

***The Gender of Genetic Futures:
The Canadian Biotechnology Strategy,
Women and Health***

**Proceedings of a National Strategic Workshop held at York University,
February 11-12, 2000.**

***Edited by: Fiona Miller, Lorna Weir, Roxanne Mykitiuk,
Patricia Lee, Susan Sherwin and Sari Tudiver
(The Working Group on Women, Health and the New Genetics, 1999-2000).***

***NNEWH Working Paper Series
September 2000
York University, Toronto***

*The papers in this volume derive from pre-circulated statements, plenary presentations and respondent commentary prepared for the Workshop.
Most of the Workshop materials are included in this collection, though some participants elected not to submit their statements for publication.
All papers have been edited for inclusion in this collection, and authors' biographies and editors' introductions have been added.
The authors retain copyright of their material.*

Acknowledgements

We would like to acknowledge the financial support of the following sponsors: the Centres of Excellence for Women's Health Program, Women's Health Bureau, Health Canada; the Medical, Ethical, Legal and Social Implications of Genomics / Genetics Research program of the Medical Research Council of Canada; the National Network of Environments and Women's Health (NNEWH), which is financially supported by the Centres of Excellence for Women's Health Program, Women's Health Bureau, Health Canada; the Department of Sociology, Faculty of Graduate Studies, and Dean of Arts at York University. The views expressed herein do not necessarily represent the official policy of our sponsors.

Table of Contents

1. Introduction

- Placing Values at the Centre of Biotechnology Policy: The Canadian
Biotechnology Strategy and Women's Health. Opening Remarks
Susan Sherwin 1

2. Opening Plenary

- The New Genetic Therapies: The Case of Herceptin for Breast Cancer
Sharon Batt 9

- Belling the Cat: Learning to know (but not necessarily trust) the new
genetics
Pat Kaufert 18

3. "Health" Theme

- 3.1 Ethics and Genetics: The Need for Transparency
Fern Brunger and Sue Cox 27
- 3.2 Geneticization and the Canadian Biotechnology Strategy: The Marketing
of Women's Health
Abby Lippman 32
- 3.3 What's So New about the "New Genetics"?: Genetic Counselling and the
Medical Management of "Genetic" Information
Fiona Miller 41
- 3.4 The Hazards of Human Developmental Gene Modification
Stuart Newman 50
- 3.5 Genetic Testing, Citizenship and Subjectivity: Implications for Women and
Health
Jessica Polzer 55
- 3.6 Risk, biotechnology and political rationality: Lessons from women's
accounts of breast cancer risks
Ann Robertson 64

4. "Wealth" Theme

- 4.1 Genetic Engineering in Agriculture and Health: Feminist Dilemmas and/or
Opportunities
Elisabeth Abergel 76
- 4.2 Engaging the State? Framing Feminist Politics in an Era of State-Led
"Reform"
Pat Armstrong 82
- 4.3 Biotechnology and Women's Health: Re-Defining the Questions

	<i>Madeline Boscoe and Sari Tudiver</i>	86
4.4	Gender and the Gene Giants: Research and action on women and the new genetics <i>Julie Delahanty, for RAFI</i>	92
4.5	Environmental Sustainability and the Canadian Biotechnology Strategy <i>Margrit Eichler</i>	101
4.6	The New Genetics in the Post-Keynesian State <i>Roxanne Mykitiuk</i>	106
4.7	One Part of an Anti-Racist, Feminist Political Standpoint against Biopiracy <i>Nandita Sharma</i>	113
4.8	Nurturing Cycles <i>Penny Van Esterik</i>	120
4.9	Biotechnology, Strategy, and Wealth for Whom: Commentary on the Theme of Biotechnology and Wealth <i>Helen Bequaert Holmes, respondent</i>	125
4.10	Preserving Cultural Diversity through the Preservation of Biological Diversity: Indigenous Peoples, Local Communities, and the Role of Digital Technologies <i>Rosemary J Coombe</i>	132

5. “Community” Theme

5.1	Stepping into the Breach: Provincial Funders Replace Federal Regulators in Defense of Public Priorities and Safety <i>Ken Bassett</i>	161
5.2	Science Education for a Science Dependent Culture <i>Ellen Larsen</i>	170
5.3	A Gender Critique of Forensic DNA Evidence: Collection, Storage and Applications <i>Patricia Lee</i>	172
5.4	The Human Genome Project and the Issue of Biodiversity <i>Priscilla Settee</i>	183
5.5	Obscuring Disability: The Pursuit of “Quality” in the CBS <i>Catherine Frazee, author and respondent</i>	190
5.6	Communities Constituted through the New Genetics: Actions and Reactions. Commentary on the Theme of Biotechnology and Community <i>Margaret Lock, respondent</i>	198

Placing Values at the Centre of Biotechnology Policy: The Canadian Biotechnology Strategy and Women's Health. Opening Remarks

Susan Sherwin

About the Author

Susan Sherwin is Munro Professor of Philosophy and a Professor of Women's Studies at Dalhousie University. Her principal area of research is in feminist health care ethics. She is the author of *No Longer Patient: Feminist Ethics and Health Care* (Temple University Press 1992). She also served as Coordinator for the Feminist Health Care Ethics Research Network which jointly produced *The Politics of Women's Health: Exploring Agency and Autonomy* (Temple University Press, 1998). Much of her current work is in the area of ethics and biotechnology.

About the Article

In these Opening Comments, Sue Sherwin explains the history of the Working Group on Women, Health and the New Genetics, and the goals of the national Strategic Workshop held on February 11 and 12, 2000 at York University in Toronto. At issue for concerned observers of the federal government's policy agenda for biotechnology, Sherwin suggests, are "basic questions of values." It is precisely the imperative of value definition and judgment which necessitates democratic rather than bureaucratic policy development in this burgeoning field. Yet the government's approach to defining values, Sherwin argues, has been inadequate at best, and incoherent at worst. Drawing on her own work in the field of feminist health care ethics, Sherwin seeks to "clarify and order the values underlying the Canadian Biotechnology Strategy" by investigating different meanings of 'freedom' and 'choice.' She advocates what she calls "relational autonomy" as a way to approach these ideals. Finally, Sherwin considers the structures and processes through which values – other than those advanced by industry – can be brought to bear in the development and deployment of policies. Despite the difficulty of such a task, Sherwin commends the importance of engaging citizens in the development of Canada-specific approaches to the assessment, promotion and restriction of biotechnology. Only in this way, Sherwin argues, can our policies "reflect and help to realize the deepest values of Canadians."

Introduction

Nearly two years ago, a small group calling itself the Working Group on Women and the New Genetics was formed under the auspices of NNEWH (National Network on Environments and Women's Health). As a group of Canadian academics and community activists sharing a concern with issues related to women, health and genetic knowledge, we structured our investigations around feminist principles of social justice. Specifically, we were concerned with the absence of concentrated gender-specific research investigating the impact of the new genetics agenda on women. With some seed money from NNEWH, we began a series of teleconferences around the need for greater research in the realm of women's health and the new genetics. The membership of this working group evolved a bit and soon settled into a core team.¹

The February 2000 workshop was actually the second in a series of two national strategic workshops. Last February (1999), we organized a preliminary workshop in Winnipeg to which we invited a small group of community activists concerned with women's health issues. They were asked to reflect on their understanding of the implications of new

genetics for women's health and their sense of research priorities in this realm. Building on the feedback from that workshop, the Working Group decided to try to focus the 2000 workshop's investigation of the implications of the new technology for women's health around the three core themes of health, wealth, and community. We re-framed our initial agenda beyond genetics to the whole range of biotechnology in the hope of having an impact on the government's current efforts to restructure its approach to the biotechnology industry. Our hope was that the national strategic workshop would provide an opportunity for participants to define and begin to address a series of fundamental, feminist questions about the Canadian Biotechnology Strategy (CBS) in relation to women and health.

It is our view that that there are basic questions of values related to the genetic modifications of humans and other organisms that must be identified and addressed. These questions cannot be resolved internally through state bureaucratic processes, since they involve questions of society's value commitments. Such decisions must be pursued through democratic processes. Indeed, recognition of the importance of public debate was a major factor behind the federal government's 1998 efforts to solicit public input on these matters through a round of policy consultations. Many of us participated in some of those sessions and were confirmed in our sense that the level of critical cultural knowledge and public understanding of biotechnology is weak. The development of socially accountable strategic frameworks for state biotechnology policy suffers from this dilemma. We are particularly troubled by the lack of attention directed at the question of what these policies mean for women. A distinctly feminist perspective must be brought to bear on the

¹ The Working Group for 1999-2000 consists of: Patricia Lee, Fiona Miller, Roxanne Mykitiuk, Yvonne Peters, Sari Tudiver, myself, and our reluctant but fearless and much overworked leader, Lorna Weir, Department of Sociology, York University, Toronto. Though Ann Rochon Ford has had to give up active membership in the group, she was a very important early member who helped to get us going. The activities of the Working Group have been facilitated by continuing support from NNEWH. That support, supplemented with grants from MRC, the Department of Sociology at York, and the Dean of Arts at York, allowed us to hold this workshop. We are very grateful to all our sponsors.

identification and investigation of the values underlying biotech policy.

We use the term 'women and health' quite expansively to refer to three processes: the impact of policy and technology on women's health; women's relationship to medicine and health systems; and women's 'interests' in health – health as women's business – personally, culturally, socially. We asked Workshop participants to focus on the following: What are the key questions to ask so that we might best understand the impact the CBS will have on women and health? What kinds of research and action need to be undertaken to answer these questions?

In deciding on participants for the workshop, we sought out individuals engaged in developing new knowledge or in carrying out advocacy work. We tried to structure the workshop to facilitate the exchange of existing knowledge, and also to produce new questions and to incite the development of new knowledge and advocacy. We intended the workshop to be a forum for the design of future research projects and activities, where resources could be identified and networks formed of individuals and groups committed to taking the issues further. The aim of the workshop was not to produce consensus. We meant to stimulate and facilitate rather than conclude. We hoped to leave with a clearer sense of what questions should be asked, what research undertaken and what advocacy pursued to deal with the Canadian Biotechnology Strategy from the perspectives of women and health. The collection of papers in this *Proceedings* suggests that we accomplished our goals.

I have the privilege of leading things off. Let me do that by situating my own research interests in the context of our agenda. I work in the field of ethics, more specifically feminist health care ethics. It is very clear that there is need for sustained feminist research directed at clarifying the

many vague suggestions found within the government documents about the values that should be guiding Canada's biotechnology strategy. We can begin by documenting the incoherence in the values expressed in the government's own statements of the values that form the basis for policy directions. For example, the expressed commitment to advancing the health and well-being of Canadians is often incompatible with the strongly endorsed value of supporting industry. Just making clear the competing and incommensurate value frameworks that are being proposed allows us to insist that government be explicit about the priorities it attaches to the various value systems at work. Toward this end, it is particularly important that we ask the familiar feminist questions as to who is likely to benefit from the various types of biotechnology and who is likely to suffer from them. Let me try to be a bit more specific.

It is essential that Canadians understand the different forms of freedom and choice that are proposed as a central value for emerging policy. The terminology of freedom and choice is often used to represent quite different value systems. Not surprisingly, industry is particularly enthusiastic about market models in which freedom is reduced to the ideal of unrestricted consumer choice. In this conception, government is assigned a role of regulating trade to ensure accuracy of information and adequate opportunities to acquire the information necessary to make a rational choice. This is especially tricky terrain for feminists for we often hear our own slogans about the importance of "choice" and personal control over decisions regarding our bodies invoked to support industry's right to market any "health" or "reproduction" related product or service directly to consumers.

We must, therefore, be very clear about the type of personal freedom we understand to be central to feminist values. Specifically, feminists need to

insist that the personal control we demand is not a matter of being granted unrestricted access to problematic technologies. Rather, we seek access to opportunities that can support women's overall autonomy, and not increase their oppression. We cannot decide whether any particular consumer option meets this criterion by examining it in isolation and seeing if it meets some particular person's current desires or needs. To determine a technology's impact on personal autonomy we need to investigate it in the context of what opportunities are created or lost by its introduction.

Elsewhere, I have proposed that we try to understand the ideal in question through a concept I call "relational autonomy" (Sherwin, 1998) The idea of relational autonomy is that we must critically examine not only the decision-making capacity of the agent to make rational choices free of direct coercion, but also the nature of the set of options from which she must choose. Emphasis on the relational dimension of autonomy (which literally means self-government) is meant to counter the familiar over-simplification by which autonomy is equated with the exercise of preferences without interference. Relational autonomy demands moral evaluation of the context in which the person is being asked to choose. In particular, agents should be free of the "double binds" of oppression that tend to reduce an individual's options to a set of harmful choices where the best she can do is to select that option most likely to minimize the resulting damage.

Relational autonomy is also distinguished from consumer freedom in its appreciation of the processes that are essential elements of becoming autonomous. It rejects the common assumption that being autonomous is achieved merely by virtue of reaching adulthood and being free of explicit coercion. Under the consumer choice model of freedom the self is expected to approach important decisions

fully formed and self-transparent; but selves are never fully formed, coherent, consistent, and clear. When individuals are faced with difficult personal decisions they often surprise themselves with the decisions they make. Real autonomy comes not from entering such circumstances with our values settled, such that all we need is respect for our well-articulated preferences, but from having the opportunity to discover what our values really are and how they apply to the situation at hand. We need to wrestle with the implications of serious options to know what we stand for and how we want to be treated. Thus, to respect autonomy for individuals it is not sufficient to leave them free to exercise their preferences; rather we must provide them with the resources necessary for discovering what they truly value and what sort of person they wish to be. It is our reflective, considered values that demand respect, not our current inclinations. Self-discovery and self-definition are relational activities that are essential pre-conditions of genuine self-direction.

Therefore, a consumer model of choice with respect to various sorts of biotechnologies cannot be equated with the moral ideal of autonomy. The fact that people are willing, perhaps even eager, to purchase some form of biotechnology is not evidence that this technology should be brought to market. Individuals are often in no position to resist technologies on their own. If some form of technology is normalized, the option of refusing it may disappear. For instance, it is already difficult for many women to resist prenatal testing of their fetuses even if they are committed to carrying the pregnancy to term and the information available from prenatal testing will be of no benefit to them. Similarly, if the crops produced by genetically modified seeds prove invasive to other crops, or if they allow production at vastly reduced rates for a few years, independent farmers may be unable to continue to plant traditional seeds in an

economically viable way. The fact that women choose prenatal testing under the mistaken belief that it will improve the health of their fetus or that farmers choose to buy seeds from the major distributors is not evidence that the individuals concerned are acting autonomously. Only if their decisions reflect their deepest values can we consider their actions fully autonomous.

We need to do more than clarify and order the values underlying the Canadian Biotechnology Strategy, of course. We also need to explore structures that can ensure that the values selected will be reflected in the policies our government adopts. This project is especially challenging, since it is difficult to see how Canadians might actually go about limiting the development of any potentially profitable biotechnology industry. While government is well positioned to foster the development of favoured industries, it is not as well equipped to restrict the undesirable ones. Biotechnology industries are particularly resistant to government restrictions, for the companies involved are typically engaged in a global, not a national, marketplace. In fact, many belong to that most postmodern of phenomena: multi-national corporations that are situated both everywhere and nowhere. Producers effectively resist national regulations on the grounds that local restrictions would put them at an unfair economic disadvantage in a competitive global marketplace. Typically, they are able to make credible threats that they will move production to a different jurisdiction if their interests are ignored. Governments are understandably reluctant to introduce policies that inhibit the growth of industries when the jobs in question can be easily moved off-shore. Indeed, governments are far more inclined to support than to restrict these new industrial initiatives. For example, Health Canada was very explicit in its recent announcement that it would shorten the waiting time needed before initiating phase

one drug trials from 60 days to two days because it hoped such a move would attract more pharmaceutical research to Canada.

Moreover, it is not only the producers who may resist national restrictions. In an era where free trade has become a mantra of politicians and economists, it is difficult for nations to develop policies that effectively protect their citizens from the potential hazards of products originating elsewhere. While consumers may welcome government's role in setting minimal safety standards and promoting truth in advertising, they tend to be rather intolerant of government restrictions on the availability of goods they personally desire. In fact, many Canadians have become quite adept at "cross border shopping." This means that if our government ever does manage to finally introduce its long-promised legislation to regulate reproductive technologies, we can anticipate that some Canadians will side-step restrictions on reproductive services (e.g., sex selection) through travel to U.S. clinics. Similar action will be taken for access to home-testing kits for genetic traits, anti-aging potions, and even organs for transplant if such products are restricted in Canada but available for purchase in other jurisdictions.

Nonetheless, I believe that Canada must develop a national policy on biotechnology. We need to do this in order to protect and promote the personal autonomy of our citizens, because individuals cannot control the social and material conditions that structure the options they face; many of the preconditions for relational autonomy can only be achieved through political action. In order to make certain that the options facing Canadians in the realm of biotechnology will promote and not limit personal relational autonomy, it is necessary for the government to develop policies that reflect our national autonomy. That is, they must be policies that reflect

and help to realize the deepest values of Canadians.²

In order to develop such policies, we must conduct exercises in collective self-discovery and self-definition about the sorts of activities well informed citizens wish to permit and the sorts of threats they wish government to protect them from. It is only through a complex exercise of communication and debate that we can decide what might constitute “Canadian values” in the diverse, multi-cultural, heterogeneous society we inhabit. In fact, the federal government has recognized that potential transformations of fundamental values and understandings are inherent in many forms of biotechnology. It has undertaken efforts to promote the conversations Canadians must undertake in pursuing the activities of self-discovery and self-definition that are essential for genuine autonomy. For example, more than ten years ago it established the Royal Commission on New Reproductive Technologies to advise on policies in the realm of reproduction. The Royal Commission conducted extensive consultations with Canadians and determined that we are united in not wanting to be a society that treats children or women’s reproductive capacities as commodities to be bought and sold. By exploring the meaning of this commitment, the Commission learned that Canadians did not think it appropriate to treat reproductive activities, including the contribution of embryos, eggs, and sperm as commodities to be auctioned off to the highest bidder.

In 1998, the federal government initiated conversations central to self-discovery and self-definition in the sphere of biotechnology broadly defined. It held a series of public consultations regarding

development of a biotechnology strategy which would “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.” (CBS, 1998). Ethical analysis was understood to be a central element of these deliberations. But as several papers noted, the motivation for discussion was couched in language aimed at facilitating the development and promotion of biotechnology industries and did not really leave room for alternative strategies to emerge. It is, therefore, essential that we make clear the inherent contradiction between a commitment to explore Canadian values regarding biotechnology and an assumption that the outcome of such analysis will be a shared commitment to support most biotechnology industries.

Last fall, the federal government took the next step in its biotechnology strategy process and appointed a 20 member Biotechnology Advisory Committee (CBAC). According to the Minister of Industry “CBAC is an expert, arm’s-length committee created under the renewed Canadian Biotechnology Strategy (CBS) to advise Ministers, raise public awareness and engage Canadians in an open and transparent dialogue on biotechnology matters. . . . CBAC will advise government on broad policy issues associated with the ethical, social, regulatory, economic, scientific, environmental and health aspects of biotechnology.” (CBAC, 1999). Its express purpose is to facilitate continued dialogue of self-direction and self-definition in the pursuit of national autonomy in the realm of biotechnology. There is, however, plenty of reason to worry about its effectiveness in achieving this task. It is arguable that the advisory panel of distinguished Canadians is not representative of all concerned citizens; certainly, there are many groups that fear their views will not be represented nor their voices heard. Health activists seem to have been deliberately excluded and I

² I do not believe that oppression of minorities reflects national autonomy at all, but rather the co-optation of ethical language in the service of immoral abuses of local power.

know of only one member who is explicitly committed to a woman's health agenda. CBAC will need to find ways to promote trust in its ability to fully engage Canadians in self-discovery and self-definition and to report accurately the outcomes of these conversations if its advice is to carry the necessary authority. One thing we can do, here and in the future, is to begin to formulate a substantive list of questions regarding the impact on women's health that CBAC should attend to in its deliberations. We might also propose procedural ways that can facilitate meaningful input from citizens who are concerned with, and knowledgeable about, women's health.

Of course, self-discovery and self-definition are not the only elements of autonomy. Self-direction is also required. So far, the Canadian government has been unwilling or unable to engage in the final step of exercising national autonomy in the realm of biotechnology. Despite the thoroughness of its public consultations and of its research and analysis, none of the 293 recommendations of the Royal Commission on New Reproductive Technologies has yet been implemented. It is still too early to determine whether CBAC will be able to contribute effectively to self-direction on biotechnology policy. It is clear, however, that there are likely to be structural impediments to its capacity to influence policy, that is, to see its moral analysis translated into national self-direction. The panel reports to an inter-governmental agency in which the Department of Industry plays a leading role; the principal responsibility of this ministry is to promote industrial development. Such an arrangement does not seem to be particularly conducive to generating policy that may require imposing restrictions or prohibitions on certain industries.

So far, then, the biotechnology strategy espouses interest in identifying and reflecting the values of Canadians but the

processes that have been put in place make it difficult for the government to hear, let alone adopt, values other than those of industry. We need to identify strategic ways to demand more accountability from government in:

1. identifying the appropriate values to guide biotech policy; and
2. ensuring that the values agreed upon do in fact structure both national and international policies.

Protecting and promoting women's health must surely be fundamental to that agenda. Our hope for the workshop was that it would help to provide direction to the research and political activities that are essential elements of translating this commitment into practice. Clearly, there is much work for feminists to do in promoting biotechnology policies that truly support women's health. The following papers provide some guidance for how to proceed.

References

Sherwin, S. 1998. "A Relational Approach to Autonomy in Health Care" in *The Politics of Women's Health: Exploring Agency and Autonomy* by the Feminist Health Care Ethics Research Network, Susan Sherwin Coordinator. Philadelphia: Temple University Press.

CBS (Canadian Biotechnology Strategy Task Force), 1998. Renewal of the Canadian Biotechnology Strategy: Roundtable Discussion Document. Available on-line, <http://strategis.ic.gc.ca/cbs>.

CBAC (Canadian Biotechnology Advisory Committee). 1999. announcement of membership and terms of reference, September. On-line, <http://cbac.gc.ca>.

The New Genetic Therapies: The Case of Herceptin for Breast Cancer

Sharon Batt

About the Author

Journalist and community activist Sharon Batt has written extensively about breast cancer issues. She is the author of *Patient No More: the Politics of Breast Cancer* (Gynergy Books, 1994) and co-founder of Breast Cancer Action Montreal. In July 1999 she began a two-year term as Nancy's Chair in Women's Studies at Mount Saint Vincent University in Halifax.

About the Article

For many women's health advocates, the challenge of genetics in relation to breast cancer is the challenge posed by a new breed of genetic tests. In this piece, Sharon Batt suggests that there are other challenges to consider. Batt introduces readers to a new treatment protocol for breast cancer, involving a genetically engineered antibody which targets a malfunction that is genetically associated – Herceptin (or Trastuzumab). As Batt discusses it, the new drug Herceptin poses both new and familiar challenges. On the familiar side of the ledger, and despite the hype to the contrary, this new genetic therapy is no miracle cure; moreover, like the better known therapeutic protocol of chemotherapy, Herceptin has dangerous adverse effects. On the less familiar side of the ledger, this drug is exorbitantly expensive, and herein lies the new challenge. While this drug and others like it that are coming down the pipe may provide new tools for fighting cancer, they may also prove unaffordable. Batt argues that if the new era of biotech medicine provides some medical assistance for the few, while contributing to the demise of a public health care system for the many, women in general are unlikely to be the winners.

Introduction

Breast cancer is the number one killer of mid-life women and has been for decades. Treatments are harsh and have limited benefits. An effective new treatment would be welcome indeed, and one that worked and had few or no adverse side effects would transform the experience of breast cancer beyond recognition. Enter the Human Genome Project, promoted as precisely the Aladdin's lamp we've been waiting for. Research mapping genes to diseases will lead us into a world of just such therapies, miraculously effective because they are based on a true understanding of how genes work. At least that's the hype. Women's health advocates need to weigh these claims, balancing our scepticism of this project against the desperate need of sick women for more enlightened therapeutic approaches to cancer.

Feminist discourse about breast cancer and genetics has concentrated on the issues related to genetic testing for breast cancer susceptibility, especially the BRCA 1 and 2 genes, and on the reductionist emphasis on genetics – to the exclusion of environmental triggers – as the basis of cancer. While these are critical issues, we can't neglect the questions arising from genetic treatments that are now coming onstream. Health Canada approved Herceptin, the first novel gene therapy for breast cancer, in August, 1999.

In the rest of this paper, I look at what we know so far about what Herceptin does for women with breast cancer, its side-effects, its cost, how advocates are responding to this new therapy, and the dilemmas the drug presents for those of us concerned about Canada's biotechnology strategy.

What is Herceptin?

Herceptin is the first therapy of its kind ever approved for the treatment of breast cancer. Unlike cytotoxic chemos which simply aim to kill the malfunctioning cell, Herceptin aims to re-balance the process that is malfunctioning. In this case, the therapy is designed to correct an over-production of the protein produced by a certain oncogene (i.e., cancer gene), which the defective gene uses to make the cell cancerous.¹ This gene has been named "HER-2 neu," a clever moniker for a drug designed for women. HER-2 refers to the protein, "Human Epidermal-growth-factor Receptor-2," and neu is the name a different scientist, who discovered the gene first, decided to call it. Geneticists refer to the production of excess protein as "overexpression". Herceptin is intended to correct the overexpression of the Her-2 protein.²

Because the Her-2/neu gene produces an excess of the Her- 2/neu protein, researchers developed what is called a "monoclonal antibody" to attack the protein and shut it down. (The body produces millions of different antibodies – which themselves are proteins –to attack invading viruses and infections. A "monoclonal" antibody is laboratory manufactured, using genetic engineering.)

Researchers working on this problem in the late 1980s were amazed and delighted when they added the monoclonal antibody to a petri dish containing breast cancer cells that overexpressed Her-2/neu: the cancerous cells stopped growing and dividing. When they injected the antibody into mice into which breast cancer cells had been implanted, the tumours shrank.

¹ NB. This genetic change is part of the cancer process; it is not inherited.

² Again, the language reverberates for feminists: women have long been chastised as overexpressing our emotions; now we have a "women's gene" that overexpresses and gives us cancer.

Over the next decade, the antibody was adapted for use in humans and then tested in clinical trials using women who had breast cancer tumours that tested positive for Her-2/neu. (Bazell, 1998:42-3)

This modus operandi is very different from traditional cancer chemotherapies, which are systemic, and which are designed to kill cancer cells. In theory, herceptin is a huge therapeutic advance. As everyone knows, conventional chemotherapy drugs have horrible side-effects, because they kill any rapidly dividing cell, healthy or cancerous. What's more, they have not been very successful in treating breast cancer, especially in patients with advanced disease – in fact, they often kill the patient before the disease does. While Herceptin was in development, the drug was touted as a treatment that would work better than cell-kill chemo and which would have no side-effects at all. A patient's dream drug.

Does Herceptin Work?

Does Herceptin Work? The answer is sometimes and sort of.

Like most new cancer therapies, Herceptin is being tested in patients with advanced cancer, that is, in women whose condition is very likely to be fatal. Twenty-five to thirty percent of women whose cancer has reached this stage have been found to overexpress HER-2 – and they are women whose disease is typically unusually aggressive, or fast-spreading.

Clinical trial data for Herceptin have been coming out since 1998. The original study, which convinced regulators to approve the drug, comprised 469 women with metastatic breast cancer. Women treated with a Herceptin-chemotherapy combination lived longer than women treated only with chemotherapy by a median time of 5 months. Those who had standard chemo lived a median time of

20.3 months from the beginning of treatment; those who had chemo plus Herceptin lived a median time of 25.4 months from the beginning of treatment. (Slamon et al 1998). After two years of the trial, researchers were announcing that the addition of Herceptin to chemotherapy increased patient survival by 22% (Zoler, 1999).

In the world of breast cancer treatments, this was considered remarkable. Very few chemotherapy trials have ever shown a survival difference between two treatments. On the other hand, this is far from the miracle women with breast cancer hope for.

The drug has been disappointing on a number of other counts. First of all, it benefits only a *subset* of women with advanced disease. To see if she qualifies for Herceptin, a woman is given a test to see if she is one of the cancer patients who are Her-2 positive; that is, one of the 25-30% of women with advanced breast cancer who overexpresses the Her-2 protein.

But even a positive Her2 test result is no guarantee that Herceptin will benefit women who take it. In the clinical trials data, 32 percent who were treated with chemotherapy alone showed tumour shrinkage compared to 49 per cent of Her2 positive women under the Herceptin + chemotherapy regimen. Even with the combined treatment, 51 per cent of Her2 positive women did *not* respond to Herceptin.

Other trials have suggested that Herceptin-alone may be a useful treatment for metastatic breast cancer. Because it was considered unethical to deny chemotherapy to women with cancer, these trials have involved women who have already had a course or more of chemo, but whose cancer has returned. In the largest trial of this kind, involving 222 women, the results were considered

significant. Herceptin produced a 15% “response rate” (in other words, 15% of these women had at least a 50% reduction in the size of their tumours), for a median time of 9.1 months. (Cobleigh et al,1999)

Adverse Effects

Though potentially a useful addition to the treatment protocol for metastatic breast cancer, Herceptin has not lived up to its advance billing. As one American activist summed it up, "While Herceptin may represent an important new direction for cancer therapy, the oncology community's excitement about a 5.1 month median survival benefit also shows how little has been achieved since the war on cancer began in 1971." (Schiff, 2000:23)

But more surprising for its proponents than its limited efficacy, has been the extent to which this drug is associated with adverse effects. On the one hand, Herceptin is generally given in combination with chemotherapy drugs. The researchers' thinking was that the antibody would hold the cancer in check, while chemotherapy attacked it (Bazell, 1998:137). If a selling point for genetic treatments is that they are more targeted and less toxic than cell-kill chemotherapy, this advantage is somewhat academic if the drug is given in combination with a cell-kill regimen. Another problem is that Herceptin can't cross the blood/ brain barrier. Some women whose metastases disappeared in their liver, lung or bones eventually died of brain metastases. (Bazell, 1998:170)

But most important is the apparent toxicity of Herceptin for heart tissue. The cell-kill chemotherapy regimen which is used is already quite toxic – especially to heart tissue. To everyone's surprise, Herceptin actually increased the heart toxicity by 25%. This was the case even for those women who had Herceptin-alone; in the trial of 222 women noted above, 4.7%

experienced what's known as “cardiac dysfunction.”

In May 2000, Genentech, the biotechnology company that developed the drug, sent out an alert to providers, warning them to pay special attention to heart function when prescribing this drug. Genentech reported 62 serious adverse events related to the use of Herceptin; 15 of these women died. The company noted that while some of these events had been observed in the clinical trials of the drug, some were more severe, or new: specifically, “adult respiratory distress syndrome, anaphylaxis and death within 24 hours of a HERCEPTIN infusion.” (Genentech, 2000)

Such extreme and fatal outcomes prompted heart specialists to speak out about the drug. They note that “heart failure, like many cancers, is a progressive disease, “and they argue that physicians should take care that “patients do not trade one lethal disease for another.” (Feldman et al, 2000:272). Fear of cancer, and particularly fear of breast cancer, is clouding clinical judgement, in the view of cardiovascular specialist Arthur Feldman of the University of Pittsburgh Medical Centre. “...if someone were to go to the FDA with a new drug for heart failure or cholesterol or high blood pressure – all of which are leading killers of people – and that drug was associated with even a 1% incidence of cancer, it would never be approved by the FDA,” said Dr. Feldman. “No manufacturer would take the drug to the FDA. Yet here is an anticancer drug that is associated with a 28% incidence of heart failure and it is approved.” (Gottlieb, 2000) *BMJ* 2000; 321:259 (29 July)]

Given these results, the future of Herceptin is not certain. What is certain, however, is that other genetically engineered drugs are on the way, and some of the issues that Herceptin raised are bound to recur.

The Price of Herceptin

No one involved in Herceptin's development ever expected the world's first designer breast cancer drug to be cheap. A book about HER-2's development, by TV journalist Robert Bazell, culminates at an oncology conference in Los Angeles at which the results of the clinical trials are presented to an audience of 18 *thousand* delegates. That evening, Genentech held a party for its researchers, for the clinical trial investigators, and for activists who had helped promote the trial. "Everyone at the party could celebrate an enormous success," Bazell (1998) writes. "Women's lives would be saved and a huge fortune would be made." (186)

Drug pricing hasn't been an issue in breast cancer until recently. The pricing of two earlier drugs, tamoxifen and taxol made some waves, but the cost of Herceptin is a *big* issue. To give away the punch line, if this drug were made available to all the women with breast cancer who test HER-2 positive it, and the imitators sure to follow, could bankrupt our health care system.

In the US, the FDA approved Herceptin in October 1998; health Canada approved the drug in August 1999. In the US, Herceptin costs about US\$2,000 a month; the Canadian price is about \$Can \$16,000 for a 6-month course (Sibbald, 1999). This is unprecedented for a breast cancer drug.

Insurance-wise, US patients fall into 3 categories:

- those covered by a private medical plan, usually via their employers;
- those who qualify for Medicaid;
- and the "working poor, the 40 million who have no medical coverage.

Genentech has agreed to provide American women in this latter category with HER-2 free of charge, although I know of no figures showing how many

women actually take advantage of this possibility.

Hoffman-La Roche, which took over Genentech in 1990 (Bazell, 1998:54-55), made it clear the company intended to cut no deals to increase women's access to the drug in Canada. In a June 1999 letter to a woman seeking access to the then-unapproved drug, Medical Director Dr Len Walt wrote:

It is important to note that the responsibility of providing new therapies to patients is a shared one. There are three critical sectors, each with definitive accountabilities, responsible for bringing new therapies to Canadian patients.

- the pharmaceutical industry develops and manufactures new products;
- Health Canada reviews the scientific evidence in support of new products and gives the manufacturer the authority to distribute new products in Canada;
- provincial and other funding agencies ensure that adequate funds are set aside to cover the costs of new products introduced into the health care system.

Each of these sectors should be held accountable for delivering on their responsibilities. The pharmaceutical industry cannot make up for the deficiencies in Health Canada or the provincial funding agencies (Personal Communication 1999).

In Canada, each of the provinces have had to decide how to deal with the drug. When it looked like Herceptin was a benign cure, Ontario and BC decided to cover the drug under medicare; it is not clear what some other jurisdictions will do, especially in light of information about adverse effects.

Our Patented Medicine Prices Review Board sets the price of drugs like Herceptin by comparing the prices in seven other countries: the US, the UK, Germany, France, Italy, Switzerland and Sweden. The Canadian price can't be higher than the median international price. When Canada approved Herceptin, the only other country the drug was available in was the US, so the price was set relative to the US price – and the US is the only country in the world that has no system of price controls on drugs.

Herceptin is being heralded as the harbinger of a new era. In her introduction to Bazell's book on Her2, geneticist Mary Claire King, harkened back to Churchill's declaration at the battle of El Alamein, in 1942: "Now this is not the end. It is not even the beginning of the end. But it is, perhaps, the end of the beginning." (Bazell, 1998:xi)

Herceptin is expected to be the first in a long line of such treatment options. And to a dying woman, the chance of being one of the few patients for whom a drug like this means a long-term remission, is invaluable – especially when the alternative is a median life expectancy of 20 months. But Genentech never intended that this drug be reserved for dying women. Cancer drugs are always tested first on the terminally ill. Genentech hoped to move Her-2 quickly to the status of a front-line treatment, that is, a drug that is prescribed immediately after breast surgery (Bazell, 1998:175). Because of cardiac toxicity, this is unlikely to happen with Herceptin, but that will certainly be the goal for other such drugs. And such a strategy, while increasing the market for manufacturers, poses additional challenges for those who pay for health care.

If the main goal of the Canadian Biotechnology Strategy is to generate jobs and goose the economy by encouraging the manufacture and sale of profitable new

treatments, Herceptin sets a positive precedent for gene therapies to come. From the standpoint of provincial treasuries, however, the high cost of Herceptin is clearly a problem.

Advocacy

From an advocacy standpoint, Herceptin is an interesting test case of the two competing philosophies described in several of the papers included in this volume.³

One can look at Herceptin as a possible breakthrough that provides sick women with a new choice, and stimulates the economy at the same time. Or one can look at Herceptin as the latest chapter in an old story, the focus on downstream solutions to cancer, while the upstream, causal factors are ignored. One can question the ethics of a system designed to spin enormous private profits from the genetic information provided by dying women praying for a few extra months of life.

Already, the cancer drug pricing issue has fostered some strategic alliances. In October, McGill medical ethicist Margaret Somerville (1999) published a paper called "The Ethics and law of Access to New Treatments for Cancer." The paper was financed by an educational grant from Bristol-Myers Squibb, the maker of taxol, another expensive cancer treatment with modest benefits for patients. Somerville argues that physicians have a primary obligation of personal care to patients, and that provinces must provide medically necessary treatments as a condition of receiving federal transfer payments. She

³ Herceptin brought other advocacy issues to the fore, including the questions of compassionate access, advocates' involvement in clinical trial recruitment, and fast-tracking of drug approval. These issues are outside the scope of the present paper.

suggests that cancer patients would be on firm ground in suing a provincial government that denied potentially life-saving care. Acknowledging the difficulty this presents for a universal system, she suggests that a parallel, private system in Canada may emerge. "This would change the locus of, but certainly not eliminate, the difficult ethical and legal issues raised by decisions on access to new or emerging treatments for cancer," she concludes.

Somerville also refers to a group of "patients and advocates", "concerned about timely access to new cancer treatments in Canada" who conducted a survey of provincial governments to find out how decisions about access to drugs are made in each province. This group has issued press statements under a number of names, including ACT (Access to Cancer Treatments) and the Cancer Advocacy Coalition of Canada, and its activities are funded by major pharmaceutical companies, including Bristol Myers Squibb. In November, 1999, the group convened a meeting of cancer patients, oncologists, and representatives from cancer agencies, to discuss questions raised in Dr Somerville's report and by their inquiry.

Interestingly, neither Dr. Somerville's paper nor the advocacy group raise the issue of drug pricing although the cost of drugs is clearly the nub of the access problem. Nor are the larger contexts of overall medical care and the environmental and social determinants of health part of their discussions.

Yet surely an ethical analysis must take up the cause of access for all needy patients, not only the privileged. And in considering the ethics of drug access, we also need to address the broader implications of skyrocketing drug costs for overall health care.

Conclusion

Even though Herceptin is beginning to seem like a false start for the new era of genetic therapies, we cannot expect this to always be the case. If the high cost of treatments like Herceptin have the potential to split our universal system into two tiers, it's fair to assume women will be over-represented in the bottom tier. It would be ironic indeed if the very women who come out in such numbers to "run for the cure" and who volunteered for clinical trials, were unable to access not only new genetic therapies, but the hospital beds, nursing care and other health services we take for granted.

As an activist, I see Herceptin as a test case for advocacy in biotech therapy. I am concerned when I see women with breast cancer, funded by industry and describing themselves as advocates, promoting access to new therapies as a right, in isolation from its likely consequences. The environmental movement calls industry-funded groups that present themselves as green lobby groups as "*Astro-turf groups*". What should we call their counterparts in the health field? I suggest we call them "*placebo health groups*" – for sugar-coated advocacy.

We need to be clear about the issue, values and vested interests behind various lobbies. Despite the novel language of biotechnology, the central political questions raised by the herceptin story are familiar to feminists. Drugs have been over-promoted to women before; the issues of rising drug prices and corporate influence on health policy are among the galvanising issues of our age.

What can we do?

The anti-consumerist organisation Adbusters has developed strategies to disrupt the consumer culture, a process its founders call "culture jamming". An example is Buy Nothing Day, their day of

“consumer fasting”. Canada’s biotechnology strategy has been honed to serve a consumerist economy, with no public discussion of the consequences: biotechnology activists need strategies for “genome-jamming”.

What might genome-jammers do?

We could oppose private ownership of genetic material for therapies; these therapies are developed from specimens donated by – or taken from – patients who hope to see treatments developed for the benefit of other cancer suffering individuals, if not themselves.

We could boycott clinical trials by companies that won't agree to price controls, and which maintain secrecy about their true R & D costs.

We could boycott Runs for the Cure, unless sponsoring agencies agree that the money raised be used to finance treatments that would be reasonably priced, and unless the funds are distributed equally to “upstream” disease prevention work.

“Choice” is an illusion if genetic treatments are the only options on the menu; that is, if prevention is excluded from serious discourse; if lower-cost interventions are not even tested; if treatment prices bear no relationship to the true benefit of the intervention for patients.

Treatment choice is also a moot advantage if we fail to provide adequately for the needs of the dying, if our society remains intolerant of people living with disease and its consequences, and if our worldview rejects the inevitability of death.

References

- Bazell, Robert. 1998. *Her-2: the making of Herceptin, a revolutionary treatment for breast cancer*. NY: Random House.
- Cobleigh, Melody et al. 1999. Multinational Study of the Efficacy and Safety of Humanized Anti-HER2 Monoclonal Antibody in Women Who Have HER2-Overexpressing Metastatic Breast Cancer That Has Progressed After Chemotherapy for Metastatic Disease. *Journal of Clinical Oncology*. 17:9, 2639-48.
- Feldman, Arthur et al. 2000. Trastuzumab in the Treatment of Metastatic Breast Cancer: Anticancer Therapy Versus Cardiotoxicity. Editorial. *Circulation*. 102, 272-4.
- Genentech, 2000. Important Drug Warning. May 3. Posted on FDA site: <http://www.fda.gov/medwatch/safety/2000/hercep.htm> (accessed Sept 5, 2000).
- Gottlieb, Scott. Cancer drug may cause heart failure. *British Medical Journal*. 321:259 (29 July)
- Personal Communication. 1999. Letter from Dr Len Walt, Medical Director, Hoffman-La Roche Ltd. (Canada) to a Canadian seeking pre-approval access to Herceptin. (June).
- Schiff, Helen. 2000. Herceptin's Track Record: What does it mean for us?, *Mamm* magazine, January.
- Sibbald, 1999. Making a case for a \$2700-a-month drug. *Canadian Medical Association Journal*. 161:9, 1173.
- Slamon D et al. 1998. Addition of Herceptin (humanized anti-HER2 antibody) to the first line Chemotherapy for HER2 Overexpressing Metastatic Breast Cancer (HER2 + /MBC) Markedly Increases Anticancer Activity: A Randomized Multinational Controlled Phase III Trial. *Proceedings of the American Society of Clinical Oncology* 17:98a (abstr 377).
- Somerville, Margaret. 1999. The Ethics and Law of Access to New Treatments for Cancer. *Current Oncology*. 6:3.
- Zoler, Mitchel. 1999. Two-year Follow-Up Shows Herceptin Ups Survival. *Family Practice News*. V29 (June 15).

