ill effects on humans and to certain clearly substantiated ill effects on cows. For example, mastitis (inflammation of the udder) is more common in cows given rBGH. The treatment for mastitis is antibiotics, and the residue of antibiotics may be passed on to those who eat the meat and drink the milk of these cows. (Consider how much milk is consumed by children, and how it is strongly promoted to women of all ages to prevent osteoporosis.) This exposure to antibiotics could lead to antibiotic resistance among those who consume the milk.

Use of rBGH has been approved in the United States; in some states labelling is voluntary and in others it is mandatory. In Canada, rBGH has not been approved for use. The decision to ban it in 1998 followed high-profiled action on the part of six senior scientists at Health Canada. When these scientists realized that the approval process for Monsanto's application for use of rBGH had many irregularities, they blew the whistle, accusing senior bureaucrats at Health Canada of showing "unusual favour" to Monsanto. As a result, the scientists were legally silenced by their superiors. However, after the Canadian Senate Agriculture Commission investigated the issue, Health Canada chose to ban rBGH.

For more information on the government's regulation of rBGH, see http://www.hc-sc.gc.ca/food-aliment/english/veterinary_drugs/bst_ in_milk.html.

The Human Genome and Genetic Research

> *"The problem with gene research is the same as its beauty. Its intellectual simplicity, its satisfying resolution of baffling medical puzzles with logical molecular explanations, creates the illusion that it will provide us with easy answers to larger human problems....We are who we are not just because of what our genes contain, but because of what has happened to us since our birth and how we use that unique genetic endowment day after day."*[16]

Genes are segments of DNA (deoxyribonucleic acid) that specify one or more functional products, such as proteins. Genes are a major means by which similarities and differences in biological traits are passed on from parents to offspring.

The Human Genome Project, an international scientific project begun in October 1990, has propelled the issues surrounding genetic testing into the common household vocabulary. A key goal of the Project was to map all of the approximately 50,000 to 100,000 human genes, determining where they are located on the chromosomes, and making them accessible for further biological study. In June 2000, the roughly 90% complete sequence of the 3 billion human DNA bases was announced to the world. Although this June 2000 announcement has been heralded as one of the most important scientific discoveries of all time, it is a very early step in understanding the human genome. The next phase of the Human Genome Project will focus on producing a 'functional genetic map' that describes how genes function; this is still decades away.

Canadian philosopher and ethicist Susan Sherwin has raised the need for caution in how we embrace the Human Genome Project.

> *"The Human Genome Project is anticipated to generate the capacity to engage in a variety of problematic practices that also threaten to have a profound effect on Canadian values. Researchers are…. pursuing the supposed genetic basis of various behaviours such as homosexuality, shyness and criminal tendencies. Before supporting development of further genetic tests we must address a variety of difficult questions: who*

16 Lois Wingerson, *Unnatural Selection: The Promise and the Power of Human Gene Research,* New York: Bantam, 1998.

wants to know this information and what is their interest? What use is to be made of this sort of genetic knowledge? What sorts of conditions should be treated as acceptable grounds for terminating fetal life, for becoming ineligible for certain types of employment, or for denying access to affordable medical or life insurance."[17]

With a growing focus on diagnosing genetic diseases and disorders, it is easy to be lulled into thinking that genetic testing holds great promise for improved health. Indeed for some of those who have access to these tests, it may hold some promise. For example, genetic screening to identify those who carry a single copy of a gene associated with Tay-Sachs disease, an inherited and often fatal condition found predominantly in Ashkenazi Jewish and some French Canadian populations, allows those carrying it to receive genetic counselling about risks to children and, if appropriate (i.e., their partner also carries the gene) and they request it during pregnancy, prenatal diagnosis.