Belling the Cat: Learning to know (but not necessarily trust) the new genetics

Patricia Kaufert

About the Author

Patricia Kaufert is a British trained social scientist who did her Ph.D. at the Centre of West African Studies, University of Birmingham. After coming to Canada in 1977, she was retro-fitted as a health researcher, courtesy of a post doctoral fellowship and National Health Research Scholar Award from Health Canada. Her areas of specialty in women's health include menopause, midwifery and mammography. Her most recent interest is in health policy, women and the new genetics. She is a Professor in the Department of Community Health Sciences at the University of Manitoba.

About the Article

To talk about the new genetics, Patricia Kaufert argues, we need not only a new language, but a new way of doing research. This new research approach must respect the fact that our subject manifests itself in a multiplicity of forms, institutions and meanings, and obliges consideration at different levels of analysis. Our research methods must be more than multi-disciplinary, Kaufert writes; "If we are to capture some element of this rapidly changing, chaotic world we ... need an approach more akin to *collage*, allowing for the constant addition of new pieces of information, new actors, new technologies." Kaufert's paper teaches by example. Pursuing an initial review of breast cancer genetics, Kaufert raises questions, and provides insight into women's complex decisions, uncertain medical options, health policy challenges and the connections between research and trans-national profiteering.

Introduction

While preparing what to say at this workshop, I read the papers that the conference organisers had loaded into my e-mail. A diverse, marvelously exciting collection – a series of bright lights shone into the ‘black box’ of biotechnology. They forced me into constantly scrapping what I had written and starting over because a paper, or a combination of papers, had sparked a new idea, suggested a new theme. What I finally wrote was not so much a paper as a series of reflections.

The background papers for the workshop covered the spectrum from micro to macro, from the individual to the community, from society writ large through to microscopy of the individual cell, from biotechnology in medicine to biotechnology in agriculture. Reading them as a package, one switches from the micro level (the women reflecting on the risk of breast cancer in Anne Robertson’s paper) to the meso (Ken Basset’s discussion of the policy issues faced by provincial governments) and then forward to the macro level (the role of the multi-nationals in the agricultural and pharmaceutical industries as discussed by Margaret Eichler and Pat Armstrong).

Trained in different disciplines, the people who wrote these papers brought insights from ethics, history, anthropology, law, the biological sciences, sociology and medicine into their discussion of the new genetics. The challenge for the workshop was to find the connections between these different voices and themes. Yet, the critical importance of the workshop lay also in its representation of so many different perspectives on the new genetics and so many different ways of collecting and collating information and doing research.

I agree very much with Abby Lippman that we need a new language in which to talk

about genetics, but we also need a new form of research. Although there are important exceptions, the primary focus of the social science literature on the new genetics has been on the meaning of genetic testing for the individual tested. Some part of this choice may be dictated by access to research funding, but it also reflects a deep commitment to grounding research on biotechnology in the experience of the individual, particularly the individual woman (Franklin and Ragone 1998). While essential that this type of focused, in depth work continue, there are also many questions about the new genetics, relevant to women, that this type of research cannot answer.

Rayna Rapp recently wrote about the need for research at the place “where the cutting edges of genetic research converge with social policy.” The problem is that this “place” is one of relative chaos, packed with a very disparate array of actors, each with a particular perspective on the new genetics. As a rough list, they include the federal and provincial governments, researchers, family practitioners, geneticists and genetic counselors, research funding agencies, family practitioners, priests and ethicists, families and multinational companies, lawyers and providers of venture capital, Myriad Genetics of Utah, Inc., and public health departments. If we are to capture some element of this rapidly changing, chaotic world we also need an approach more akin to collage, allowing for the constant addition of new pieces of information, new actors, new technologies.

In putting this paper together, I used the background papers, but also drew on a study with Margaret Lock in which we are looking at the process by which a genetic test moves out of the laboratory and into the clinic. In addition, I made use of the bric-a-brac of news and information picked up from the media or the internet, as well as small pieces of academic gossip, books

read, conferences and meetings attended and conversations held. I also drew on my own background and experience in different areas of research on women's health, although the result is best described as idiosyncratic rather than self-reflexive. This is a collage rather than a structured academic paper. It provides very little by way of answers, but raises a lot of questions.

Cassandra(s) and the Information Age

The first of these questions is the product of a sleepless night, the result of talking with Madeline Boscoe and then going back to re-read what Abby Lippman had written. At four o'clock in the morning, I asked myself: "Can we stop it?" "It" being roughly everything that sits under the label 'biotechnology'; "we" being the doubters, the luddites, those sceptical of the promises of the new genetics, the critics and questioners. Reluctantly, my answer had to be "No". Less optimistic of the possibility of revolution than Abby (particularly at four o'clock in the morning), I see the momentum as too advanced, the forces as too strong; the motivators – particularly fear and money – as too powerful. Where does this leave us? Possibly in the role of Cassandra; a set of truth tellers, crying doom, but condemned never to be believed.

Yet, while pessimistic, I do not think that things are altogether dark. There is evidence, admittedly scattered, that some people in some places are making some choices. Companies have 'chosen' not to use genetically modified foods. A number of European countries chose to oppose Canada and the US over the importation of 'Franken' foods. Offered the opportunity, some individuals have 'chosen' not to be screened for genetic diseases. Women are very key to this process as the implementation of many of the new technologies depends on their compliance, whether a willingness to

buy/not-buy genetically modified foods, or to be screened/not screened, or to have their fetus screened/not screened. To make decisions about the new genetics within the terms of their own lives, women need information and they need information of many different sorts in many different forms.

In the sense of being put together from bits and pieces, patched together into a whole fabric, we need research by *bricolage*. As a brief illustration of what this might mean, I have taken a single topic and pursued it across different disciplines and up and down different levels of analysis from micro to meso to macro and back again. There was time and space only to raise questions rather than find answers, but finding answers is not the purpose of the exercise. It is rather to show how the questions change with every boundary crossed, but also how a single question may have multiple answers at many different levels.

Micro: the woman and the prophylactic oophorectomy

My starting point is a prophylactic oophorectomy. Attending a meeting of oncologists, geneticists and genetic counselors last year, I heard some one discuss the advisability of a woman, tested positive for BRCA1, having a prophylactic oophorectomy. Looking back, I am not sure why this shocked me as much as it did, for I was already familiar with the literature on the increased risk of ovarian cancer among women testing positive for BRCA1 and BRCA2. Possibly it was because discussion was about a real body, a real person, rather than part of an academic debate.

Yet, my reaction was partly a product of my work on menopause and my knowledge of that clinical literature. The bilateral oophorectomy, included in that literature as a surgical form of menopause,

is recognized in this literature as having a more severe impact on the body and as producing more severe symptoms than natural menopause. The orthodox clinical response is to put a woman on immediate and long term hormone therapy to control her symptoms, protect her heart and the density of her bones. As a quasi-epidemiologist, the key question for me was whether or not the routine prescription of estrogen therapy would be advisable for a young woman with a genetic predisposition to breast cancer. Yet even as the question was framed in my mind, I knew that not only is no information immediately available, but that it is unlikely to be in the future. For given the current inability to closely monitor the ovaries for the first signs of cancer, it would be unethical to set up a controlled trial in which healthy women with the same genetic test results and the same surgery are randomized to take or not take estrogen. Unfortunately, this is only one of the many questions within the new genetics for which there is no absolute answer.

Still thinking as a quasi-epidemiologist. I wondered also what was the quality of the evidence being used to advise a test-positive woman to have a bilateral oophorectomy? A MEDLINE search produced a small but very recent collection of papers including one on the costs of screening Ashkanazi Jewish women for BRCA1 and BRCA2. Its authors claimed an economic benefit, but only if women who tested positive underwent prophylactic surgery. Reviewing their evidence, this conclusion represented an enormous leap of faith even for a health economist. More cautiously, the Cancer Genetics Study Consortium advised that there was “insufficient evidence to recommend for or against prophylactic oophorectomy as a measure for reducing ovarian cancer risk”, but added that: “Women with BRCA1 mutations should be counseled that this is an option open to them (Burke et al. 1997). The European

Familial Breast Cancer Collaborative Groups came to a very similar conclusion. While conceding that the data were insufficient, they also advised that the prophylactic oophorectomy was “a reasonable option in high risk women”. A third review of essentially the same literature concluded that prophylactic oophorectomy resulted in, at most, small gains in life expectancy (Schrage et al. 1997).

Why would the members of these different study groups and consortia – largely geneticists and oncologists – recommend something for which the epidemiological evidence was weak by their own admission. Broadening the initial MEDLINE search by dropping ‘genetics’ as a key word produced several papers on the use of prophylactic oophorectomy in healthy women with healthy, but postmenopausal, ovaries. Two of the studies in the search reported on reviews of the medical records of women with ovarian cancer to determine if there had been an earlier, but missed, surgical ‘opportunity’ to save them. (The opportunity being the body opened, the uterus removed, the ovaries left in place, but subsequently becoming cancerous.) Another paper, a survey of Irish surgeons, reported that 88% of the participants would remove the post-menopausal ovary. A third paper based on a 1996 survey of gynecological surgeons in Alaska, found that 98% said that their usual practice was to remove apparently normal ovaries in postmenopausal women; 86% said they would perform a prophylactic hysterectomy in women with a strong family history of ovarian cancer regardless of age; 71% would be influenced by a family history of breast cancer.

My naïve assumption that prophylactic oophorectomy had gone out of style was misplaced; it was clearly normative for the majority of the surgeons in the two surveys. Even more interestingly from my perspective, the design of the two medical

record reviews implied that failure to remove was blameworthy. In all of these studies, the underlying model is that the ovaries, seen as likely to go bad, are best removed before they can damage or destroy the whole body. These few papers were also a reminder that the “new” genetics comes into being in the context of “old” medical practice, which includes existing beliefs about heredity and danger, but also this very particular fear of the cancer-prone ovary. The very new contribution of the new genetics lies in being able to test closely related women and determine which ones are vulnerable and which not. The problem is, however, that this information is somewhat in advance of the technological capacity to determine when a predisposition turns into an actual cancer, leaving the prophylactic oophorectomy as still the primary response.

Another part of my reaction, however, was as an anthropologist rather than an epidemiologist and owed something to Terri Kapasalis’ (1997) account of the history of the bilateral oophorectomy. Once known as “Battey’s operation”, practiced on slaves in the American South, it became fashionable in the late nineteenth century as treatment for insanity in women. Although losing favor among psychiatrists, the use of oophorectomy was revived in the 1930s and 1940s by gynecological surgeons, who saw all ovaries as potentially diseased and took pride in removing them whenever possible. The temptation was to write off the incorporation of this surgery into the genetics discourse as another example of the medicalisation of the female body. My problem with this interpretation was that it both cuts off further discussion and turns women into passive victims rather than active figures in the increasingly complex dance that decision making has become in heredity cancer clinics across North America.

In population terms, ovarian cancer is relatively rare, but for the geneticist or oncologist working in the heredity cancer clinic, or for a woman from a family with a history of heredity cancer, it is a common and known risk. They have experiential knowledge, based on actual women with ovarian cancer, patients or family members. Relative to this knowledge, statistical knowledge questioning the quality of the epidemiological evidence in support of a prophylactic oophorectomy will probably seem a relatively meaningless component in the decision making process. Yet, if one moves up a level, from the micro to the meso, to the level of provincial governments and provincial cancer agencies, then this information takes on a new relevance as necessary evidence in health policy decision making. Social scientists, but also bioethicists although in a more abstract sense, have tended to focus at the micro level, the level of the woman and those who meet with her in the clinical encounter, namely the geneticist, the oncologist, the genetic counselor. In the next section, I want to shift to the meso level, focusing initially on just one of these figures, the genetic counselor.

The Clinic, the Government and the Breast Cancer Gene

Seen through the eyes of a woman waiting for her test results, a counselor should be empathic, supportive and able to provide her with the information she needs in language she can understand. Most Canadian women testing positive for BRCA1 or BRCA2 within Canada will have seen a genetic counselor, as their need for counseling is still one of the most taken-for-granted assumptions of the Canadian programs. Some Canadian women have traveled to the United States for testing; their number is unknown and so also is the quality of their counseling care. Women go to the United States usually because they do not meet the strict criteria for testing set

by Canadian centres, or they do not want to wait. When this paper was written (February, 2000), the waiting period to see a genetic counselor in my own province of Manitoba was approximately one year.

The implications of waiting can be studied at the micro-level by talking to the women waiting and their families as was done by Lodder et al. (1999). Alternatively, the analysis can be moved to the meso level and questions formulated at the level of the clinic, the research agency, the provincial ministry of health, and a local cancer foundation or breast cancer support groups. At this level, many of the key questions are framed in terms of traditional health policy issues, such as training, funding, access, cost effectiveness and evidence based decision-making. Other questions, however, have to do with the politics (but also the ethics) of health care delivery.

There is, for example, an international shortage of clinical geneticists and genetic counselors, a reflection of the gap between the rapid expansion in genetic testing and the time needed to train those capable of doing the diagnostic work-up and the counseling. Around the time that testing for BRCA1 was just getting started in 1995, there were only two medical geneticists per million population in the UK and only about a 1000 board-certified genetic counselors in the United States (Reilly 1995). Many of these counselors and geneticists will have trained when the expectation was that they would work within a prenatal screening clinic with very different clients to those seen at a hereditary cancer clinic, a different set of diseases, and very different data on risk and probabilities. How should training change given a rapidly changing knowledge base? How should the numbers in training be increased? Who should pay for this expansion? Counseling has increasingly become the responsibility of obstetricians and family practitioners; most of whom had very little

undergraduate training in genetics and systematic postgraduate training in genetics is even more rare (Harris and Harris 1999). Should the problem of access to counseling be met by 'retro-fitting' other health professionals, not only the family practitioners, obstetricians and oncologists, but also nurses and social workers? Who should pay for further training for these groups? Is one-on-one counseling the best or only way? Would an interactive video serve as a substitute, or supplement to a live counselor as Pershkin and Lerman suggest (1999)?

The issues and the questions are also political. Access to genetic testing and genetic counseling has rarely been evenly distributed across geographical or social space, favoring the white, the urban and the middle class. As discussed in Ken Bassett's paper, so long as the scale has been small and largely invisible outside the amniocentesis or genetics clinics, there has been little concern or protest. Is this likely to change with the expansion of genetic testing into high profile diseases such as breast and ovarian cancer? Already there are rumors of pressures on ministers of health to increase the number of counselors and to expand the number of clinics testing for hereditary cancers.

The list of questions is long, although by no means exhaustive. They are left without answers, as their purpose is to suggest that the questions about the genetic counselor to be asked at the health policy level have a quite different resonance than if asked within the clinic of the woman waiting. Yet, the length of her wait is determined by how these questions are answered. Possibly part of our obligation as latter day Cassandra's is to keep women informed on how health policy in this area is made and implemented.

An equally long, if different set of questions could be generated about the test itself and looking towards the future.

At present, most testing for BRCA1 and BRCA2 in Canada is done in major research laboratories. Who will own the laboratory in which the test is done, pay for its staff and its equipment, as testing becomes a routine clinical service? Will it be the government or the private sector? If genetic testing becomes part of routine clinical service, will it have to be shifted to laboratories licensed by a foreign patent holder? Will government still retain the right to regulate all laboratories in the province, or will the patent holder set standards? Who will set the price of the test and who will pay? Does genetic testing, as some health bureaucrats in some provincial ministries might argue, fall outside the scope of the Canada Health Act? Would making the woman pay fall inside or outside her entitlements under that act? Should we urge women that this is an occasion for political protest and lobbying the politicians for equitable access to testing?

Genetic testing up until mid-1990s has been a cottage industry, a small item on the overall medicare budget line, often part of block grants to departments of pediatrics. Suddenly all this is changing and very rapidly. The 'old' system is still in place for the very rare genetic diseases and for prenatal testing, but the money used in genetic testing for BRCA1 or BRCA2 is more likely to have come out of a research budget, or a line item in the budget of a cancer foundation. This situation clearly cannot last, but how important is it that women understand their options?

What are these options? Answers, self-obvious at the micro-level of the woman being tested, are less clear at the level of government or advocates for women's health? Will the demand for access to genetic testing and counseling for breast and ovarian cancer not only increase, but become a woman's health issue or at least an issue for the breast cancer movement? Yet, health bureaucrats might say that the

evidence of benefit from prophylactic oophorectomy is too weak to justify the use of public monies. While some health activists might question what place genetic testing for ovarian cancer should occupy on a priority list of women's health needs given that current thinking suggests that only 5% of ovarian cancers are genetic in origin?

Macro: Global Companies and Global Politics

Moving from meso to macro, the questions shift from cost to money and profits. This level is occupied by a vast array of speculators, venture capitalists, multinational pharmaceutical companies, universities, biotechnology companies, and different levels of government, all hoping to grow rich or at least financially benefit. Even we benefit, doing research, attending workshop such as this.

The sums involved are quite large; for example, a quick scan of the *Breast Cancer Bulletin* (Summer, 2000) published by the Canadian Breast Cancer Initiative suggests that well over half the award made out of a total of \$14.4 million was spent on some form of genetic research.

Research The connections between the different institutions are also quite tight. Myriad Genetics, the company holding the patent for the BRCA1 and BRCA2 breast and ovarian cancer susceptibility genes, recently made a deal with the National Cancer Institute in the US to do full BRCA testing at a cost of \$1,200 per person, "less than half the commercial costs", but only for researchers funded by NIH. Myriad's own Web site notes that the company has formed strategic alliances with a remarkable list of multinational pharmaceutical companies, including Bayer, Eli Lilly, Hitachi, Pharmacia, Novartis, Roche, Schering AG and Schering-Plough.

Research A small item of news late last year noted that Myriad was trying to move forward its patent claims in the European market. British scientists were furious over Myriad claims to exclusive patent rights to what they saw as their own, British discovered, genetic property, the BRCA2 gene. Myriad countered by questioning the quality of British testing.

An awareness of the history of our health care has perhaps made women more skeptical than men of the bright promises of science. They also have somewhat greater awareness than men that their sicknesses may be profitable to others, but mainly in the form of physician incomes being increased by a little extra surgery, a few more visits. The money to be made in the new genetics is of a quite different order and the mechanics of its making very different to understand.

Conclusion

As the latter-day daughters of Cassandra, our task may be less one of crying doom, but rather one of collecting, sorting, analyzing, critiquing and disseminating information to women. To do this effectively will require a degree of openness to different types of knowledge, a willingness to collaborate across disciplinary boundaries, and the capacity to seek out information from many different sources. It will also require being able to say when a question cannot be answered, because there is no information or the information is inaccessible. The consequences of informing women as health consumers may be as unexpected and radical as learning to read the bible proved to be for the making of the English working class.

References

Franklin S. and Ragone H., (Des) (1998) *Reproducing Reproduction*, University of Pennsylvania Press, Philadelphia

Rayna, R., "Extra chromosomes and blue tulips; medico-familial interpretation". In, *Living and working with new medical technologies: intersections of inquiry*, M. Lock, A. Young and A. Cambrosio (eds) Cambridge University of Press, Cambridge, 184-208.

Grann V., Whang W., Jacobson J. Antman K. Neugut A. (1999) "Benefits and Costs of screening Ashkenazi women for BRCA1 and BRCA2". *Journal of Clinical Oncology* Vol 17, No 2, 494-500

Burke W., Daly M. Garber J., Botkin J. for the Cancer Genetics Studies Consortium (1997) "Recommendations for follow-up care of individuals with an inherited predisposition to cancer: BRCA1 and BRCA2". *Journal of the American Medical Association*, Vol 277, No 12, 997-1003

Vasen H. and the European Familial Breast Cancer Collaborative Group (1998) "Current policies for surveillance and management in women at risk of breast and ovarian cancer". *European Journal of Cancer*, vol 34, no 12, 1922-1926)

Schrag D., Kuntz K., Garber J., and Weeks, J. (2000) "Life expectancy gains from cancer prevention strategies for women with breast cancer and BRCA1 or BRCA2 mutations". *Journal of the American Medical Association*. Vol 283, No 5, 617-624

Rozario D., Brown I., Fung Kee Fung, M., Temple, L. (1997) "Is Incidental prophylactic oophorectomy an acceptable means to reduce the incidence of ovarian cancer". *The American Journal of Surgery*, vol 173, 495-498)

Greary M. Geoghegan A. and Foley M. (1997) "Prevention of ovarian cancer: a survey of the practice of prophylactic oophorectomy by consultant gynecologists in Ireland" *Irish Medical Journal* Vol 90, No 5, 186-187

Conklin B., McGuire, P., Weiler P., Webb D. (1996) "A survey of the practice of prophylactic oophorectomy by gynecologists in the State of Alaska". *Alaska Medicine* April, 71-74

Terri Kapasalis (1997) *Public Privates: performing gynecology from both ends of the speculum*, Duke University Press, Durham and London

Reilly, P. R. (1997) *The Gene Letter* Vol 1, Issue 4

Lodder, L. Frets P., Trijsburg R., Meijers-Heijboer, E., Tibben A., (1999) "Presymptomatic testing for BRCA1 and BRCA2: how distressing are the pre-testing weeks". *Journal of Medical Genetics* Vol 36, No 12, 906-13

Harris, R., Lane B., Williamson P., Dodge J, Modell B. and Alberman, E. (1999) National Confidential enquiry into counselling for genetic disorders by non-geneticists. *British journal of Obstetrics and Gynecology*, Vol 106, 658-663

Pershkin B. and Lerman C. (1999) "Genetic counselling for hereditary breast cancer". *The Lancet* Vol 353, 2176-2177

Breast Cancer Bulletin "More Funds for breast Cancer Research in 2000." (Summer, 2000)

Reynolds J.C. (2000) NCI-Myriad Agreement offers BRCA testing at reduced cost". *Journal of the National Cancer Institute*, Vol. 92, No 8 596-597

<http://www.myriad.com/crp.html>

Ethics and Genetics: The Need for Transparency.

Fern Brunger and Susan M. Cox,

About the Authors

Fern Brunger is a post-doctoral fellow at the Centre for Applied Ethics and the Centre for Health Services and Policy Research. Fern uses the framework of cultural anthropology to understand genomic research, examining the cultural, economic and political contexts in which genomic knowledge is produced and applied. She is primarily interested in how culture and genomic research are mutually defining and transforming. Her current research focuses on the values, interests and practices that shape population-specific genomic research; and how this “culture” of genomic research shapes, and is shaped by, the values, interests and practices of researched communities.

Sue Cox is a post-doctoral fellow at the Centre for Applied Ethics, UBC. Sue has a long-standing interest in the social and ethical dimensions of the new genetics; other research interests include gender and interpersonal communication, and the role of narrative in sociological investigation and ethical analysis. Her work focuses on the moral issues and experiences most salient to individuals and families at risk for adult onset hereditary illness. She emphasizes the value of adopting an interpretive approach to studying hereditary risk within the context of everyday life.

About the Article

Fern Brunger and Sue Cox remind researchers to be aware of the social location of their own criticisms. “Political, economic and cultural contexts not only shape the production of biotechnology knowledge,” they write; “they also shape how critiques of biotechnology are produced and applied.” Observing their own advice to be transparent about the motivations behind research agendas, Brunger and Cox outline two research priorities which are intended as contributions to a strategy for building broader public debate. First, they argue that “everyday meanings and experiences” in the encounter between patients/consumers and biotechnologies must be attended to. Second, they recommend a way to move beyond the limitations of individual consent or group consent in research decision-making - through a process of collective negotiation.

Introduction

The production of genomic/ genetic knowledge occurs within political, economic, and cultural contexts, and in turn reshapes those contexts (Brunger and Bassett, 1998). As the lines between science, industry, and government (as well as patients, subjects, and consumers) are becoming increasingly blurred, it becomes more and more difficult to devise a research strategy that will promote public reflection on the range of effects that seemingly beneficent technologies may have on individuals, communities, and society. How can we best ensure that typically silenced voices are actively engaged in debate in ways that promote accountability and transparency of science/ industry to the public?

Political, economic and cultural contexts not only shape the production of biotechnology knowledge and its application; they also shape how critiques of biotechnology are produced and applied. The beliefs, values, and norms of academic critics, no less than industry/ science, necessarily advance specific perspectives, valorizing some voices and not others. Given that research funding within the social sciences is increasingly linked to industry- and/ or community-alliances, we must be absolutely vigilant about transparency, conflict of interest and perceptions of conflict of interest. In other words, deciding on strategies and setting research agendas is a situated activity and it is therefore not a value-neutral activity. There is an "agenda" just as the word suggests. Thus it also follows that we ought to make explicit the values, economic incentives, and relations of power which shape and guide our prioritization of particular research areas or 'agendas'.

If we reject the notion that genetics has one correct model of risk and reality that the lay people are deficient in, then we

must also reject the notion that academics have a privileged way of understanding the potential effects of biotechnology on the lives of individuals and communities. Lay knowledge and understanding is a legitimate and specialized means of making sense of the world; it is in this sense never incorrect. It may be inconsistent with other forms of knowledge but it is never "wrong". For example, women asking for increased access to genetic testing for breast cancer may promote geneticization in a way that is counter to prevailing feminist critiques of biotechnology, but the perspectives and experiences of such women should inform our understanding of geneticization, and not be dismissed as naïve or the effects of false consciousness. Following from this, we recognize that as academics whose research focuses on the ethical and social effects of new health technologies, we have a moral obligation to be explicit about the values and contexts that shape our research; to engage the public in debate around our research and its conclusions; and to ensure that our research agendas do not inadvertently silence important voices.

What follows is a description of the research 'agendas' that we have been and wish to continue advancing. These agendas involve collaborating with communities to strategize for change in a way that privileges the knowledge of individuals in the everyday context.

1. Engaging with patients/ "consumers"¹

¹The following is based on issues raised in a research project on "Ethical and Moral Dimensions of Genetic Risk: Huntington Disease and Breast/Ovarian Cancer Experiences" (Burgess, Cox, and D'agincourt-Canning); and in a project on "The Social Construction and Clinical Management of the Hereditary Aspects of Autosomal Dominant Polycystic Kidney Disease (Starzomski, Cox

It is crucial for feminists and activists critiquing the biotech industry to continue to focus on the political, economic and social contexts shaping the production, application and distribution of genomic/genetic knowledge. However, it is equally important to not lose sight of how the understanding and use of genomic/genetic knowledge both shapes and is (re)shaped by individual fear and suffering within families and communities (Cox and McKellin 1999; Cox 1999). This entails learning how genetic information is understood, used, resisted, and reshaped by patients/ consumers and moreover, how this in turn shapes and transforms our understandings of the process of geneticization. Research must therefore include examinations of the moral issues and experiences most salient to individuals and families who are the potential or actual patients/ consumers of genetic services. This includes learning how the everyday meanings and experiences of those at risk shape their decisions to be or not be tested; and how their experiences and decisions work to promote or reshape geneticization.

An emphasis on everyday meanings and experiences around the use or non-use of genetic services by potential or actual consumers continues to provide an important counter to clinically-based studies which typically employ a battery of psychosocial questionnaires; it also offsets bioethics' traditional concern with assisting clinicians in determining their ethical responsibilities vis a vis other patients. Research to date has almost exclusively studied the social and familial effects of genetic testing as a clinical medical event, emphasising ethical issues that raise problems for the delivery of services to individual participants in genetic testing. We direct attention toward the non-clinical understandings of, and effects of, genetic testing in relation to everyday ideas about

and Cameron).

heredity and familial or ethnic identity in the community setting.

2. Engaging with communities/ "subjects"²

Genomic/ genetic research poses complex issues of consent, banking, sharing of data, recruitment, negotiating with specific communities, and intellectual property arrangements. Some of the ethical concerns biotechnology raises for communities, such as biopiracy in relation to community DNA banking, insurance discrimination related to ethnicity-based genetic testing, and concerns about the use of linked data bases to identify social risk factors such as sexual preference or workplace environment, fall outside of the scope of the traditional ethics review process. These broader concerns involve risks to non-participants in the research. The effects of genomic/ genetic research on groups, that is, on those who do not participate in research but are affected by it, requires an assessment of whether harms to non-participants are justified.

Traditionally in research ethics, individual consent suffices. Informed consent is the cornerstone of contemporary research ethics with its historical roots in Western scientific medicine and liberal theory (Beauchamp and Faden 1986). In this tradition, the collective good that is likely to follow medical research cannot alone justify the risks to individual participants. Rather, individual participants must knowingly accept the risks to them of participation in specific research projects.

Informed consent does not work for authorizing the effects of research on groups. Some have suggested expanding the notion of consent to include group

²The following is based on issues raised in a research project on "Culture, ethnicity, and genetic testing" (Brunger, Burgess) and in Burgess and Brunger, in press.

“consent” (e.g. Weijer et al 1999). That approach, however, raises complex issues around representation and relations of power: Who represents the group?

Paternalism – which is explicitly rejected and avoided through the mechanism of individual consent – is inevitable when authorizing the effects of research on groups, since someone has to speak for the group.

Understanding the effects of research on a group, and decisions about whether research is acceptable to a group, must be based on a carefully negotiated understanding of diverse values and beliefs within the group; and this information must be understood in the context of relations of power within and between groups (Burgess and Brunger in press). This negotiation, to be genuine, must be conducted in ways that do not overextend the authority of researchers, group leaders, or ethics review boards. Where possible, community-based research should be conducted with, rather than “on”, community members, to enable community members to help direct research objectives and goals, to shape research design and implementation, and to participate in the dissemination of research findings.

Summary

Our research strategy for identifying and managing ethical issues raised by biotechnology is to begin by learning how individuals as “subjects” and “consumers” are being shaped by, and also shaping, geneticization. This entails emphasizing the values and beliefs which shape the production of genomic/ genetic knowledge (e.g., the relationships between science, industry, and government); and how this “culture” of science affects, and is affected by, the experiences of families and communities. This background understanding of the everyday meanings around biotechnology within the context of

family and community life is, for us, an important step to knowing what kind of research agenda to set.

Our goal is to not arrive at answers to questions about the effects that the biotech industry may have on families or communities. It is, rather to come up with a strategy for widening the space of public debate in a way that:

(1) provides the public with information about the production, distribution and application of genetic knowledge;

(2) legitimizes lay knowledge;

(3) attends to a multiplicity of voices;

(4) welcomes dissent as a sign that all voices are being attended to;

(5) allows the debate to be transparent and public; and

(6) promotes the accountability of government/ industry/ science to the public.

References

- Brunger F. and Bassett K. 1998. Culture, ethnicity and genetic testing. In BM Knoppers, ed. *Socio-Ethical Issues in Human Genetics*. Les Editions Yvon Blais Inc. 7-42.
- Beauchamp T.L., Faden R.R. 1986. Informed consent: II. Meaning and elements of informed consent. In Reich W.T., Faden, R.R. and Beauchamp, T.L. eds. *A History and Theory of informed Consent*. New York: Oxford University Press.
- Burgess M. and Brunger F. in press. Negotiating the collective acceptability of health research. in M. McDonald, ed. *The Governance of Health Research with Human Subjects*, Report produced for the Law Commission of Canada.
- Cox, Susan M. and McKellin, William H. 1999. 'There's This Thing in Our Family': Predictive Testing and the Social Construction of Risk for Huntington Disease. In Peter Conrad & Jonathan Gabe. eds. *Sociological Perspectives on the New Genetics* (pp. 121-45). Oxford: Blackwell Publishers.
- Cox, Susan M. 1999. "It's Not a Secret But..." Predictive Testing and Patterns of Communication about Genetic Information in Families At Risk for Huntington Disease. Doctoral Dissertation, University of British Columbia.
- Weijer, C, Goldsand, G and Emanuel, EJ. 1999. Protecting communities in research: current guidelines and limits of extrapolation. *Nature Genetics*, vol 23, (November): 275.

Geneticization and the Canadian Biotechnology Strategy:

The Marketing of Women's Health

Abby Lippman

About the Author

Abby Lippman divides her life between academia and activism, teaching and doing research (McGill University, Epidemiology and Biostatistics), and devoting long hours to extensive community work (provincially and nationally). A long-time feminist critic of genetic and reproductive technologies and of "geneticization," she's been a member of national and international groups that deal with social justice issues related to women's health. Despite a quarter century of living in Montréal, Abby has yet to speak English and French without a Brooklyn accent.

About the Article

"Genetics," "gender" and "choice" have all become mantra words, and in her work, Abby Lippman raises concerns about how these terms are used, if not manipulated, with respect to women's health. Thus, "genes," she writes, "may have something to do with disease, but they certainly have little to do with women's HEALTH." And in her piece, Lippman examines the consequences of applying the qualifier "genetic" to health and to health care. She raises similar questions about the effects of identifying certain health matters as being about gender, as distinct from sex, pointing out how the increasing marketing of, and markets for, genetics and women's health, constantly twist the meaning of these words as well as co-opt the concept of "choice."

Introduction

The Canadian Biotechnology Strategy is an expression of what I have called the process/ideology of geneticization (Lippman 1991).¹ The CBS, in the name of health and health care, and with the goal of national economic growth, is geared to support the "translation" of basic genetic research into such "choices" as genetic testing, genetically engineered drug design (e.g., "pharming" and "designer" drugs), genetically engineered animal organs for human transplantation, and gene "therapy." In fact, the CBS is rationalized, in large part, on the promise of increasing women's choices with respect to health and health care. In what follows, I will focus on the issues of "choice" and geneticization, making some general remarks about each and proposing how some of the dangers to women's health embedded in them might be approached.²

Marketing (multiple) choice(s).

With health and economic policies merging in the politics of neoliberalism, and with health (care) seen as a source of economic development, increasing the choices women have is becoming a major way to stimulate the economy. As a consequence, feminist objectives for

¹ Geneticization refers to the increasing tendencies to make distinctions between people on the basis of what one believes are genetic differences, to view most disorders, behaviors and physiological variations as determined (wholly or in part) by genes, and as I have defined and use the term, comprises ways both of thinking and of doing, applying genetic technologies to diagnose, treat and categorize conditions previously identified in other ways.

² More detailed examinations of choice and of geneticization can be found in a recently published paper, from which sections of this text have borrowed heavily: Lippman A. 1999.

health, and the principle of choice that women introduced into the health care arena as essential for our well-being, are being appropriated by politicians and industry and turned into an array of biomedical options for us to use or undergo. Industry is encouraged (even subsidized with public funds) to develop, market and sell us choices in the form of new drugs, new technologies and new programs which, among other things, can not only identify our health risks, but also provide ways to manage them. And, with risk increasingly the lens through which choice is filtered – "you are at risk for...; you can choose to do/undergo/... to manage it" – a dangerous synergy between a "tyranny of risk" (Lupton 1995) and what has become a "tyranny of choice" is catalyzed.

Clearly, this market-driven approach to health (care) co-opts and manipulates concepts of choice to rationalize industry-driven health goals. It also enables the accelerating transfer of health financing and services (in Canada and elsewhere) from the public to the private sector in the search for cost-containment (governments) and profit (industry).

More and more, women's demands for choice in how our health is promoted/protected, and in how (and what) care is available when we need it, are being answered in the form of various (multiple choice) biotech-based menus. These list options from which individuals are supposed to make selections for personal curative medical care and preventive risk management (with the selections often unattractive – and almost certainly not equally accessible to all women).

For instance, in response to demands for healthy pregnancies and healthy babies, women are offered a gamut of prenatal tests. In response to demands for safer, cleaner environments from which carcinogenic materials are removed to

protect our health, we are offered costly procedures that will screen us for DNA patterns thought to be associated with an increased risk of developing breast cancer, as well as with "prophylactic" mastectomies, or expensive drugs (of unproven safety) alleged to prevent breast cancer (Batt 1994). The huge growth of the commercial, for-profit health information industry (Minkler 1989), which produces books, magazines, websites and packaged exercise programs to educate us, as well as the boom in computer/informatics technologies to identify "manageable" risks and monitor our health and health care (for example, algorithms to assess a woman's risk of breast cancer), result in still further options for us. But the choices thereby manufactured do not promote our health, ensure social justice, and support a holistic view of women's health. Rather, these "choices" are evidence of the marketability of women's health issues and concerns, produced primarily for political/ economic reasons and private profit.

This commercial – and downstream – response to women's demands (for choices), articulated both implicitly and explicitly in the CBS, fails to address the kind of choice in health care women have fought for, and certainly does not meet our demands for the powers we need to choose and to protect our health. With industry increasingly portraying itself as responding to women's needs when it offers multiple choices for our self-improvement, health promotion becomes more of a product (i.e., objects, programs, devices, etc. we can buy) than a goal (Milio 1988). Even more, rather than supporting structural changes that will lead to improved health, the language of health promotion is employed to justify the further development of more technological and pharmaceutical options, more sources of information on health and so-called life-style, and more wellness programs for us to purchase.

This market approach reinforces libertarian self-reliance without promoting true self-determination and choice. Worse, it serves to privatize want: 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 women truly need. These include the resources (financial, social, supportive) that would allow a woman to mother a child with Down syndrome; the guarantees that the water we drink is not polluted with harmful chemicals or bacteria. Downstream choices (menus) of biologically-tailored drugs are insufficient; the upstream availability of safe jobs, clean environments, safe contraceptives and women-friendly work schedules are needed for avoiding known risks to health and preventing the disorders the drugs are created to treat.

The manufacture and manipulation of "choice" as a tool to commercialize and further privatize health (care) presents special risks for women insofar as options are construed as gender related. Thus, the commercial value in the (belated) recognition by researchers and industry that "women are not small men" is vast. It is, perhaps, but a further stage in the "corporatization of medicine" that Starr (1982) described almost 20 years ago, wherein health problems are seen as good for business and economic growth. Today, specific attention to women and their medical risks and alleged needs for medication creates a niche market with lucrative potential; new commercial projects to develop female-specific product lines in health businesses turn chronic conditions into investment opportunities (Fuller 1998), with women's health problems (e.g., osteoporosis, menopause, depression, fertility/ infertility in particular) among those likely to have the best return on their investments (into research and production of new drugs, new diagnostic technologies, DNA markers of susceptibility, new food products).

This commercial application of “gender awareness” to justify female-specific health product development for the marketplace is a dangerously reductive view of women's health needs. It helps to hide, if not perpetuate, the many differences between women and the origins of health problems in inequitable social/ political/ economic arrangements, with this most recently exemplified, in Canada, with the newly begun marketing of women-specific cancer insurance policies.

In co-opting women's demands for empowerment, for choice, and for gender-based care, research and policy, governments (as in the CBS) and the private sector are playing on our reasonable fears of paternalism, overmedicalization and exclusion. Furthermore, the current dominance of economic conceptions of health and health care displace/ manipulate feminists' perceptions of these as having primarily social, political, and economic determinants. This makes it imperative to be wary whenever "choice" is offered to us as a solution to women's health concerns. To re-establish choice in women's terms, to put choice in women's hands, means not to focus on how to give women responsibility for their health, through the creation of multiple options, as the CBS would have it, but on how to ensure all women can be "response-able."³

To see how this might be operationalized, how women could become able to make the responses and choices they want for themselves, consider, for an example, prenatal screening and testing. Why not require that for every government dollar spent for these programs, \$10, \$100,

\$1000 or more must be spent for the children and their families living with the condition for which testing is offered? This might help make refusing prenatal testing as much a choice as accepting it appears to be. As well, it might give community groups and disability activists the resources they need to develop material about the conditions for which genetic testing is offered, to counter the stories coming from the biomedical world, thereby helping to ensure that women's choices can be truly informed.

Further, why not insist that companies developing screening tests (or expensive medicines) for something that ails us apply some of the profits from their sales of these products towards addressing the social determinants of women's ill health. A formal "tithing" system, with money deposited into a blind trust to be used to care for those for whose disease one seeks a DNA association, might be another approach. And to give such policies "clout," companies that contribute could perhaps be offered some tax advantage, with those refusing heavily penalized.

As another policy, why not insist that "charitable" status be granted to groups and organizations that advocate for change rather than allow this privilege only for those that "pick up the pieces" of harmful government policies. And in place of "stakeholders" setting the policy agenda for women's health and genetic and other biotechnologies, why not insist on more participatory democratic approaches (e.g., citizen juries, consensus conferences) and engage in more discursive processes (Davidson et al 1997) to debate and decide on the choices we want for ourselves and our communities.

Geneticization.

Geneticization is as much implicit as it is explicit in the CBS, and it is at odds with

³. Insofar as “response-able” refers to what a person is enabled to do, it embodies feminist principles and avoids the potential for victim-blaming contained within the sound-alike term, “responsible.”

the concepts of health and health promotion as understood by the women's health movements and other social justice seeking groups. Regrettably, however, most of the critiques of the "new" genetics have concentrated on the potentially harmful consequences of using the information that genetic (mapping, testing, screening) projects will provide, and on how the undesirable effects can be (must be) controlled. In general, the "problems" investigated are sequestered for analysis in "ELSI"⁴ projects that deal with a variety of ethical, legal and social issues related to human genetics. The existence of these projects suggests that by understanding these problems, by maintaining specific rules and regulations, and by adhering to standard ethical principles, we can avoid the undesired consequences. But this downstream, managerial approach is grossly insufficient, and perhaps even irrelevant.

To begin, the majority of these critiques tend, themselves, to be based on reductionist thinking. They also legitimize the very assumptions of essentialism and determinism that they would otherwise fault. Putting aside the need to distinguish, when appropriate, between essentialism, reductionism and determinism, it nevertheless remains insufficient to restrict analysis of geneticization to psychological, legal and ethical consequences and their management, and to base regulatory proposals on misconceptions of what genes do (see, for comparison, Caulfield 2000). Though necessary, these critiques are not sufficient; they are certainly not primary. They appear to take further development and use of genetic technology, and of geneticization, as faits accomplis, and to perpetuate artificial distinctions between means and ends, between effects and side-effects, between use and mis-use. They ignore how geneticization is a new way of thinking

⁴. ELSI is the acronym for Ethical, Legal and Social Issues.

even more than a new way of doing. Thus, even when the hyperbolic claims made for genetics are shown to be unsubstantiated, the tendency to see "genes as the answer" persists.

Prevalent "ELSI-type" assessments of developments in applied genetics continue to privilege liberal individualism, and the latter, as Susan Wolf (1996) underlines, mostly preserves those with power in society. These assessments also gloss over the importance of group membership, isolating processes, techniques, and services from societal trends (e.g., privatization, commercialization, globalization, etc.) in which they are embedded. Clearly, more fundamental analyses of geneticization – social evaluations in particular – are required to clarify if "responsible genetics" is an oxymoron, or if it can actually be practiced (Vandelac, Lippman 1991). And new, imaginative ways to assess geneticization, fresh metaphors for speaking and writing about things genetic, are urgently needed if we are to begin these.

There are no detailed recipes for how we might do these analyses or reframe our thinking, but there are some practical things we might consider. To start, if health (and not the elimination of disease and disability) is our societal goal, collective approaches might be better than individualized ones. If we want "genetic responsibility," might it not be more efficient to reverse the usual order of subject and object and make society, rather than the individual, accountable for protecting our genetic "heritage." This kind of approach would lead to such things as supporting serious efforts to remove known mutagens from the workplace, renovating substandard housing to remove lead-based paint, and demanding limits on agribusiness, rather than to screening for and then removing or vaccinating "susceptible" workers or children. Screening for situations "of risk" seems far more sensible – and far more equitable as

corrective justice – than screening for persons "at risk."

Risk situations, even more than genetic risks, are not equally distributed. Moreover, the likely synergy between physical and chemical risks, and the unequal distribution of the determinants of health, may necessarily increase the exposure of some groups of women (e.g., underemployment → work in a bar → exposure to second-hand smoke; poverty → decreased resources for organic food → increased pesticide exposure; racism → ghetto-ized housing → increased exposure to toxic dump sites).

Geneticization, and the CBS of which it is an expression, are pushed not only by people claiming to do good, but also by those with corporate interests and eugenic idea(l)s. Geneticization is advanced by people who seek financial gain by doing – or underwriting – genetics: governments and corporations, and also the media which use "human interest" stories, supposedly involving genetics, to sell their papers and programs. Justifying mapping the genome as the way to improve health, and to provide medical cures, is doubtless productive for molecular geneticists, pharmaceutical companies, manufacturers of laboratory equipment, insurance companies, police forces, genetic engineers and health ministers, among others. But seeing things this way closes the debate, suggesting we need only regulate the "costs" (albeit broadly defined in ethical, legal and social terms) of genetics to obtain all the benefits. It is to overlook how costs and benefits are *not* distributed to the same groups, and how risk management, as "exposure," is clearly gendered. Moreover, more than costs and benefits (economic and otherwise) are involved in assessing the genetic approach. It may be ethical – "cost-beneficial" in some currency – but still dangerous to women's health. The genetic perspective itself, and not just its consequences, is problematic.

Therefore, we need to change critical strategies and go to the source, to question the very ways geneticization frames our thinking about such things as similarities, differences, health, illness, social justice and what it takes to have a good life. We need not only to understand – and underscore – the biological limits of what a gene is and can do but, even more, to devise ways to approach genetics/geneticization that may help us reclaim our rights as citizens for health and health promotion.

One way to begin might be to delete the word "health," a holistic term, when we really mean the absence of disease, and to reject the notion that there is something usefully called "genetic health." Not only are we unlikely ever to reach consensus about its meaning, but trying to do so may be a distraction. Genes may have something to do with disease, but they certainly have little if anything of relevance to women's *health*. In a similar vein, we could insist on a research agenda in which it is assumed that biological conditions have social explanations and actively search for and invest in these. After all, one can as reasonably link housing conditions and osteoporosis, racism and cardiovascular disease, ageism and hip fracture, pet ownership and hypertension, as one can link DNA patterns to these conditions. Let's make these findings media friendly so that they become the banner headlines of newspapers.

Next, let's make it a practice to ask, whenever we see the word "genetic" used as an adjective, "why?" What is gained and what is lost, and by whom, by this qualification of some test, disease, diagnosis. Similarly, let's ask, whenever we see "autonomy" advanced as the basis for ethical analysis, whether individual choice or a richer concept is meant. Adopting Sherwin's (1998) relational notion of autonomy would at the least remind us that the notion of genetic

"response-ability," what a person is enabled to do, is at least as important as the notion of genetic "responsibility," that which those with power must assume.

For some final suggestions, let me invoke the concept of justice. If we assume that justice is simultaneously intragenerational and intergenerational, and not think of it merely as the principle for providing equal access to some service, we might begin to view health as a general (social) benefit, not as a commodity to be bought and sold in the marketplace. Thus viewed, our health policies would, contrary to the CBS, focus on such things as income-redistribution, employment programs, neighborhood revitalization, trade agreements and global corporations. Similarly, we might see social determinants of health (poverty, racism, illiteracy, etc.) NOT as barriers for an individual to overcome but, instead, as objectives for social/ societal change. Going further, we might recognize a need to redistribute health equitably, with the consequence that some of us, the more privileged today, may have to give up some of our alleged benefits (use of high-tech genetics, for example) to ensure that others share equally in the resources needed for health, even perhaps requiring programs of affirmative action as necessary to correct past injustices locally and globally.

In this regard, "responsible genetics" ("responsible biotechnology") might at the outset be defined as a policy which acknowledges that we can't afford, either economically or socially, the most recent high-tech approach to disease(s). It would favor a long-term sustainable approach that gives priority to problems in proportion to their importance in causing (or resulting from) ill health and disability (see, for comparison, the African American manifesto about limiting genomic sampling until there is improvement in the health and education services to the community: Jackson 1997). Following this policy (and

again adopting from Sue Sherwin 1992), only technologies which do not, in their application, feed into oppressive circumstances (for groups without power) would be considered for research and development, with only those that foster the interests of un(der)privileged groups in society admissible in practice. Thus, a prerequisite for setting up any prenatal diagnosis program would be the guaranteed provision of adequate, sensitive and baseline prenatal care for all. No "new" technologies/ programs/ services would be introduced for some women until a basic level of care was assured for all women. Similarly, a new technology or a new application of an old technology (e.g., prenatal diagnosis) might be considered for provisional use, but only if it was demonstrably a resource to respond to a situation for which no other solution was thinkable, for which no other way to resolve the particular problem could be imagined (e.g., prenatal diagnosis for Tay Sachs disease if painful death is unavoidable for a child with this condition). And, while I once proposed doing health impact assessments before the introduction of – even before supporting the research for – a genetic or reproductive technology, I would now suggest what Labonte (1999) calls a "health inequity impact assessment": will use of this technology, will geneticization, however defined, decrease health inequities, especially those inequities between and among women (rich and poor, in the North and the South). Instead of ELSI analyses, we need "ELSocJust" studies; beyond ethical, legal and social issues, we must also consider social justice issues.

Geneticization might possibly contribute to the solution of some "problems" of disease, it might even contribute to the decrease of inequities downstream (a possible example being the development of medications for infectious diseases based on knowledge of the DNA of the organism), but we can't assess this yet –

and seem far from it. But, do we want to intervene only downstream? Because I don't believe doing so will either conform to feminist principles of social justice or address the many and varying women's health needs and problems, I suggest that we look upstream and first unpack the problems whose solution is framed through the lenses of biotechnology and

geneticization. Does either the definition of a "problem" or the response to it in technological terms lead to a better solution for everyone than we might devise if we asked why there was a problem in the first place? Whenever genes (or biotechnology) are said to be "the answer," we must immediately ask: what is the question? And who is talking.

References:

- Batt S. 1994. *Patient no more: The politics of breast cancer*. Charlottetown PEI: Gynergy.
- Caulfield T. 2000. Underwhelmed: Hyperbole, regulatory policy and the genetic revolution. *McGill Law Journal*, 45 (2): 437-480.
- Davison A, Barnes I, Schibeci R. 1997. Problematic politics: a critical review of surveys of public attitudes to biotechnology. *Science, technology and human values* 22: 317-348.
- Fuller C. 1998. *Caring for Profit*. Vancouver: New Star Books and the CCPA.
- Jackson F. 1997. Assessing the human genome project: An African American and bioanthropological critique. In *Plain talk about the human genome project*, Smith E, Sapp W (eds), Tuskegee: Tuskegee U, 95-103.
- Labonte R. 1999. Some Comments on the Acheson report. *Critical Public Health* 9(2): 171-174.
- Lippman A. 1999. Choice as a risk to women's health. *Health, Risk and Society* 1 (3): 281-291.
- Lippman, A. 1991. Prenatal genetic testing and screening: Constructing needs and reinforcing inequities. *American Journal of Law and Medicine*, 17:15-50.
- Lupton D. 1995. *The Imperative of Health: Public health and the regulated body*. Thousand Oaks Calif: Sage Publications.
- Minkler M. 1989. Health education, health promotion and the open society: an historical perspective, *Health Education Quarterly* 16:17-30.
- Milio N. 1988. The profitization of health promotion. *International Journal of Health Services* 18 (4): 573-585.
- Sherwin S. 1992. *No longer patient: Feminist ethics and health care*. Philadelphia: Temple U Press.
- Sherwin S. 1998. A relational approach to autonomy in health care. In *The politics of women's health: Exploring agency and autonomy*, Philadelphia: Temple U Press, 19-47.

Starr P. 1982. *The social transformation of American medicine*. NY: Cambridge U Press.

Vandelac L, Lippman A. 1991. Cartographie et séquençage du génome humain: Questions d'éthique et d'évaluation sociale des technologies. Dans *Le génome humain*, Melançon M, Lambert RD (eds), Laval: Les Presses de l'université Laval, pp 83-97.

Wolf SM. 1996. Erasing difference: Race, ethnicity and gender in bioethics. In Donchin A, Purdy LM (eds) *Embodying bioethics: Recent feminist advances*, Lanham MD: Rowmann & Littlefield, 65-81.

What's So New about the "New Genetics"?: Genetic Counselling and the Medical Management of "Genetic" Information

Fiona Alice Miller

About the Author

Fiona Miller is a postdoctoral fellow in the Centre for Health Economics and Policy Analysis at McMaster University. She has been a member of the Working Group on Women, Health and the New Genetics since its inception. Her vantage point on the place of biotechnology in medicine and health care is two-fold: she is an historian of 20th century science and medicine whose chief research interest is medical genetics; and, she has been a participant in the women's health movement with a particular concern for reproductive and genetic technologies.

About the Article

Fiona Miller argues that genetic information has been, and will continue to be, the chief product of the biotechnological "revolution" in medicine. While the quantity of this information is certainly growing, there is, she argues, little that is fundamentally "new" about such an approach. Given the non-revolutionary nature of much of the "new genetics," Miller suggests that insight can be gleaned from an examination of its history and she offers a review of genetic counselling practices, practitioners and disease scope. Miller's review suggests that new technologies are unlikely to be the sole determinants of the use of genetic information, and of changes in the health care system which result from their use. Equally influential will be negotiations over the medical control of genetic counselling practices, and the malleable and potentially expansive ways of defining genetic disease. She adds that since women's lives and feminist politics have played such a complex role in the histories of genetic medicine and genetic counselling, a gender-neutral analysis is unlikely to prove fruitful in the future.

Introduction

“Health” constitutes one of the principal industrial opportunities under the Canadian Biotechnology Strategy (CBS). While a range of products are being sold under this heading – vaccines, biologics, biopharmaceuticals – a key product continues to be genetic tests, tests which provide information which is predictive, to a greater or lesser extent, of specified disease outcomes. Indeed, such tests are expected to proliferate. Reading through current medical and biomedical journals, one is struck by the assumption that the Human Genome Project heralds an era of widespread molecular genetic tests, predicting both Mendelian diseases, and those diseases in which genetic factors may play some ‘pre-disposing’ role (e.g. SACGT 1999). Insofar as genetic biotechnology promises a revolution in medicine, it promises a revolution in the availability of genetic information. Therapeutic capacity, when discussed, is generally acknowledged to lag far behind diagnostic capacity (the ‘therapeutic gap’). For the foreseeable future, and for most people, genetic medicine is principally about genetic information.

As an historian, what is especially striking to me about expectations for the future of genetic medicine is how non-futuristic they seem. In this paper, I suggest that the recent history of efforts to gather, interpret and deal with genetic information concerning health, disease and disability – a process we can abbreviate by the phrase “genetic counselling” – can tell us quite a bit about current and future practices. At the least, it can shed light on what the real “drivers” of change are. For while proponents of biotechnology in health care would have us believe that a revolution is upon us, and that this revolution is a direct product of new scientific and technical capacity, I would argue that there is both more and less to the story.

In this paper, I tell four over-lapping historical stories about genetic counselling. The first history sets out the basic chronology since the Second World War, the second story adds questions about health and medicine to this narrative, the third interrogates the ‘genetic’ status of these practices, and the fourth story asks questions about women.

Story One: Genetic Counselling

Today, genetic counselling is an acknowledged practice – a key complement to and justification for genetic testing (Task Force 1997). The current state of professional genetic counselling has been developing since the 1940s, when heredity counselling began to take institutional shape in the Euro-American world, and clinics were established in Universities and research hospitals in Canada, the US and the UK.

To a considerable extent, the timing of early developments was a function of shifts within the eugenics movement. As Molly Ladd Taylor has argued, genetic counselling promised a voluntary and individualistic eugenics that dispensed with the older strategy of enjoining members of the middle classes to observe their *duty* toward the race – a strategy which had clearly failed by the late 1930s. Instead, heredity counselling worked to foster middle class *desire*. Its chief advocates promoted a narrative of large, happy families of “normal” children which saw little place for divorce, disability or childlessness (Ladd Taylor 1999). Into the 1960s, with the word ‘eugenics’ not yet a universal term of opprobrium, genetic counselling was frequently discussed as a practical form of eugenics (Paul 1998).

Through the 1950s and 1960s the number and scope of genetic counselling services increased in tandem with the science and

profession of human genetics, which assumed an institutional identity in North America with the founding of the American Society of Human Genetics (ASHG) in 1948. Indeed, genetic counselling should be seen as a defining characteristic of the emerging discipline of medical genetics (then, a sub-field of human genetics), and central to professional identity.

The 1970s brought increased visibility to genetic counselling through the expanded scope made possible by prenatal diagnosis using amniocentesis, and the expanded visibility of genetic science in a decade of highly public efforts at *in vitro* fertilisation, recombinant DNA (cloning DNA), and genetic screening among specified sub-populations (i.e. Ashkenazi Jews for Tay-Sachs disease, African-Americans for Sickle Cell Anemia). As a consequence, this decade witnessed professional innovation and consolidation in genetic counselling practices and practitioners. The post-W.W.II generation of medical geneticists who had pioneered genetic counselling, and repeatedly debated its form and function, set out to clarify the definition of the practice. This new definition, published in 1975, highlighted the centrality of communication, non-directiveness, voluntarism, and the provision of support for decision-making (ASHG 1975).

In many ways, the new definition simply codified existing protocols. But it differed in one important respect from tradition. Where genetic counselling had originally been embedded within the research routine of a professional medical geneticist, the new definition conceived of genetic counselling as a self-contained practice. This shift reflected the fact that, in its success, genetic counselling was expanding beyond the purview of that small band of researchers who had been its pioneers. In fact, the 1970s witnessed the emergence of a new practitioner category which would devote itself exclusively to the now self-contained

practice of genetic counselling. Originally called the 'genetic associate' and soon to be called the 'genetic counsellor,' this new semi-profession involved a Master's level education which mixed scientific knowledge with more formal training in counselling practices (Kenen 1984;1997).

In the 1980s, molecular genetic tests began to be added to the complement of genetic tests already available for genetic counselling. In addition to the predictive or diagnostic information that could be gleaned from family histories and biochemical and cytogenetic (chromosomal) tests, some few rare diseases could be assessed using recombinant DNA technology. It is these molecular genetic tests that are expected to expand so greatly in number, scope and significance in the coming years as a direct consequence of the Human Genome Project and allied research. According to the US Secretary's Advisory Committee on Genetic Testing, which conducted "A Public Consultation on Oversight of Genetic Tests," in the Summer of 2000, genetic testing is clinically available for more than 300 diseases or conditions in the US, and tests are under development for at least 300 more diseases or conditions (1999:5).

Story Two: What's So Medical About Genetic Counselling?

Contemporary discussions of genetic counselling presume the obvious clinical significance of this practice, and the relevance of medical involvement in, and management of, its conduct. Yet the medical status of genetic counselling is a relatively recent and contested phenomenon. This peculiar fact about the history of genetic counselling is very important to the interpretation of its current and future incarnations.

The pioneering band of post-W.W.II medical geneticists who institutionalised

genetic counselling in North America were researchers first and foremost. Many were trained as PhDs, but those who were MDs were (as was not uncommon) working as scientists. Genetic counselling should not properly be called a 'clinical' practice, then. It was an applied form of human genetics, or eugenics. It piggybacked on clinical institutions such as hospitals, and benefited from collaboration with clinicians with the competence to diagnose disease, but was often funded as research, and took much of its justification from its articulation with research projects.

In addition, genetic counselling, as a central component of medical genetics, was distanced from the main traditions in medicine in other ways in the inter-war and early post-W.W.II decades. First, genetic counselling proposed a rather different modality of care than that traditionally advanced by medicine. Rather than treatment, genetic counselling offered reproductive management in light of information about the risk of disease in offspring. Second, genetic counselling proposed rather different protocols of provider-client interaction than medicine: emphasising knowledge transmission and client decision-making, rather than physician decision-making and paternalist models of information management. Finally, in addition to advancing work on Mendelian diseases – diseases that observed simple genetic laws – medical genetics emphasised chronic and congenital conditions with complex systems of causation. In these early years, medical genetics pressed notions of 'pre-disposition' even to infectious diseases – as part of a marginal tradition within academic medicine which resisted the dominance of the 'infectious disease paradigm' with its 'magic bullet,' antibiotic-driven approach. At one of its early annual meetings in 1952, for example, the American Society of Human Genetics sponsored a special symposium on the genetic aspects of resistance to chronic infectious diseases such as pulmonary

tuberculosis, poliomyelitis and rheumatic fever.

The growing acceptance of genetic testing and counselling as aspects of 'health' care since the 1970s can, in part, be attributed to the developing congruence between genetic counselling and new patterns in medicine: the rise of a patients' rights agenda; the emphasis on prevention, especially through lifestyle management; and, growing interest in chronic and congenital disease. But while the success of genetic counselling reflects these elements of conceptual convergence between medical genetics and medicine, it has also been hampered at an organisational level by the outsider-status of genetic counselling within the halls of professional medicine.

In the first instance, professional medical geneticists have faced significant problems in securing funding for, and retaining authority over, genetic counselling. In particular, since many medical geneticists were PhDs rather than physicians, much manoeuvring was required to avoid the strictures of medical specialisation. In Canada, in the 1970s, medical geneticists pursued block-funding of genetic counselling through regionalised centres, rather than a fee-for service system, and they established a national college in 1975 (Canadian College of Medical Geneticists) to provide some system of professional accreditation and allow PhD-trained medical geneticists to provide genetic services.

In the US, medical genetics began the formal process of becoming an acknowledged medical specialty in the early 1990s, with the formation of a College and Board. By the latter-half of the 1990s, this new specialty was able to participate in the funding and practice negotiations of the medical profession. This is an extraordinary medical specialty – one that permits PhD-trained workers to practice clinically. Moreover, genetic

counselling continues to be definitional to the identity of the medical geneticist. Treatment protocols pertaining to genetic disease, or which derive from genetic information, are not managed by medical geneticists but are dispersed among a wide array of medical specialties. The medical genetics specialty continues to be defined by the ability to diagnose and counsel: to procure and manage genetic information in the clinical encounter.

Despite this formal success, the integration of medical genetics within medicine continues to be fraught. PhD medical geneticists are a declining proportion of medical genetics practitioners, as the pioneering pattern of blending research with applied practice passes into memory. Moreover, those medical geneticists who work principally as genetic counsellors (rather than running laboratories, for example) are devalued within the medical profession. Charles Bosk (1992), in his ethnographic study of medically-trained genetic counsellors in a major eastern US city, argued that the devaluation of these practitioners is attributable to their engagement in “social dirty work” (63). In recent decades, then, while the enthusiasm for genetic medicine has increased, the status of genetic counselling has come increasingly into question. A reduced status is exemplified by the rise of the Master’s level trained practitioner, the genetic counsellor. Moreover, there is much interest in routinizing the genetic counselling encounter, and shifting the obligation to primary practitioners, with only complex or highly risky cases referred to specialist practitioners. Specialist genetic counsellors, whether trained at the doctoral or master’s level, are often supportive of such an approach which promises to raise their status. Yet this tiering of genetic counselling, and the successful integration of genetics into medicine upon which it is premised, implies a loss of control by professional

medical geneticists over the protocols which govern genetic counselling.

The recent medicalization of medical genetics – most obvious in calls for standardized medical curricula for genetics – promises to alter both the practices and practitioners of genetic counselling. It is likely that increased medicalization will be an important force for enhanced and more routinized use of genetic information in the clinical encounter. Moreover, medicalization encourages fee-for-service systems of compensation, which are themselves drivers of increased use.

Story Three: What’s so “Genetic” About Genetic Counselling?

Much of the current interest in the expansion and routinization of genetic counselling rests on the belief that, as some enthusiasts put it, “genetic testing will soon become a commonly used tool in primary care practice.” For this to happen, advocates suggest, genetic testing will have to expand beyond its current focus on diagnosing a range of comparatively rare disorders, to test for “genetic predispositions” to various common diseases (Cho et al 1997:314). Testing for such “predispositions” could, at best, provide individuals with complex statistical risk estimates, and would seem to create new dilemmas, as well as new opportunities, for genetic counselling.

Many critics have identified problems with the predisposition approach. Problems stem from the uncertain predictive power of such tests, and thus their potential relevance to significant proportions of the population (Hubbard and Lewontin 1996). Moreover, the genetic predisposition approach gives primacy to genetic forces in systems of multiple causation. Such an approach has been christened “geneticization” by Abby Lippman (1991) and sustains what Dorothy Nelkin and

Susan Lindee (1995) call the “DNA mystique.”

Though divided on the question of merits, both proponents and critics of expanded genetic testing are united in their conviction that the predisposition approach, and the uncertainties involved in such diagnoses, are new. But are they? I would argue that genetic counselling has *consistently* dealt in uncertain predictions and multi-causal conditions. Indeed, it has *grown* by advancing an expansive reading of genetic disease. Early genetic counselling was premised on a slippage between congenital and genetical disease – between genetic disease and birth ‘defect’ – promising to help people “avoid the tragedy of a defective child,” as one popular periodical put it (Katz 1954:32). Moreover, much of the advice provided in the genetic counselling encounter involved statistical risk estimates for conditions for which no obvious Mendelian patterns of transmission were known – for example, cleft lip or palate. Finally, the development and expansion of prenatal diagnosis in the 1970s entrenched the slippage between congenital and genetical. Prenatal diagnosis is, after all, principally concerned with congenital conditions – with problems manifest at birth – however clear the genetic mechanisms of causation may be.

Social historians of medicine have consistently argued that disease identity is never obvious. Instead, disease identity is a contingent product of professional identity, institutional relations, technological capacity and patient experience. Genetic diseases are no different. What gets defined as a genetic disease, and managed by medical geneticists and genetic counsellors, is not pre-determined by technology alone. Over the course of their history, genetic counsellors have expanded their professional standing and medical significance through a form of genetic imperialism, or geneticization. They have

claimed to possess interpretive capacity with respect to a broad spectrum of diseases, and have had to deal in statistical risks concerning predisposition. The genetic status of genetic medicine is contingent and need not be accepted as simply true. New molecular tests for genetic predispositions, which suggest that almost all diseases are *genetic* diseases and can be managed through *genetic* medicine, must be seen, in part, as professional claims-making.

Story Four: Women and Genetic Counselling

Women’s lives, their social roles and feminist politics have intertwined in complex ways with the histories of genetic medicine and genetic counselling. If, as I’ve suggested, genetic counselling has a contingent relationship with medicine, and genetic disease is a malleable concept, then making sense of these historical contingencies requires a gendered analysis.

First, genetic counselling has drawn heavily on women workers. In Canada, the messy and marginal science of human genetics was pioneered in the inter-war and war-time years by workers who were marginalised by their gender. Indeed, the preponderance of women in early human genetics research that was a result of women’s marginality as scientific workers has been influential in ensuring a significant presence of women in the field today. Moreover, as these women worked to promote genetic counselling in Canada in the 1940s and 1950s, they often defended their place in university and hospital communities by suggesting women’s inherent capacity to engage in such work. Women’s sensitivity and communicativeness were advanced as resources in the expansion of genetic counselling.

The gendered social roles drawn upon by pioneering Canadian practitioners, in the 1940s and 1950s, served as a more general resource in the 1960s in the creation of a feminised semi-profession to aid in the genetic counselling encounter. Sarah Lawrence College in the US, originally a women's college, initiated the first Master's level training program for what were then called 'genetic associates' in 1969. In establishing this new semi-profession, its founders sought to service a growing field with scientifically educated women who otherwise had restricted employment opportunities. Over the course of the 1970s, counselling training was added to the curriculum and by the end of the decade the term 'genetic associate' was coming to be replaced by the term 'genetic counsellor.'

Master's level trained genetic counsellors have struggled with the low status and constrained authority that is the corollary of a female-dominated profession. At the same time, this profession has been consistently supportive of a feminist ethos with respect to reproductive rights, voluntarism and decision-making autonomy (Wertz 1997). The challenged status of genetic counselling within medicine is symbolised and sustained by the female dominance of this activity. That genetic counsellors do what Bosk characterises as 'social dirty work' demands investigation as a gendered phenomenon.

In addition to the prevalence of women practitioners in genetic counselling, women have consistently, if only implicitly, been conceived of as the principal objects of such activities. In the early years of genetic counselling, women were positioned as the keepers of family records. They were represented as most likely to know about family patterns of illness and thus were a crucial resource for human geneticists as they reconstructed pedigrees. Women were also deeply implicated by patterns of familial disease,

being responsible for managing the households affected by such ailments. Moreover, enduring patterns of maternal blame have been reproduced in genetic counselling discussions, notably through women's responsibility for disabilities associated with 'late' maternal age and for X-linked diseases. Long before prenatal diagnosis situated women at the centre of much genetic counselling activity, women's lives and bodies were centrally implicated by the reproductive decision-making, and the gendered constructions of genetic risks, that have been constituted through genetic counselling.

Finally, women's politics have been implicated in the advance of genetic counselling and genetic medicine generally. While it would be false to suggest that abortion rights were advanced solely through demands for genetic (or eugenic) abortions, the threat of congenital disease has consistently been one of the triumvirate of needs, including rape and maternal ill-health, that women have used to justify abortion to a resistant medical profession, and the wider public. On the eve of the 1970s in Canada, amniocentesis was heralded as a technology that might legalise abortion; and in the US, one prominent women's magazine opined that prenatal diagnosis could serve the career woman who wished to postpone childbearing, without increasing her risk of bearing a child with Down's syndrome.

Perhaps more importantly, and as has been consistently observed, the women's health movement, in its demand for choice, access to information, and preventive self-care, has articulated a politics that seems consonant with the demands pressed by genetic counselling and advanced through genetic testing. Moreover, this liberal feminist ethos is of sustained relevance to many women today, and is a significant resource for proponents of an expanded role for genetic testing in medical and self-care.

Conclusion

The Canadian Biotechnology Strategy takes for granted the merits of new genetic technologies for use in health care. It advocates the development of these technologies, and assumes that they necessarily herald a new era of biotech medicine. The histories that I've recounted here suggest some ways to critically evaluate these assumptions.

First, insofar as biotech medicine involves genetic tests, there is much that will *not* be entirely new about this new era. Genetic tests pre-date the molecular testing promised by the Human Genome Project and allied research, and many of the dilemmas of genetic tests – their uncertain meaning, statistical complexity and decoupling from treatment options – are decades old. I am not suggesting that nothing is new here. Indeed, there are new and significant challenges for medicine and health care that are posed by biotech medicine – such as the high cost of these tests, their private ownership and thus the difficulty of integrating them into conventional lab routines. It is important to recognise that what is *new* here are not the technologies alone, but the new social arrangements in which they are embedded – social arrangements which are the product of public policy decisions, such as over-extended patent protection for biotech “inventions”.

Second and by extension, genetic tests have been and will be propelled into use by very specific actors in the health care system, even while the CBS fails utterly to consider such actors. Genetic information has been introduced into and managed within clinical settings by an evolving mix of practitioners who have jockeyed with each other and with such institutional powers as organised medicine. Who provides genetic counselling, and in what clinical context, matters. If more medical

management of genetic information is pursued, then we need to address the tendency of medical practitioners to be more directive than counsellors, and the perverse incentives created by fee-for-service systems of compensation. I am not suggesting that more investment in Masters-level trained genetic counselling is necessarily a better option, however. While the feminised status of genetic counselling may be responsible for its under-resourcing, a feminist response would not necessarily be to advocate for more access to such services. We might, on the contrary, wish to question the construction of ‘communication’ as a women’s issue, and to question the relevance of a woman and health agenda in supporting such services. What should be understood is that the practice of genetic counselling – whoever does it – has been and will continue to be fundamentally facilitative of genetic medicine, and of an expanded use of genetic tests.

Third, the extent to which genetic tests are necessarily *genetic* is part and parcel of negotiations over the practice of genetic counselling and medical genetics. I would argue that the commitment of human genetics to genetical explanations is historically contingent, rather than necessary or inevitable. Moreover, I would argue that the extent to which a disease is understood and managed as *genetic* is a negotiated outcome. The new era of biotech medicine, if it is upon us, *can* be managed differently – to emphasize social and environmental systems of causation and solution, for example.

The CBS would have us believe that we are powerless before the advance of science and technology. The best response is to get on the bandwagon and take what profits we can from this new direction. Yet it is clear that there is a great deal of contingency here – and social analysts and activists can and *should* have an impact on future directions.

References

- ASHG. 1975. Committee on Genetic Counseling. "Genetic Counseling." *AJHG* 27:240-242.
- Bosk, CL. 1992. *All God's Mistakes: Genetic Counseling in a Pediatric Hospital* Chicago and London: University of Chicago Press.
- Cho MK, Arruda M, Holtzman NA. 1997. "Educational Material About Genetic Tests: Does it Provide Key Information for Patients and Practitioners." *AJMG*. 73:314-320.
- Hubbard, R and RC Lewontin. 1996. "Pitfalls of genetic testing." *New England Journal of Medicine*. 334:1192-4.
- Katz, Sidney. 1954. "She knows the kind of Children you'll have," *Maclean's Magazine*.
- Kenen, R. 1984. "Genetic counseling: the development of a new interdisciplinary occupational field." *Social Science and Medicine* 18(7):541-549
- . 1997. "Opportunities and Impediments for a Consolidating and Expanding Profession: Genetic Counseling in the United States." *Social Science and Medicine* 45(9):1377-1386
- Ladd Taylor, Molly. 1999. "Eugenics and the Baby Boom." Unpublished MS. Presented at Women, Science and Health in Post-War North America: Comparative Canadian-American Perspectives. March 5, York University, Toronto.
- Lippman, A. 1991. Prenatal genetic testing and screening: Constructing needs and reinforcing inequities. *American Journal of Law and Medicine*, 17:15-50.
- Nelkin, D. and MS Lindee. 1995. *The DNA Mystique: The Gene as a Cultural Icon* NY: Freeman.
- Paul, D. 1999. *The Politics of Heredity: Essays on Eugenics, Biomedicine, and the Nature-Nurture Debate* Albany: SUNY Press.
- SACGT. 1999. *A Public Consultation on Oversight of Genetic Tests*. December 1, 1999 – January 31, 2000. Secretary's Advisory Committee on Genetic Testing. National Institutes of Health Web site. Available at: <http://www4.od.nih.gov/oba/sacgt.htm>. Accessed: January 20, 2000.
- Task Force. 1997. *Promoting Safe and Effective Genetic Testing in the United States. Final Report of the Task Force on Genetic Testing*. Eds. Neil Holtzman and Michael Watson. National Human Genome Research Institute Web site. Available at: <http://www.nihgri.nih.gov>. Accessed January 20, 2000.
- Wertz, D. 1997. "Is There a "Women's Ethic" in Genetics: A 37-Nation Survey of Providers." *JAMWA* 52(1):33-38.

The Hazards of Human Developmental Gene Modification

Stuart Newman

About the Author

Stuart Newman is a Professor of Cell Biology and Anatomy at New York Medical College, Valhalla, NY. He directs a federally funded laboratory in developmental biology, has contributed to several scientific fields, including the theory of biochemical networks, protein folding and assembly, and mechanisms of the development and evolution of biological form, and has written on the cultural background and social implications of biological research. He is a member of the Board of Directors of the Council for Responsible Genetics (Cambridge, MA), a public interest organization concerned with guarding against misuse of biological science and technology.

About the Article

Unlike many contributions to this collection which provide critiques of biotechnology, and biotechnology policy in general, Newman focuses on a specific technology – human developmental gene modification, sometimes (though problematically) termed germ-line gene “therapy”. Newman identifies specific dangers for women and for their children where genetic modification of human embryos or fetuses is pursued. This paper also presents an important gender analysis – pointing out that this kind of genetic experimentation is reliant on the powerful desire and expectation that women will do *anything* for their children. Further, Newman points to the fact that growing pressures to pursue genetic experiments on developing fetuses and embryos are concurrent (and congruent) with the increasing restrictions on women’s ability to gain access to abortion in the United States. “Opposition to germline engineering, and to other developmental manipulations such as cloning,” he argues, “clearly has natural affinities to ongoing efforts to promote women’s rights.”

Introduction

Genetic modification of human embryos or fetuses has been proposed for purposes of both prevention of disease and enhancement of capacity. The development of sophisticated *in vitro* fertilization methods, preimplantation DNA analysis, improved techniques for gene transfer, insertion, or conversion, and embryo implantation procedures, have made such interventions technically feasible.

The hazards of genetic modifications to humans have usually been discussed in terms of *somatic* (body cell) modification, in which only non-reproductive tissues are affected, and *germline* (egg or sperm cell) modification, in which changes to an individual's DNA can be passed down to future generations. Indeed, this division has led to the general belief that the only, or main hazard of developmental modification is the potential of transmission of undesired alterations in the germline.

But genetic modification of early embryos – as well as chromosome and nucleus transfer techniques, including cloning – present hazards to the developing individual, and in certain cases to the mother, even if there is no germline transmission to future generations. Genetic manipulation of the human embryo, with or without changes to the germline, is referred to as *developmental* modification.

The hazards of germline transmission of DNA modifications are obvious from a reading of the literature on transgenic animals. For example, germline introduction of an improperly regulated normal gene resulted in progeny with unaffected development but enhanced tumor incidence during adult life (1). Such effects may not be recognized for a generation or more.

It is important to recognize that many hazards of developmental gene modification are not eliminated if there is no germline transmission. The biology of the developing individual will still be profoundly altered by the manipulation of his/ her genes at an early stage. Laboratory experience shows that miscalculations in where genes are incorporated into the chromosomes can lead to extensive perturbation of development. The disruption of a normal gene by insertion of foreign DNA in a mouse caused lack of eye development, lack of development of the semicircular canals of the inner ear, and anomalies of the olfactory epithelium, the tissue that mediates the sense of smell (2).

Interactions among genes and their products are highly integrated, having been refined over evolutionary time scales, and often serve to stabilize developmental pathways (the sequence of structural and biochemical changes that an embryo passes through on the way to becoming a fully-formed organism) and physiological homeostasis (the normal state of dynamical balance among the body's many processes) (3-5). In addition, the biochemical pathways used by the organism and its cells to achieve this stability and balance are overlapping, rather than discrete or separable (6) ensuring that any developmental genetic alteration will have broad, uncontrolled ramifications. Through experimental error, unanticipated interactions among different versions of the same gene, or poorly understood regulatory mechanisms such as imprinting (the parental source of the gene – mother or father – affecting its function), developmental genetic manipulation risks altering sensitive biological equilibria. Disrupting these interactive systems is likely to have complex and uncertain biological effects, including some which only become apparent during the development or functioning of specific cells or tissues (7).

Genetic alterations to the germline are possible even where only body (somatic) cells are targeted for DNA transfer. This represents a hazard in many of the more than 200 somatic gene therapy protocols now in use. For example, the viruses that are used to transfer DNA in some somatic gene therapy protocols were able to infect isolated mouse eggs in laboratory studies, leading to germline transmission of a transgene in the progeny (8). Although removal of the external “shell” of the egg was a prerequisite for infection of the eggs *in vitro*, these “shells” are absent in the early development of eggs in the ovaries. These experiments thus raise the possibility that modification of ova may occur in women undergoing somatic gene treatments, with unknown and uncontrolled consequences to their progeny.

In protocols that attempt somatic gene therapy for life-threatening illnesses, saving the life of the individual patient is a value that must be balanced against developmental risks, including those to the germline of that individual, and indeed, such considerations also pertain to chemotherapy in cancer patients (9). With respect to deliberate developmental modifications, the story is quite different. Not only is the “patient” (embryo or fetus) and its progeny at risk from the procedure, but so is the pregnant woman if the genes are to be introduced *in utero*, since such genes can also infect her tissues, including her own germline, and entail other risks to herself, such as cancer. Clearly she is not in a position to give informed consent on behalf of herself, or the developing embryo, for a procedure that has not yet been tested in humans, and which promises no direct benefits to her health (the usual justification for experimentation on humans). However, she will inevitably be under pressure to assume such risks for the sake of her baby.

Even if the procedure is to be done *in vitro* rather than *in utero*, the basis for informed consent remains problematic. Here there is no existing person whose life is in jeopardy, but rather an embryo in a petri dish that the egg or sperm donor (or whoever else may gain the right to its disposition) would like to have turn out genetically differently. No truly informed consent on the part of the potential parents is possible, because no reliable information would be available when it is first attempted.

It is clear that pressures on women will be growing over the coming years to submit themselves to experimental genetic procedures, first to prevent disease, and eventually to enhance the appearance, performance, and so forth, of her baby. It is no accident that there are increasing proposals to use newly obtained genetic information to “improve” embryos by manipulating the embryo (11, 12), rather than for prenatal diagnosis. The new genetic research has flourished during a period in which there have been aggressive attempts to reverse abortion rights in the U.S.; consequently, the use of prenatal diagnosis as a justification for public funding of the science has been taboo. This period has also been one in which patenting and commercialization of genes has been possible for the first time (10), and eugenic ideologies, after their post-World War II eclipse, have gained new respectability among opinion makers (13).

In evaluating proposals to use the new genetics to remake human biology, women should be aware of hazards to themselves and their offspring from the primitive state of the science and technology, as well as the commercial and reactionary political agendas behind these efforts. Opposition to germline engineering, and to other developmental manipulations such as cloning, is emerging among public interest advocates (14-16). This new movement clearly has

natural affinities to ongoing efforts to

promote women's rights.

References

1. Leder, A., P. K. Pattengale, A. Kuo, T. A. Stewart, and P. Leder. 1986. Consequences of widespread deregulation of the c-myc gene in transgenic mice: multiple neoplasms and normal development. *Cell* 45: 485-95.
2. Griffith A.J., W. Ji, M.E. Prince, R.A. Altschuler, and M.H. Meisler 1999. Optic, olfactory, and vestibular dysmorphogenesis in the homozygous mouse insertional mutant Tg9257. *J Craniofac Genet Dev Biol* 19:157-63.
3. Strohman, R. C. 1993. Ancient genomes, wise bodies, unhealthy people: limits of a genetic paradigm in biology and medicine. *Perspect. Biol. Med.* 37: 112-45.
4. Newman, S. A. 1995. Interplay of genetics and physical processes of tissue morphogenesis in development and evolution: The biological fifth dimension. pp. 3-12 in D. Beysens, G. Forgacs, and F. Gaill, eds. *Interplay of Genetic and Physical Processes in the Development of Biological Form*. World Scientific, Singapore.
5. Wilkins, A. S. 1997. Canalization: a molecular genetic perspective. *BioEssays* 19: 257-262.
6. Fambrough, D., K. McClure, A. Kazlauskas, and E. S. Lander. 1999. Diverse signaling pathways activated by growth factor receptors induce broadly overlapping, rather than independent, sets of genes. *Cell* 97: 727-41.
7. Jaenisch, R., M. Breindl, K. Harbers, D. Jahner, and J. Lohler. 1985. Retroviruses and insertional mutagenesis. *Cold Spring Harb. Symp. Quant. Biol.* 50: 439-45.
8. Tsukui, T., Y. Kanegae, I. Saito, and Y. Toyoda. 1996. Transgenesis by adenovirus-mediated gene transfer into mouse zona-free eggs. *Nat. Biotechnol.* 14: 982-5.
9. Bridges, B. A. 1979. An estimate of genetic risk from 8-methoxypsoralen photochemotherapy. *Hum. Genet.* 49: 91-6.
10. Rifkin, J. 1998. *The Biotech Century: Harnessing the Gene and Remaking the World*. J. P. Tarcher, New York.
11. Silver, L.M. 1998. *Remaking Eden: How Genetic Engineering and Cloning Will Transform the American Family*. Avon, New York.
12. Stock, G.B. and J. Campbell. 2000. *Engineering the Human Germline: An Exploration of the Science and Ethics of Altering the Genes We Pass to Our Children*. Oxford Univ. Press, Oxford.
13. Caplan, A.L., G. McGee and D. Magnus 1999. What is immoral about eugenics? *West. J. Med.* 171: 335-7.