There are, however, some facts to remember when we think about genetic testing, whether it is for pregnant women, for newborns, or for adults. First, to learn that something is associated with a detectable DNA pattern does not mean that the person carrying the gene will inevitably develop that disease. Nor will this knowledge allow one to predict how complicated or severe the condition will be if it does occur. The genetic nature of a disease is complex: some gene-associated diseases are not inherited but rather result from a mutation in the single egg or sperm cell that results in the development of an individual; some are the result of mutations within specific cells after development is underway. Moreover, even when a DNA pattern associated with increased susceptibility to certain disabling conditions is detected in prenatal life, it may require products from other genes and biological processes for a problem to develop. This is the case for cancer. For many cancers to develop, a cell must undergo several (probably 5 to 10) separate gene mutations. Some of the mutations might be inherited, but some occur from exposure to gene-damaging substances in the environment. We do not fully know how much of each factor is at play and how the two interact.

Currently, genetic testing is being sold as a choice to which women are all entitled. Those doing testing seem to feel that by

17 Presentation by Susan Sherwin, "Biotechnology and Health: The Place of Ethics in a National Strategy", at "New Technologies in Health Care", Congress of Social Sciences and Humanities, May 30, 1998, Ottawa.

FOCUS: Genetic Testing for Breast Cancer

All women carry some form of the BRCA1 and the BRCA2 gene. When the gene is in its most common form, it is believedoachkeep cell division in check; when it is in a mutated form, cell growth can turn inachcancer. Certain genetic mutations in BRCA1, BRCA2 or other genes, some of which may be inherited from a parent, may increase the potential for an individual achdevelop breasthcancer.

When the firsthso-called "breasthcancer gene" was isolated in 1994, the discovery was seen as a very important advance for women. However, consumer groups and breasthcancer organizations have been quick achpoina out thaa only 5-10% of women with breasthcancer actually carry the mutated BRCA1 or BRCA2 gene, and for those whchdo, one or more environmental ariggers are required for the disease achdevelop. Similarly, less than 1% of women in the generalhpopulation carry this mutation, so the actual numbers of women whchare goodhcandidates for testing is relatively small. Nevertheless, it is understandable thaa many women with a strong family history of the disease (e.g. they have two or more firsthdegree relatives — mother, siblings, offspring whchare affected) may be eager ac have this test.

Organizations thaa advocate for women with breasthcancer (such as the Canadian BreasthCancer Network and BreasthCancer Action Montreal) have been working hard ac try to influence policy about this controversial test. They have helpedoacheducate the generalhpublic about the limitations of the test, and have poinaed out thaa inaerventions achpredict, detect and treat breasthcancer are second best achpreventing the disease.

These advocates stress that women who are found by testing achhave a mutated gene needoachbe aware of the following: 1) testing "positive"hdoesn't necessarily mean that ahey will develop breasthcancer, and testing "negative"hdoesn't mean they won't; it simply means that they do or do nothhave one of many possible factors which may increase their likelihoodhof getting cancer; 2) testing positive leads to limited options — at present these are: a double mastectomy and unproven experimental approaches such as the drugs tamoxifen and raloxifene;[18] 3) testing positive could resula in discrimination from potential employers and insurers. Breasthcancer advocacy organizations have staged ahcampaign achhelp fight thaa discrimination.

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18 For more information on some of the concerns associated with tamoxifen and raloxifene, see "Medical and Non-medical Approaches to Disease Prevention", a background paper prepared by Sharon Batt for the Working Group on Women and Health Protection; to be posted on the Working Group's website in late 2000 (gooachElf.web.net/~desact, and click on "Health Protection").

allowing women to give what they call "informed consent", whether this be in a research study of testing or in a clinical setting, they as "testers" are free of any further responsibility. However, is it possible for a woman to give full and informed consent if she does not have all the information needed to consent? Many of the tests are looking for variations in DNA associated with conditions for which there is no known, or no effective treatment. Others, by identifying a woman who will then be seen as at greater-than-average risk of developing some disorder, may lead to discrimination against her. In these situations, knowing one's status may not be seen as useful or helpful.