14. Lippman, A. *et. al.* (1993). Position paper on human germ line manipulation presented by Council for Responsible Genetics, Human Genetics Committee Fall, 1992. *Hum. Gene Ther.* 4: 35-7.
15. Billings, P. R., Hubbard, R., and Newman, S. A. (1999). Human germline gene modification: a dissent. *Lancet* 353: 1873-5.
16. Brave, R. 2000. Building better humans. *Salon* (June 27).
<http://www.salon.com/health/feature/2000/06/27/germline/index.html>.

Genetic Testing, Citizenship and Subjectivity: Implications for Women and Health

Jessica Polzer

About the Author

Jessica Polzer is a Ph.D. Candidate in the Department of Public Health Sciences, University of Toronto. She has an M.Sc. in Behavioural Science from the University of Toronto and has been a Research Associate, Project Coordinator, and Consultant on many health-related qualitative research projects. Her research addresses the relationship between individual experiences of health, broader political and economic arrangements, and the cultural aspects of disease in Western societies. Drawing primarily on the work of Michel Foucault and others working in the area of “governmentality”, her dissertation research will examine how women construct themselves as ethical subjects through their participation in genetic testing for breast cancer risk.

About the Article

In this paper, Jessica Polzer draws on her previous research experience with persons at genetic risk for familial melanoma to raise questions about the political underpinnings and personal implications of genetic testing for breast cancer risk. She also proposes some ways of thinking about the individual’s relationship with the test process and test results which draw on sociological theories about identity and governance.

Introduction

As more genetic mutations are 'discovered' as being implicated in the development of particular diseases, our understanding of health risks is becoming effectively geneticized (Lippman, 1991). The case of breast cancer provides a useful example of this geneticization of risk. The identification of genes implicated in the development of breast cancer (e.g. BRCA1, BRCA2), has resulted in the proliferation public information about genetic risk for breast cancer through the mass media. As well, this knowledge has been translated into the development of genetic testing 'clinics' that provide women with genetic risk information – that is, numerical estimates of their genetic susceptibility for breast cancer.

Public and professional discussions of genetic testing and genetic risk more generally tend to emphasize the benefits of these biotechnologies for individual and population health. For example, one clinical genetics reference book describes genetic testing as having "enormous implications for prevention and treatment (Offit, 1998: ix) by identifying those individuals who are genetically 'at risk' for particular diseases (e.g. breast cancer). The potential benefits of genetic testing technologies are also highlighted in the Canadian Biotechnology Strategy Health Sector Consultation document which identifies early cancer screening and detection (enabled by technologies such as genetic testing) as a 'key surveillance area' to facilitate health protection for the population as a whole.

Drawing on my experience conducting interviews with individuals at risk for familial melanoma, my primary aim in this paper is to show how individuals' experiences of genetic testing are related to broader political, economic and social arrangements. First, I situate genetic testing as a neoliberal political technology,

and thus situate this growing public health and medical practice in its broader context (social, economic, political). In the second section of this paper, I generally describe the major themes that emerged from the interview data in an effort to situate individuals' experiences of genetic testing politically. In particular, I suggest that the practice of genetic testing creates possibilities for conducting oneself as a moral and responsible citizen – citizens who acquire knowledge of their genetic risk, manage their genetic risk through lifestyle modification and greater bodily surveillance, and who inform their relatives of their genetic susceptibility. In the final section, I draw some conclusions and identify some areas that deserve further attention, debate and analysis.

I. Genetic Testing as a Neoliberal Biotechnology

What is Neoliberalism? For the purposes of this paper, I use the term neoliberalism to characterize a particular way of governing, or way of problematizing the questions of government. In contrast to a more straightforward description of neoliberalism as a reactivation of market principles or laissez-faire politics, this conceptualization of neoliberalism directs our attention towards thinking about "government" as a way of thinking about and acting upon problems. In other words, neoliberalism is not just a set of political ideals, but is a "political rationality" (Foucault 1991; Gordon 1991) or "formula of rule" (Rose 1996) that informs how government is practiced.

From this point of view, questions concerning government are not limited to questions about the state or political process. Rather, acts of governance occur in many places and take many forms (Dean 1999; Rose 1993). In the case of genetic testing, for example, practices of governance would include those carried

out by the state (e.g. policymaking), the practices related to the creation of knowledge about genetic risk (e.g. the Human Genome Project), the translation of such knowledge into clinical practice (e.g. the institutionalization of genetic testing clinics), the education and training of genetic specialists (e.g. medical geneticists, genetic counselors) and the practices of self-governance by which individuals use genetic risk information to alter their own behaviours.

Genetic Testing, 'Right to Know' and 'Informed Choice': Understood broadly as a political rationality, neoliberalism involves problematizing the questions of government not in terms of top-down state intervention, but rather towards the development of conditions that facilitate autonomous self-regulation (Petersen 1999). This characterization of neoliberalism as a political rationality allows for a consideration of how individuals are governed through their own self-regulation and exercise of choice (Miller & Rose 1994).

The practice of genetic testing, and discourses on genetic risk more generally, are guided by the rhetoric of 'right to know' and 'informed choice' (Petersen 1998). Being able to make informed decisions or choices about one's health is typically used as a rationale for obtaining genetic risk information. Consider the following quote from a book on the psychological consequences of genetic testing:

*The provision of genetic information in medical practice has the **potential to facilitate patients' informed decision making about reproduction and personal risk modification**. As such, these advances have **profound implications for reducing the incidence of genetic disorders and for reducing morbidity and mortality through early detection of disease in individuals at risk**. (Croyle & Lerman 1995:11, emphasis added)*

The argument that genetic information leads to informed choices which, in turn, will lead to reductions in morbidity and mortality relies on a conception of the individual who not only exercises her 'right to know' her genetic risk status, but who also acts responsibly on the basis of that information by modifying her lifestyle accordingly (e.g. increasing frequency of breast examinations). Indeed, this expectation of 'personal risk modification' is stated explicitly in the above quote.

The importance of making 'informed decisions' has also been taken up by women with a family history of breast cancer advocating for more accessible genetic testing. For example, a recent court ruling that women with a strong family history of breast cancer would receive provincial medical coverage for genetic testing was described as an 'important victory' because it "could allow hundreds of women to make informed decisions about whether to take drugs or have their breasts or ovaries surgically removed as precautions against developing cancer" (Abraham 1999).

Genetic Testing and Citizenship: Genetic testing, as a practice and domain of knowledge, constitutes one site for the construction and exercise of citizenship within neoliberal modes of governance. Within neoliberal political arrangements, experts (e.g. researchers, genetic counselors) act as advisors and define norms, yet individuals are called upon to take an active role in decision-making (Petersen 1999), to exercise their right to know so that they can make informed choices about their health. This imperative is reflected and institutionalized in the practice of genetic counseling which emphasizes the importance of counseling individuals in a 'non-directive' manner. Thus, active involvement in decision-making can be considered as a key mechanism by which individuals regulate *themselves*—not through being coerced,

but through the exercise of their freedom of choice (Petersen 1999; Rose 1993; Rose 1999).

As with other kinds of health risks (e.g. lifestyle, environmental), the ways in which ideas about genetic testing are framed and clinically applied are founded on a conception of the individual as an 'enterprise' who is required to adopt a calculating attitude in terms of how they conduct themselves (Lupton 1995; Petersen 1997; Robertson 2000). This is consistent with neoliberal political rationalities in which individuals are expected to govern themselves through "processes of endless self-examination, self-care and self-improvement" (Petersen 1997: 194). The practice of genetic testing is an especially effective tool for activating these processes. That is, through their participation in genetic testing, individuals are able to obtain information about their genetic risk status, compare themselves to genetic norms established by epidemiological research, and receive advice from health professionals as to how they should regulate their own behaviours (in light of their knowledge of a genetic risk) to avoid disease onset in the future.

II. The Construction of Responsible Citizens: Implications of Genetic Testing for Subjectivity

In this section I discuss how the practice of genetic testing constructs individuals as responsible citizens who seek out and act on genetic risk information to protect their personal health as well as the health of their family members. To do this, I have included some insights from my experiences interviewing individuals who had were at various stages in the process of undergoing genetic testing for familial melanoma risk.

Constructing Women as Agents of Self-Regulation: The Duty to Manage Personal Risk

The previous theoretical discussion suggests that genetic testing recruits individuals into processes of risk management involving self-examination and lifestyle modification. At a glance, this may not seem different than non-genetic forms of medical screening and surveillance. However, genetic testing has considerable potential to shape how individuals understand and practice health *in the absence of disease or symptoms*, and thus to blur the distinction between health and illness (Gifford 1986). In this sense, genetic risk information constructs particular body parts as potentially dangerous (e.g. ovaries, breasts) prior to the onset of symptoms. Thus, the practice of genetic testing has serious implications for how women experience their bodies and construct their identities (Hallowell 1998; Koenig & Stockdale forthcoming), and can encourage a person to experience their own body as potentially dangerous in everyday life (Kavanagh & Broom 1998; Robertson 1998; Robertson 2000). As Koenig and Stockdale note with regard to their work in the area of breast cancer:

How will women understand 'risks' that literally reside within them, in their genes, over which they have little control, and which they may already have passed on to their children? Will breasts and ovaries be experienced as potential time bombs, harboring the early stages of cancer, in need of constant surveillance? (Koenig & Stockdale forthcoming: 20)

Furthermore, unlike environmental or lifestyle-related health risks, genetic risk is 'embodied' (i.e. located within the body) and is typically not considered to be amenable to therapeutic intervention (Kavanagh & Broom 1998). While genetic risk is distinct from lifestyle- or environment-related risks, I believe it is an error to consider different types of risk discourses in health (e.g. genetic, lifestyle,

environmental) as completely independent. This is because such a separation neglects a major assumption underlying genetic testing – that a woman's knowledge of her genetic risk status will enable her to make 'informed choices' with regard to her health. Rather, by constructing new categories of genetic normality, and situating particular body parts as potentially dangerous, genetic testing recruits asymptomatic individuals as agents of self-regulation who manage their health risks through self-imposed lifestyle modifications (e.g. increased frequency of breast self-examinations, low fat diet). In turn, individual responsibility for health through personal risk management is emphasized.

The importance of informed decision making, and its implications for how individuals see and act upon themselves, was obvious in my interviews with individuals who were considering, undergoing, or who had undergone, genetic testing for familial melanoma risk. In these respondents' accounts, there was a general consensus that **"the more information one had about one's health, the better"** because this allowed one to gain a greater **"awareness"** of health risks and of bodily signs of normality and abnormality (irregular moles). In particular, the process of genetic testing influenced how individuals recognized 'healthy' and 'unhealthy' moles such that they began to examine their bodies through 'clinician's eyes'. In this sense, **genetic risk information was seen as part of a plan of prevention** since it allowed individuals to take appropriate and more informed action through increased self- and medical surveillance. As well, the need to become more vigilant in terms of bodily surveillance was seen by participants as incredibly important since **early detection** is key in avoiding more invasive forms of treatment for malignant melanoma.

Constructing Women as Carriers of Health Information: The Duty to Inform

Genetic risk information, being familial in nature, not only has implications for individuals undergoing genetic testing, but also has implications for their family members. While much research has focused on the personal implications of being identified as a 'carrier' of "defective" genes, less attention has been paid to the familial implications of identifying individuals who are identified as genetically at risk.

As a family-implicating medical technology, genetic testing has specific implications for the considerations individuals make when deciding to accept or defer genetic testing. For example, in the interviews I conducted, it was clear that decisions to accept testing were often rooted in a sense of obligation to inform current or future family members of any undesirable traits that may have been passed on. **Information about genetic risk was seen as especially useful to "pass along to the family"** to increase familial awareness about potential health risks and signs of possible hereditary disease (e.g. irregular moles). In particular, **genetic risk information was seen as having preventive benefits for children** by encouraging parents to protect their children from the sun, and by encouraging their children to be more 'aware' of their bodies and more vigilant in protecting themselves from sun-related risk

With respect to women in particular, other research has shown that women will overlook their own desire to not know their genetic risk status for breast or ovarian cancer so that they can provide genetic risk information to their family members, in particular their children (Hallowell 1999). This calls into question whether decision-making is really autonomous, an aspect of decision-making that is promoted by genetic counseling.

Thus, genetic testing create opportunities for new forms of citizenship based on familial obligation wherein individuals are constructed as 'carriers', not only of 'defective' genes, but also of genetic risk information. Within this logic, individuals are recruited as agents of 'health' doing all they can to ensure that their family members are 'armed' with the information necessary to manage and minimize their own personal health risks. This 'duty to inform' family members of potential genetic susceptibility may have specific implications for women, as they have been traditionally considered responsible for family health.

Concluding Comments

The previous discussion illustrates how individuals are recruited as agents of self- and familial regulation, processes that are consistent with active citizenship under neoliberal forms of governance. It is not my intention to propose that genetic testing is necessarily oppressive, or to suggest that these individuals are suffering from false consciousness which is masking an underlying 'truth' or 'reality'. Certainly, the majority of individuals who I interviewed on the familial melanoma project experienced genetic testing as positive overall, and as providing them with information that enabled them to make personal health-related decisions, and that they could pass on to other family members. Still, the discussion presented in this paper points to a number of areas that are in need of further research, analysis and debate.

The construction of individuals as agents of self-regulation assumes that individuals have the psychological and material resources necessary to reduce health risks, and, even if these resources **are** available, that personal risk management should take precedence over other matters concerning everyday life.

Furthermore, this assumes that personal risk management through lifestyle modification is a straightforward task, and does not acknowledge that there may be an overwhelming number of recommendations for risk management which may contradict one another (e.g. conflicting mammography guidelines). Finally, the focus on personal risk modification reinforces a conception of health, and responsibility for health, as an individual undertaking, and thus other conceptions of the determinants of health (e.g. environmental influences on breast cancer) and the actions which may be taken to improve health (e.g. collective action) are overshadowed.

The underlying assumption of one's duty to inform family members of potential genetic susceptibility neglects to consider personal and familial circumstances (e.g. recent death of family member) which may influence the amount of anxiety one experiences from genetic testing, and how individuals understand and communicate risk information. Also, this assumption does not consider that some individuals may want to protect their family members (in particular their children) from knowing their genetic susceptibility to disease. In a similar vein, the potential negative effects on individuals and families of having knowledge of genetic susceptibility are often overlooked. In the interviews I conducted, individuals felt that they were well informed during genetic counseling about the potential psychological effects of knowing their genetic risk status yet, for some, unexpected concerns emerged only after they gave blood for genetic testing. As well, more attention should be paid to the personal consequences of receiving a negative/ indeterminate genetic test result, for such a test result may not necessarily lead to feelings of relief as it can position an individual in a state of greater uncertainty regarding their genetic susceptibility and the risk adjustments that they should make in response to a negative test result. In short, while genetic

risk information is often framed as providing individuals with greater control over their health, this claim should be systematically evaluated through in-depth empirical inquiry of individuals' experiences of genetic testing.

Last, there is a need for research on how women perceive and experience genetic testing and genetic risk information in the context of their everyday lives. While research on 'lay' perceptions of health risks is growing, a substantial amount of this research focuses on the 'accuracy' of lay perceptions of risk (Gabe 1995) – that is, on whether lay perceptions are aligned with biomedical perspectives. Implicit in such research is the conviction that lay perceptions are somehow lacking and are in need of better and more timely information so that individuals can become better governors of their genetic fates. This perspective on lay perceptions needs to be countered with research that focuses on how individuals understand risk information and create meaning about genetic risk in the context of their everyday lives. Such an approach to research would take into account a woman's entire 'stock of knowledge' (Petersen 1999) with regard to genetic risk (including mass media, for example) and would illuminate how women actively construct meanings around genetic risk. In particular, the specifically gendered way in which women experience a sense of familial obligation as a result of their participation in genetic testing would be a fruitful area of research, and would have serious implications for both practice and policy. A focus on women's experiences with genetic testing would also help provide a more complete picture of the ethical implications of such practices, as it would shed light on the influence of genetic testing on the everyday lives of women and their families. In this regard, the concept of citizenship provides a promising way to conceptualize personal experiences of genetic testing within larger political programmes. A focus on women's

everyday knowledge about genetic risk and genetic testing not only promises to illuminate the links between subjectivity and broader political currents, but may also "provide the basis for exploring the contradictions and tensions around genetic knowledge and prevention and for contesting the imperatives surrounding genetic health." (Petersen 1999: 137). A major challenge will be to create mechanisms that allow for input from such research into decision making processes and policy making.

References

- Abraham, C. 1999. Tenacious woman scores medical victory. *The Globe and Mail*. August 27
- Croyle, R., & Lerman, C. 1995. Psychological impact of genetic testing. In R. Croyle (Ed.), *Psychosocial Effects of Screening for Disease Prevention and Detection*. New York: Oxford University Press.
- Dean, M. 1999. *Governmentality: Power and Rule in Modern Society*. London: Sage Publications.
- Foucault, M. 1991. Governmentality. In G. Burchell, C. Gordon, & P. Miller (Eds.), *The Foucault Effect: Studies in Governmentality*. London: Harvester Wheatsheaf.
- Gabe, J. 1995. Health, medicine and risk: The need for a sociological approach. In J. Gabe (Ed.), *Medicine, Health and Risk: Sociological Approaches*. Oxford: Blackwell.
- Gifford, S. M. 1986. The meaning of lumps: A case study of the ambiguities of risk. In C. R. Janes, R. Stall, & S. M. Gifford (Eds.), *Anthropology and Epidemiology: Interdisciplinary Approaches to the Study of Health and Disease*: D. Reidel Publishing Company.
- Gordon, C. 1991. Governmental rationality: An introduction. In G. Burchell, C. Gordon, & P. Miller (Eds.), *The Foucault Effect: Studies in Governmentality*. Chicago: University of Chicago Press.
- Hallowell, N. 1998. Genetic risks and responsibilities, or how the neutrality of genetic counselling is compromised. *International Sociological Association*.
- Hallowell, N. 1999. Doing the right thing: Genetic risk and responsibility. *Sociology of Health and Illness*, 21(5), 597-621.
- Kavanagh, A. M., & Broom, D. H. 1998. Embodied risk: My body, myself? *Social Science and Medicine*, 46(3), 437-444.
- Koenig, B., & Stockdale, A. (forthcoming). The Promise of Molecular Medicine in Preventing Disease: Examining the Burden of Genetic Risk. *Ethical Issues in Health Promotion and Disease Prevention*.
- Lippman, A. 1991. Prenatal genetic testing and screening: Constructing needs and reinforcing inequities. *American Journal of Law and Medicine*, XVII(1,2), 15-50.
- Lupton, D. 1995. *The Imperative of Health: Public Health and the Regulated Body*. London: Sage.
- Miller, P., & Rose, N. 1994. On therapeutic authority: Psychoanalytical expertise under advanced liberalism. *History of the Human Sciences*, 7(3), 29-64.

- Offit, K. 1998. *Clinical Cancer Genetics: Risk Counseling and Management*. New York: Wiley-Liss.
- Petersen, A. 1997. Risk, governance and the new public health. In A. Petersen & R. Bunton (Eds.), *Foucault, Health and Medicine*. London: Routledge.
- Petersen, A. 1998. The new genetics and the politics of public health. *Critical Public Health*, 8(1), 59-71.
- Petersen, A. 1999. Public health, the new genetics and subjectivity. In A. Petersen, I. Barns, J. Dudley, & P. Harris (Eds.), *Poststructuralism, Citizenship and Social Policy*. London: Routledge.
- Robertson, A. 1998. *Our bodies, our enemies: Women's perceptions of risk for breast cancer*. Paper presented at the British Sociological Association Conference, Edinburgh, Scotland (April 6-9).
- Robertson, A. 2000. Embodying Risk, embodying political rationality: Women's accounts of risks for breast cancer. *Health, Risk and Society*, 2(2), 219-235.
- Rose, N. 1993. Government, authority and expertise in advanced liberalism. *Economy and Society*, 22(3), 283-299.
- Rose, N. 1996. Governing 'advanced' liberal democracies. In A. Barry, T. Osborne, & N. Rose (Eds.), *Foucault and Political Reason: Liberalism, neo-liberalism and rationalities of government*. Chicago: University of Chicago Press.
- Rose, N. 1999. *Powers of freedom: Reframing political thought*. Cambridge: Cambridge University Press.

**Risk, biotechnology and political rationality:
Lessons from women's accounts of breast cancer risks**

Ann Robertson

About the Author

Ann Robertson is Associate Professor in the Department of Public Health Sciences at the University of Toronto. Her research interests include discourses on health, risk and the body, and the social implications of human genetics research.

About the Article

Ann Robertson considers the issues for women of increasingly available genetic tests. Drawing on social theory, Robertson analyses how women make sense of their personal risks for breast cancer, and what control they feel able to exert over the disease, as individuals or as members of a group. From this vantage point, Robertson understands the CBS's goal of balancing dangers and opportunities as a valid one, and she hopes, through her work, to contribute to achieving that balance.

The ... point is not that everything is bad, but that everything is dangerous ... If everything is dangerous, then we always have something to do. (Foucault 1984:343)

Introduction

The purpose of this discussion paper is to explore the personal and political implications of current discourses on health and risk, and to suggest some of the ways in which these discourses are produced and shaped, in part, by existing and emerging biotechnologies, specifically diagnostic and screening technologies. I use the term “discourse” in the sense that Michel Foucault used it to refer to ways of thinking, speaking and writing about a particular area of knowledge, as well as the actual practices associated with those ways of thinking, speaking and writing. Biomedicine, for example, continues to be one of the major discourses on health, tending to dominate over alternative perspectives on health and healing such as holistic or traditional medicine. This paper is based on the premise that discourses on health are never just about health. Particular discourses on health emerge at particular historical moments and gain widespread acceptance primarily because they are more or less congruent with the prevailing social, political and economic order within which they are produced, maintained and reproduced. That is, discourses on health are always contingent. Moreover, because they are always attached to other interests and agendas – professional, economic, political, cultural, ideological – discourses on health, including discourses on health risks, also function as repositories and mirrors of our ideas and beliefs about, among other things, what it means to be human and the kind of society we can imagine creating and how best to achieve it. In this sense, discourses on health are fundamentally prescriptive.

This paper is informed, in part, by empirical research that I have conducted on women’s accounts of breast cancer risks. While the study discussed in this paper has a phenomenological focus, in focussing on women’s experiences in the context of their everyday lives, it also is based on the assumption that women’s health experiences – specifically, the ways in which they talk about their own personal risks for breast cancer – are located within the broader social, political and cultural context which produces and shapes those experiences. In other words, a “phenomenology of risk” is a *situated* phenomenology. This paper argues that diagnostic/screening technologies are not only part of the context that shapes women’s health experiences, they are also produced and implemented within that same context. In addition, particular diagnostic/screening technologies both make possible and are made possible by particular discourses on risk, which themselves are produced within a particular context. In other words, there is a dialectical relationship between women’s health experiences, prevailing discourses on health risks and emerging diagnostic/screening technologies. This means that they must all be analysed within the same social, political, moral, cultural and ideological context.

It should be made clear at the outset that this paper is not intended as a neo-Luddite diatribe against biotechnology in general. Some biotechnologies clearly have enormous potential to improve health overall – and women’s health, in particular. However, it was clear from the CBS documents that there exists a tension between, on the one hand, the consideration of social and ethical issues related to the development and deployment of biotechnology (Canada 1998a) and, on the other hand, the belief that “industrial growth should be the primary objective of the CBS renewal, along with “provision for ‘unencumbered’

basic research", (Canada 1998b). As noted in the CBS Health Sector Consultation Document (Canada 1998c:8), "the health sector bears a particular responsibility to provide leadership to society in imagining creative solutions that articulate and *balance* emerging social values with expanding technological capabilities within regulatory policy development" (emphasis added). This paper seeks to contribute to achieving this balance. Moreover, I will argue that in addition to considering the social and ethical implications of biotechnology as the CBS documents call for, the dialectical relationship between prevailing discourses on risk and emerging diagnostic/screening technologies also has significant personal and political implications which must be considered.

This paper consists of three parts: first, a brief overview of my empirical study of women's accounts of breast cancer risks; second, a discussion more broadly about what this study indicates about the personal and political implications of prevailing discourses on health risks, and some speculation about how these results relate to current and emerging diagnostic/screening technologies; and finally, a consideration of questions – empirical, policy, moral – which a critical social science research agenda might address with respect to the social management of biotechnology.

I. Our Bodies, Our Enemies: Women's Accounts of Breast Cancer Risk

There have been a number of studies, recently, specifically investigating women's perceptions of risk for breast cancer (Black, et al. 1995; Breast Cancer Bulletin 1995; National Forum on Breast Cancer 1993; Hallowell 1999; Kavanagh and Broom 1998; Koenig and Stockdale forthcoming; Lipkus, et al. 1999; Lloyd, et al. 1996; Mannheimer 1992; Potts 1999). However, with a few exceptions, most of

the studies of women's perceptions of breast cancer risk have employed a number of psychosocial measurement instruments and structured interviews with, until recently (Hallowell 1999; Koenig and Stockdale forthcoming), very few phenomenological investigations of women's accounts of risks for breast cancer.

According to Sandra Gifford (1986), one of the few researchers who has conducted phenomenological research on women's perceptions of risk for breast cancer, risk for breast cancer becomes internalised and is experienced as a state of being, which leads to an ambiguous relationship between health and ill-health: "This ambiguity results in the creation of a new state of being healthy *and* ill; a state that is somewhere between health and disease ..." (215). As with illness narratives, personal narratives of risk may help women make sense of breast cancer risk by providing an "arena for the negotiation of reality" (Early 1982:1491). At the same time, by leaving women feeling "precariously perched between illness and health" (Garro 1994:784), awareness of risk "forces an awareness of the body as separate from self" (782). As Baines says: "For women with breast cancer, it is a chronic disease; for women generally, it can be a chronic problem" (Baines 1990:20).

In order to investigate the extent to which this was the case, I undertook a study of women's accounts of breast cancer risks. Focus groups and in-depth interviews were conducted with 20 women recruited from a pool of women who had attended a Breast Health Clinic at a metropolitan teaching hospital and had not been diagnosed with breast cancer. Participants were divided into 3 clinically-designated risk groups – low, medium and high – based on certain clinical criteria. Focus groups and interviews were tape-recorded and transcribed. The transcripts were then subjected to a standard qualitative data

analysis to elicit common themes that emerged from the women's accounts of risks for breast cancer.

The following analysis focuses, in particular, on what study participants said about two issues with respect to breast cancer risk: firstly, their perceptions of their own personal vulnerability to breast cancer; and, secondly, how much control they felt they, personally, and women in general have over whether or not they ultimately develop breast cancer. For the sake of brevity, the three major themes which emerged from analysis of the data are briefly outlined below. Data, in the form of direct quotes from the study participants, supporting these themes is provided in a longer paper based on this study (Robertson 1999)

Breast worry: vulnerable and flawed – All the participants expressed varying degrees of “breast worry”. This worry had three essential components: the inevitability of breast cancer, the constancy of this worry about breast cancer, and the sense of the breasts as flawed body parts (employing terms like “time bombs” and “Achilles heel”).

Managing uncertainty: numbers and risk status – Linked to the constant awareness of vulnerability to breast cancer that these women felt was the theme of uncertainty. For some women this was expressed as an awareness that uncertainty was something they simply had to live with. For others, it was expressed as a desire for more certainty. One of the most common strategies that women in this study used for managing this uncertainty was to figure out their own breast cancer risk status. Many women appeared to be continually adjusting their sense of their own risk status over time as a result of incorporating additional information or making changes in their own health behaviour.

Playing the odds: individual responsibility/no control – Nearly every woman in this study talked about the individual responsibility that she and all women have for reducing their personal risks for breast cancer. This was always framed in terms of individual responsibility at the level of lifestyle behaviours such as diet, smoking and alcohol consumption, behaviours which they were well aware of as “risk factors” for breast cancer.

While there was a general emphasis on this kind of individual responsibility, at the same time, many of these same women recognised that there were many risks for breast cancer that they had no real control over. Significantly, even though most women spoke about environmental issues like polluted air, water and soil and food additives, which they all considered to be major contributors to increasing risks for breast cancer, not one of the women in this study talked in terms of collective action at the social, political and economic levels for reducing breast cancer risks, such as lobbying for stricter environmental controls or food regulation.

What appeared to happen was that women tried to reconcile these two conflicting issues – individual responsibility in the face of limited or no control – with the notion of “playing the odds”. One participant expressed how going back and forth between these two poles of responsibility and control kept her poised on the edge of uncertainty. The result was a fundamental bifurcation of body and self. While this is a particularly eloquent and poignant expression of this, every woman in this study expressed some degree of this bifurcation of body and self.

... I think that there's – say there's two of me and one of me goes low-fat [diet], doesn't drink or has the odd drink, doesn't smoke, exercises, and the other one smokes and drinks and eats so that they're out like this, yeah, I think I'm gonna – this one over here

[indicating the “healthy lifestyle” self] is going to have a lot better chance of not developing cancer than this one over here [indicating the “unhealthy lifestyle” self]. I would say this one over here will develop it if she has ... the propensity. But then the thing is both these two people have the genes. They both have an eighty-five per cent chance. Yeah, and I would say this one over here, the fat one, the smoking, alcoholic fat one, will develop it. And this one over here, the exercising obsessive, maybe she won't get it; but there's a good chance she will. But she seems to be smart enough that she looks after her body and she takes care of herself that she'll get the proper help to deal with it better emotionally, *she'll nip it in the bud because she's aware of it and she's doing things about it, and she won't die*; whereas this one over here may not realise she has it until it's too late. (Donna, HR:29 - 31).

Donna, like all the women in this study, have literally embodied prevailing discourses on breast cancer risk, and along with them, a particular political rationality.

II. Embodying Risk, Embodying Political Rationality

“Risk” has become one of the defining cultural characteristics of Western society at the end of the twentieth century (Beck 1992b; Douglas 1994; Douglas and Calvez 1990; Douglas and Wildavsky 1982; Giddens 1991; Nelkin 1985; Renn 1992; Scott, et al. 1992). Perhaps, most significant is that, in the current context, the meaning of risk has shifted away from being a neutral mathematical probability, and has come to signify impending danger (Douglas 1990; Lupton 1994b). A common theme in much of this literature is that risk consciousness reflects a new social, political and moral order: “[the] risk debates around which much of modern

politics has been shaped are quintessentially tied up with ... the search for new forms of legitimate order and authority” (Wynne 1996:78).

As in other areas of life, “risk” has become has become central to discourses related to individual health; that is, risk has become a common construct around which health in Western society is described, organised, and practiced, both personally and professionally (Bunton 1992; Hayes 1991; Hayes 1992; Lupton 1995; Petersen 1996). The results of this study demonstrate the extent to which the participants embody discourses on risk, in general and discourses on breast cancer risk, in particular. This embodiment of risk is expressed by the women in this study in terms of a phenomenological experience of “being at-risk” for breast cancer. There has been much recent discussion about the implications of this “at-risk” consciousness (Castel 1991; Crawford 1994; Greco 1993; Lupton 1994a; Petersen 1998; Petersen 1996).

Firstly, and as indicated by the results of the present study, such consciousness contributes to the emergence of a particular form of subjectivity – that is, a particular way of thinking about, relating to the self in terms of the broader social and political context within which the self is embedded/located. The particular subjectivity made possible by current discourses on health and risk and the resulting “at-risk” consciousness has been described as the “entrepreneurial subject” (Petersen 1996; Rose 1990; Rose 1993). This captures the notion that “life should be an enterprise of oneself” (Petersen 1996:48), a personal project, to be continually and actively assessed, managed, worked and improved upon (Greco 1993; Lupton 1995; Petersen 1997; Petersen 1996; Rose 1993; Rose 1990); in turn, “this requires the individual to adopt a calculative and prudent attitude with respect to risk and danger” (Petersen 1996:51).

For the women in this study, this enterprise is essentially an embodied one: they manage their anxiety about being “at-risk” for breast cancer by managing their bodies, that is, by adhering to particular lifestyle behaviours such as low-fat diets, not smoking, controlling their alcohol consumption, practising stress management strategies and managing of their reproductive options in particular ways. Where they are not actually engaged in such “healthy” lifestyle choices, they exhort themselves to become so. Other investigators have talked about “panic bodies” (Lupton, et al. 1995b; Lupton, McCarthy et al. 1995), “risky bodies” or “risky selves” (Nettleton 1997), and even “dangerous bodies” (Hallowell 1998) and “malignant bodies” (Williams and Bendelow 1998). The women in the present study appear to manage their uncertainty and anxiety about breast cancer by negotiating an uneasy pact with their “treacherous bodies”.

The phenomenological experience of the women in this study does not, of course, occur in a vacuum; such experience is always situated and located – socially, politically, historically. In analysing the portrayal of risks for breast cancer in popular media, Deborah Lupton (1994a:73) found that the Australian press drew upon “dominant cultural metaphors and discourses concerning femininity, the individual’s responsibility for illness, and medical and technological dominance”. These same themes were reflected in the accounts the women in this study give of their vulnerability to breast cancer.

Many scholars have written about how the role of public health is central to the reproduction of this risk consciousness. (Bunton, et al. 1994; Bunton 1992; Lupton 1995; Nettleton 1997; Petersen and Lupton 1996). For example, the phenomenological consequences of the

public health practice of “risk assessment” for the entrepreneurial subject are clear.

Preventive medicine and statistical calculations in the context of epidemiology are part of a *moral technology*; by being made aware of risks, the individual is told to provide for and discipline the future, to calculate future actions and dealings. (Adelswards and Sachs 1998:207; emphasis added)

The scope of public health would appear to be almost limitless, for as Castel observes, “for what situation is there for which one can be certain that it harbours no risk, no controllable or unpredictable chance feature” (Castel 1991:289). And it is diagnostic/screening technologies – such as mammography and genetic testing for breast cancer – which, in part, have provided the means for public health and preventive medicine to cast an ever-widening “clinical gaze” – or more specifically, a “technological gaze” – over the health and lives of women, such that “to be suspected, it is no longer necessary to manifest symptoms ... it is enough to display whatever characteristics the specialists responsible for the definition of preventive policy have constituted as risks” (Castel 1991:287).

Diagnostic/screening technologies are instrumental in defining and assessing these “characteristics”, resulting in a “technologization” of risk. To date, these have been largely imaging technologies – such as mammography, ultra sound, bone-density testing – but with the enormous global effort being put into the Human Genome Project, these “characteristics” are becoming increasingly genetic, surely confirming Lippman’s (1992) early insights into the “geneticization” of risk. With the current push to make genes the ultimate “risk factors”, the individualization of health, and health risks, is complete. Health risks are in the very “building blocks” that make up

the person and not in the social, physical or political environment.

Prevailing discourses on risk, and the biotechnologies which both make them possible and are made possible by them, also have implications at a social and political level. It could be argued that the phenomenological experience of the women in this study represents an embodiment of a currently prevailing neo-liberal rationality (Burchell 1993; Castel 1991; Greco 1993; Petersen 1997; Rose 1993; Rose 1990). The argument here is that neo-liberal notions of individual autonomy, the free market and limited government are related, in a mutually producing and sustaining way, to the imperatives to “self-care” (Greco 1993) – in the form of self-surveillance and self-regulation – which themselves are a consequence of the phenomenological experience of being “at-risk”. Petersen makes this link between risk consciousness and the prevailing political order, characterised, in part, by the rapid retreat of the welfare state.

Neo-liberalism calls upon the individual to enter into the process of their own self-governance through the processes of endless self-examination, self-care, and self-improvement. Given that the care of the self is bound up with the project of moderating individual burden on society, it is not surprising ... that since the mid-1970s there has been a clear ideological shift away from the notion that the state should protect the health of individuals to the idea that the individuals should take responsibility to protect themselves from risk. (Petersen 1996:48-49)

In other words, the entrepreneurial subject is reconceived – and reproduced – as a new kind of citizen: a neo-liberal citizen who is autonomous, responsible and self-governing. Within this kind of rationality, health and health risks are individualized and, thus, depoliticized. It should,

therefore, not be surprising that the women in the study discussed here readily took up prevailing discourses on breast cancer risk, assigned themselves a “risk status” and talked about the management of breast cancer risk only at an individual level and not at a collective or political level.

It is to this extent that it could be argued that, for the women in this study, embodying risk represents the embodiment of a neo-liberal rationality. Diagnostic/screening technologies are firstly imagined, and then developed and deployed, within that same political rationality which they, in turn, reinforce and reproduce.

III. Implications for a Canadian Biotechnology Strategy

The preceding discussion is offered as some preliminary thoughts about the dialectical relationships between prevailing discourses on health risks, emerging biotechnologies (specifically, diagnostic/screening technologies) and the prevailing social, political, moral, cultural and ideological order (more specifically, the current neo-liberal rationality). This raises a number of questions at several levels – social, political, ethical. What I will attempt to do in this final section is to raise two fundamental questions, to begin with, which a critical social science research agenda might address in relation to the current Canadian Biotechnology Strategy.

Firstly, at a phenomenological level, I think we need to understand more about how women take up prevailing discourses on health risks. It would appear that women, generally, have willingly taken up certain practices of self-surveillance and self-governance (eg. breast self exam, annual mammograms, lifestyle management). It is poignant to reflect on the extent to which the notion of “Our Bodies, Our Selves” (reflecting a political intention, on the part

of the women's health movement, for women to "re-own" their bodies – i.e. to remove them from the clinical gaze) has, within 30 years shifted to "Our Bodies, Our Enemies" (reflecting a turning back of the clinical gaze on oneself). But is this what is actually happening? Do women take up prevailing discourses on risk – and submit themselves to the diagnostic/screening technologies – wholly, uncritically? Or are there pockets of resistance to these risk discourses? What do these discourses of resistance look like and, remembering Foucault's injunction to "look to the margins", where are they located?

In this respect, there are clear limitations to the study reported here because of the selective nature of the study sample. The participants were all English-speaking women of European – mostly northern European – descent, middle-class, mostly working and largely professional. More significantly, they were all either self-referred or referred by their family physicians to the Breast Health Centre of a major downtown teaching hospital in a large urban centre. This in itself speaks to a certain pre-selection in terms of class, education, and other social locations of these women. Because of this limitation, the investigation of potential differences in terms of a variety of social locations – class, race/ethnicity, mother tongue, sexual orientation – representing different experiences of embodiment, was not possible. For theoretical reasons, one might expect very different results from women who attend a Community Health Centre in a low-income neighbourhood, women who are recent immigrants, women who live in rural settings or women who have some other racial/ethnic/cultural origin besides northern European. Further research would illuminate how differently embodied subjects take up, interact with and transform prevailing discourses on health risks in general and breast cancer risks in particular.

In addition, remembering that phenomenological experience is always situated, comparative research would indicate what and how different discourses on health risks emerge within different professional, political, legislative and regulatory contexts (e.g., UK, USA and Canada). For example, is there now a global discourse of breast cancer risks or are there jurisdictional variations? And how does this impact on women's health experiences within these contexts?

Secondly, and related to the above question (in ways which remain to be explored) is the question of public participation in the setting of the Canadian public policy agenda for the development and deployment of emerging biotechnologies. The CBS documents appear to address this issue, but the nature of the suggestions and recommendations makes it clear that this represents a kind of "tokenism", referring to the "information needs" of the public and strategies for "increasing public awareness and understanding of biotechnology products and processes" (Canada 1998d:15). The assumption here is that the public somehow doesn't "get it" with respect to biotechnology, and that public knowledge is somehow a "degenerate" form of knowledge. This is often reflected in the reference to "scientific evidence" and "lay beliefs", as if science, itself, were not a belief system. The solution, according to the CBS, is to make scientific knowledge more "accessible" to the public.

Research points to gaps in consumer awareness and understanding of biotechnology ... The attributes of biotechnology applications often are not directly evident to citizens. More work is needed to determine the best way to inform them about such technologies. (Canada 1998d:14)

In other words, the suggestion here seems to be that the biotechnology sector needs

to engage in a public relations campaign. Note, also, that not only understanding, but also accepting, scientific knowledge has become an attribute of citizenship. An alternative view is to regard public (or "lay") knowledge as a legitimate, competing knowledge system alongside scientific knowledge (Brown; Balshem 1991), albeit less systematically articulated. Further research into public knowledges about health risks and what happens to them as they enter the public policy arena would be illuminating. Again, comparative research would indicate how

different jurisdictions have addressed the issue of ensuring (or, alternatively, limiting) public participation in setting the public policy agenda with respect to the development and deployment of biotechnology.

This Discussion Paper is offered in the spirit of David Suzuki's caution that "science is too important to leave to the scientists". What this means for social scientists is that, as Foucault said, "we always have something to do".

References

- Adelswards, V. and Sachs, L. (1998) Risk discourse: Recontextualization of numerical values in clinical practice, *Text*, 18(2), pp. 191-210.
- Baines, C. J. (1990) Ruminations on Breast Cancer, *Chronic Diseases in Canada*, 11, pp. 20-21.
- Balshem, M. (1991) Cancer, Control and Causality: Talking about Cancer in a Working-class Community, *American Ethnologist*, 18, pp. 162.
- Beck, U. (1992) *Risk Society: Towards a New Modernity* (London, Sage).
- Black, W. C., Nease, R. F. and Tosteson, A. N. A. (1995) Perceptions of Breast Cancer Risk and Screening Effectiveness in Women Younger than 50 Years of Age, *Journal of the National Cancer Institute*, 87(10), pp. 720-6.
- Breast Cancer Bulletin (1995) Listening to Women at Increased Risk, Vol. December, (Toronto, National Cancer Institute of Canada).
- Bunton, R. (1992) More than a woolly jumper: Health promotion as social regulation., *Critical Public Health*, 3(2), pp. 4-11.
- Bunton, R., Nettleton, S. and Burrows, R. (1994) *The Sociology of Health Promotion: Critical analyses of consumption, lifestyle and risk*. (London, Routledge)
- Burchell, G. (1993) Liberal government and techniques of the self, *Economy and Society*, 22(3), pp. 267-82.
- Castel, R. (1991) From dangerousness to risk, in G. Burchell, C. Gordon and P. Miller (Eds.) *The Foucault Effect: Studies in Governmentality* (London, Harvester/Wheatsheaf).
- Canada. (1998a) *Health Sector Summary Report*. Canadian Biotechnology Strategy Secretariat. Available online at: <http://strategis.ic.gc.ca/cbs>.

- Canada. (1998b) *Health Industries Summary Report*. Canadian Biotechnology Strategy Secretariat. Available online at: <http://strategis.ic.gc.ca/cbs>.
- Canada. (1998c) *Health Sector Consultation Document*. Canadian Biotechnology Strategy Secretariat. Available online at: <http://strategis.ic.gc.ca/cbs>.
- Canada. (1998d) *Roundtable Consultation Document*. Canadian Biotechnology Strategy Secretariat. Available online at: <http://strategis.ic.gc.ca/cbs>.
- Crawford, R. (1994) The boundaries of the self and the unhealthy other: Reflections on health, culture and AIDS, *Social Science and Medicine*, 38(10), pp. 1347-65.
- Douglas, M. (1990) Risk as a forensic science, *Daedalus*, 119(4), pp. 1-16.
- Douglas, M. (1994) *Risk and Blame: Essays in Cultural Theory* (London, Routledge).
- Douglas, M. and Calvez, M. (1990) The self as risk taker: a cultural theory of contagion in relation to AIDS, *The Sociological Review*, 38(3), pp. 445-64.
- Douglas, M. and Wildavsky, A. (1982) *Risk and Culture: An Essay on the Selection of Technological and Environmental Dangers* (Berkeley, CA, University of California Press).
- Foucault, M. (1984) On the Genealogy of Ethics: An Overview of a Work in Progress, in P. Rabinow (Ed.) *The Foucault Reader* pp. 340-72 (Harmondsworth, Penguin).
- Garro, L. C. (1994) Narrative Representations of Chronic Illness Experience: Cultural Models of Illness, Mind, and Body in Stories Concerning the Temporomandibular Joint (TMJ), *Social Science and Medicine*, 38(6), pp. 775-88.
- Giddens, A. (1991) *Modernity and Self-Identity: Self and Society in the Late Modern Age* (Stanford, Stanford University Press).
- Gifford, S. M. (1986) The Meaning of Lumps: A Case Study of the Ambiguities of Risk, in C. R. Janes, R. Stall and S. M. Gifford (Eds.) *Anthropology and Epidemiology: Interdisciplinary Approaches to the Study of Health and Disease* pp. 213-46 (New York, D. Reidel Publishing Co).
- Greco, M. (1993) Psychosomatic subjects and the "duty to be well: Personal agency within medical rationality, *Economy and Society*, 22(3), pp. 357-72.
- Government of Canada (1998a) *Renewal of the Canadian Biotechnology Strategy: Roundtable Consultation Document*. (Ottawa, Industry Canada).
- Government of Canada (1998b) *Health Sector Consultation Document: Renewal of the Canadian Biotechnology Strategy*. (Ottawa, Industry Canada).
- Hallowell, N. (1998) Feminine bodies = dangerous bodies: the dilemma faced by women at risk of breast or ovarian cancer. Paper delivered at the British Sociological Association, Annual Conference, Edinburgh, April 1998.

- Hallowell, N. (1999) Reconstructing the Body or Reconstructing the Woman? Perceptions of Prophylactic Mastectomy for Hereditary Breast Cancer Risk, in L. K. Potts (Ed.) *Ideologies of Breast Cancer: Feminist Perspectives* (London, MacMillan).
- Hayes, M. V. (1991) The risk approach: Unassailable logic?, *Social Science and Medicine*, 33(1), pp. 55-70.
- Hayes, M. V. (1992) On the epistemology of risk: Language, logic and social science, *Social Science and Medicine*, 35(4), pp. 401-7.
- Kavanagh, A. M. and Broom, D. H. (1998) Embodied risk: My body, myself?, *Social Science and Medicine*, 46(3), pp. 437-44.
- Koenig, B. and Stockdale, A. (2000) "The Promise of Molecular Medicine in Preventing Disease: Examining the Burden of Genetic Risk," in D. Callahan (Ed) *Promoting Healthy Behavior: How much freedom? Whose Responsibility?* (Georgetown, Georgetown University Press)
- Lipkus, I. M., Iden, D., Terrenoire, J. and Feaganes, J. R. (1999) Relationships among breast cancer concern, risk perceptions, and interest in genetic testing for breast cancer susceptibility among African-American women with and without a family history of breast cancer, *Cancer Epidemiological Biomarkers Prevention*, 8(6), pp. 533-9.
- Lippman, A. (1991) Prenatal genetic testing and screening: Constructing needs and reinforcing inequities., *American Journal of Law and Medicine*, XVII(1,2), pp. 15-50.
- Lloyd, S., Watson, M., Waites, B., Meyer, L., Eeles, R., Ebbs, S. and Tylee, A. (1996) Familial breast cancer: A controlled study of risk perception, psychological morbidity and health beliefs in women attending for genetic counselling, *British Journal of Cancer*, 74(3), pp. 482-7.
- Lupton, D. (1994a) Femininity, Responsibility, and the Technological Imperative: Discourses on Breast Cancer in the Australian Press, *International Journal of Health Services*, 24(1), pp. 73-89.
- Lupton, D. (1994b) Risk as moral danger: The social and political functions of risk discourse in public health, *International Journal of Health Services*, 23(3), pp. 425-35.
- Lupton, D. (1995) *The Imperative of Health: Public Health and the Regulated Body*. (London, Sage).
- Lupton, D., McCarthy, S. and Chapman, S. (1995a) 'Doing the Right Thing': The Symbolic Meanings and Experiences of Having an HIV Antibody Test, *Social Science and Medicine*, 41(2), pp. 173-80.
- Lupton, D., McCarthy, S. and Chapman, S. (1995b) 'Panic Bodies': discourses on risk and HIV antibody testing, *Sociology of Health & Illness*, 17(1), pp. 89-108.
- National Forum on Breast Cancer (1993) Survey of Breast Cancer Survivors. (Support, Networking and Advocacy Subcommittee).

- Nelkin, D. (1985) *The Language of Risk* (Beverly Hill, CA, Sage Publications).
- Nettleton, S. (1997) Governing the risky self: How to become healthy, wealthy and wise, in A. Petersen and R. Bunton (Eds.) *Foucault, Health and Medicine* (London, Routledge).
- Petersen, A. (1996) Risk and the regulated self: the discourse of health promotion as politics of uncertainty, *Australian and New Zealand Journal of Sociology*, 32(1), pp. 44-57.
- Petersen, A. (1997) Risk, governance and the new public health, in A. Petersen and R. Bunton (Eds.) *Foucault, Health and Medicine* (London, Routledge).
- Petersen, A. (1998) The new genetics and the politics of public health, *Critical Public Health*, 8(1), pp. 59-71.
- Petersen, A. and Lupton, D. (1996) *The New Public Health: Health and Self in the Age of Risk* (London, Sage).
- Potts, L. K. (Ed.) (1999) *Ideologies of Breast Cancer: Feminist Perspectives* (London, Macmillan).
- Renn, O. (1992) Concepts of Risk: A Classification, in S. Krimsky and D. Golding (Eds.) *Social Theories of Risk* pp. 53-79 (Westport, CT, Praeger Publishers).
- Rose, N. (1990) *Governing the soul: The shaping of the private self* (London, Routledge).
- Rose, N. (1993) Government, authority and expertise in advanced liberalism, *Economy and Society*, 22(3), pp. 283-99.
- Scott, S., Williams, G., Platt, S. and Thomas, H. (Eds.) (1992) *Private Risks and Public Dangers* (Aldershot, UK, Avebury).
- Williams, S. J. and Bendelow, G. A. (1998) Malignant bodies: children's beliefs about health, cancer and risk, in S. Nettleton and J. Watson (Eds.) *The Body in Everyday Life* (London, Routledge).
- Wynne, B. (1996) May the Sheep Safely Graze? A Reflexive View of the Expert-Lay Knowledge Divide, in S. Lash, B. Szerszynski and B. Wynne (Eds.) *Risk, Environment and Modernity: Towards a New Ecology* pp. 44-83 (London, Sage).

Genetic Engineering in Agriculture and Health: Feminist Dilemmas and/or Opportunities

Elisabeth Abergel

About the Author

Elisabeth Abergel recently completed her PhD in the Faculty of Environmental Studies at York University. She has been working on Genetic Engineering issues from different perspectives: as a research scientist trained in molecular biology and, as an environmentalist and feminist involved in environmental, agricultural and health issues. Her dissertation work consisted of a scientific and sociological evaluation of environmental risk assessment of genetically engineered herbicide tolerant canola in Canada. She is currently working as a consultant for several Canadian NGOs.

About the Article

Agricultural biotechnology is the focus of Elisabeth Abergel's paper. In illuminating the recent history of GE foods in Canada, she identifies the way that the current prevalence of GE crops and GE foods has been hidden from Canadians. The CBS is, for Abergel, only the most recent version of a developing policy agenda at the federal level which has worked to promote the industry, while obscuring the awareness of Canadians and marginalizing ethical and social issues. Abergel's analysis also highlights tensions for feminists. The positioning of women as consumers, she suggests, limits the nature of the critique that can be made in the name of women and women's health. A feminist critique, by contrast, needs to advance a broader social justice analysis. How, Abergel asks, will these two positions interact

The Context

The use of genetic engineering (GE) in agriculture is highly controversial. The ecological and human health impacts of this technology for food production are uncertain and contested. Throughout the world, a growing number of scientists, politicians and activists have been criticizing the way in which GE has been introduced in our fields and our food system, pointing to the lack of rigorous testing methods and the limited knowledge about long-term health and ecological consequences. European anti-GMO (Genetically Modified Organisms) protest has resulted in the adoption of a precautionary approach to the regulation of GE foods and the blockage of imports of North American crops. Canada is a major player in agricultural biotechnology; it is the third largest producer of GE crops in the world. Large public investments have helped to foster the Canadian biotechnology industry in the last two decades. The Canadian government has played a conflicting role in biotechnology, simultaneously promoting and regulating the products of genetic engineering.

North American resistance to GE is growing, largely as a result of worldwide concern. While the movement to block GMOs in food is often associated with a new health and environmental risk awareness, it also represents a global political movement, cutting across issues of race and class, linking the struggles of women, North and South, against the new trade agenda. Feminist opposition to agricultural genetic engineering has focused on the corporate domination of the food system, the ownership and control of vital biological resources and the marginalization of women's role in global food security.

As this short piece suggests, however, health and medical applications of the technology divide feminists in much more

profound ways, highlighting the complexity of biopolitical issues facing women today. The Canadian Biotechnology Strategy (CBS) did not provide a viable forum for women's views to be heard, as no opportunities to discuss the wider implications of the technology existed.¹ Early discussions about biotechnology policy excluded public participation and the development of regulations replaced any kind of formal technology assessment. The Canadian federal government has played a contradictory role in the area of biotechnology policy, promoting the industry while protecting the health of Canadians. As a result, the opportunity for women's groups to debate the use of genetics for various applications was missed. Canadian feminist discourse has remained fairly compartmentalized in terms of its critiques of biotechnology, mostly relating to changes in healthcare and the delivery of services for women.

Agricultural Biotechnology Policy

The first genetically modified organism to be introduced in Canada was herbicide tolerant canola in 1995, and there are currently over 40 GE crops approved for environmental release and commercial application. Crops such as herbicide tolerant and insect resistant corn, soybeans and potatoes have been introduced into the Canadian food system. Indeed, it is now estimated that over 60% of all processed foods sold in Canada contain GE ingredients.

Agricultural biotechnology has, until now, targeted industrial applications (food production and processing) leaving the public wondering how GE might affect them. These so-called "first generation"

¹ This is separate from the Royal Commission on New Reproductive Technologies that dealt with a wide array of technologies which did not exclusively involve genetic engineering.

GE crops have opened the way for “second generation” products also known as “nutriceuticals,” incorporating pharmaceutical and/or nutritional components such as vitamins and minerals considered essential to a “healthy” diet.

When it comes to agricultural biotechnology, Canada is characterised by a lack of public debate and openness in decision-making. Although the success of GMOs was premised on consumer acceptance, the Canadian public has been systematically excluded from discussions regarding the desirability and safety of these products. As a result, these products have largely remained hidden from public view, in the regulatory system and in the supermarket.

Canadian Regulation of GMOs

The Canadian federal government designates all new plant varieties and new foods derived from them as ‘Plants with Novel Traits’ and ‘Novel Foods’, equating biotechnology with traditional techniques of genetic modification such as plant breeding. In practice then, regulations focus solely on the new characteristics of GMOs (and foods derived from them) in what has been called a reductionist approach. New characteristics (genetic traits) in themselves are rarely seen to pose any new environmental or health risks (i.e. herbicide tolerance can be achieved through means other than GE and herbicide tolerant plants are not new). The adoption of a product-based regulatory system focuses the approval of ‘novel’ organisms independently from their method of production. A product or commodity focus makes the techniques and processes of genetic engineering irrelevant as possible sources of hazards. This ignores the inherent risks posed by the technology, focusing the attention of regulators and the public on the outward characteristics of the novel plant and away

from GE. The environmental and health approval of GE foods is based on a method of analogous reasoning comparing the hazards/ safety of modified crops against their natural counterparts. Hence, the hazards of conventional agriculture and current food practices establish the normative baseline for the assessment of GMOs. As a result, the acceptability of risks is a negotiated process occurring between regulators and crop developers. The scientific data submitted for approval of new crops is provided by the applicants (mostly industrial interests); the results of field and nutritional trials are not peer-reviewed, nor are they independently assessed by scientists; this information remains strictly confidential and away from public scrutiny.

On a more direct level, there are no public information requirements for foods derived through biotechnology and foods containing GE ingredients. They are not labelled. The system in place at the moment in Canada is “voluntary labelling,” meaning that food producers or manufacturers have a choice to keep the content of their products from consumers. Unfortunately, despite repeated demands by the Canadian public for the mandatory labelling of all GM foods and ingredients, the federal government persists in defending the rights of industry to withhold that information. Similarly, public campaigns requesting the segregation of GE from conventional crops have been deemed too costly (it is argued that costs would be passed on to consumers) and too difficult to manage through the food handling and processing system. What is clear is that in this case, labelling would give consumers the choice to knowingly *not* purchase GE products. The results of many public polls confirm this statement. In any case, it is obvious that by keeping GE out of the sight and mind of Canadians, the industry hopes to gain acceptance.

While labelling and segregation are important issues in the anti-GMO campaign, they also constitute a false debate. For GE opponents, the question is not simply about labelling or segregating but it is about maintaining access to non-GE foods and products and calling for sustainable alternatives.

Now that GE products have been around for a while and that people have been consuming them, it becomes easier to “banalize” the use of GE food. That is precisely the strategy used in Canadian biotechnology policy.

From NBS to CBS: Twenty Years of Biotechnology Policy

Through the various phases of the Biotechnology Strategy, first known as the National Biotechnology Strategy (NBS) and more recently the Canadian Biotechnology Strategy² (CBS), the federal government charted the course of biotechnology policy. It has provided the impetus for the development of a Canadian biotechnology industry through funding programs and policy formulations. The three phases of the CBS have mirrored technological developments, from R&D to marketing and more recently to issues of commercialization and “public participation.” The three phases proceeded as follows:

1. Research and Development (1983-1988): funds were allocated to stimulate

² The change in name reflects not only regional interests in biotechnology but issues of nationalism. Quebec has been a strong supporter of biotechnology in the past and represents an important player in the pharmaceutical industry, however, objections were raised about the “national” focus of the last strategy. For this reason, the Strategy Office at Industry Canada decided to rename its latest policy forum the “Canadian Biotechnology Strategy.”

the development of the industry in various strategic sectors of the economy;

2. Industrial Development and Regulatory Policies (1988-1997): during this period the regulatory framework was finalized in order to facilitate the commercialization of new biotechnology products, and finally;

3. Public Concerns (1998-): this latest effort is marked by the formation of a Canadian Biotechnology Advisory Committee whose primary function is to channel public concerns to relevant government agencies.

The fact that public concerns formed the focus of the most recent biotechnology strategy is indicative of the federal government's commitment to the success of the industry. For many critics of the Canadian approach, it appears as though the Canadian biotechnology industry is largely the product of the federal government's involvement, through various policy initiatives and generous public investments. This bias is expressed in the framework developed for regulating GE products which facilitates commercialization (treating GE as inherently safe) and serves to enforce the acceptability of transgenic agriculture. As a result, the formation of an arm's length advisory body to deal with socio-ethical issues reflects the government's lack of commitment to ensuring a fair and balanced policy process. In addition, the choice of an advisory body as the preferred mechanism for public participation in biotechnology issues after GE products have been approved for consumption and marketed to Canadians without their knowledge seems like inverted logic.

The sequence of events of the NBS to the CBS has essentially served to remove the implicit 'ethics' contained in the current regulatory system from public debate. This was successfully achieved by the exclusion and marginalizing of alternative

voices during the development of the technology. In other words, biotechnology has often been described as an autonomous technology, simply because it did not originate from public demand but instead from scientific advances. As a result, it is recognised that this type of technology generally neglects the “public good,” leaving out important social questions about technological change and unintended health/ environmental consequences. For this reason, the policy process has tended to reflect the federal government’s enthusiasm for the industry at the expense of the public interest.

The social acceptance of biotechnology has been tacitly built into government promotional and management programmes facilitated through the CBS. However, It is now apparent that this strategy has not been successful at silencing critics of the biotechnology industry. Clearly, one of the biggest challenges to biotechnology is democratic.

Feminist Issues

The 'biopolitical' issues raised by this technology divide women and feminists. Debates over GE have largely been portrayed as consumer issues. The fact that women are the primary purchasers of food and pharmaceutical products and are often responsible for feeding and maintaining the health of their families is used to support this view. This implies that resistance to these products and technologies are defined as being essentially 'consumer-based.' However, the issues raised by GE go beyond this simple analysis. For many women, resistance to GE food is linked to wider social and ethical questions about the collective rights of people to be self-reliant, have access to safe and healthy food and live sustainably on the land. For many activists such as myself, resistance to GE in agriculture is one way of reflecting upon the broader questions about the use of

that technology to transform nature and ultimately humans.

It has been my personal view, as a feminist involved in agricultural and health issues, that opposition to GE, although it has the potential to express much deeper concerns about the social use of biotechnology for defining particular models of society, raises some difficult issues for women. I personally find the separation of health from food and from environmental issues as a whole artificial and somewhat short-sighted. While there is widespread agreement among women that GE food may not be desirable for a variety of reasons, the medical uses of GE and the issues they raise are more divisive. It appears as though public reaction to the use of genetic technologies for producing pharmaceuticals and for medical interventions, such as gene therapy or genetic screening, have been mixed. They are generally viewed more positively than the production of transgenic foods. Unlike opposition to GE foods, differences in the level of concern raised by these technologies in healthcare often emphasise deep disparities among women, further polarizing feminists. Unlike food issues that stress the collective purpose of political action, many of the possibilities offered by genetic technologies as they relate to women’s “health” tend to individualise problems, leaving women with difficult if not impossible choices. For other women, the lack of access to these genetic technologies is the issue. However, the same “life science” companies are appropriating, controlling and manipulating genes for food and medical purposes. They are, along with compliant governmental authorities, precipitating the rapid commercialization of new foods, drugs and new technologies derived through biotechnology without public debate and consensus. For critics such as Vandana Shiva, corporate and technological control over reproduction (in plants, animals and humans) represents

the ultimate patriarchal project. Opposition to a technology such as GE is an opportunity to reflect upon the values embodied in that science and to consider the role of women for the genetics industry.

Questions to Consider

While I do not offer any solution to the issues raised in this short paper, I propose some questions that may provide the basis of further discussions:

- *How can feminists concerned about biotechnology reconcile these differences while respecting the diversity of women's individual experiences?*

- *How can a conversation about women and health incorporate these apparent contradictions?*

- *Do such differences weaken feminist discourse around genetic technologies?*

Engaging the State? **Framing Feminist Politics in an Era of State-Led “Reform”**

Pat Armstrong

About the Author

Pat Armstrong is co-author of such books on health care as *Heal Thyself; Managing Health Care Reform; Wasting Away: The Undermining of Canadian Health Care; Universal Health Care: What the United States Can Learn From Canada; Vital Signs: Nursing in Transition; and Take Care: Warning Signals for Canada's Health System*. She has also published on a wide variety of issues related to women's work and to social policy, including three editions of *The Double Ghetto: Canadian Women and Their Segregated Work*. She has served as Chair of the Department of Sociology at York University and Director of the School of Canadian Studies at Carleton University. She is a partner in the National Network on Environments and Women's Health and is currently chairing a working group on health reform that crosses the Centres of Excellence for Women's Health.

About the Article

Given the focus of most papers on the negative role of the state – as key promoter of biotechnology – Pat Armstrong's reasoned and critical defence of the state provides a fresh perspective. The state is, she argues, the only agent capable of providing goods such as universal health care, and comprehensive social services. Armstrong does not adopt a romantic view of the state, however. She notes that the state has been principally active in serving the needs of corporations. But this leads her, once again, to seek to use the state: “It is precisely because the state is now so activist,” she writes, “that we need to make demands on it.” Armstrong's analysis is especially cogent in an era of widespread state-led “reform” of health and social services – reform which can seem deceptively attractive in light of past state failings. She cautions feminists to ensure that our arguments are not turned against us. The feminist critique of the welfare state, for example, is sometimes used to reduce social services; and the feminist critique of medical priorities, and their often auxiliary role in generating health, has been used to shrink health care services.

Feminists have been very critical of both the welfare state and of medical practices. And feminists have warned against a nostalgia for the past, for defending a welfare state that did not support women's welfare or women's health. In light of these legitimate concerns, the state-sponsored restructuring of health and social services that has been underway in recent years – often presented to the public as “reform” – can seem very attractive.

With reforms done in the name of challenging medical dominance and welfare practices, many feminists have found it difficult to oppose reforms and many even offer support for reforms that seem to respond to their issues. Indeed, with reformers talking about empowerment and community, patient rights and continuity of care, evidence-based decision-making, efficiency and effectiveness, and a focus on primary care combined with de-institutionalization and the breaking down of the silos that separated aspects of care, it is understandable why reforms may have some appeal.

However, I would argue that these reforms are conducted within a context and paradigm that result in these processes meaning very different things to reformers than they do to feminists, meanings that are harmful for most women. The new paradigm is a business paradigm, where the business of government is business and the only line is the bottom line. Powerful forces – ones that are about what Brendan Martin (1993) in his book *In the Public Interest* calls the grubby hands hidden behind the so-called free market – at the international, national, provincial and local levels are shaping reforms so that efficiency and effectiveness are defined in not only numerical but monetary terms, and empowerment is based on ability to pay. Continuity is for processes not people; community means dumping care work and costs on families, and

within them on women; evidence is defined by the powerful in very positivist scientific terms; entrance through a primary care giver means both restricted access and more formulas for care; and patients' rights mean individual responsibility, rather than collective strength and shared risk.

This issue of patient rights can be particularly thorny for feminists, even in their own paradigms. As Sheryl Burt Ruzek (1999:304) points out:

Individualism and choice are deeply ingrained concepts in Western feminism. They have been critical precepts for extending reproductive rights, widening options for maternity care and giving patients a say in decision making, in requiring consent for medical care. But as useful as individual choice is in these arenas, can choice be taken as the first principle on which to base a national medical system? Are there other and competing and conflicting principles that warrant equal or greater consideration? Will a market-driven consumer model of health address pressing issues of access and equity? To what extent do individualism and choice conflict with the need of society to ensure a single, affordable standard of care for all?

Ruzek is talking to a US audience and of a US system, where universal health care has never existed. But her questions do have resonance for Canadians, especially as we increasingly look to the US for models of reform. Her argument leads me to another important issue in the feminist approach, the problem of class and race centred views dominating feminist approaches to reform.

Many of these reform processes and proposed institutions, as well as the stress on individualism and choice, have positive meaning for white, middle class feminists

living in urban centres, but may be very different for women with other locations. For the homeless, the movement of care "closer to home" may be punishment rather than release from oppressive institutions, empowerment may mean denial of access to institutional care, and choice based on finances or physical location may mean no care at all.

I would also argue that we have no choice but to look to the state for strategies that can lead to better health care. Only the state can provide universal access, only the state can provide the overall planning that can make care efficient in people terms, only the state can create stability and continuity, only the state is subject to democratic control. Only the state is powerful enough to counter the power of the global corporations. This is not to argue that the state has served women well, or served to reduce inequalities among women, or lately, to improve health care. Rather, I would argue that the current state is very active in serving the interests of corporations, in regulating to create markets and control populations, increasingly directly through households and through the privatization of health care. It is precisely because the state is now so activist that we need to make

demands on it. It *does* make a difference, and we need to make sure that the difference it makes is *different*, both from what the state is doing now and from the past. To argue that the state did not create equality is a challenge rather than an indictment.

A second, and related issue, is the matter of health determinants. Originally championed by political economists stressing the social forces that shape our collective lives, health determinants have been taken up as the new truth for health reformers of every stripe. Indeed, the health determinants literature has been used as a justification for dramatic downsizing within the public health care system. However, as is the case with other concepts, health determinants have been transformed within this new context. Unemployment, income, social support, etc, have been redefined as individual problems rather than as collective ones. The risk, and responsibility, is understood as individual, with that responsibility increasingly enforced in Ontario and Alberta by a neo-conservative state. I think we have to re-appropriate health determinants, initially by insisting that states and markets be included in the list as major determinants of health status.

References

Martin, Brendan. 1993. *In The Public Interest? Privatization and Public Sector Reform*. London. Zed Press.

Ruzek, Sheryl Burt. 1999. Rethinking Feminists Ideologies and Actions. in Adele E. Clarke and Virginia L. Olesen (eds). *Revisioning Women, Health and Healing*, New York: Routledge, pp 303-324.

Biotechnology and Women's Health: Re-Defining the Questions

Madeline Boscoe and Sari Tudiver

About the Authors

Madeline Boscoe, R.N., is the Advocacy Coordinator at the Women's Health Clinic, Winnipeg. She is a member of the Transitional Council of the Manitoba College of Midwives and is co-chair of the federal Advisory Committee on Reproductive and Genetic Technologies. She also serves as the Executive Director of the Canadian Women's Health Network. CWHN programs include direct information services, such as a toll-free telephone line, a clearinghouse, an extensive web site, and on line databases. The CWHN participates actively in the Centres of Excellence in Women's Health research program where she serves as a member of the Steering Committee.

Sari Tudiver, Ph.D., is a researcher, writer and consultant on women's health issues. An anthropologist by training, her research interests include the social impacts of reproductive and genetic technologies, the international pharmaceutical industry, and the development of gender-sensitive health care policies, programs and practices. From 1993-1998, she worked as the Resource Coordinator at the Women's Health Clinic in Winnipeg, providing consumer health information to women and developing resources on many aspects of women's health. She serves as Associate Editor of *A Friend Indeed*, a well-respected newsletter on menopause and midlife, and on the Board of Directors of Inter Pares, an international development agency. A founding member of the Canadian Women's Health Network, Sari has recently moved from Winnipeg to Ottawa.

About the Article

Boscoe and Tudiver write from the vantage point of decades of experience advocating for improving women's health and health services in Canada. Having been centrally involved in developing critiques of technologies and policies, the authors now turn their attention to the practicalities of regulation and control. "How," they ask, "can we contribute to the regulation and management of bio-technologies?" This is not a simple question, both because the models of regulation are contested, and because, as their paper demonstrates, relevant policies, legislation and agencies constitute a complex web. Their contribution lies in posing hard questions about the uncertainties of the long-term impacts of new technologies and the nature of citizen engagement in constructive opposition to the commercialization and globalization of bio-technologies and their products.

Introduction

We are writing from our perspectives as women who have worked for many years in a community-based, women-centred health centre, the Women's Health Clinic. In addition to providing health services to women, the clinic is committed to health education, advocacy and research responsive to women's needs. We have participated in a wide range of federal and provincial committees and task forces related to new reproductive and genetic technologies (RGTs); helped to develop policy papers; conducted qualitative research on women's experiences with RGTs; and have experience with coalitions and networks in the women's health movement, locally nationally and internationally. We are committed to developing critical consumer health information resources that locate issues in a broader context, capture the nature of current debate and discussion, and are accessible to women from diverse backgrounds.

Like many feminists, our interest in biotechnologies has been principally focused on the new reproductive and genetic technologies, where genetic science and women's bodies meet most intimately. Recognising these points of intersect between our individual experiences and the wider political and social context allows "teachable moments" – or crucial learnings to occur. For example, we not only ask: "Should I have this prenatal test?" and "Do I and my family have the capacity to cope with a child with particular disabilities and challenges?" but also, "Does my community provide the supports we will need?" and "Should public or private money be allocated to making such testing available?"

Our contribution takes the form of a series of basic questions. Some of these are crudely formulated, because it is difficult at

times even to ask "the right" question. We hope they will stimulate discussion and contribute to a clearer understanding of how to develop broad-based strategies for generating knowledge and research and for public education and action. Despite promises of future benefits and cures, we worry that the development of commercially-driven biotechnologies poses new, unforeseen risks to human health and raises profound ethical implications which have only begun to be considered in public discourse.

How can we contribute to the regulation and management of biotechnologies?

Social research and activism related to biotechnologies have focused mostly on the development of well articulated "critiques". While some general frameworks for regulation have been suggested, there are few models proposed which would address the specific challenges of regulation or other ways of managing the technologies. We believe this is an area of urgent need.

We can learn from discussions of reproductive and genetic technologies by women's health groups. There have been strong analyses and critiques, documenting the discourse and meaning of the technologies, as well as the "choices" they provide. In contrast, there has been little exploration of models for regulation and management. Indeed, there is ongoing debate regarding use of federal criminal powers to regulate and even prohibit certain technologies. Mechanisms for management of prenatal genetic testing are unresolved.

The development of regulatory mechanisms for biotechnologies needs to be situated in the context of existing and shifting regulatory mechanisms and the challenges these present. Health Canada

is engaged in a “Transition Process” which may offer opportunities for new linkages and integration among departments on these issues. A “Risk Management Framework” is being developed. This is an area for further research, public debate and synthesis. This framework will need to be reviewed with a cautious eye. The language and vague terms do not adequately describe what processes or specific standards will be put in place. There is a need for greater transparency and public access to information about regulatory decisions. For example, the pressure from manufacturers and from some consumers to bring drugs to market more rapidly has implications for the public’s health and safety since shorter time frames for clinical trials means we know less about long-term effects prior to public use. As well, apparent gains in public access to information are hard won and often limited. For example, the recent World Trade Organization decision permitting labelling of genetically altered foods for export does not in itself address issues of safety, research, development and corporate control. There is need for a more sophisticated analysis of regulatory mechanisms for both research and use of these materials.

In the context of the regulation and management of biotechnologies, how will research be managed?

It appears difficult to clearly separate laboratory research, research trials and therapeutic or product applications of biotechnology research. For example, research in biotechnologies in plants, animals and particularly humans removes the concept of a “safe laboratory” or “sealed environment.” As well, *in vitro*, *in vivo*, clinical trials and clinical therapeutic uses of biotechnology products are often carried out simultaneously, ensuring products are brought to market very rapidly. While the use of inadequately tested drugs, products and devices is not

a new phenomenon (e.g. DES; other hormones; and blood products), biotechnologies seem to raise even greater health and environmental concerns. As consumers, professionals and activists, we feel we are always having to play “catch up” with new technologies and techniques, asking to regulate technologies, the introduction and implications of which should have been debated at a much earlier research stage.

We ask: how are proposals for biotechnology research reviewed and how is the resulting research monitored? Are there constraints on the transparency of such research? What is the impact of corporate secrecy in research and development? How is increasing commercialization of research within universities affecting the climate of critique concerning research and monitoring? With reduced public funding for university-based research, there is increased pressure for corporate-university partnerships. How do university based ethics review boards function in this environment and to what standard? Do we need new review processes?

What is the impact of the proliferation of private research institutes on the potential regulation and management of biotechnologies? What will be the impact of the restructuring of health research within the Canadian Institutes of Health Research and the proposed peer review process? What mechanisms can be put in place to track the impact of this restructuring? Can the role and scope of Research Ethics Review Boards be strengthened, for example, to include the use of “citizen panels” and juries in reviewing complex ethical questions? What effective models are there that could be used? How can the public learn about biotechnology research in an accessible way, exploring the broader implications?

We look to those involved in the ethical review of research proposals to address

the wider context within which such research is being conducted and the goals to which it is directed. Hopefully, there is the will and capacity in the independent academic / research community to do so. The question remains: How will this be done to benefit the public and not just the individual or corporate sector?

Can we think “seven generations ahead”?

Can we learn to think beyond the present, even “seven generations ahead,” as Aboriginal elders teach? How can the “precautionary principle” be realistically applied to specific situations in the present, but envisioning the future? More immediate pressures for livelihood often overshadow a long-term perspective and sound public health practices. For example, we have seen communities argue that environmental regulations should be weakened or ignored because of proposed short term benefits, such as access to well paying jobs and the influx of capital to sustain rural communities.

What does it take to develop broader public consciousness in relation to health and long term sustainability – to think beyond the next paycheck (if there is one) to future generations? What are some of the personal, social, economic costs/ risks of thinking this way? What are the costs/ risks in **not** doing so? How can we get our governments, attuned to electoral time lines, to apply the “precautionary principle” with a vision of the future?

Must we always say “No”?

While wary of the possible long term hazards of biotechnology, we ask: Are there some aspects and applications of biotechnology research that offer therapeutic value and improved human health outcomes to future generations – or is that truly impossible to know? For

example, is there a qualitative difference between some genetically modified products (e.g. soy products; crops for hardier climates) and “terminator technology” seeds? Are there important directions to research and applications that mitigate suffering (e.g. genetic screening for Tay-Sachs disease) but that do not lead to the denials of human dignity and human rights underlying eugenics? Should we screen for diseases – or susceptibilities to diseases – for which there is no known cure, or which may be triggered by complex social/ environmental/ emotional factors? What about germ line research? Is there a “continuum” with its inevitable “slippery slope” – or are there qualitatively different types of research? Is the question solely about the capacities of the technologies or is it also about who controls the knowledge and its application within private and public domains?

Further, if we in Canada say “no” to a technology (e.g. cloning), what are the implications of “leaky borders” – the legalization of the same practice in another country? How do patents and international trade agreements shape Canada’s ability to act within its borders? In the realities of increasing corporate consolidation, global markets and commercialization of the products of conception, what does it mean to say “no”?

Can we nurture ‘critical consciousness’?

Human genome mapping has the public’s attention; the almost daily announcement of a new gene discovery nurtures an ideology of “geneticization” (as Abby Lippman so insightfully characterizes it), in which genetics is assumed to play a determining role in social life. Biotechnology research has transformed the impossible into the possible. What appeared unthinkable several years ago is

now considered inevitable: buying and selling genetic materials; patenting life forms; trans-species genetic transfer; cloning; selling Iceland's "gene pool" for research purposes. To our children, and increasingly to us, these are 'normal' news items.

What does 'normalizing' these processes do to developing a critical evaluation and assessment of the new biotechnologies? As women hear about new technologies and products, they naturally want options to maximize their health and the health of their families. But personal choices and options are necessarily set in a context that excludes other possibilities. The challenge for policy makers is to direct resources to social needs which will have a broad impact on population health, while also addressing the specific needs of particular groups and individuals. How can we distinguish in a meaningful way between "real risk" and "presumed risk" for individuals and 'populations' and create a clearer lens for analysis? How do we apply understandings of gender and social class to this analysis? For example, we know that in addition to appropriate health care services, health is best addressed through reduced stress, sound nutrition, exercise, healthier work environments and better housing – and by reducing poverty and violence which affect the overall well-being of so many women. Where does/ should biotechnology research fit in the context of addressing these social determinants of health?

Are there creative and effective ways to develop critical public consciousness about the political, economic and scientific "drivers" of biotechnology research and applications? How do we debate the alternatives?

GOING FORWARD

How can we make information about biotechnology and its implications

accessible to women and men from a variety of backgrounds and experiences?

How do we create spaces for discussion and debate?

We have few opportunities to examine the issues suggested by biotechnology research. In fact, we are often confronted with the implications and dilemmas of these technologies in our role as consumers: Should we purchase genetically modified foods? Should we consent to genetic screening? Would we participate in a clinical trial for a procedure using biotechnology? Should we donate our embryos or cord blood? These dilemmas take place in an environment characterized by 'individual consent' and limited information. Often, the issue is raised at an emotionally charged time, such as a crucial stage of pregnancy or during family illness. The questions are narrowly framed. The commercial and other interests behind the development of many of the technologies are rarely considered.

Schools have little time or capacity to teach about and discuss these issues to prepare students for future dilemmas. Ethicists, scientists and health professionals may debate these issues but the content of the discourse is usually not accessible to the public. Sometimes the press and other media raise issues and initiate debate. Infrequently, public discussion is generated through art or film (for example, the NFB film, "On the Eighth Day" on new reproductive technologies).

There is a lack of time, opportunities and resources for most adults to engage in constructive debate on these issues. Governments, to date, have relied on researchers and lobbyists to provide them with policy direction. Public opinion is measured by the numbers of letters to ministers, attention in the public media and polling results. Yet, as educators, we know that it is in discussion and debate that

adults learn best and that we can come to a much deeper understanding of the broader social context to complex issues. Appropriate information in accessible formats is essential to help generate such debate. Face to face or other types of encounters (e.g. internet chat groups) can offer settings for listening to others from different backgrounds and perspectives. Despite conflicting interests and opinions, there may be the potential to develop a 'working consensus' or at least define the terms of 'constructive opposition'.

Recently, governments have become more overtly committed to the involvement of the public in policy development and decision making. This change within the regulation development processes offers opportunities for engagement, but also raises concerns. For example, the goal of citizen engagement has been adopted throughout Health Canada. (An Office of Consumer and Public Involvement has been created within the Health Products and Food Branch). Women's groups and other non-governmental organizations are receiving numerous requests for input on crucial issues such as transgenic human transplantation and regulation of natural products – but few have the resources and capacity to respond. As well, while some processes for public involvement seem to be committed to broad and diverse input, other consultations appear carefully controlled and managed as to content and outcome.

We must continue to ask: How will women's groups and organizations, particularly those that address the front-line health needs of women and their families, find effective mechanisms for education, critical synthesis and debate

AND for input into the decision making processes on research and commercial developments in biotechnology? Will there be adequate resources for groups to be able to respond and engage? At present, some NGOs and individuals with interest and expertise in these issues are part of working groups that communicate online. They require financial resources to continue to develop well-researched information, effective workshops and symposia. Can policy and decision-makers in government engage with women's groups on these issues in mutually respectful, authentic ways? If so, how?

How does an agenda of social change, as articulated, for example, in the Beijing Action Plan, and in concepts such as "Health For All by the Year 2000" move forward? What, if any, is the role of social protest movements in the year 2000 in advancing these agendas? Strong opposition has emerged in Europe to genetically modified foods and to the development and trade policies of the major financial institutions. Protests (Seattle, Montreal, Prague) show these social movements capable of attracting media attention and influencing global institutions on these issues.

Activists, researchers, independent academics and others from the environmental, social justice, consumer rights, farm and women's movements, etc are raising fundamental questions about the course of development in the 21st century. Biotechnology and its commercial applications are at the centre of their concerns. Perhaps the protesters are reminding us that answers are being proposed before many of the most basic questions have been asked.

Gender and the Gene Giants:

Research and action on women and the new genetics

Julie Delahanty for RAFI

About the Author

Julie Delahanty is a Researcher and Programme Manager at RAFI working primarily on biopiracy, human genetic research, and new technologies. Julie was formerly a Researcher in Gender Equality at the North-South Institute, an Ottawa-based international development research organization. She is the author of numerous publications on gender, health, labour rights and macroeconomic reforms.

The Rural Advancement Foundation International (RAFI) is a non-governmental organization head-quartered in Winnipeg, Canada, with 5 full time and 3 part time staff and offices in Ontario, Quebec, North Carolina and Queretaro, Mexico. For twenty years, RAFI has done groundbreaking research, public education and policy advocacy – on agricultural biodiversity, the impacts of biotechnology, intellectual property rights, and indigenous peoples' knowledge. Now available on the Internet, RAFI's publications are used regularly by people in 65 countries, and at many educational events. RAFI has conducted seminars all over the world, and has received extensive media attention for its work. RAFI does not stop at research and education. They use their analysis in the multilateral arena, and work with NGOs from around the world to influence such decision-making bodies as the U.N Food and Agricultural Organization and the Convention on Biological Diversity. They have challenged patents on crop species and human tissues, and have forced several plant and human patents to be revoked. Whether assessing the impact of biotechnology on farmers, or of bioprospecting and intellectual property regimes on indigenous peoples, RAFI analyzes industry trends from a "North-South" and social justice perspective. As the first NGO to address these issues globally, RAFI provides timely research and advocacy within a growing global network of non-governmental organizations concerned about the loss of genetic resources, monopolization of living organisms, and peoples' knowledge about them.