The women's movement has argued for years that our options (particularly relating to reproductive issues) have been restricted, therefore we need more choice. This in turn can make it difficult for someone to reject the offer, the "choice" of a test. However, health is not simply a consumer choice, and "choice" is not the basis on which to base these arguments. Informed choice hinges on who is offering the test as well as a full understanding of what the purpose is of the option, and on a woman's ability to act. If the information only comes from those who stand to gain (financial profit, academic success, reduced health care costs, etc.) from the use of the new technologies, then we know all sides are not being represented. Moreover, as Abby Lippman notes:

> *"…what seems to be a personal choice (e.g., to have prenatal testing, to take tamoxifen) may really be merely a substitute for societal failures to provide what I truly need (the resources — financial, social, supportive) that would allow me to mother a child with Down Syndrome; the guarantees that the water I drink is not polluted with harmful chemicals."*[19]

Genetic Testing and People with Disabilities

Advocates for people with disabilities have argued that genetic testing is a form of discrimination against disabled people. They point out that we are already a long way from collective acceptance of disability as an expression of human variation, and that the emphasis on genetic testing will only set us back further. Catherine Frazee, Canadian disability rights activist and Chief Commissioner of the Ontario Human Rights Commission from 1989 to

19 Abby Lippman, working notes for workshop, "Canadian Biotechnology Strategy: Assessing its Effects on Women and Health", February 2000, Toronto.

1992, made this observation when studying all the documentation related to the Canadian Biotechnology Strategy:

> *"…[the word] disability appears nowhere in the documents that highlight the strategy's features, benefits, guiding principles, goals, development and progress…. It is alluded to…. It is implied, surely…. But the shadowy foe never declares itself."*[20]

Advocates for the disabled also fear that people who decline to be screened might be discriminated against. Dr. Ruth Hubbard, a scientist at Harvard University, has argued that genetic testing perpetuates the idea that it is more beneficial to society for certain people to have children than others, and for them to have only certain kinds of children. When the Human Genome Project made its announcement in 2000, the Canadian Down Syndrome Society released its official position calling for "regulation and research protocols for genetic testing and gene therapies that will protect the dignity, worth and equal rights of all people, regardless of handicap or disability". As the Human Genome Project generally and genetic testing in particular receive more and more public attention, we can expect advocacy groups for people with disabilities to become even more vocal about what this means for them.

Genetic testing runs the risk of leading us into thinking that a wide range of human problems can be prevented or cured once science learns how to identify and manipulate our genes. Along with many others, Ruth Hubbard has argued that this way of thinking puts far too much emphasis on heredity and keeps us from addressing critical health problems caused by the environment, and by social, political and economic factors.

Genetically Engineered Products and Gene Modifications

Developing ways to produce drugs using genetic technology, and changing the genes of microorganisms, plants, animals and ultimately humans is an important and expanding field for the Canadian biotechnology and pharmaceutical industries. These products and gene engineering technologies are presented as having the possibility of providing therapeutic options

20 Catherine Frazee, "A Rough Reflective Sketch" for workshop, "Canadian Biotechnology Strategy: Assessing its Effects on Women and Health", February 2000, Toronto.

for those facing hereditary diseases, as well as for those dealing with diseases where non-inherited genetic processes may be involved (e.g., cancers). The business sections of major newspapers in Canada repeatedly report on "spectacular developments" in this industry as shares "shoot up" for the country's major genomics companies. Is our level of health increasing as rapidly as these stock prices?

Among the gene-based products and proposed "therapeutic" approaches, three warrant particular attention:

1. "DESIGNER DRUGS"

The most rapid growth in the field of genetic therapies is in the area known as "designer drugs". Hormones, drugs, vaccines, and antibodies produced from isolated human genes are the basis of several highly experimental and expensive therapies. The proliferation of these designer drugs raises questions about the allocation of health care dollars in Canada. For example, genetic research has led to the creation and patenting of an antibody-based drug known as Herceptin (generic name, Trastuzumab). It is available in Canada to women with advanced breast cancer who have changes (mutations) in a particular gene known as Her-2. The presence of protein products from this gene are indicative of a very aggressive breast cancer that is likely to recur, since this protein stimulates the growth and division of the cancer cells. Herceptin is a designer drug that has been developed to recognize and then block the activity of this protein. It is a very expensive drug: treatments for an individual woman cost more than $2500. per month. Some provincial health insurance plans already cover these costs even though Herceptin has only been shown to extend survival for some women by about five months. There are also increasing concerns about the toxic effect of this drug on heart tissue. Therefore, while Herceptin has some limited positive effects, one must wonder if its considerable adverse effects — and tremendous cost to the health system — have been discounted at least in part because of the potential for patents and profits to the biotechnology industry.