About the Article

Julie Delahanty selects four developments that are of keen interest for RAFI, the Rural Advancement Foundation International, and outlines gender-equality concerns and issues for further research and action. Delahanty's paper is motivated by the need to inform people about the range of issues – from corporate concentration in agribusiness, through human genetic diversity and pharmaceutical research – that are linked to the benign-sounding Canadian Biotechnology Strategy. Delahanty's paper also establishes a plan of action for feminist research and action. Her paper demonstrates both the usefulness of applying a specific "gender lens" to these seemingly gender-neutral issues, and the importance of building any concerted feminist response on the knowledge foundation built by NGOs like RAFI.

Introduction

Separating the issues of health, wealth and community in the context of women and the new genetics proved a difficult exercise, perhaps highlighting their appropriateness. I have chosen four main issues that are important to RAFI's work. These include:

1. *the use of genetic research in the pharmaceutical industry,*
2. *the corporate concentration in the life industries.*
3. *the Terminator and Traitor technologies,*
4. *the threat of genetic biowarfare.*

A brief discussion of each issue is followed by the key gender equality issues and research and action needs.

1. Research and use of genetics in the pharmaceutical industry.

Human Genetic Diversity Research is being conducted and commercialized at an alarming rate. Were the commercial value of human genetic diversity research ever in doubt, those misgivings were unambiguously laid to rest when Iceland sold its genetic heritage to the genomics company deCODE, who, in turn, hawked the human data to Hoffman LaRoche of Switzerland for US \$200 million. The spectacular and controversial deal turned genomics research overnight from an obscure biotech niche industry into a mainstream commercial venture.

Suddenly, almost unheard of genomics companies like Millennium (US), Genset (France), and Axys (US), are turning diversity studies into a multi-billion-dollar commercial product strategy aided and abetted by researchers at universities and even some governments. The extension of patentability by the US Patent and Trademark Office to single nucleotide polymorphisms (SNPs- the smallest unit of

genetic variability) has further galvanized commercial pharmaceutical enthusiasm for the new industry. SNPs are the genetic basis upon which diversity researchers define their investigations and distinguish individuals and human populations from one another.

Given this full-scale commercial foray into diversity research in combination with the new methods of sampling and sequencing, the pressing question for ethnically unique populations and particularly for indigenous peoples is no longer "Will we be sampled?" but rather "Who will have access to human genetic diversity, and will it be subject to exclusive monopoly control?" The commercial race for diversity material is not faceless, but involves the lives of particular groups of people in increasingly alarming ways. The potential violation of basic human rights, particularly with respect to research subjects' health and social well-being, appears to be increasing. Further, in many of the studies it seems likely that researchers are not obtaining fully informed consent from their research subjects. Finally, more general ethical questions about the patenting and commercial use of this genetic material have simply not been adequately addressed.

An example of these problems in genetic research can be found in studies by genetic diversity researchers at Harvard University who, in collaboration with a number of pharmaceutical companies, including Millennium Pharmaceuticals, a biotechnology firm based in Cambridge Mass., have been conducting large scale genetics studies in China. At least 14 projects are underway in China, encompassing as many as 200 million Chinese citizens. The projects include research on obesity, schizophrenia, pulmonary disease, atherosclerosis, hypertension, and colon cancer.

There is a mounting body of evidence suggesting that the rights and protection of the research subjects, mostly located in Anhui Province in China, are being violated. In many cases, the research is being conducted under conditions where proper informed consent is likely not being obtained. The real health risks associated with many of the research studies are accentuated by a situation where health systems, particularly in the rural areas, have completely broken down due to the changes in the Chinese economy. According to many health workers and other observers, the blood supply is heavily contaminated and syringes and needles are re-used and unsterilized. In many cases, the research is being conducted in China specifically because the population does not have access to modern medicine. The Harvard researchers are not ensuring that their research subjects are provided access to known therapeutic drugs – a situation that would not be tolerated in the US.

In a country where researchers cannot guarantee the privacy of their research subjects, confidential information may lead to prejudiced government authorities having full access to the research data. Serious ethical questions arise in projects that attempt to uncritically capitalize on the poor human rights situation in China, for example, by using the detailed reproductive records of Chinese women. Not least, many of the studies will be of absolutely no benefit to the people being studied – who need a bowl of rice, not gene therapy.

Key Gender Equality Issues:

- What are the specific threats to women of genetic diversity research?
- How does gender inequality in health care affect the risk posed to women from such research?

- How can feminist concepts of informed consent be used in discussing this issue?
- How has the notion of "choice" advocated by western feminists been co-opted by corporate and commercial interests (and by the Canadian government) in discussions about the new genetics and health.

Research and Action:

Research.

- Monitoring the increasing commercialization of genetic diversity: who is doing the research, where is it conducted, which groups are the targets of the research, what are they looking for.
- Follow-up research focusing on individual cases of abuse.

Action.

- Life patenting, particularly patenting gene sequences, needs to be challenged in the courts, the legislature and by the public. In particular, there is an urgent need for a public debate on this issue which is currently being decided in the courts rather than through a democratic and accountable process. The meaning of the CBS in the discussion about patenting is clear: they mean to ensure that patenting is approved in Canada.
- Cases of abuse of research subjects need to be publicized. Peoples and governments should declare a moratorium on all human diversity collection and commercialization until certain agreements are in place. At the international level, action must be expected from the UN Human Rights Commission, from the World Health Organization, and from UNESCO's International Bioethics Committee (which has woefully neglected the intellectual property and commercial

issues arising from human DNA collection).

- Nationally, governments could review their medical ethics and research protocols to guarantee the rights and dignity of their citizens. In particular, governments might consider legislation that would criminalize the collection or removal of human germplasm without the prior informed consent of the individual, their community, and the national government.
- The issue of the patentability and Human Rights associated with human tissues must be discussed by the UN General Assembly. An outstanding concern is the place of human biodiversity within the framework of the Biodiversity Convention. Although most countries concur that human diversity should not be managed by the 1992 Convention, legal interpretation of the Convention suggests that human biodiversity is part of the agreement. In order to correct this problem and assign responsibility more appropriately, the General Assembly may seek an Advisory Opinion from the International Court of Justice (ICJ). The ICJ could be asked to determine the position of humans within the Biodiversity Convention and whether or not patenting of human tissue, as required by the World Trade Organisation (WTO) contravenes Human Rights.

2. The corporate concentration in the new genetic industry

The intense corporate concentration, and the financial incentives which characterize the new genetic industry are the clear backdrop to much of the Canadian Biotechnology Strategy. Any concerted feminist response to the CBS requires an understanding of just how significant these interests are. Important elements of this concentration involve the issues of intellectual property and ownership of life,

both of which are important subtexts in the Canadian Biotechnology Strategy.

The 'life industry' comprises the giant, transnational enterprises that dominate commercial products for agribusiness, food and pharmacy. Loosely defined, the Gene Giants include the transnational enterprises that dominate commercial sale of pesticides, seeds, pharmaceuticals, and food and animal veterinary products. The 1990s saw a swift and bold concentration of power in the life industry – a trend that has shown no signs of abating. A steadily shrinking number of corporate Gene Giants control expanding market share over agribusiness, food and pharmacy. These are the transnational enterprises that aim to manipulate, control, patent and profit from life. Market dominance combined with monopoly patents gives the Gene Giants unprecedented control over the products and processes of life – the biological basis for commercial food, farming and health.

To conclude that transnational corporations rival the power of the nation state is a gross understatement. Indeed, the *Economist* reported that when corporate executives were negotiating the merger of Travelers and Citicorp, one of the negotiators mused: 'Can anybody stop us?' The only response was 'NATO.'

Since 1996, virtually every major seed/ agrochemical company has invested in plant genomics research. Driven by the increased efficiency of genomics technology and fierce competition among major agbiotechnology firms, investment in crop genomics has accelerated dramatically. Particularly noteworthy is the very minor participation of public sector researchers in agricultural genomics. After the Gene Giants and their genomics partners stake patent claims to molecular bits and pieces of commercially important plant genomes – what will be left for the public sector? With patents in hand, the Gene Giants have the legal right to

determine who will get access to plant genomic material and at what price.

Unchecked corporate power coupled with the vanishing role of public sector research will affect all areas of global health, agriculture and nutrition. Neglect of the public good is inevitable when the research agenda is determined by the private sector in pursuit of corporate profits. There is a widening knowledge gap between rich and poor, men and women, both within and between the industrialized North and the impoverished South. Access to food, health and nutrition – once considered a fundamental human right – is now subject to the whims of the free market system.

Key Gender Equality Issues:

- With the development of so-called 'functional foods' and 'nutraceuticals' the lines between food and medicine are blurring, further enticing food processors, agbiotech firms and drug companies to merge complementary interests in food, biotechnology and pharmaceuticals – what are the implications of these changes for women who are the primary consumers of such products?
- How does corporate concentration in the life industry affect the ability of women to resist?
- How does this concentration further polarize gender inequality in wealth and control and access to resources?
- How quickly is the gap widening as a result of the unchecked corporate power?
- How has public sector research been affected by the increase in corporate concentration and what impact has/will that have on women's health concerns?

Research and Action:

Research.

- Continue monitoring the Gene Giants to determine what direction the mergers are headed in.
- Examine the implications of the consolidation of the power of the Gene Giants on world food security and gender equality.
- Pay close attention to consolidations and mergers, for example, pharmaceutical companies are "vertically integrating" by taking over cancer research centres. In other words, who is paying the doctors who are prescribing the drugs.

Action.

- The concentration of economic power in the hands of the Gene Giants, and the privatization of science and technology is not being systematically addressed by intergovernmental bodies. These issues should be at the top of the list for UNESCO.
- The Consultative Group on International Agricultural Research (CGIAR) – the world's largest international agricultural research network – runs the risk of irrevocably distorting its mandate to serve the world's poor farmers if it pursues the path of high-tech proprietary science in partnership with transnational Gene Giants. It must instead strengthen its research synergy with national programs and small farmers, including women farmers.
- The Food and Agriculture Organization (FAO), which 20 years ago held a major conference on agrarian reform and rural development, urgently needs to revisit and strengthen its commitment to farmers and food security.

3. Terminator and Traitor Technology

The infamous Terminator technology identified by RAFI in March 1998 is a

technique for genetically altering a plant so that the seeds it produces are sterile. It is a threat to agricultural biodiversity and the wellbeing of 1.4 billion rural people, most of them women, who depend on farm-saved seed and local plant breeding. In January 1999 RAFI revealed that virtually all the Gene Giants (Monsanto, Novartis, Astra/Zeneca, DuPont, BASF, Rhone Poulenc) are working on their own genetic seed sterility patent claims. Over two dozen new patents reveal that engineered seed sterility is not an isolated research agenda, it's the Holy Grail of the agricultural biotechnology industry. As a result of public pressure, Monsanto has backed down from its position on the Terminator, however, the US government still holds the patent and refuses to agree not to use it. In fact, both the corporation, Delta and Pineland, and the USDA which jointly hold the patent are planning on going full speed ahead with this technology. The corporations which rejected Terminator, including Monsanto, have since morphed and spun off parts of their company, indicating how flimsy corporate promises can be in a climate of increased mergers and consolidations.

The new generation of Terminator patents goes beyond the genetic neutering of crops. The patents reveal that companies are developing suicide seeds whose genetic traits can be turned on and off by an external chemical 'inducer' – mixed with the company's patented agrochemicals. In the not-so-distant future, we may see farmers planting seeds that will develop into productive (but sterile) crops only if sprayed with a carefully prescribed regimen that includes the company's proprietary pesticide, fertilizer or herbicide. The latest version of Monsanto's suicide seeds won't even germinate unless exposed to a special chemical, while Astra/ Zeneca's technologies outline how to engineer crops to become stunted or otherwise impaired if not regularly exposed to the company's chemicals. A Novartis patent (US 5,789,214) describes

a process for chemically regulating a number of developmental processes in plants – such as germination, sprouting, flowering, fruit ripening, etc. The patent specifically mentions that the chemical regulator can be applied to plants in combination with a fertilizer or herbicide. RAFI calls it 'Traitor Technology.' (For more information and in-depth analysis, see RAFI Communiqué's and press releases on Terminator and 'Traitor Tech,' at <http://www.rafi.org/>).

If companies can genetically program suicide seeds to perform only with the application of proprietary pesticide or fertilizer, it means they will dramatically increase sales of their patented agrochemicals and other proprietary inputs. Chemically-dependent suicide seeds are a dazzling technological achievement and a brilliant marketing strategy, but it's grim news for farmers, the environment and global food security.

Key Gender Equality Issues

- Given that the majority of the world's farmers are women, and that the majority of the world's seed savers are also women, the issue is dramatically important to the well-being of women. The seeds are cultivated and exchanged in accordance with local needs and traditions. The loss of the potential characteristics of traditional varieties is a matter of survival for women who anyway cannot afford agricultural inputs. Most of the genetically modified varieties are for herbicide resistance, however, women in most of the world, particularly in the south perform the weeding activities, therefore the impacts on women of these varieties may be different in terms of labour.

Research and Action:

Research.

- Further research to monitor Terminator and Traitor patents.
- Research on the potential socio-economic and health effects of Terminator and Traitor on women.

Action.

- The USDA must be pressured to reject the Terminator.
- Other national governments should take action at the WTO and elsewhere to reject Terminator and Traitor technologies on the basis of public morality.
- The Ad Hoc Working Group revising the Biological and Toxic Weapons convention should challenge the US research as a violation of Article One of the Protocol.
- The Convention on Biological Diversity must reverse its earlier decision allowing commercialization of the Terminator and related technologies.

4. A Related Risk: The Specter of Biological Warfare:

Those of us who monitor biotechnology have paid too little attention to its military applications or its impact on democratic institutions. It is almost impossible to distinguish between peaceful, humanitarian uses of genetic research and the development of genetic weaponry. According to Dr. Pauline Lane of the University of East London, 'The line between medical research and warfare is often difficult to distinguish and [it] is a difficult area to monitor.' (Lane, 1999). A report released in January 1999 by the British Medical Association warns that biomedical research could be perverted to develop 'weapons which may become a major threat to the existence of Homo sapiens, and a development of biotechnology which perverts the humanitarian nature of biomedical science.' (Boseley, 1999. The report is

entitled "Biotechnology, Weapons and Humanity," by Prof. Malcolm Dando).

Although RAFI first expressed concern over the likelihood of crop-targeted biological warfare at Bogève in 1987, our warnings elicited little interest until the Terminator patent was granted on March 3rd, 1998. Suddenly, the potential to switch a suicide sequence in the seed on or off with a chemical promoter posed real concerns about economic sabotage – the real "eco"-terrorism. Would it be possible to insert the Terminator into seed exports and "bury" the trait for several generations of planting – or activate the trait through some remote command, chemical, or atmospheric condition? Such speculation seemed paranoid to many. However, the basis for concern was provided exactly one year to the day before the Terminator patent was allowed. On March 3rd, 1997, the South African Government, having admitted that the former apartheid regime had undertaken biowarfare research on both crops and ethnic populations, tabled a list of twenty crop pathogens it had investigated for possible weaponization. South Africa's study was presented in Geneva to the ad hoc group of countries considering ways to strengthen biological warfare treaties. Then, in June, 1999, *Scientific American* published a stunning report by researchers at the University of Bradford in the UK that chronicled crop and livestock biowarfare research not only in South Africa but also in the USA, the UK, Russia, and Iraq. While some of the history dates back to World War II or the Vietnam War, the Iraqi work took place in the 1990s and included bioengineering of wheat pathogens that could have devastated food security in the Middle East.

In November 1998, the London *Sunday Times* reported that scientists are attempting to engineer deadly biological organisms to produce 'ethno-bombs' that are capable of targeting human victims by

ethnic origin (Mahnaimi and. Colvin, 1998).

In early January 1999, Craig Venter of Celera Genomics told the American Association for the Advancement of Science that his company was on the threshold of constructing the world's first simple artificial life form, based on 300+ genes borrowed from a simple microbe. But Venter's team announced that it would halt further work because artificial organisms could be misused and become a template for deadly biological weapons in the hands of bioterrorists (Cohen, 1999).

In a world in which a handful of transnational enterprises dominate agricultural biotechnology; in a world where the Terminator is the platform technology upon which all new biotech breeding is undertaken; it is not difficult to believe that corporations or governments would use the technology to impose their will. A textiles trade dispute with South Asia, for example, could lead to the denial of a modified Roundup herbicide needed to ensure the rejuvenation of Monsanto's cotton seeds containing the Terminator sequence. An agricultural dispute with France could lead to the same threat to France's BT maize crop. Brazil's soybean harvest – a major export competitor with U.S. farmers – would be rendered defenseless if the U.S. soybean breeder – or the US government – withheld the critical chemical protector. Eco-terrorism could prove to be far cheaper and much faster as a means of resolving trade disputes than WTO arbitration processes that are both lengthy and uncertain. In the 1970s, a U.S. Secretary of Agriculture appointed by the same U.S. president who unilaterally dismantled biowarfare stockpiles nevertheless felt entitled to acknowledge that food is a political weapon. The policy continues.

During the World Food Summit of 1996, the United States argued that the Right to

Food should not become part of the final declaration. They eventually lost. However, the USA won its argument that sovereign states need not strive to be food self-sufficient as long as they were food self-reliant – that they could afford to buy the difference between national need and national production. Now, with Terminator Technology, food deficit countries are faced with the possibility that their national production will be wholly dependent upon foreign exports of critical chemical inducers.

Key Gender Equality Issues:

- How can women, particularly in developing countries, resist the danger of economic bio-terrorism?
- What are the differential impacts on women from such biological disasters?
- Women are less likely to grow cash crops than men in the developing world, how would this affect the impact on women of bioterrorism? Could there be a "feminist bomb?" (maybe there are characteristics that all feminists share??!?!)
- How might the right to be food self-reliant rather than food self-sufficient have a differential impact on women?

Research and Action:

Research.

- Research on the questions identified above.
- Monitoring new traitor technologies.
- The connection between the military and the human diversity collections must also be monitored.

Action.

- Action could be taken at the level of the 1972 Biological and Toxic Weapon Convention (BTWC), signed by 141 countries, which bans the development and production of biological weapons.

The Convention is currently impossible to enforce because it lacks mechanisms for oversight and enforcement. In 1998 negotiators met in Geneva to strengthen the BTWC, but efforts to develop a legally-binding compliance protocol were stalled because pharmaceutical and biotech

representatives voiced concern about industrial espionage and the theft of intellectual property (Anonymous, 1998). A conference to review the 1972 Convention is due in 2001, which might be an opportunity to raise the issues of the use of terminator and traitor technologies as biological weapons.

References

- Anonymous, 1998. Biological and Toxins Weapons Convention resumes in Geneva: Pharma and biotech sectors assess impact of convention on their industries. *European Biotechnology Newsletter*. 24 June, pp. 1-3.
- Boseley, S. 1999. Medics sound genetics weapon alarm. *The Guardian*. January 22.
- Cohen, P. 1999. A terrifying power. *New Scientist*. 30 January, p. 10. Genetic Weapons.
- Lane, P. 1999 Fighting Genetic Wars. *SPLICE*. February/March, p. 11.)
- Mahnaimi, U. and M. Colvin, 1998. Israel Planning Ethnic Bomb as Saddam Caves In. *Times of London*. 15 November 1998.
- RAFI Communiqué, 1999. Traitor Tech: The Terminator's Wider Implications. January/February, 1999. Available on the internet: <http://www.rafi.org>.

Environmental Sustainability and the Canadian Biotechnology Strategy

Margrit Eichler

About the Author

Margrit Eichler is Director of the Institute for Women's Studies and Gender Studies at the University of Toronto, and a Professor in the Department of Sociology and Equity Studies in Education at OISE/UT. She has published widely on feminist issues, including family policy, reproductive technologies, feminist methods, women's studies and un/sustainability.

About the Article

Margrit Eichler takes the Canadian Biotechnology Strategy to task for its claim to support Sustainable Development. Eichler proposes a set of criteria for *truly* sustainable development, and evaluates the CBS in light of these criteria by focusing on the CBS's claims relating to agricultural biotechnology and bioengineered foods. Eichler demonstrates that the risks of bioengineered foods are ignored by the CBS in its inflated listing of potential benefits. Hazards to health, and to sustainability, are posed by these products, and by the environmental and social relations of their production. "The problems that genetically modified foods are supposed to solve," Eichler argues "are all due to a combination of economic, social, cultural and government factors, and need to be solved at that level."

Introduction

In its CBS documents, the government repeatedly commits itself to sustainable development within the framework of its biotechnology strategy. For instance, it identifies advancing the principle of sustainable development as one of its roles (Canada 1998a:6, 8-11) and presents it as one of the prominent guiding ethical principles and values identified in other countries for biotechnologies (12).

Sustainable development is defined as "a commitment to consider the needs of both present and future generations" (12). In the following, I will provide a short critique of this definition and propose an alternative one, and then apply it to the issue of biotechnology and food.

Critique of the CBS definition of sustainable development

A commitment "to consider" the needs of future generations is no guarantee that these needs will be respected. To be meaningful, there needs to a firm prohibition against engaging in practices that are likely to harm future generations or that would lead to passing on fewer natural resources than are available to this generation.

An undifferentiated statement concerning "generations" makes no acknowledgement of different access to various resources within a generation (present or future). At present, the world has ample resources to satisfy the needs (although not the wants) of all humans on earth. Canada, in particular, has ample resources to satisfy the needs of all Canadians. Nevertheless, a larger number than ever before lack the necessities of life at present. This is relevant at two levels: for one, unless there is perceived social justice at present, people will be unwilling to give up anything for future generations. For the other, a

society that fails to distribute resources equitably for people who are currently alive will have no yardsticks with which to determine what is equitable between generations. Indeed, our reckless utilization of non-renewable resources demonstrates that we are incapable of preserving these resources, and our utilization of theoretically renewable resources (fish, forests, water, high quality farm land, etc.) demonstrates that we deplete them not only for future generations but even for those alive now.

Alternative definition of sustainable development

Sustainable development can be defined as a condition in which all human imperatives, and particularly the economic, social, cultural and governance imperatives, are met – subject to the constraints imposed by the ecological imperative to remain within the planetary bio-physical carrying capacity.

We can understand:

- the **economic** imperative as securing an adequate material standard of living for all;
- the **social** imperative as the creation or maintenance of social structures that are beneficial to all those involved;
- the **cultural** imperative as a cultural and spiritual base that acknowledges our dependence on the ecosystem, our interdependence with other humans, transcendence of material accumulation as the road to human fulfillment and commitment to non-violence; and
- the **governing or decision-making** imperative as an effective and legitimate decision-making structure capable of

implementing policies to fulfill the other imperatives (see Eichler 1999).

We now have a set of criteria that we can apply to biotechnology. If a particular policy moves us closer to meeting these imperatives, while remaining within the bio-physical carrying capacity of the earth, these technologies are either sustainable, or at least more sustainable than present alternatives. Either condition must be seen as positive. If a policy fails to move us forward, it cannot be identified as sustainable.

Applying the sustainability criterion to bioengineered food

Bioengineered food is put forward in the CBS as a means to protect health and prevent disease. The following benefits are detailed (Canada 1998b:6-7):

- it will enable us to produce more healthful food with higher nutritional quality;
- it can produce novel, desirable nutrient and medicinal contents in food that will virtually eliminate human and animal nutritional deficiencies;
- it will improve the availability of therapeutic products;
- it will provide an inexpensive and abundant supply of compounds with potential health benefits, such as fructans, which are good for digestion and can be used as low-calorie fat substitutes;
- it will prevent diseases by enhancing the levels of those compounds in food that are known to have beneficial physiological effects, such as carotenoids in tomatoes and peppers that have

anti-cancer properties or onions with elevated levels of quercetin-a (a compound that can prevent stomach cancer);

- it facilitates the development of new foods for Canadians who suffer from food intolerance disorders, e.g. new plants or cereals that are similar to wheat but non-toxic to persons with coeliac disease.

There are apparently no negative effects that merit mention.

Let us compare this list of benefits with the statements made in a recent World Health Organization report (Daar and Mattei 1999:89-96). Here we find some discussion of potential problems with bioengineered food. Such problems include:

- bioengineered food may result in unpredictable allergies to proteins not usually found in food products, but now present as a result of inserted genes;
- many food products are being introduced stealthily. "For example 60% of consumer food products (margarine, chocolate bars, baby food) contains soybean material, much of which is now sold, sometimes without labeling, as a mixture of unmodified and genetically modified soybeans" (94);
- there are reports of lapses in observing guidelines/ laws regarding agricultural release into the environment;
- there are potential dangers of conflict between nations in the future with respect to issues of patents, "bio-piracy" and the sharing of the fruits of

research. "Thus, it seems, there are enormous potential, perceived, and unquantifiable risks." (94)

In other words, the World Health Organization identifies both potential health risks, as well as other problems, with genetically modified foods.

Taking a step backward, we need to ask ourselves whether the problems that bio-engineered foods are supposed to address are identified appropriately. In general, the most healthful food is locally produced, and fresh. There is enough food available in the world (although it is not clear whether in Canada) to feed all. Canada imports a lot of food, but that is tied up with the demise of local food production, and the desire for exotic foods, rather than an incapacity, in principle, to feed ourselves. Canada's – as well as the world's – food needs are thus an economic, social and political (and partially cultural) problem, rather than a technological one.

While the rhetoric employed often sounds noble – e.g. to alleviate or even eradicate hunger in the world – the driving force behind all of these efforts is profit. Hence the major effort is not directed towards developing healthier foods for consumers, but in genetically engineering crops to make them pesticide tolerant, improve appearance, allow for longer shelf life and allow for long distance transportation. All of these are practices which directly increase our already very high level of unsustainability, by increasing pesticides – a poison in nature – over organic methods of farming, by favouring agribusiness over local production.

Such practices are at least partially responsible for creating some of the problems bioengineered foods are proposed to solve. This is particularly the case for food intolerance. We have witnessed a huge increase in immune system deficiencies in the last two

decades, of which food allergies are only one. One might argue that the pollution in our environment, which includes large use of pesticides, is a cause of such breakdowns. It seems ironic, then, to propose as a cure more of the same.

I would argue that the problems that genetically modified foods are supposed to solve are all due to a combination of economic, social, cultural and government factors, and need to be solved at that level.

Looking briefly at the four imperatives in my definition of sustainable development, there is a great likelihood that genetically modified crops will worsen the situation both for family farms in Canada and for third world farmers. GM crops will make Canada even more dependent on large-scale agribusiness and further reduce local autonomy over our food supply. Agricultural biotechnology therefore runs counter to the economic imperative as well as the social imperative. With respect to the cultural imperative, open-air planting (of GM crops) is disrespectful, in a multitude of ways, toward the ecosystem – denying our ultimate dependence upon it. There are already documented cases of unintended cross-pollination between genetically modified and non-GM crops under open-air planting conditions. Several species of insects are threatened by the genetically modified crops (the Monarch butterfly has received some public attention recently). There is no long-term, cautious testing of the potential long-term impact of GM crops on the ecosystem, as would certainly be appropriate, given the potentially very serious consequences (cf. Weizacker 1995). Just as antibiotics resulted in so-called "superbugs" which do not respond to these same antibiotics, so the profligate use of pesticides may result in super-pests as well as weeds which are hardier than other crops – to name just one of the many dangers. With respect to the government imperative, our governments

are giving up more and more of their decision-making to corporate entities as they push biotechnology as a prime industrial growth strategy.

Looking at this selection of factors, then, we must conclude that contrary to the claims made in the CBS documents genetically altered food may have potential health hazards, and that it moves us in a direction of even greater unsustainability.

References

Canada. 1998a. *Roundtable Consultation Document. Renewal of the Canadian Biotechnology Strategy*. Ottawa: Canadian Biotechnology Strategy Task Force.

Canada. 1998b. *Health Sector Consultation Document. Renewal of the Canadian Biotechnology Strategy*. Ottawa.

Daar, A.S. and J.F. Mattei. 1999. Medical Genetics and Biotechnology: Implications for Public Health. (With assistance and guidance from the WHO Working Group on Genetic Manipulations and Modifications suggested by the October 1998 Expert Group). World Health Organization, unedited draft report, Dec.

Eichler, Margrit. 1999. Sustainability from a Feminist Sociological Perspective: A Framework for Disciplinary Reorientation. in Egon Becker and Thomas Jahn, eds. *Sustainability and the Social Sciences. A Cross-Disciplinary Approach to Integrating Environmental Considerations into Theoretical Reorientation*. Paris: UNESCO, Frankfurt: ISOE, London: Zed Books, pp. 182-206.

Weizacker, Christine von. 1995. Error-Friendliness and the Evolutionary Impact of Deliberate Release of GMSs. in Vandana Shiva and Ingunn Moser, eds. *Biopolitics. A Feminist and Ecological Reader on Biotechnology*. London : Zed Books, Penang: Third World Network, pp.112-120.

The New Genetics in the Post-Keynesian State

Roxanne Mykitiuk

About the Author

Roxanne Mykitiuk is an Assistant Professor of Law at Osgoode Hall Law School, York University, where she teaches in the areas of Bioethics, Health Law and Family Law. She is also the mother of a two and a half year old son, Misha and has learned through experience about gender and genetic medicine. She is the author or co-author of a number of articles and book chapters investigating various legal and social implications of new reproductive technologies and the new genetics. She is also the co-editor with Martha Fineman of *The Public Nature of Private Violence* (Routledge, 1994). From 1990-92 she was Senior Legal Researcher for the Royal Commission on New Reproductive Technologies. She is one of the founding members of the Working Group on Women and the New Genetics. Her current research projects investigate the legal construction and regulation of gender and disability in health law and policy; and the construction of normalcy in the context of genetic counselling.

About the Article

Roxanne Mykitiuk understands the Canadian Biotechnology Strategy, and the genetic technologies which it promotes, to be both a contributor to, and signifier of, the changing nature of the state. The state is currently undergoing restructuring, Mykitiuk argues. These changes are commonly attributed to the forces of 'globalization'; they are effected by state-sponsored 'de-regulation,' and result in widespread 'privatization' of formerly *social* responsibilities. Mykitiuk's argument is that the new genetics plays a key role in these processes. On the one hand, the new genetics contribute to a re-defined 'neo-liberal' self, which is responsible for the private management of real and potential risks to health. On the other hand, the new genetics appeal to the state as a means to develop the industrial potential of the knowledge-based economy, particularly in the health care market. It is these latter developments which Mykitiuk focuses on in this paper. The Canadian Biotechnology Strategy and the reorganization of the federal Health Protection Branch, together with legislative foot-dragging on the new reproductive and genetic technologies, point to what Mykitiuk characterizes as, "a shift in state policy from social protection to the encouragement of capital accumulation. This form of privatization is paralleled by a move to the individual as the site of governance through the self regulation of genetic risk."

Introduction

The link between genetics and privatization is not intuitively obvious. Genetics is a branch of biology that deals with the heredity and variation of organisms, and understands such variation to be located in one's genes.¹ Privatization refers to the process of state restructuring attendant on the economic and political forces set off by globalization.² Contrasted in this way, genetics is aligned with the realm of the natural, the empirically verifiable and the material essence of the individual organism. Privatization stands on the opposite side of the nature/culture divide. It is a politically inspired project; the creation of human design. However, as I suggest in this paper, there is a significant affinity between the new genetics and the recent projects of privatization and neo-liberalism.

Privatization is largely a political and economic phenomenon – entailing a shift in state form from Keynesianism to neo-

¹ Victor McKusick (1993:2351), whose catalogue of human genetic conditions is a classic in the field, defines "genetics" in the following way:

[T]he science of biological variation; *human genetics*: the science of biological variation in humans; *medical genetics*: the science of biological variation as it relates to health and disease; and *clinical genetics*: the part of medical genetics concerned with health and disease in individuals and their families or the science and practice (art) of diagnosis, prevention, and management of genetic disorders.

² For the past three years I have been part of a SSHRC funded collaborative research project – based at Osgoode Hall Law School – on Women, Law and the Challenge of Privatization. This paper emanates from my part in that project – a study of genetics in a post-Keynesian era – and is adapted from a presentation made before the Feminist Legal Analysis Section of the Canadian Bar Association, March 25, 2000.

liberalism, as well as a shift in governing practices. It derives its economic momentum from the notion that the Canadian state must reduce the fiscal burden of social welfare programmes which have become too costly in the globalized market economy, while simultaneously creating the conditions for capital accumulation. In one sense, privatization refers to the effort to reduce public debt and alleviate the pressures on public finance by eliminating, scaling back or transferring to the private realm of the market or the family, services that were formerly provided by the welfare state. Privatization also refers to a more far-reaching restructuring of social and economic institutions, and aims at the actual promotion of private sector interests in the economy as a means of meeting global competition. In this sense, privatization refers to an active and conscious restructuring of state institutions to favour the market and private investment. Increasingly, the public sphere embraces as its governing logic market rationales and practices. As Janine Brodie (1995:6) suggests: "governments are effectively acting as the midwives of globalization, transforming the state apparatus, development strategies and regulations to respond to the 'perceived exigencies' of a global economy."

At a discursive level, privatization is also about privacy, individual choice and self-reliance. One of its core ideas is that the preferred mode of social arrangement is one that allows individuals to control their lives as they see fit, without interference by others and government. It is a view about economic arrangements and normative social relations that distrusts collective solutions to problems, indeed imagines problems as individualized and, therefore, outside the purview of collective response. Thus, within neo-liberalism, the best form of regulation is one which is self-governing, where the governance of individual subjects promotes processes of

self-regulation and provides the circumstances under which people may effectively govern themselves.

My original entry into thinking about privatization and state re-structuring in the context of globalization was through the doorway of genetic and reproductive technologies – but, primarily genetic technologies. When I first began thinking about this issue, I was principally interested in examining how genetic technologies and therapies – the anticipated fruits of the much celebrated and publicly-funded international effort to map and sequence the human genome – were going to be configured in the post-Keynesian, restructured, neo-liberal state. If genetic services were truly the public goods they were promised to be, how would they be allocated/ accessible in a health care context where evidence-based medicine, cost containment, individual/consumer choice and restructuring were the mantras of the day? At the same time, I was also concerned about, and interested in, how the information that is the product of genetic testing and screening was going to be used in the context of the leaner, meaner state. If genetic diagnostics are capable of producing information about the health risks and genetic characteristics or capacities of the individual tested – or their biological family members, fetus or possible progeny – will this information be used in invidious ways to mark certain citizens or prospective citizens, or their characteristics, as deviant, abnormal, socially undesirable or risky? Is there a sense in which the new genetic technologies are being used, or are capable of being used, as a means of literally *creating* the responsible, autonomous, citizen of neo-liberalism – that citizen who makes no legitimate claims on the state but rather, who freely exercises their capacity for choice and manages their own self care?

The ways in which specific genetic technologies serve to restructure, and privatize the relationship between the citizen and her/his health have been the subject of considerable feminist scholarship in recent years. These are certainly areas of concern. Yet, more is at work at the level of state practices and legislation in relation to the new genetics. In Canada, genetic technology as a whole is being actively promoted by some branches of the state, in particular, Industry Canada. At the same time, Health Canada, the branch of government which indeed has the mandate to regulate the social, legal and health consequences of the new genetic technologies, lags further and further behind. The Canadian Biotechnology Strategy and the reorganization of the federal Health Protection Branch point to a shift in state policy from social protection to the encouragement of capital accumulation. This form of privatization is paralleled by a move to the individual as the site of governance through the self regulation of genetic risk.

The advent of the new genetic technologies and the policies of privatization corresponding to globalization are not independent of one another. The pattern emerges of an interdependent process whereby biotechnology is at once promoted by the state as the high technology answer to the hollowing-out effects of globalization, and justified on the basis of its contribution to health. The changing understanding of health and health care brought about by genetic technologies in the post-Keynesian state connects the fostering of biotechnology as a form of industrial production, and the privileging of individual responsibility and risk management in the realm of health. In this sense, the role of biological technologies may be seen as both symptomatic and as an important constitutive factor in the transformation of the state in the post-Keynesian era.

The Canadian Biotechnology Strategy

The development of the Canadian Biotechnology Strategy (CBS) is a key component of an industrial strategy aimed at reaping the benefits of a “knowledge based economy” to meet the challenges of globalization. It is a way of capitalizing on genetic information. It is worth noting that the Organization of Economic Cooperation and Development (OECD) defines “knowledge” in the “knowledge based economy” as, “the acquisition of intellectual property through learning or research” (OECD 1989). It is important to recognize that the appropriation of genetic information as intellectual property is an integral aspect of the knowledge based economy in general and the Canadian Biotechnology Strategy in particular.

The “vision statement” of the CBS was formulated as,

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 (CBS 1998a:8).

The CBS and Health

According to the federal government, “[B]iotechnology’s greatest impact both in Canada and world wide has been in the health field. More than 90 percent of the advanced biotechnology products on the world market are related to health” (CBS 1998b:1) Projections are that health products will continue to dominate the biotechnology arena. It is significant that the lead Department for the co-ordination and development of the Canadian Biotechnology Strategy is Industry Canada with the involvement of six other departments, including Health. Moreover, the strategy seems to be one designed to accommodate the ethos of the

marketplace and not that of the health care system. While the CBS is promoted as a strategy to develop the tools to improve the health and well being of Canadians through “more reliable health surveillance, disease diagnoses and therapies,”(CBS 1998b:3) its principal goal is to promote industrial activity and economic returns “to position Canada as a responsible world leader in the development and sale of biotechnology products and services” (CBS 1998c:2).

Genetics and Changing Definitions of Health

There cannot be an industrial strategy without a market. In the new biotech age, that market is intended to be primarily in health products and processes. However, in the creation of that market, our very definition and understanding of health is transformed. In adopting a new genetic understanding of health, we are changing our definitions of health and disease and creating entirely new categories of embodied individual health risk. Genetic technologies constitute a significant departure from conventional medical technologies in that these new technologies do not, for the most part, treat an existing condition or diagnose a disease in progress. Genetic testing often has the effect of identifying individuals with genetic susceptibilities to particular diseases, but who are otherwise well, as unhealthy, or at least, to mark their health as suspect. Thus, the alleged predictive ability of genetic testing is problematic as it takes for granted that awareness of one’s personal risk status, as defined by genetic testing, is important to the individual, and that awareness will encourage behavioural changes such as to prevent the future development of the predicted condition. By creating the category and increasing awareness of genetic risk, the biotechnology industry creates a market for its products – genetic tests – which the responsible health care consumer feels

compelled to use in order to determine their own risk status or that of their future offspring. A prime example of this dynamic was at work in the case of BRCA1&2 testing with the attendant controversy and litigation about public funding for private testing in Ontario.

The Health Protection Branch of Health Canada and its “Transition” Program

Nowhere has the shift in governmental roles been so apparent as in the recently proposed transformations of the Health Protection Branch within Health Canada. It is this branch which is responsible for, among other things, regulating the safety of drugs and devices including those related to the new genetic technologies. Arguing that the new reproductive, and especially the new genetic, technologies do not correspond physically or conceptually to the medical devices and pharmaceuticals traditionally licensed and regulated by the Health Protection Branch, Health Canada has suggested that its regulatory and legislative framework is inadequate, and launched a so-called “transition” program. This initiative to renew Health Canada’s mandate of health protection corresponds to the restructuring of the Canadian state in a climate of privatization. Not surprisingly, the transition program includes strategies to externalize the costs of regulation by enhancing cost-recovery and the development of stronger relations with industry. The effort to externalize the costs of regulation corresponds with a reduction of in-house research and scientific activity. One of the central safeguards proposed under the HPB Transition Program is to pass legislation making it illegal for a manufacturer to place a dangerous product on the marketplace. Such legislation is expected to force *manufacturers* to be more explicitly responsible for ensuring product safety due to enhanced and more rigorous liability. As the law now stands however, it

is the Federal government, and ultimately the Minister of Health, who is responsible for ensuring product safety before approving a product for release onto the market. Currently, the government is primarily accountable to the public for safety and the protection of public health. The proposed legislation alters this situation by shifting responsibility from the government to private industry. Moreover, it creates a situation where instead of Health Canada being primarily responsible for ensuring product safety *prior* to public exposure, industry carries this responsibility. Health Canada’s interventions are activated *after* a danger has been detected through market use (i.e. protection through the threat of a harsh punishment, instead of protection by preventing product entry onto the market in the first place).

Health Canada acknowledges that its regulatory system is shifting away from a model where assessments are made in-house towards one, which it calls a “networked” model, including universities and industry. This new model is defended as more consistent with access to the best scientific knowledge and expertise, although the Health Protection Branch transition team is apparently still grappling with the problems of accountability raised by this model. I suggest that this new model is consistent with the relativized position of the post-Keynesian state, testifying to the contradictions of the state’s role in health protection versus industrial promotion. To illustrate, one of the goals of the transition process is to promote “efficiency” in speeding up regulatory approvals. Speedier introduction of new pharmaceuticals is obviously in the interests of industry, but glosses over the potential tradeoffs between accelerated introduction of new products and the assessment of possible risks. The changing emphasis in health protection is consistent with the goals articulated in the Canadian Biotechnology Strategy. Increasingly, the Health

Protection branch will depend on its clients to achieve the regulatory purpose of its mandate. Diffusion of accountability and responsibility forms its own kind of “privatization”.

There is no evidence that Health Canada or the federal government seeks to abandon its mandate in health protection, or that it is blind to the ethical concerns which have been raised. Instead, the renewal of the mandate for health protection occurs in a context where the role and meaning of the state is shifting, and where the autonomy of the Canadian state in relation to international trade agreements, and the demands of multinational corporations, is shrinking. The implementation of the privatization agenda is not therefore bringing about the deregulation of health, rather the manner in which health is being regulated is changing. Health is increasingly being regulated as a commodity rather than as a public good, and health care as a business rather than as a public service. In this context, it is interesting to note that one of the proposed name changes of the Health Protection Branch was to call it the “Management of Risks to Health” branch. No longer is the federal government to be involved in protecting the health of society from unsafe pharmaceuticals and medical devices, but it is positioning itself to manage the risk inherent in such commodities and mediate between the interests of industry and the citizen public. From a central concern with health care provision and public safety, the state has now shifted to a principle concern with the requirements of production and capital accumulation.

The Regulation of Genetic and Reproductive Technologies

Despite the fact that the Royal Commission on New Reproductive Technologies reported more than seven years ago (1993), no new legislation has

been passed regulating the health and social implications of these technologies despite a significant amount of public support for such regulation. The federal government did introduce one piece of legislation, Bill C47, which died on the order paper of the last Parliament, and one discussion paper with legislation promised before the Fall of 2000. The important fact, for my purposes here, is not what is *in* the proposed legislation but the discrepancy between the urgency with which the Canadian Biotechnology Strategy and the restructuring of the Health Protection Branch have been pursued, and the hesitancy and caution with respect to the introduction of legislation to regulate the health effects of the new reproductive and genetic technologies. In the climate of state restructuring and privatization, study of the new genetics reveals how the priorities of the state in relation to health have shifted from protecting the public good to promoting the interests of industry, and creating the conditions for health to be a site of corporate profit making and capital accumulation.

Conclusion: About New Biotechnology, Accumulation, The Discursive Shift around Health, The Role of the State and Law.

I have arrived at two major conclusions with respect to the introduction of genetic technologies and the ways in which these are regulated in Canada. The first conclusion – little discussed in this paper, but discussed more widely in feminist monographs³ – concerns the ways in which the market for genetic technology shapes our understanding of health and

³ Both areas of privatization are discussed and analysed, in depth, within my book chapter, “Private Bodies, Public Parts: Genetics in a Post-Keynesian Era,” in the forthcoming book edited by Brenda Cossman and Judy Fudge. (Toronto: University of Toronto Press, 2001).

risks to health. With genetic tests marketed as a kind of health-risk kit, individuals are being called upon to undertake self-surveillance in the name of reducing the burden of disease on themselves and on society as a whole. Thus, genetic testing and genetic understandings of health, are seen as a means to create the ideal citizen of the post-Keynesian order – one vigilant about her/his economic burden or contribution to society and willing to discipline themselves or their procreative activity in the name of maintaining healthy and productive citizens. It is particularly through the genetic surveillance of potential offspring that women become the gatekeepers of the new social order, with genetic technology introducing a new gendered division of labour with respect to maintaining a disciplined order of productive citizens.

The second conclusion has to do with the nature of regulation and law in the post-Keynesian era of the new genetics. Here, the problem or phenomenon we witness is not simply “deregulation” in the service of the market, but rather a different kind of regulation and a shift in the legal paradigm

of regulation. Instead of deregulation, we find a re-regulation intended to make possible the greater appropriation of intellectual property and its capitalization. What the Canadian Biotechnology Strategy, the restructuring of the Health Protection Branch and the paralysis with respect to legislation on reproductive and genetic technologies illustrate is not just the promotion of the biotechnology industry, but a redefinition of the public interest. The state no longer sees itself as defending the public interest against the private interest of private actors, but sees itself as promoting the interests of private actors as the potential benefactors of the public through the production of health commodities. In so doing, however, the state is also changing the nature of regulation. In moving away from defining and representing the public interest, and towards a model of product liability and intellectual property, the state is shifting the arena of adjudication into the area of commercial law and away from public and constitutional law. This entails not only a different set of concerns, expertise and evidentiary rules but also a shift into a social arena with its own gendered hierarchy.

References

- Brodie, Janine (1995). Canadian Women, Changing State Forms, and Public Policy. In Janine Brodie, ed. *Women and Canadian Public Policy*. Toronto: Harcourt Brace, 1-28.
- CBS (1998a). Canada. *The Canadian Biotechnology Strategy: An Ongoing Renewal Process*. Distribution Services: Industry Canada.
- CBS (1998b). Canadian Biotechnology Strategy Task Force. *Health Sector Consultation Document: Renewal of the Canadian Biotechnology Strategy* Industry Canada.
- CBS (1998c). Canada. *Factsheet: Key Elements of the Renewed Canadian Biotechnology Strategy*. Bio-Industries Branch, August 6.
- McKusick, Victor A. (1993). Medical Genetics: A 40-Year Perspective on the Evolution of A Medical Speciality From a Basic Science. *Journal of the American Medical Association* 270.
- OECD (1989) *Biotechnology: Economics and Wider Impacts*. Paris.

One part of an anti-racist feminist political standpoint against biopiracy.

Nandita Sharma

About the Author

Nandita Sharma, Ph.D. is currently a post-doctoral 'fellow' in the sociology department at the University of British Columbia where she is engaged in research regarding one of the major consequences of acts of biopiracy: displacement. She is examining the links between the present crises facing an ever growing number of people actively involved in international migration and the policies of national governments that facilitate the entry and subsequent marginalization of specific groups of migrants in nationalized labour markets. She examines the connective role that the globalization of capitalism, racism and patriarchies plays in these processes of displacement and exploitation. Nandita is a founding member of the international campaign: Open the Borders! as well as the anti-biopiracy organization, Basmati Action Group which is opposed to all forms of life patenting (including the US patent given to Rice Tec Corporation for basmati rice).

About the Article

Nandita Sharma discusses Vandana Shiva's (1997) argument that the development of agricultural biotechnology is akin to the closing of the commons. Like the latter social revolution, biotechnology grants private rights to previously shared properties – in this case germ plasm and plants, rather than fields and forests – but with many of the same social consequences. Sharma's analysis suggests why genetically modified (GM) foods have provoked such opposition, not only among consumers in the global North, but among small-hold farmers, many of them women, in the global South. Sharma argues that the "ethical values" proposed by the CBS are untenable – being premised on faith in the value of genetically engineered (GE) crops and foods. She warns against any accommodation by feminists, arguing that total opposition is the only credible stance.

In the document, *The 1998 Canadian Biotechnology Strategy: An Ongoing Renewal Process*, the Canadian government outlines how best to market biotechnologies. Indeed, this is the major aim of this report. This becomes clear through a number of statements, such as “The Government of Canada has consistently expressed its support for biotechnology as a priority” or the government’s position that biotechnologies “offer significant economic benefits, particularly in exports and job creation” and to “safeguard the environment.”

Nowhere in this document are the concerns expressed by independent women, farmers, scientists and other concerned groups. Instead, the government presents its public relations strategy designed to pacify people in Canada into accepting the legitimacy of the biotechnology industries’ plan to expand and make greater profits. Although the biotechnology industry is engaged in a wide array of initiatives in further technology development, including reproductive and genetic technologies, pharmaceutical products and a number of key areas in agriculture, it is the latter that I will concentrate on. Indeed, the biotechnology industries’ incursion into agriculture has been one of the main rallying points upon which groups in the global South and North have galvanized people’s opposition. This is not a coincidence.

It may be difficult for those of us in the North who, when we think of farming, picture the gigantic mono-cropped fields of the North American prairies, but 80% of the world’s farmers continue to be engaged in *small-scale* farming. Nowhere in the world have industrial agricultural methods become more entrenched than in North America. There are still small-scale farmers left in Europe. And, of course, most of the farmers of the global South continue to be small-scale farmers. Thus,

it is no coincidence that the greatest struggles against the biotechnology industries have occurred in the South and, to a lesser extent, in Europe, and most of them have been organized by or through small-scale farmers and organizations run by them or working with them in solidarity. Nor is it a coincidence that here, in North America, we are just beginning to organize ourselves effectively on the issue of biotechnologies and agriculture.

The furor over the “life sciences” foray into agriculture rests on the basic fact that the biotechnology corporations have arrived at new technologies of colonialism. That is, they have devised new means by which to continue to dispossess people of their ability to live outside of a capitalist political economy – new processes by which to enslave them. Let us not forget that the social process by which people are transformed into workers continues to mark the expansion of capitalism. The wide-scale destruction of the rural economy in the South can be said to be the major effect of this latest period of “globalization.” It is the movement of women and men from a devastated and privatized countryside into the “free export zones” throughout the South (and increasingly the North) that has allowed for the creation of a “global assembly line.”

One of the key technologies of colonialism today is the patenting of life forms. Through this process, biotechnology corporations are engaged in a wide-scale appropriation of common property. As Vandana Shiva rightly points out, patenting is the late 20th century form of “enclosing the commons” (1997). As in the past, this theft is ideologically concealed through claims of the sanctity of private property. This argument is apparently legitimate for those whose consciousness has been wholly shaped through acceptance of white, capitalist patriarchies. In the global South, at least, it is women who produce the majority of

their own, their family's and their community's everyday needs. It is women who, year after year, save the seeds necessary for survival. Indeed, women everywhere have created elaborate, community-strengthening, ways to honour their productivity and the productivity of nature. By patenting their very means of survival and saying that it is the private property of the owners of some transnational corporation that is usually located half-way around the world, the biotechnology corporations – and the governments and international governing institutions supporting them – are ensuring the destruction of the rural economy and its replacement with industrial agriculture on farms owned by fewer and fewer people. This is the goal. It achieves two things: the replacement of small-scale, ecologically-sound agriculture with industrial agriculture and, two, the creation of a working class dependent solely on capitalists for their livelihood. This goal is currently being achieved in many ways.

The main goal of the promoters of industrial agriculture has always been to prevent farmers from saving their seeds. This is now possible through biotechnologies, such as the “Terminator” technology, the “Traitor” technology and, ultimately (and even without these), the patenting of life forms. Of course, it is not the technologies alone that are responsible. They are only the mechanism of ruling, not the rulers themselves. What makes these technologies possible and perhaps more importantly, actionable today, are social relations based on unequal exchange between the North and the South, racism, sexism and capitalist political economies.

Thus, it comes as no surprise that one of the major selling points of the new “life sciences” in regard to the “advantages” of biotechnologies is its promise to “feed the growing world's population.” In this one statement is condensed the entire gambit

of white, capitalist patriarchy. In this one statement it is assumed that

- a) *population growth results from ‘Third World’ women having “too many” babies;*
- b) *people starve because of this and;*
- c) *‘Third World’ peoples need the help of ‘First World’ people and their and “advanced” technologies.*

Of course, embedded within this discourse is the notion that it is ‘backwards’ to be a small-scale farmer, that the destruction of the rural economy is a “good” thing and that finding an industrial job is the goal of the world's people. Indeed, this is the textbook definition of a “modern” person in the “development” literature. These ideological notions contribute to the expansion of white, capitalist patriarchies that make women the dependents of men, make people the dependents of capitalists and make the South dependent on the North. Also hidden from view is that in reality it is men who exploit the wealth of women's labour, it is the capitalists who steal the fruits of workers' labour and it is the North whose ravenous consumption practices are dependent on the theft of Southern wealth.

The Canadian state is a wholesale supporter of continuing to base social relations throughout the world on this exploitative model. Indeed, this government is acting according to a script that reads as if it was written by people in biotechnology industries. For example, the government says that “biotechnology has the potential to increase...sustainable development” (Canada, 1998:5). Contrary to growing evidence, but in a repetition of the company line, the government says that genetically engineered (GE) crops allow farmers to apply fewer chemical pesticides and herbicides.

This government also wants Canada to “have a prominent role in the emerging science of genomics, including genome

mapping and gene sequence technologies” (Canada, 1998:19). They further add that they want to make “Canada’s international development assistance policies and programs” fit into the CBS vision and goals, “particularly with regard to the developing countries to which Canada exports or is likely to export” (Canada, 1998:16). And, the government states that “modernizing Canada’s intellectual property laws and ensuring their effective administration would significantly improve the domestic investment climate in biotechnology” (Canada, 1998:16). In other words, they want to make sure that current patent laws in Canada are in line with WTO (World Trade Organization) guidelines that sanction life patents.

Importantly, throughout this document is the government’s concern that people (re-defined as consumers) accept and be confident in and comfortable with new genetic technologies. In particular, the government is concerned with people’s fears of eating genetically engineered foods. For instance the government’s own polls show that a majority want to see labeling of such foods so they can distinguish between them and untampered foods. Thus, they stress that “the public wants assurance that biotechnology products and services are safe for humans, animals and the environment” (p.14). Not coincidentally, the Canadian government has gone into a communications venture with the biotechnology industry in a new media institution designed to convince people that there are indeed benefits to the consumption of genetically engineered foods and that this is safe. I, like many of you, have been subjected to corporate propaganda being voiced as if it was a public health message (e.g. GE is nothing new. Organically making cheese is a form of GE. So is the process of making yeast, beer, etcetera. Genetically adding alien nutrients is sound science and good public health policy, ad nauseum).

While the government recognizes that a much more effective sell job is needed before people will happily eat genetically engineered foods, it argues that the best way to sell biotechnologies is to link them with community health concerns. In the Canadian Biotechnology Strategy document, then, the government states that “people are more likely to accept applications such as new drug therapies that clearly address health needs, and are less likely to accept applications that offer less obvious benefits.” Is it a coincidence, then, that we have been seeing huge spreads within *the Globe and Mail* (just to use one example) on the health benefits of patenting and biotechnologies?

Another one of the ways the government wants to secure public approval for biotechnologies is to have so-called public consultations on what are called the “core values” of an ethics framework. This is especially troublesome since the government makes it very clear that they wish 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” (Canada, 1998:8). Obviously, this set up already precludes a real debate since it takes the application of biotechnologies for granted.

I believe that we need to take a very strong position against attempts to co-opt the women’s movement into participating in the establishment of the so-called ethical “core values” on the use of biotechnologies. It is simply impossible to simultaneously act ethically while working to enclose people’s common spaces, destroy people’s ability to be self-determinant, concentrate the world food supply in a small number of hands, cross-pollinate GE crops with organic ones, etc. It is the practices of the biotechnology corporations that are unethical. We cannot allow ourselves to separate their actions

from an abstract, philosophical statement on the “ethical” standards of biotechnologies.

First, this method of securing “approval” is manipulative as it only gets to the lowest common denominator. We have seen this occur through other government consultations, namely “public consultations” on immigration policy, citizenship policy, social welfare policy, poverty, etc. whereby the concerns of feminists have been pitted against the concerns of neo-Nazis, corporate lobbyists and anti-feminists and the government has been able to slide up the middle (which itself has shifted much to the Right) and act as the reasonable arbitrator of “public” interests.

Secondly, the government has provided a built in role for biotech corps by saying that one of their key goals is commercialization of biotech and then stating that it is the private sector that has the “lead responsibility” for this (Canada, 1998:10). Moreover, would any of us seriously consider that the Canadian government is going to uphold whatever “ethical” standards we might like to see given that commercialization of new biotechnologies is the government’s biggest priority?

I believe that we need to radicalize our message in total opposition to the biotechnology industries. In this regard, let me repeat the position of the Basmati Action Group (of which I’m a founding member). We support the outright banning of GE crops being grown and sold in Canada. This is the only ethical response by those living in a country that is a major producer and exporter of GE foods.

We believe that by simply labeling GE foods, we fail to act in solidarity with those people who have little choice in what they eat, those people whose main source of food is not from the grocery store and those farmers around the world who are trying to maintain GE-free crops. By

saying that we will settle for labeling of GE foods, we are buying into the liberal-choice model that tells us that those who eat chemically-infested foods are “choosing” to do so, that those who eat food that is GE (after it has been labeled as such) are also “choosing” to do so. This takes the heat off the people who are supplying us with toxic food.

By settling for labeling of GE foods, we are saying that we don’t value the Precautionary Principle. We say that by allowing consumers the “choice” to buy GE foods or not, that we are ready to leave it to the market to determine whether this food is safe or not. Finally, the issue for most of the world’s people is not what is being sold on the shelf but what is being grown in the field. Only by banning GE crops can we ensure that natural biodiversity will not be destroyed.

Following the mass, direct action in opposition to the WTO in Seattle in November, 1999, I can attest to the fact that radicalizing our message and mobilizing people in total opposition to processes that unleash oppressive and exploitative practices is more effective than trying to make reforms.

For me, my involvement in the protests in Seattle was a turning point. It was in Seattle where I saw our power as a grassroots movement against capitalist globalization being strengthened, consolidated and radicalized. This is partly because our direct actions showed the moral and strategic bankruptcy of the small minority who would have us co-operate with the WTO instead of shutting it down. These are the people who allow themselves to be co-opted by national governments in desperate need of a legitimacy fix. These are the people who have allowed themselves to be portrayed as the “reasonable protestors” in contrast to “the violent rabble” on the street. Indeed, after the grassroots’ power that people demonstrated in Seattle, it is more

distressing than ever to see a small number of NGO “leaders” selling the WTO as “fixable,” as “reformable,” as “open to democratization” when it is clear to most that the only good WTO is no WTO.¹

What we need to do is figure out how to re-shape people’s consciousness to recognize the benefits of overthrowing the current ways of organizing our world. The best way to do this is to provide alternatives. One thing that is really inspiring is the knowledge that in agriculture (as in safe, effective reproductive health), women already know how to realize an alternative to white, capitalist, patriarchal forms of organizing our relationship to our food and with each other. In agriculture, there are women who know how to grow food organically, in small-scale, with community help. This is the only kind of agriculture that we can support ethically. Eating the fruits of this kind of labour should not be a luxury-commodity available only to a small number of relatively well off people in the world. We need to keep in mind that just 40 years ago, most of world was able to grow and eat organic foods. It was the values of the so-called ‘Green Revolution’ that was sponsored by industrial agricultural and petrochemical industries, promoted by national governments and enforced by the World Bank and the International Monetary Fund, and the

incredible proliferation of chemicals into the world’s food supply, that resulted in the loss of organic food for life forms on the planet. This is what we must reclaim.

A radical position on biotechnologies is the message we ought to be sending to the recently established Canadian Biotechnology Advisory Committee that reports to the new Biotechnology Ministerial Coordinating Committee, responsible for overseeing the implementation of the government’s strategy. We in the Basmati Action Group have been circulating a flyer pointing out the government’s position on biotechnologies and giving people the address and e-mail of the CBS taskforce so they can directly send this message to these guys. Much more grassroots work needs to be done by all of us. The only hope we collectively have for the continued life of this planet and for the struggle for social and ecological justice is to mobilize a mass movement in opposition to the biotechnology industries and the people whose sexism, racism and able-ism fuel the global capitalist system.

¹ It should come as no surprise that those who led the most effective protest seen in North America for the last thirty years were those of us who did not see much, if any, benefit from the supposed “golden days” of the 1950s and 60s. We were the ones who never saw any good come from “negotiating” with the beast. We, Indigenous activists, street-identified young people, women of colour, working-class women and men who were never included in the labour aristocracy, Gen X’ers (who perhaps knew better than many in North America that the beast had no loyalties to them) and more – all of us, together, refused to compromise. Here, in the belly of the beast, we became indigestible.

References

Canada. 1998. *The 1998 Canadian Biotechnology Strategy: An Ongoing Renewal Process*. Ottawa: Canadian Biotechnology Strategy Secretariat. Available electronically at: <http://strategis.ic.gc.ca/cbs>.

Shiva, Vandana. 1997. *Biopiracy: the plunder of nature and knowledge*. Toronto: Between The Lines.

Nurturing Cycles

Penny Van Esterik

About the Author

Penny Van Esterik is a Professor in the Department of Anthropology at York University. She is a founding member of WABA (World Alliance for Breastfeeding Action) and writes on a wide range of topics related to food and gender. She is the editor with Carole Counihan of *Food and Culture: A Reader* (Routledge, 1997); her most recent book is *Materializing Thailand* (Oxford, 2000). Most of her field research is in Southeast Asia.

About the Article

Moved by a recent trip to Laos, Penny Van Esterik links her analysis of the Canadian Biotechnology Strategy to the lives of women in Canada and abroad by contemplating the role of genetically modified food-stuffs. Her narrative highlights the jarring inconsistencies between the promises made in the name of biotechnology, and the lived experience of most of the world's women. Van Esterik's analysis also highlights some of the inconsistencies between feminist and consumer models of protest. "As consumer protests against GE foods increase," Van Esterik asks, "will poor women make ends meet with discount produce, cardboard tomatoes, and processed foods that last longer on the shelves, but that have been rejected by others with more resources – both knowledge and money?"

Introduction

After a recent trip to Laos (Lao PDR) in January 2000, as a member of a team which introduced food security and gender into a project on natural resource management, I find that I view genetically engineered (GE) foods and biotechnology strategies in a different light. Here I want to raise points from a personal and advocacy perspective which derive from this experience.¹

Lao Stories - January 2000

On the plane, on the way to Vientiane, the capital of Lao PDR, I overhear Asian-Canadian businessmen discussing new crops introduced into Vietnam through the Canadian International Development Agency's (CIDA's) joint ventures. They discuss the opportunity for field trials in Lao PDR. Settled in my hotel room in Vientiane, I am hooked up to CNN and between news of the Montreal meetings on the Protocol on Biosafety are interspersed commercials for "Life Industries" and the wealth they will bring to Asian entrepreneurs and their western business partners. The next day I travel 40 kilometres in 3 hours over non-existent roads to the village of Ban Hai Tai where I speak with women about food security. Food security to them is the ability to feed their children, access to land to grow local varieties of glutinous (sticky) rice, and access to forests for wild products (providing food diversity and medicines). There has been little incentive to introduce HYV (high yielding varieties) of glutinous rice to Lao PDR, because there is no commercial market and farmers prefer the taste of their local varieties.

¹ I have written in a more academic manner on issues of infant feeding, food security and development in: Van Esterik, Penny, and Carole Counihan. Eds. 1997; Van Esterik, 1999a, 1999b, 1997, 1996a, 1996b, 1996c.

In spite of extreme poverty, exceptionally high maternal mortality rates (656/100,000) and high infant and child mortality rates (142/100,000), the community is sustained by two interaction cycles:

1. *the production of breastmilk and its delivery to a newborn, and the transfer of knowledge about breastfeeding from grandmother to mother to daughter;*
2. *the production of food from seed to plant to seed to plant and the transfer of knowledge about how to grow and prepare food in different localities, seasons and circumstances.*

Just as these women know how to preserve their own seeds for future harvests, so breastfeeding women preserve and transmit knowledge of breastfeeding. In contrast, North American women came close to losing knowledge about breastfeeding, so that there was nearly a lost generation who did not value breastfeeding or know how to manage lactation. Seeds and children both have to be nurtured to grow and reproduce. Nothing should break these self-reliant cycles of nurture. Yet both cycles are under threat by some of the same processes – even the same corporations.

Consider the research on genetically engineered human proteins which were bred into Herman, the first transgenic dairy bull, bioengineered to carry a human gene for producing milk with human proteins, lysozyme and lactoferrin. Lactoferrin has natural anti-oxidant, anti-bacterial, anti-viral, and immune stimulating properties and is present in human milk. When added to infant formulas, this "wellness ingredient" was said to simulate the composition of breastmilk. Herman's female offspring were to produce these proteins at a lower cost for commercial uses such as in infant formula. The

products were to be launched in 1996. For some reason, the bioengineering of human milk proteins was considered "ethically safe." That is, manufacturers did not expect resistance. However, after protests from several groups (including the Rural Advancement Foundation International, RAFI and International Baby Food Action, IBFAN), the transgenic product was redefined as containing modified lactoferrin and was sold as a product to cure AIDS.

Infant formula made from human protein bioengineered in the milk of transgenic dairy cattle is certainly not human milk, and is far removed from breastfeeding. But the GE ingredients would provide an opportunity for the development of new marketing strategies: "just like mother's milk" would have a new appeal. New infant feeding products with ingredients such as nutritional oils providing two essential acids DHA and ARA, present in breastmilk but until recently absent from all breastmilk substitutes, are targeted for fullterm and preterm infants – a marketing strategy which may be used with GE foods. The proliferation of soy-based infant formulas is particularly disturbing, since GE soy is a key ingredient, and the health effects on premature and fullterm infants is as yet unknown.

In March, 1998, the Delta and Pine Company patented the terminator technology, a biotechnology invention that will permit its owners to create and market sterile seeds by programming plant DNA to kill its own embryos, irretrievably breaking the plant to seed to plant cycle on which human life depends. The purpose of this technology is to increase the value of seed owned by American companies and open up new markets in third world countries. In 1999, these companies vowed not to commercialize terminator seeds. But according to RAFI, Delta and Pine Land Seed Company is moving aggressively to commercialize these "suicide seeds." Monsanto bought

the company that developed and patented this terminator technology in May, 1998 and in June, 1998 American Home Products (AHP), home of Wyeth along with many agro chemical products, attempted to buy Monsanto. AHP would have become the largest agro/ chemical/ pharmaceutical/ "Life Industries" company in the world, if the merger had not fallen through over disagreements over who would be "boss". And as agrottoxins bioaccumulate in the food chain and begin to appear in mother's milk, we would have come full circle, as Wyeth also produces infant formula.

And so I think back to these Lao women, managing to feed their families with so few resources, and wonder what the future will bring, with a new bridge to Thailand, and new roads to Vietnam bringing in tins of "old" infant formula without the "new" ingredients already present in their own milk, and the possibility of our oversees development assistance programs funding field trials for "new" seeds to improve on their "old" seeds.

Women and Food

At the World Food Summit in 1996, Maria Meiss and Vandana Shiva organized a Women's Food Day to highlight how the policies being decided largely by men in the formal FAO summit were likely to affect women. They asked why women were not consulted and why the concerns of women farmers, entrepreneurs and consumers were not being heard. Perhaps it is because what many women know about food is used to nurture others; this knowledge is hard to protect, easily shared through communal cooking, food and recipe exchanges and "potluck" meals. Women's influence on the food system is greatest in households and communities. What many men know about food becomes property, commodity, with access protected through intellectual property rights, copyrights and patents.

The faces of men are particularly visible at national and international food forums where they represent industry and trade concerns. In a world where everyone was dependent on multinational corporations – or worse, one giant corporation – for their seeds, medicines and food, whose views would prevail? Consider the inducements that companies would offer to end such self-sufficient practices as planting a garden with your own seeds or breastfeeding your baby. To share food and seed is normal practice for women; will it become a crime to share ideas or seeds according to the new regimes run by companies like Cargill and Monsanto?

Currently, I am introducing this topic to my nutritional anthropology class, using Nottingham's (1998) *Eat Your Genes* as a text. The book has no entry for women, feminism, gender, reproduction or any suggestion that GE foods are of special concern to women. However, what women are putting in their bodies has implications for their own health and that of the next generation.

As family food managers on a daily basis, women are targets for industry messages designed to promote acceptance of GE foods. Messages will appeal to women's sense of fairness, to give the new products and companies a fair hearing, and to think of those who do not have access to sufficient food. Industry knows the appeal of the argument that GE foods are the answer to hunger and food insecurity. And they will no doubt stress the 'right to choose', a phrase that has a special meaning for many women activists, yet should flash warning lights when used by government and industry.

Women have been in the forefront of protests against the speed and extent of the introduction of GE foods. In matters of family food, women are cautious, suspicious of changes, for whoever cooks is tuned into how new foods taste and cook.

Food Security??

Food security means having enough food to maintain a healthy and productive life today – and in the future. Communities enjoy food security when all individuals in all households have access to food – adequate in quantity and quality, affordable, acceptable, appropriate and readily available from local sources on a continuing basis.

In the fall of 1999, an article in the *Toronto Star* featured a number of male chefs banding together to protest the use of GE foods; they planned to use only organic foods in their expensive restaurants. In this city of food boutiques and food banks, where will the foods containing GE foods be located? As consumer protests against GE foods increase, will poor women make ends meet with discount produce, cardboard tomatoes, and processed foods that last longer on the shelves, but that have been rejected by others with more resources – both knowledge and money?

What will GE foods do to ease the burden of hunger and food insecurity in Canada and elsewhere? What assurances do we have that future generations will not be affected by what they were fed before and after birth? Monsanto, Cargill and Nestle, among the largest corporations in the world, are exercising increasing control over what we eat and feed our children, and even the governments we elect, but they are not contributing to food security. In our advocacy work, it is important to examine how corporate power is exerted in places in the world where Canadian technology has spread, often through CIDA's development assistance programs.

GE foods are presented by industry as "nothing new" but a result of our increasing control over the domestication of plants and animals over the past 10,000 years. My position is that GE foods are a

radical break in the evolution of food production, not a continuity. Why? Because of the speed with which changes are occurring, and corporate control over

the process. Thus, we are in need of totally new policy, research and advocacy approaches to address problems raised by GE foods.

References

Nottingham, Stephen. 1998. *Eat Your Genes: How Genetically Modified Food is Entering Our Diet*. London, New York: Zed Books.

Van Esterik, Penny, and Carole Counihan. Eds. 1997. *Food and Culture: A Reader*. New York: Routledge Press.

Van Esterik, Penny. 1999a. "Gender and Sustainable Food Systems: a Feminist Critique". In M. Koc, R. MacRae, L. Mougeot and J. Welsh, eds. *For Hunger-Proof Cities: Sustainable Urban Food Systems*. Ottawa: IDRC. pp.157-161.

-----, 1999b. "Right to food; right to feed; right to be fed: the intersection of women's rights and the right to food. *Agriculture and Human Values* 16:225-232.

-----, 1997. "Women and Nurture in Industrial Societies". *Proceedings of the Nutrition Society* Vol.56, No. 1B:335-343.

-----, 1996a. "Food and the Refugee Experience: Gender and Food in Exile, Asylum, and Repatriation." In P. Van Esterik, W. Giles, and H. Moussa, eds. *Development and Diaspora*. Dundas, Ontario: Artemis Press. pp.61-74.

-----, 1996b. "Nurturance and Reciprocity in Thai Studies." In P. Durrenberger, ed. *State Power and Culture in Thailand*. New Haven: Yale University, Southeast Asian Studies Monograph 44.pp.22-46.

-----, 1996c. "The Cultural Context of Breastfeeding and Breastfeeding Policy". *Food and Nutrition Bulletin* Vol. 17, No. 4:422-431.

Biotechnology, Strategy, and Wealth for Whom:

Commentary on the Theme of Biotechnology and Wealth

Helen Bequaert Holmes

About the Author

Helen Bequaert (Becky) Holmes currently is coordinator of her independent research archive, the "Center for Genetics, Ethics and Women," in Amherst, Massachusetts. She has a Ph.D. in genetics and has taught high school and college science. In 1995-96 she was Principal Investigator for the grant "Impact of the HGI on Society: A Women's Studies Approach" from the ELSI (Ethical, Legal, and Social Implications) Branch of the U.S. Center for Human Genome Research. In 1984-85 she was a visiting scientist in the Program in Science and Society/Biology at the University of Groningen in The Netherlands and, in 1986, a Fulbright scholar in Women's Studies at the University of Waikato in New Zealand.

She is co-founder of the international network "Feminist Approaches to Bioethics," founded in 1993, and has served as a co-coordinator and as editor of their Newsletter.

Her primary research interests are feminist technology assessment of reproductive technologies, feminist bioethics, and women-and-genetics. Books she has edited or co-edited include *Birth Control and Controlling Birth: Women-Centered Perspectives*, *The Custom-made Child? Women-Centered Perspectives*, *Feminist Perspectives in Medical Ethics*, and *Issues in Reproductive Technology*.

About the Article

Becky Holmes reduces the Canadian Biotechnology Strategy to its most fundamental element. The Strategy, she writes, "is about wealth – simply put." Yet this wealth is not equally distributed, nor are the negative consequences of advancing biotechnology necessarily encountered by its beneficiaries. Reviewing several papers in the collection which take biotechnology and wealth as their theme, Holmes outlines some of the contradictory ways that wealth and health interact in the CBS. She warns against several of the most commonly invoked "band aid" solutions, and advocates those that might work to assert the management of biotechnology in the *public* interest. Finally, Holmes encourages Canadians to take advantage of international perception – however flawed. "Make use of that moral argument," she writes, "... that Canada should do what is morally right and be proud of an international stance that holds morality above expediency."

Introduction

The Canadian Biotechnology Strategy is about wealth – simply put. The government documents are filled with phrases such as 'economic potential,' 'worldwide market,' 'generate revenue,' 'future jobs,' 'increase ... international competitiveness.'

The Working Group on Women, Health and the New Genetics and the rest of the Workshop participants constitute a sample from the wealthiest 10% of North Americans – the wealthiest 2% of the world's citizens. From wealth, can we step aside and analyze wealth?

For some 10 years now I've done feminist technology assessment using a system of queries I've devised. From that system, I shall select one query: For whom are the benefits? To whom fall the costs/ risks? In this situation we can look at wealth as one benefit and poverty as one risk.

Let's look at a semi-hypothetical example: Suppose we bioengineer a wheat plant minus the gene that gives people wheat allergies. Who benefits, besides the biotech companies? People with wheat allergy who also have enough money to buy it. To whom fall the costs? Many people: workers in and near the fields and other consumers, who develop allergic reactions to the much more potent allergens in the pesticides and herbicides necessary to allow that new plant to grow. Wealth and health go hand-in-hand in this example: wealth with health versus indigence with illness. It would be cheaper to devise and manufacture delicious breads from ordinary corn and rice, which almost everyone could afford to eat.

Now for the Canadian Biotechnology Strategy, who is to get wealthy? Multinational corporations? In most of the submitted papers the answer is a strong 'yes.' These corporations are driven to

accumulate wealth not only for their CEOs and Board members, but also for their stockholders. Stockholders! I'll come back to these later.

Who else is to get wealthy? Will the Canadian government coffers expand through taxes on corporations? And then, will the government use those monies to improve the health determinants (see Pat Armstrong's essay, this volume) for Canadians? Theoretically this could couple health for citizens with wealth for tax coffers. But, note in the CBS's *Health Sector Consultation Document* that Canada claims to have the most generous research tax credits in the world. The policy priority then, appears to be ensuring private profit rather than wealth distribution.

Who else is to get wealthy? Will it be many citizens of Canada, as individuals, who gain employment in those biotech firms? Although a very small percentage of the population may acquire job opportunities, many of the technician-level jobs may be hazardous, healthwise. In any countdown, however, one must offset such gains by jobs lost in agriculture.

Let's turn from the benefits list to the costs. Some costs will accrue to farmers, especially women-as-farmers, as Margrit Eichler makes abundantly clear. Some costs will accrue to women-as-food-shoppers, women-as-cooks, and women-as-unpaid-home-nurses. Some costs will accrue to women-as-health-care-consumers, since their health may be jeopardized both by the food they eat and by their encounters with the medical system. A very few may have improved health due to some high-tech treatment, with ancillary cutback in health care for the majority of Canadians. A biotech emphasis may indirectly (and possibly directly) maintain the diversion of monies from improving health determinants and

increase the gap between the haves and the have-nots.

Let's look at Penny Van Esterik's excellent example: the chefs of Toronto protest GE foods and do not use them in their haute cuisine, while the poor and homeless eat them in food pantries and soup kitchens.

Let me put out, however, two examples that seem to uncouple the health-with-wealth partnership. One is the drug herceptin, as discussed by Sharon Batt. Women who can purchase or can persuade their health insurers to purchase for them (in both cases, 'wealthy') might find themselves taking a drug that may be a hoax or has serious side effects.

My second example is the use of the drug DES in Chicago in the 1950s. In hospitals there, white women who threatened miscarriage got the drug, but it was never offered to black women, obviously because of racial prejudice. The result is that clear cell cancer of the cervix is extremely rare in black women.

Papers in the "Wealth" Session

Now I turn to a few comments on specific papers in the collection for this session. I commend and praise these authors for their perception and their ability to hit nails on their heads. I shall emphasize and expand a few of their points and be a bit skeptical about some proposed solutions.

First let me underscore Julie Delahanty's and RAFI's concern about Human Genome diversity research – research to sample populations all over the globe to see how little bits of their DNA differ. Humans have 98% of the same DNA as chimpanzees, and each one of us in this room has 99.999% of the same DNA as each other. A tremendous amount of wealth is passing among corporations over finding those teeny 0.001% differences. Shares of their stocks rise on the stock

market. RAFI's term 'Gene Giants' puts it very well. Yet there's no 'product.' The rich are getting richer, and they can afford it when the bubble bursts.

Iceland is a clear example. Samples of DNA of 261,000 of the 270,000 citizens of Iceland are now in the freezers of Hoffman LaRoche in Switzerland. I believe they plan to follow each citizen until he or she dies. And then try to find the differences in DNA between the stroke victim and the diabetic, between the fisherman who fell through the ice and the drunkard. Wealth, real wealth, enters the picture here. But scientists are divided as to whether citizens of Iceland will benefit in any way (Lewis, 1999).

Jumping from Iceland to Canada, I endorse Nandita Sharma's point that the main aim of the *Canadian Biotechnology Strategy* is to market biotechnologies. As she says, "throughout this document is the government's concern that people accept and be confident in and comfortable with new genetic technologies." "The media," she continues, "are being used to promote the benefits and safety of genetically engineered food." Finally, she notes, "corporate propaganda [is] being voiced as if it was a public health message."

It happens that allaying the public's fears, and promotion of its project, also were and still are the unwritten goals of the U.S. Center for Human Genome Research's ELSI program (Ethical, Legal, and Social Implications) (Andrews 1999:206). For instance, many grants are awarded for so-called 'education' projects, although that word is not in their title. (The word 'education' here simply means propaganda or indoctrination.) ELSI has never awarded a grant to any project suspected of being critical of the basic premise: the very existence of the Human Genome Project.

Now let me turn about and ponder one of Elisabeth Abergel's concerns. She admits

the fact of "governmental promotional programmes," but feels that although most women would agree about opposing GE food, the medical uses are, as she puts it 'more divisive' among women. This is an important point. For we cannot, must not, forget women who are not in our midst, for example, the mothers of children with genetic disabilities. Many of them believe that biotechnology is on the verge of finding a genetically engineered cure for the disease in their families. My own view is that such beliefs result from propaganda, but should feminists quench their faith and dreams? If so, how?

Similarly, Madeline Boscoe and Sari Tudiver ask, "Must we always say NO?" And then flush out this question wondering, "Are there some aspects ... of biotechnology ... that reflect careful evaluation, promising therapeutic ... outcomes in the long term ... not necessarily dependent on corporate monopoly control for their development and marketing?"

By 1992 in the United States there were over 130 'genetic support groups,' each one focused on a particular genetic trait in their members' kindreds. Eighty percent of these had women CEOs or presidents. These leaders are very knowledgeable about how close the search is for finding 'their' gene, who is searching, and what, if any, attempts at treatment are going on. To be sure, they are middle class and educated, so the 'wealth' issue surfaces here again. And here again are faith and dreams, but among some very well-informed women.

This leads into Pat Armstrong's concern about a "market-driven consumer model of health." We need reforms in medicine and welfare, she says, but the new focus is harmful to most women, simply because the paradigm is business, and efficiency is measured in monetary terms. The women who are empowered are those with the ability to pay. Look again at the women

CEOs I just mentioned. Most of the genetic conditions in their kindreds are rare diseases, ones that occur so infrequently in the population that it would never lead to corporate profits to develop a test to detect that gene – the so-called orphan diseases. Therefore, these women pressure foundations for grants; some of them lobby Congress to develop such tests or to subsidize corporations to do it. In recommending policy we need to know that such women exist.

Now, to return to Hoffman LaRoche in Switzerland and its ilk. Rare diseases are not profitable. So they turn to the big killers of the wealthy. Most wealthy people in this world do not die of rare genetic diseases, but of heart attacks, strokes, diabetes, AIDS, Alzheimers, and various cancers. And let's add in murder and suicide so we can invent a violence gene and a suicide gene. The ultimate in genetic reductionism is to find in human DNA the predispositions to such conditions as these. Just exactly how is my personal Grim Reaper going to stalk me? The Gene Giants can make big bucks saying that they've found the codes for a given Reaper. What happens then? Their clients can do little but worry. Yes, they can abort a fetus or impose a 'life-style change' on their kids or themselves. But when the doorbell rings, it then might be another Grim Reaper.

Solutions: Band-Aid Approaches

Band-aid approaches are what Industry Canada hopes, I think, will satisfy any public clamor, measures that can allay the public's worries so that biotech can go full steam ahead. Two of these that worry me are:

- A) Labeling of all GE food. The basic drawback to labeling is that it accepts the existence of GE food – labelling implies approval and acceptance of GE foods, as Sharma explains.

Another drawback is that it forces woman-as-shopper to make choices. A woman simply trying to feed her family should not have to do an ethical evaluation of each specific engineered food: has the introduced gene escaped into weeds, does it require specific pesticides and fertilizers sold at high cost, does it produce sterile seeds, etc.?

B) Putting regulations in place and announcing this to the public. In her opening comments Sue Sherwin describes the 20-member advisory committee (the Canadian Biotechnology Advisory Committee, CBAC) as not representative and including no health activists. Thus, the first problem with band-aid approach B is how to get the government to form an appropriate regulatory body. Because of current love affairs between governments and global corporations, any regulatory body most likely will be designed to keep that love relationship intact.

Two weeks ago I was witness to a good example of governmental fear of genuine regulation. I attended a 'public consultation' in Baltimore on 'supervision of genetic testing.' An excellent committee, more than half of them women (and some of those, feminists-in-spite-of-themselves), had prepared the document we were to critique (SACGT, 1999). But it was clear that this blue-ribbon committee was under the strong constraint of not impeding any biotech firms from devising more and more genetic tests. Their document avoided the word 'regulation' and used instead 'guidelines.' I found myself in a miserable little discussion group with several representatives from biotech companies. "Too much regulation already," they said.

Most of you have heard that in January 2000 the U.S. National Institutes of Health (NIH) halted gene therapy trials at the

University of Pennsylvania (Barbour, 2000: 384; Horton, 2000: 329). After one death came to light, it was eventually discovered that there had been 691 deaths or serious incidents in other clinical trials of gene therapy (Nelson and Weiss, 2000: A01). For some two years the U.S. Food and Drug Administration (FDA) has been in charge of genetic engineering experiments; it keeps confidential any reports it gets (Smaglik, 2000: 5). Adverse events are also supposed to be reported to the NIH, but many researchers said they did not know about that requirement (*ibid.*). Some scientists claim that the deceased patients would have died anyway from their condition, since most of them were terminally ill with cancer (*Ibid.*).