2. GENE TRANSFER.

Although gene transfer has received a lot of media attention, it is still highly experimental. It is, moreover, the field of development which the biotechnology industry is most keen to enhance since its potential for growth is enormous. The basis of gene transfer is recognition that cellular processes can be altered by splicing [adding] genes directly into a diseased or non-functioning organ. Once introduced, these genes can work either to replace something the person lacks, or to alter

harmful cellular processes. The aim is to treat or eliminate disease specifically in the person receiving treatment. There is sparse evidence to date of the success of this approach in spite of all the promotion of and attention to it. In fact, some people have been harmed by it; some gene transfer attempts have resulted in the death of the patients. Many questions have been raised about the way informed consent for these experimental procedures has been obtained. Furthermore, the same techniques that might be used to treat disease can also be adapted to "enhance" the functioning of specific biological processes, raising still other problematic issues about this form of intervention.

3. GERM LINE MODIFICATION /INTERVENTION.

Unlike gene transfer experiments that involve transferring genetic material into mature body cells, germ line interventions involve purposely transferring genetic material into gametes or embryonic tissue. Importantly, this means that these changes can be passed on to future generations, and differs from the interventions noted above which only work at the somatic cell level (i.e., any resulting genetic change would occur only within that individual, not their offspring). When there is germ line intervention, any introduced DNA would then become part of the nuclei of all cells of the developing body — including their reproductive organs and ultimately their gametes. This constitutes a deliberate 'engineering' of the human genome and, even more than somatic gene transfer, opens the door to interventions aimed at enhancement (as of height, behaviours), not at the prevention or elimination of disease. There are now many examples of this type of experimentation being conducted on animals. Although germ line gene modification may sound a bit like science fiction, its eventual implementation has been promoted by several high-profile scientists. Many governments around the world have already banned it, but its prospects remain viable in the United States where reproductive manipulations in the private sector are completely unregulated. Several U.S. and U.K. organizations have emerged to oppose development of this and related technologies with eugenic goals.[21]

21 See, for example, the website of the Council for Responsible Genetics, www.gene-watch.org.

Conclusion

Women and women's organizations have been at the forefront of many campaigns to raise awareness about actual and potential harms to our health, and we must be no less vigilant with the proliferation of biotechnology and the new genetics. In particular, we need to monitor developments proposed in the Canadian Biotechnology Strategy and Canada's commitment to a plan "designed to fit the model of the marketplace, not the demands of healthcare".[22]

A growing number of academics, health care activists and environmental organizations feel that genetics has been elevated to an inappropriate place in our health care system and are dismayed by how genetics and biotechnologies are being sold as a way to improve the health care of Canadians. When we consider the new commitment (financial and other) that Canadian lawmakers and the Canadian biomedical communities have made to genetics, it is also important to ask what is not getting done because of this shift. For example, are new technologies such as a testing for certain genetic information, being introduced at the expense of cheap and effective programs such as basic public health measures for pregnant women? Are designer drugs being introduced at the expense of environmental clean-up programs?

Over the past 25 years, Health Canada has made a strong commitment to health promotion and disease prevention and has recognized that a multitude of factors — social, economic, environmental, cultural and biological — strongly influence our health. On an international level, Canada in fact has quite a progressive history with respect to understanding and respecting the role of input from its citizens on matters of such critical importance. Focussing so much time, energy and finances on genetics and biotechnology, without more accountability from the populations who will be affected by these changes, runs counter to Canada's broader commitments.

22 Presentation by Susan Sherwin, "Biotechnology and Health: The Place of Ethics in a National Strategy", at "New Technologies in Health Care", Congress of Social Sciences and Humanities, May 30, 1998, Ottawa.

Glossary of Terms

biodiversity: "The variability among living organisms from all sources including terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are a part; this includes diversity within species, between species and of ecosystems". (from the U.N. Convention on Biological Diversity)

biopiracy: The theft of biological resources and traditional knowledge from indigenous peoples in developing countries.

biotechnology: "The use of living organisms, or their parts, for the production of goods and services" (Canadian Environmental Protection Act). Biotechnology today is principally about new genetic technologies, and is sometimes called genetic engineering.

cell: The smallest structural unit of a living organism whose nucleus contains genetic material.

cell line: Cells that have been altered to allow them to grow, often indefinitely, outside a living organism under laboratory conditions.

chromosome: Structure in a cell that contains genes.

cloning: The making of one or multiple identical copies, whether of genes, molecules, cells or whole organisms, through use of DNA technology.

DNA: Deoxyribonucleic acid, a double-stranded molecule that specifies the linear sequences of an organism's RNA and protein molecules.

eugenics: The attempt to improve hereditary qualities of a population of organisms by selective breeding or genetic manipulation.

gamete: A reproductive cell, either an egg (from a female) or a sperm (from a male).

gene: A segment of DNA that specifies the linear sequence of a protein. Genes are passed on from each parent to the offspring.

gene transfer (somatic): Genetic interventions used to replace a defective or non-functioning gene or add a new gene to an individual in an effort to prevent or cure a hereditary disease.

genetic modification: A process involving the insertion of a DNA molecule into the cells of other species where it can then replicate itself. Somatic modification affects only the body cells of an individual. Germ line modification also or exclusively affects the reproductive cells, and can therefore be passed on to future generations.

genome: A complete set of genetic material (in the chromosomes and the mitochondria) of an organism.

mitochondria: Special cellular structures that produce energy for cells and which contain DNA inherited only through maternal lines.

mutation: Any change in a DNA sequence that results in a new, often harmful, function.

protein: A molecule composed of one or more chains of amino acids in a

specific order, depending on its gene coding. Examples are hormones, enzymes and antibodies.

recombination: The artificial production of new genetic material by joining (splicing) segments of DNA from different chromosomes and/or from different organisms.

"Terminator Technology": "Biotechnology that is used to exert control and ownership rights over biodiversity by producing plants with infertile seeds." (RAFI)

transgenesis: The transfer of genes from one organism to another with which it does not normally breed.

transgenic organism: A new organism produced by inserting genes from one species into another through the use of genetic interventions.

xenotransplantation: Animal-to-human organ, cell, and tissue transplantation, often using genetically modified pigs and non-human primates.

Resources on the Internet

Alliance of Genetic Support Groups
http://www.geneticalliance.org/

Biotechnology Information Center
(operated by the U.S. Dept. of Agriculture)
http://www.nal.usda.gov/bic

Canadian Alert on Genetic Engineering
http://www.sustainability.com/cage/

Council for Responsible Genetics
http://www.gene-watch.org

Genetics and Ethics
http://www.ethics.ubc.ca/brynw/

Human Genome Project Information
http://www.ornl.gov/hgmis/medicine/medicine.html

International Centre for Technology Assessment
http://www.icta.org/

National Human Genome Research Institute
http://www.nhgri.nih.gov

Office of Biotechnology Activities (in the National Institutes of Health)
http://www4.od.nih.gov/oba

Rural Advancement Foundation International
http://www.rafi.org

The Western Canadian Citizen Conference on Food Biotechnology
http://www.acs.ucalgary.ca/~pubconf/Citizen/citizen.html

Union of Concerned Scientists
http://www.ucsusa.org

Women and Genetics in Contemporary Society
http://www-unix.oit.umass.edu/~holmes/