Here I tease out several points:

- (1) it's obvious that we have to be vigilant that regulations do not backfire – so that they end up not benefiting the public because they have stirred up a backlash; we have to be ready to deal with the complaint that regulations hold back the progress of science;
- (2) corporations may protest regulations by going where there are no regulations in place, for example, in the U.S. where government-funded experiments on embryos are forbidden, preimplantation diagnosis and other fiddling with human embryos simply goes on in the private sector or in countries without regulations;
- (3) any regulations should define 'adverse events' and include a specific place and method to report these. Let us all dream that any such events in genetic experimentation (plants, animals, humans) must be reported to the Women's Health Movement.

Solutions: Possible Effective Approaches

Use the media. Several commentators noted that the media are part of the problem. Yes, they are mesmerized by

biotechnology. If a scandal breaks out, they'll zero in on that temporarily, but then go back to being mesmerized. For example, although the 'gay gene' is only a hypothesis based on equivocal evidence, the media often now blithely mention 'the gay gene.'

One problem in the U.S. is that the major commercial networks and newspapers are parts of huge conglomerates that include pharmaceutical houses and agribusinesses. Television documentaries are definitely censored. It's hard to believe – when you seem to be getting both sides of a question in investigative reporting – but any TV documentary that appears has already passed corporate censorship. Yet as individuals, most journalists are ethically committed to the truth, even if their stories get suppressed.

Because of this basic personal integrity, one way to use the media is to go first through the alternative press, which will welcome reports we write. The February 2000 issue of *Mother Jones* published "Pandora's Pantry," an article on GE foods. Such pieces may then be seen by reporters from the mainstream media, and from time to time critical articles *have* appeared in the *New York Times*.

Go through stockholders. Can we get biotech stockholders to take a stand? We all know the example of South Africa. Big stockholders, usually institutional investors, such as universities and labor unions egged on by their constituencies (students, workers, alumni), divested stocks from firms that were doing business in South Africa. Or, they chose not to divest when companies were following the 'Sullivan Principles' of human rights with their employees. This led to the fall of apartheid. Now, can we invent principles under another name and try the same thing with genetic engineering? How about the 'Sherwin Principles'?

Global Activism. We can join global actions or create and recruit globally to our own actions. Fritolay, a subsidiary of Pepsico, has told its suppliers that it won't buy genetically engineered corn. Apparently this did not come from stockholder pressure, but Fritolay realized that consumers were getting wary. (As far as I know, they still use bt potatoes for their potato chips.) And after the country of Brazil forbade the planting of GE soybeans, more and more countries switched to buying their soybeans from Brazil (Passoff, 2000).

Help from the state. Despite its poor track record with women, the Canadian government can protect its citizens. Pat Armstrong says, "Only the state is powerful enough to counter the power of the global corporations . . . precisely because the state is now so activist [in serving the interests of corporations] we need to make demands on it." Nandita Sharma has far less faith as she describes a government in league with corporations broadcasting propaganda as if it were a public health message. Yet – and it really has nothing to do with GE – it's ethically right for the state to take responsibility for health determinants.

Hold fast on not patenting life forms. I want to urge Canadians to hold fast to your current patent laws, and not succumb to the argument to "modernize Canada's intellectual property laws," i.e., not to put them in line with the World Trade Organization guidelines.

In Sum

I have a strong affection for Canada having spent at least 35 summers camping or traveling in many of your provinces, dating back to the fifties when a picture of the Queen was in every parlor. And Canada produces some remarkable feminists, many of whom have intellectually and spiritually enriched my

life. **So** – my pro-Canada sentiment wants Canada to be wealthy or, better expressed, wants no one in Canada to be poor.

I am not alone in these positive feelings about Canada. Canada has an international reputation of high moral standards, of being a moral leader. Many Canadians scoff at such an interpretation, because you know only too well about so

many specific instances of immoral actions, especially against your aboriginal peoples. But I am speaking of the global perception of your country, whether or not this can withstand close scrutiny. Thus I urge you to make use of that moral argument, the argument that Canada should do what is morally right and be proud of an international stance that holds morality above expediency.

References:

Andrews, Lori N. 1999. *The Clone Age: Adventures in the New World of Reproductive Technology*. New York: Henry Holt.

Barbour, Virginia. 2000. The Balance of Risk and Benefit in Gene-Therapy Trials. *The Lancet*. 355: 384.

Horton, Richard. 2000. [Editorial] Gene Therapy Under Cloud. *The Lancet* 355: 329.

Lewis, Ricki. 1999. Iceland's Public Supports Database, but Scientists Object. *The Scientist* 3(15): 1.

Nelson, Deborah and Richard Weiss. 2000. Earlier Gene Test Deaths Not Reported: NIH Was Unaware of 'Adverse Events'." *The Washington Post* 31 Jan: A01.

Passoff, Michael. 2000. Genetically-Engineered Food: Threats to Shareholder Value. *GeneWatch* 13(4): 10-15.

SACGT. 1999. Public Consultation on Oversight of Genetic Tests December 1, 1999. January 31, 2000. Secretary's Advisory Committee on Genetic Testing. National Institutes of Health Web site. Available at: <http://www4.od.nih.gov/oba/sacgt.htm>. Accessed: January 20, 2000.

Smaglik, Paul. 2000. NIH Tightens Up Monitoring of Gene-Therapy Mishaps. *Nature* 404(6773, 2 Mar): 5.

Preserving Cultural Diversity through the Preservation of Biological Diversity: Indigenous Peoples, Local Communities, and the Role of Digital Technologies

Rosemary J. Coombe
July 25, 2000

About the Author

Rosemary J. Coombe is Professor of Law at the University of Toronto where she is cross appointed to the Munk Centre of International Relations and the Department of Anthropology. She is the author of *The Cultural Life of Intellectual Properties: Authorship, Appropriation and the Law* (1998 Duke University Press).

About the Article

Rosemary Coombe was unable to attend the workshop, but she graciously agreed to contribute this paper.

In this article, Rosemary Coombe outlines the links that exist between cultural diversity and biological diversity (biodiversity). "Biodiversity preservation," she writes, "is an inherently multicultural process." Coombe's focus is an international legal instrument which is principally concerned with the preservation of biodiversity: the Convention on Biological Diversity (CBD). She also examines the contested role of intellectual property rights (IPRs) in relation to the preservation of cultural diversity, and the ways of amending conventional IPR approaches so as to limit their role in the misappropriation of traditional cultural knowledge. Coombe's examination of the efforts and obligations of council parties to the CBD (of which Canada is one) suggests that Canadian policy relating to IPRs cannot focus solely on the obligations created by membership in the World Trade Organization (WTO). Where the latter organization enjoins members to expand IPR protection. Parties to the CBD are *also* obliged to concern themselves with the preservation of biological diversity – obligations which enjoin more restrictive approaches to domestic and international IPR rights. Coombe's article suggests that the recently established Canadian Biotechnology Advisory Committee would be well advised to consider Canada's obligations under the CBD when it examines issues of IPR.

PLEASE NOTE: This article was prepared for the Council of Europe under its Cultural Diversity, Cultural Policy Programme. The author circulates it for comment with the request that it not be reproduced or cited without permission.

Introduction

In international policy circles it is increasingly recognized that the conservation of biological diversity (or biodiversity) is integrally related to the preservation of cultural diversity and that indigenous peoples and local communities hold traditional ecological knowledge of great potential value and importance in global efforts to achieve sustainable development objectives. Such peoples and their knowledges are endangered. This paper will consider global efforts to value and preserve traditional ecological knowledges, the use and significance of digital technologies in facilitating the preservation of this cultural diversity, and point to issues that require further research.

After introducing the policy issues, the paper will consider the obligations of Austria, Belgium, Bulgaria, Canada, Luxembourg, Switzerland, and the United Kingdom (hereinafter the Council Parties) under the Convention on Biological Diversity (hereinafter the CBD), and initiatives taken by the Council Parties to protect traditional ecological knowledge both domestically and internationally; it also addresses some important regional initiatives and provides examples of academic and non-governmental organization (NGO) activities. Given the importance that the CBD attaches to intellectual property rights (IPRs) and the enormous body of literature that addresses the propriety of IPRs as a means of protecting traditional environmental knowledge, the paper then considers the role of IPRs with respect to the preservation of cultural diversity¹ and

¹. A recent survey of important works may be found in King and Eyzaguirre. An enormous bibliography is maintained by Graham Dutfield and is operated from Oxford University at the website for the Working Group on Traditional

proposals to amend IPRs to make them less conducive to the misappropriation of cultural knowledge. The paper next addresses indigenous uses of the Internet, with particular attention to cultural revitalization efforts. More general usages of digital technology to assist in the protection of biodiversity and indigenous knowledge are then surveyed with emphasis upon the potential cultural impacts of these activities on indigenous peoples and local communities. Areas of recommended research are identified at the end of each section.

The Relationship Between Cultural Diversity and Biodiversity

Human cultural diversity, it is believed, is threatened on an unprecedented scale (Posey 3). Languages are generally seen as major indicators of cultural diversity—the codifications, heritages, and frameworks which constitute a society's unique understanding of the natural and social world. An estimated half of these will disappear within the next century (UNESCO). Since 4,000 to 5,000 of the 6,000 languages in the world are spoken by indigenous peoples, and these are the most endangered of languages, the loss of cultural diversity will affect these peoples disproportionately. The countries which contain peoples speaking the largest numbers of languages are also those that house the greatest biological diversity in terms of species and variations in interspecies, and include the greatest numbers of indigenous and communities with traditional, near-subsistence livelihoods. Although no universally accepted definition of indigenous peoples or of traditional communities exists, the majority of the world's rural populations live in direct dependence upon their knowledge of and use of local ecosystem

Resource Rights:
<<http://users.ox.ac.uk/~wgtrr/bib1.htm>>.

resources. These resources are also disappearing at an alarming rate with dire consequences for those peoples whose livelihoods depend upon them.²

The world's poor rely upon biological products from local sources for 85% of their needs (e.g., for food, fuel, shelter, medicine, etc.), over 1.4 billion rural people rely upon farm-saved seeds and local plant breeding for their subsistence, more than three quarters of the world's population relies on the knowledge of local health practitioners and traditional medicines for their primary medical needs, and over half of the world's drugs are derived from plants (Crucible II Group 1:1). New plant genetic resources are needed in the pharmaceutical, agricultural, and biotechnological industries on a regular basis, yet the social and cultural conditions that nurture their ongoing development and ensure their continuing variation are threatened.

Plant genetic diversity is considered a human legacy but it is one that is sustained largely by the uncompensated

². According to an Australian report on biodiversity, "[t]he loss of rich, biologically diverse environments (such as the Amazonian forests) through activities such as logging, land clearance and mining and development has profound consequences in its impact on the culturally diverse groups of indigenous peoples whose livelihoods depend on these environments. There is in this sense a direct relationship between biological diversity and cultural diversity; maintenance of the former can help preserve the latter. The reverse is also true, since indigenous peoples are often the custodians and stewards of biological diversity, the maintenance of cultural diversity is an important factor in the conservation of biological diversity." Commonwealth of Australia, Biological Diversity and Indigenous Knowledge, Research Paper 17 (1997-8). Available at <<http://www.aph.gov.au/library/pubs/rp/1997-98/98rp17.htm>>. See Muhlhausler for further discussion of the relationship between language, culture, and biodiversity.

work of culturally diverse, politically vulnerable, and impoverished peoples.³ Only to the extent that such practices are supported, encouraged, and maintained by *in situ* conservation measures will biodiversity be maintained.⁴ Hence, the CBD Preamble recognizes the "close and traditional dependence of many indigenous and local communities embodying traditional lifestyles on biological resources, and the desirability of sharing equitably benefits arising from the use of traditional

³. As Swaminathan and Castillo write: "Tribal and rural farming communities have a long tradition of serving as custodians of genetic wealth, particularly landraces often carrying rare and valuable genes for traits like resistance to biotic and abiotic stresses, adaptability, and nutritional quality. Several land types that carry valuable genes are preserved by farmers for religious functions and they constitute valuable material for conservation and sustainable use. Women in particular have been the principal seed selectors and savers" (Swaminathan and Castillo xii).

⁴. According to the Crucible II Group:

Local and indigenous peoples who speak ancestral languages are severely threatened by loss of sovereignty over land, resources, and cultural traditions and the promotion of linguistic assimilation. As they become increasingly marginalised local people lose local scientific knowledge, innovative capacity, and wisdom about species and ecosystem management. As one scholar concludes: "Any reduction of language diversity diminishes the adaptational strength of our species because it lowers the pool of knowledge from which we can draw." The loss of traditional farm communities, languages, and indigenous cultures all represent the erosion of human intellectual capital on a massive scale. It is tantamount to losing a road map for survival, the key to food security, environmental stability and improving the human condition. Thus, it is increasingly difficult to talk about the conservation and sustainable use of genes, species and ecosystems separate from human cultures (Crucible II Group 1: 9-10 citing R. Bernard).

knowledge, innovations and practices relevant to the conservation of biological diversity and the sustainable use of its components.” This is indicative of a global recognition that biodiversity preservation is an inherently multicultural process.

Indigenous knowledges may be understood as the cultural knowledges of local peoples concerning the everyday realities of living that are the product of a direct experience with nature and a particular, local ecosystem.⁵ Indigenous knowledge, “the unique, traditional, local knowledge existing within and developed around the specific conditions of women and men indigenous to a particular geographic area” (Grenier 1998), is collectively held and, until recently, was also predominantly communicated orally and from generation to generation. Such knowledge is dynamic and adaptive, socially shared and communicated, and usually recognizes an equilibrium among natural forms understood to form elements of a cosmos. It embraces knowledge of location, movements, spatial relationships and temporal cycles, and is not restricted to knowledge of entities and their parts. “Nature” is less likely to be understood as something to be conserved and more likely to be understood as an extension of society and an integral part of human interdependence.

Just as indigenous peoples and local communities are increasingly under siege by forces of urbanisation, proletarianisation, linguistic assimilation, logging, mining, and large-scale development projects, they find that the genetic resources they manage and develop using their knowledges and technologies are of increasing value to others. “Biopiracy” of genetic resources

⁵. For a discussion of the various definitions of indigenous knowledge and how these are situated in relation to conventional, formal, or scientific knowledges, see Dei, Hall and Goldin-Rosenberg.

and traditional knowledge is believed to be on the rise.⁶ For example, a survey conducted by the Indian Drug Manufacturers’ Association found that of the 668 pharmaceutical patents filed in 1997, the vast majority included the use of ayurvedic knowledge (traditional Indian medicinal systems) with minor modifications in methods of extraction and processing.⁷ Research to ascertain the use of indigenous and traditional knowledge innovations and practices (hereinafter ITKIP) in the intellectual properties granted to others is both difficult and expensive to accomplish given the limited information that most states provide to the public and the limited forms of disclosure required of most patent applicants. States concerned with the preservation of cultural diversity should consider amending their intellectual property regimes to enable such research.

Although claims concerning the biopiracy of traditional knowledge abound, it is not always clear precisely *how* traditional knowledge practitioners are or will be precluded from continuing to engage in applying and developing such knowledge as a consequence of these appropriations. Moreover, it is not at all evident that patents based upon ITKIP are, in fact, valid given that they generally involve an “obvious” technology applied to ITKIP that lacks the quality of novelty. Nonetheless, it is manifestly inappropriate for state regimes to put the onerous and expensive burden of challenging the validity of such

⁶. As Graham Dutfield explains, “[a]lthough outsiders have collected knowledge and biological resources from traditional peoples for centuries, ‘bioprospecting’ (the search for and collection of biological material and traditional knowledge for commercial ends, with particular reference to the pharmaceutical, biotechnological and agricultural industries) has intensified in recent years.” Dutfield, *Rights* (505).

⁷. Cecilia Oh citing Vandana Shiva, “India: Granting MNCs Absolute Monopolies.” Third World Network Features. 1999.

IPRs upon the impoverished and vulnerable holders of such knowledge (or even upon the nonprofit NGOs that support them).

IT IS RECOMMENDED THAT COUNCIL PARTIES UNDERTAKE FURTHER RESEARCH TO CONSIDER:

- Means to amend intellectual property regimes to enable interested parties to ascertain when and if intellectual property rights are being granted for works and innovations that appropriate indigenous and traditional knowledge, innovations, and practices and are thereby invalid to the extent that such knowledge, innovations and practices are not novel and the uses made of them are obvious amongst those peoples or in those communities.

The Convention of Biological Diversity and the Recognition of Traditional Knowledge

States who are party to the CBD are obliged : 1) to respect, preserve and maintain knowledge, innovations and practices (KIP) of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity (Article 8(j)); 2) to develop and use traditional and indigenous technologies (Article 18(4)); 3) to promote the wider application of such knowledge with the approval and involvement of the holders of such KIP; 4) to encourage the equitable sharing of benefits arising from the use thereof; and, 5) to ensure that their intellectual property regimes support rather than undermine these objectives (Article 16(5)). Technology transfer to less-developed countries is encouraged in exchange for the provision of such knowledge. For some advocates, “the cumulative effect of these provisions is to make it mandatory for governments to

enact a law recognizing indigenous and local community knowledge systems. In any event they are entitled to enact such a law to fulfil their obligations under the CBD” (Nijar, *Perspectives*). With very few exceptions,⁸ states that are party to the CBD have yet to introduce legislation explicitly protecting ITKIP, or to consider what the interaction between a system of collective rights and a traditional IPR regime would involve.

Existing international trade and intellectual property agreements do not pose any obstacles to undertaking such an initiative. Indeed, to the extent that Article 8 of the Trade Related Aspects of Intellectual Properties Agreement (hereinafter TRIPs) under the World Trade Organization (WTO) allows states to take measures to protect public health and nutrition and to promote the public interest in sectors of

⁸. Exceptions include laws in the Philippines and Peru. In the Philippines, the Indigenous Peoples’ Rights Act of 1997 recognizes that indigenous cultural communities and indigenous peoples have, as part of their rights to cultural integrity, rights to control bio-genetic resources, indigenous knowledge systems, in addition to rights to control, develop, and protect vital resources, health practices, resource management systems, and agricultural technologies. For a critical discussion of the legislation see Rovillos, *Indigenous Peoples. The Ley de Biodiversidad* or Biodiversity Law passed in Costa Rica in 1998 initiated the process of developing a *sui generis* regime for protecting the KIP of indigenous and local communities but also explicitly established the juridical recognition of these rights without any requirement of registration or prior declaration. The parameters of these community intellectual rights will be determined in consultation with indigenous peoples and peasants. See discussion in Dutfield, *Intellectual Property* 110-3. In Thailand, a draft bill recognizing the collective rights of traditional healers and benefit sharing for the commercial use of traditional knowledge provoked an almost immediate challenge by the United States in 1997. See Correa.

vital importance to their socio-economic and technological development, it can be argued that measures taken for the protection of ITKIP fulfill these objectives. After all, more than 80% of the world's peoples depend upon such knowledge for their health care, ongoing pharmaceutical development depends upon it, and the continued viability of local agricultures ensures global food security.⁹

The Council Parties have all signed and ratified the CBD. Most of the Council Parties are funding research into ITKIP relevant to the maintenance of biological diversity. Other Council Parties (for example, Belgium, Luxembourg, and Bulgaria) have not linked their commitments to preserve biodiversity with considerations of cultural diversity and have approached biodiversity largely as if it pertained entirely to natural environments untouched by human interaction.¹⁰ This, however, is rarely the case.

⁹. Indeed, according to Gurdial Singh Nijar, “[a] law to protect and further the knowledge systems of indigenous peoples and local communities would clearly contribute to the promotion of technological innovation in furtherance of the social and economic welfare of large segments of the Third World’s populace” (Nijar, *Perspectives*).

¹⁰. Bulgaria, for example, ranks amongst the most biologically diverse countries in Europe with huge numbers of endemic species and is home to many traditional and rare cultivars. Not surprisingly, given its accessibility to Western researchers, it has also been subject to exploitation including the illegal gathering (and export) of edible fungi, medicinal plants, snails, and reptiles (Bulgaria 6). Bulgaria is a rich source for botanical drug species within Europe and is eighth in the leading export countries in the botanical drugs trade. Wild botanical drugs continue to be collected by villagers who have traditional knowledge of their usages (Lange and Mladenova 135-46). Although, restrictions on collecting, trading, and exporting species have been established, legislative initiatives have been oriented towards the preservation of biological

Traditional knowledge held within the European Council Parties includes KIP in relation to hedgerow maintenance, animal husbandry, forestry, fish-pond and bog management, orchard fruit growing, herbal medicines and traditional knowledge of phytonutrients. To a limited degree, the cultural dimensions of these practices are recognized in domestic legislation and regional regulation. Austria has passed legislation to document, protect, conserve natural and cultural landscapes. Switzerland defines the preservation of biological diversity so as to imply the “protection and maintenance of rare habitats of great value, including traditional and cultural landscapes” (Swiss Agency 25). The European Council Parties are also subject to European Union (EU) regulations with respect to the conservation, description, collection and use of genetic resources in the agricultural sector (Council of the European Union, Reg. No 1467/94) and European Community (EC) objectives to maintain agricultural and forestry sectors that manage resources so as to preserve cultural landscapes. Cultural landscapes can only be preserved to the extent that the traditional KIP which developed them is simultaneously safeguarded.

Surveys of domestic biodiversity in Council Parties are ongoing and, in some cases, the cataloguing activity has been accompanied by a corresponding digital database network with international linkups (e.g., Austria 21). Inventories of the biogenetic reserves of the Council of Europe are currently in preparation and most of the Council Parties are still in the process of documenting autochthonous animal and plant species. Council Parties understand that the homogenization of modes of cultivation threatens the existence of certain species and that

resources rather than the continued cultivation of the cultural knowledge that sustains this biodiversity.

species will likely decline to the extent that heterogenous cultivation activities are abandoned.¹¹ Therefore, although few specific measures to protect domestic traditional KIP have been taken, the importance of the relationship between the presence of particular species and particular forms of cultivation—many of which are likely to vanish unless recognized, recorded, and supported—is widely acknowledged. Council Parties have implemented a number of measures as incentives to preserve the *in situ* preservation of biodiversity.¹²

¹¹. For this reason, Austria has committed itself to the objective of sustainable agriculture which “couples an ecological, site-specific adaptation of production methods to a highly structured and diverse cultural landscape” (Austria 14). Agricultural policy in Switzerland aims “to sustain forms of traditional exploitation, particularly those which have contributed to the formation of landscapes and to increase the diversity of ecosystems” (Swiss Agency 33), whereas the United Kingdom recognizes “the importance of those traditional skills and practices upon which many valued habitats depend” (United Kingdom 28). Switzerland has long had legislation designed “to preserve indigenous animal and plant species, biotopes and landscapes” (The Federal Law on the Protection of Nature and Landscape (1966) in Swiss Agency 15), a land planning law that allows for the protection of areas “of great ecological or cultural importance” (The Federal Law on Land-Use Planning (1979) in Swiss Agency 16) and, most recently, a fund of Sfr. 50 million was established “to contribute to the conservation of traditional rural landscapes, and to safeguard ancient methods of exploitation, cultural heritage, and natural landscapes” (Swiss Agency 17).

¹². Commitments to traditional cultivation methods may be matched by “compensation payments for disadvantaged areas” (Austria 26) that serve to encourage farmers in marginal areas, such as montane farming zones, from abandoning agriculture and thereby help to ensure the continuing cultivation of local biodiversity. More generally, agro-environmental grants and “ecological compensation” programmes have been

Ex situ collections of genetic resources—including genebanks, seedbanks, herbariums and microbial culture collections—exist in most of the Council Parties.¹³ As the United Kingdom’s National Report on Biological Diversity

established by Council Parties to remunerate farmers for conservation activities, cultivation of traditional varieties, sowing indigenous wild plants in fallow lands and gardens, engaging in organic and integrated agriculture, safeguarding biotopes, and as compensation for lost income caused by the abandoning the practice of more intensive resource use. More still could be done. It is estimated that Europe has lost 75% of its plant genetic diversity within the last century and that the revitalization of genetic and cultural diversity will depend upon support for organic plant breeding, the development of organically produced seeds and *in situ* management of a “diversity of cultural plants [which have] evolved from generation to generation, in the hands of many farmers and in many different landscapes” (Wyss and Wiethaler, 37). On these points, see Eric Wyss and Cornelia Wiethaler eds., Final Report on the International Conference on Biodiversity and Organic Plant Breeding, 2nd and 3rd December 1999 in Frick Switzerland. The Report provides information on the organic breeding sector in all of the European Council Parties except Bulgaria. A database of available organic seeds and a bulletin board for exchange of information on organic breeding and propagation will be created at <<http://www.biogene.org>>. For a series of studies on the importance of preserving agricultural genetic diversity *in situ*, see Brush, ed.

¹³. The Swiss Federal Office of Agriculture, following upon the Food and Agricultural Organization’s World Plan of Action, emphasised preserving the adaptive potential of cultivated plants. To this end, the Swiss Commission for the Conservation of Cultivated Plants (CPC) has attempted to inventory all concerned institutions and the genetic material that they safeguard. The Millennium Seedbank Project at the Royal Botanic Gardens in the United Kingdom both banks and supports the reintroduction of plant species and the Commonwealth Potato Collection is also an important repository.

acknowledged, however, much “biodiversity information remains scattered across the country in many different and incompatible forms” (United Kingdom 26). Only to the extent that information networks are created that are accessible, regardless of where the information is held, will the potential of information technology to promote biodiversity begin to be realized.

Most Council Parties house or are party to the network of international genebanks established under the Food and Agriculture Organization (FAO) and the FAO promotes widespread access to these resources. Currently the network includes 12 genebanks but 31 additional countries have declared an intention to join their genebanks to this network. If accomplished, this amalgamation would incorporate into one network 46% of all of the planet’s plant genetic resources (Austria 46). The vast majority of crop germplasm held in these banks was collected from farming communities in the developing world (Crucible II Group 1: 20-22). However, the rights of providers of this material to have a stake in any profits made in the successful commercial application of it is still under dispute. A related area of controversy requiring further research is the propriety of IPRs in genetic resources held in trust by the Consultative Group on International Agricultural Research (CGIAR) in the sixteen international agricultural research centres it supports. In 1996, the CGIAR endorsed the principle that its centres would not claim legal ownership or apply IPRs to the germplasm held in trust and would require recipients to abide by the same principles. What remains disputed is the propriety of claiming IPRs in varieties and technologies developed from CGIAR germplasm to the extent that this germplasm was developed by indigenous peoples and local communities. Mechanisms to provide compensation to the farmers’ communities from which such

germplasm was taken may need to be developed.

Many of the European Council Parties have participated in and contribute to the ministerial process, “Environment for Europe,” which is intended to implement the “Pan-European Biological and Landscape Diversity Strategy” that, in turn, provides the European framework of the CBD. Within Europe, the location of biological diversity in economically underdeveloped regions has been recognized and more developed Council Parties have devoted resources to the preservation of biodiversity in these less developed regions.¹⁴ The degree to which development initiatives in Eastern Europe could be linked to efforts to document and preserve traditional KIP needs to be further investigated.

Amongst the Council Parties, the United Kingdom is unique in having Dependent Territories with both biological and cultural diversity that are considered endangered. The British Virgin Islands (BVI), the Cayman Islands, Gibraltar, Jersey and St. Helena are included in the UK’s ratification of the CBD. However, at least seven other territories are not included. In all of these territories, older members of the local populations are likely to have significant traditional knowledge about local biospheres that is undocumented and, without recognition or support, is not likely to be passed onto successive generations. A biodiversity database is being developed in the BVI, but no recognition of ITKIP appears to accompany this initiative.

¹⁴ Switzerland, for instance, has supported projects to conserve biological and cultural diversity in the region of Lake Onrid, between Albania and Macedonia, in addition to other ecosystem management projects in Estonia, Hungary, Bulgaria and Russia. The UK Darwin Initiative has supported the development of local expertise in peatland management in Eastern Europe.

Development priorities in many Council Parties have focussed upon environmental issues in less-developed countries, but such commitments to sustainable development are not always coupled with any evident concern for the relationship between natural resource management and cultural diversity.¹⁵ This is an area that requires considerable research if 'sustainable development' initiatives are to support the preservation of cultural diversity.¹⁶

In Canada, indigenous and traditional knowledge has been the subject of several commissioned research reports and traditional knowledge is now considered a source for consultation in environmental impact assessments. However, the

¹⁵. The Belgian government, for example, has invested in regional environmental management and database projects in West and Central Africa (as well as in China and Eastern Europe) but the cultural dimensions of these initiatives are underdeveloped. The Swiss Agency for Development and Cooperation, on the other hand, has a portfolio of 36 projects devoted to biodiversity in Latin America, Asia, and Africa, several of which have the conservation of indigenous knowledge of cultivation as a priority (Swiss Agency 50). The Darwin Initiative funds UK biodiversity experts in projects that will help developing countries meet their obligations under the CBD. The EU funds the Central Cordillera Agricultural Program in the Philippines, a project which has attempted to integrate indigenous peoples' resource management knowledge and practices as well as traditional health methods into its community development programmes. Tragically, a lack of understanding on the part of development authorities and government environmental officials about the effect of introducing new species alongside indigenous varieties led to the extinction of traditional varieties of great significance to local cultural practices (Rovillos, *Interphasing*).

¹⁶. In recognition of this, the Canadian International Development Agency supports the work of Cultural Survival in compiling an international directory of indigenous conservation projects in the Americas.

Northwest Territories is the only provincial government to have developed a policy pertaining to traditional knowledge. Acknowledging that aboriginal knowledge is a valid and essential source of information about the natural environment and its resources, this policy recognizes that traditional knowledge is best preserved through continued use and practical application, expresses a commitment to incorporate traditional knowledge into government decisions and actions where appropriate, and also commits to provide in kind support to aboriginal cultural organizations studying traditional knowledge.¹⁷ Indigenous peoples have been on the Canadian delegations to the CBD and Canada has funded off-delegation indigenous NGOs to participate in CBD discussions of traditional and indigenous knowledge protection. A World Intellectual Property Organization (WIPO) fact-finding mission in November 1998 involved consultations with indigenous groups across Canada to consider the viability of IPRs for protecting ITKIP.¹⁸

NGOs based in the Council Parties have been active participants in international fora focussing upon these issues and in specific projects in developing countries that are documenting and preserving

¹⁷. See <http://www.gov.nt.ca/Publications/Policies/52-06_6.htm>. The Dene Cultural Institute, for example, is providing guidelines for use and access to traditional knowledge for government and industry planning projects and environmental impact assessments. See <<http://www.deneculture.org/tradknow.htm>>.

¹⁸ The Union of British Columbia Indian Chiefs hosted an international conference on the protection of indigenous knowledge in February 2000 entitled "Protecting Knowledge: Traditional Resource Rights in the New Millennium" (February 24-26, 2000 at Vancouver, British Columbia, Canada). For more information on this conference, see <<http://www.ubcic.bc.ca/protect.htm>>.

ITKIP.¹⁹ European NGOs, however, have been critical of the EC's draft Biodiversity Action Plan, noting that the discussion paper circulated in January 2000 made no reference to issues of food security, TRIPs, bioprospecting, or biopiracy.²⁰ One reason for this was the failure of the EC to involve NGOs in the early stages of the discussion process.²¹ NGOs with global

¹⁹. In Austria, the Austrian Rainforest Program is involved in projects in cooperation with indigenous peoples in Brazil and Costa Rica, while the Vienna Institute for Development and Cooperation has been working with the Embera peoples in Panama to reactivate their traditional knowledge about tree species so as to conserve and revitalize these varieties. The International Development Research Council (with offices in Canada and Switzerland) has funded the Crucible II Group project, and funds projects for preserving indigenous knowledge and digital networking in India, Peru, the Philippines, Vietnam, Nepal and Papua New Guinea (PNG). Rural Advancement Foundation International (RAFI) in Canada, has been instrumental in bringing the issue of biopiracy to international attention and in researching and challenging intellectual properties that are based upon indigenous knowledge of plant genetic resources. See the following materials from Rural Advancement Foundation International (RAFI): [Captain Hook, the Cattle Rustlers, and the Plant Privateers: Biopiracy of Marine, Plant, and Livestock Continues](#). 11 May 2000; and, [Plant Breeder's Wrongs: An Inquiry into Potential for Plant Piracy through International Intellectual Property Conventions](#). 26 August 1998.

<<http://www.rafi.org/web/publications.shtml>>.
²⁰. These European NGOs include: Fern, Greenpeace European Policy Unit, Birdlife International, Royal Society for the Protection of Birds, Swedish Society for Nature Preservation Arbeitsgemeinschaft für Regenwald und Artenschutz, Friends of the Earth England Wales and Northern Ireland, World Wide Fund for Nature. See Joint NGO Comments on the draft EC's Biodiversity Plan (Version 12/1/2000) at <<http://www.gn.apc.org/fern/NGO%20statements/biodiversity%20action%20plan.htm>>. Posted February 13, 2000, 3.

²¹. These European NGOs point EC member states to Articles 5 and 6 of the Council

links to indigenous peoples are often the most significant source for information about ITKIP and the threats posed to indigenous peoples' cultural survival.

Finally university research institutes and independent researchers in most Council Parties are engaged in biodiversity research related to ITKIP in both domestic and foreign arenas.²² Overseas projects are often undertaken in conjunction with developing countries' governments and researchers with the aim of improving international cooperation on biodiversity and cultural landscapes. In many of the regions that these researchers visit, local peoples are engaged in the task of recording traditional knowledge.²³ Such researchers do not always share their

Resolution on Indigenous Peoples which notes "the key role played by indigenous peoples in the conservation and sustainable use of natural resources, the positive contribution of indigenous peoples in the development process, the vulnerability of indigenous peoples" and the need for development projects that contribute to enhancing indigenous self-development. Articles 5 and 6 of the Council Resolution on Indigenous Peoples are annexed to the Joint NGO Comments. See note 20, 6-7.

²². The Swiss Academy of Sciences project, The Swiss Biodiversity Forum, for instance, is supporting a research project on "Local Ecological Knowledge of Swiss Farmers and its Influence on Actual Landuse Behaviour". For information on this research project, see the homepage at <http://www.unibas.ch/mco/research_mueller.htm>.

²³. For example, local researchers are attempting to archive the over 814 distinct cultures in PNG in order to ensure the survival of forms of indigenous knowledge. This knowledge will be put on the Internet to make it more widely available. With one of the largest concentrations of biodiversity in the world, coupled with its cultural diversity, PNG attracts researchers from around the world. For more information on this archival project, see "Webbing New and Traditional Knowledge." <<http://www.PanAsia.org.sg/hnews/pg/pg01i001.htm>>.

information with people within the country, however, and local peoples are often unaware of even published information pertaining to their own cultural ancestry and ITKIP. Research into the feasibility and consequences of making government research funding and publication subventions contingent upon the repatriation of research information to local informants and host governments is needed. This might be one means by which Council Parties could contribute to developing countries' efforts to preserve cultural diversity.

IT IS RECOMMENDED THAT COUNCIL PARTIES UNDERTAKE FURTHER RESEARCH TO CONSIDER:

- How states can link their commitments to preserve biodiversity with considerations of cultural diversity and the cultural dimensions of ITKIP in both domestic legislation and regional regulation.
- How the relationship between natural resource management and cultural diversity can be recognised in all environmental protection measures such that the preservation of cultural landscapes serves to preserve the ongoing development of cultural diversity.
- How a system of collective rights that recognizes ITKIP, encourages its use, and facilitate the equitable sharing of benefits derived therefrom would be integrated with or recognized by domestic intellectual property regimes.
- How surveys of domestic biodiversity which aim to protect domestic traditional knowledge could involve the participation of older members of the local populations in order to obtain and incorporate undocumented traditional knowledge about local biospheres and

involve younger generations so as to increase their appreciation for such knowledge.

- What type of support is needed for organic plant breeding, the development of organically produced seed, and *in situ* management of a plant diversity amongst different farmers and in different landscapes.
- The propriety of claiming IPRs in varieties and technologies developed from CGIAR germplasm developed by indigenous peoples and local communities as well as compensatory mechanisms for farmers' communities of origination.
- The degree to which development initiatives in Eastern Europe could be linked to efforts to document and preserve ITKIP.
- How the relationship between natural resource management and ITKIP can be recognized to develop sustainable development initiatives that support the preservation of cultural diversity.
- The desirability of making government research funding and publication subventions contingent upon the repatriation of research information to local informants and host governments and how this could be funded by Council Parties as one way of assisting developing countries in joint efforts to preserve cultural diversity.

The Contested Role of Intellectual Property Protections

Obligations under the CBD that serve to protect cultural diversity by preserving ITKIP relevant to biological diversity are congruent with the Council Parties' obligations pursuant to international environmental commitments and human

rights covenants as well as domestic foreign aid policies oriented towards sustainable development. They are also in accord with the current agenda of the WIPO which has made the protection of traditional knowledge a priority. WIPO's 1998 fact-finding missions on traditional knowledge, innovations, and culture involved holders of ITKIP in consultations regarding the dimensions of regional ITKIP, the development of research protocols to govern scholarly and research access to ITKIP, the need to distinguish between sacred and secular dimensions of ITKIP when considering dissemination and reproduction, and the need for recognition of traditional knowledge in policy-making processes for sustainable resource management.²⁴ The lack of any such fact-finding mission to European countries was unfortunate as these missions have raised consciousness about the significance of ITKIP around the world and have helped to mobilize traditional communities and indigenous peoples to document and protect such knowledge and to consider the appropriate means for its valuation and exchange.

The active role of WIPO in raising public awareness of the significance of ITKIP does not, however, indicate any broad consensus that the intellectual property framework is appropriate for recognizing, valuing, and compensating ITKIP. Indeed, many indigenous peoples and NGOs representing traditional farmers and those practising subsistence agriculture have denounced attempts to impose intellectual property protections on third world countries.²⁵ These are not isolated

²⁴. For example, see World Intellectual Property Organization, Fact Finding Mission on Traditional Knowledge, Innovations, and Culture to North America. November 16-30, 1998. Doc. No. WIPO/ FFM N-AM/IMR/98/4. 11 November 1999.

<<http://www.wipo.org/eng/main.htm>>.

²⁵. In its Programme for the Protection and Promotion of Biodiversity and Community Rights, for example, the Third World Network

opinions. The resistance to patents in the area of food and agriculture has provoked street riots involving over a half million farmers in India, various indigenous refusals to permit researchers to enter ancestral areas, and dozens of declarations by indigenous peoples, including The Seattle Declaration of Indigenous Peoples at the WTO meetings in 1999 (which continues to make the rounds on the Internet and to attract the signatures of more and more indigenous peoples and NGOs).²⁶ The Seattle Declaration opposes the patenting of lifeforms, micro-organisms, plants animals and all of their parts and natural processes and insists upon the principle of prior informed consent and the right of veto by indigenous peoples with respect to the appropriation of indigenous seeds, medicinal plants, and related knowledge

(TWN) has commissioned a series of papers on the ways developing country governments should implement their Trade-Related Aspects of Intellectual Properties Agreement (TRIPs) obligations while taking into account the need to protect and preserve biodiversity and community knowledge, innovation and practices (CKIP) and the means to ensure that traditional and indigenous knowledge is given a vital role in scientific and technological policies relating to the sustainable use of biodiversity. In nearly all of the papers commissioned for the second year of the programme, the patenting of lifeforms is rejected and the intellectual property system itself is denounced for undermining indigenous peoples' rights, knowledge, and livelihoods. See, for example, Egziabher; Ho and Traavik; and, Tauli-Corpuz.

²⁶. One of the many websites where this document can be found is: <http://www.wtwatch.org/library/admin/uploadedFiles/Indigenous_Peoples_Seattle_Declaration.htm>. Ultimately, it suggests that the cultures of indigenous peoples, their knowledges, cosmologies and values provide the most viable alternatives to dominant models of economic growth and export-oriented development and that the imposition of IPRs forecloses the capacity of indigenous or traditional knowledges to serve this vital role.

about these lifeforms. It is increasingly unlikely that existing IPR regimes will be used as the primary means for protecting ITKIP.²⁷ However, there is still further

²⁷. For various legal and administrative reform proposals see Dutfield, *Rights*; Australian Institute; and Simpson. Although Volume One of The Crucible II Group provides an excellent coverage of the policy framework and the opportunities and constraints that it provides, Volume Two (forthcoming) promises to provide more precise options for legal reform.

As Victoria Tauli-Corpuz (Director of Tebtebba Foundation, Inc., the Indigenous Peoples' International Center for Policy Research and Education) writes in "TRIPs and Indigenous Peoples":

Intellectual property rights are monopoly rights given to individuals or legal persons (such as transnational corporations) who can prove that the inventions of innovations they made are novel, involved an innovative step, and are capable of industrial application. Indigenous knowledge and cultural heritage are usually collectively evolved and owned. If indigenous peoples have to use Western IPRs to protect their own knowledge and innovations, they will have to identify individual inventors. This will push unscrupulous indigenous individuals to claim ownership over potentially profitable indigenous knowledge which will cause the further disintegration of communal values and practices. It can also cause infighting between indigenous communities over who has ownership over particular knowledge or innovation.

The concept of exclusive ownership and alienability which is inherent in TRIPs will have to be internalized and imbibed by indigenous peoples even if it goes against their usual practice of making available such knowledge for the common good. The identity and survival of indigenous peoples as distinct peoples depends to a large extent on the age-old practice of common sharing of some resources, knowledge and skills which are not alienable. With TRIPs, indigenous peoples will now have to think of how their knowledge will be protected against so-called 'biopirates.' Sharing of

research to be done to determine how IPR regimes can be improved so as not to undermine forms of cultural diversity.

Despite a fairly overwhelming consensus that IPRs will not serve the range of relevant indigenous needs, it is widely recognized that membership in the WTO creates state obligations which will require the introduction of some new legal rights and the need to legally justify the refusal to introduce other forms of intellectual property protection. Current legal regimes, it is argued, sanction the usurpation of farmers' traditional knowledge.²⁸ Only if

knowledge becomes a dangerous proposition because it might be appropriated by those who have the capacity to use the system to claim exclusive ownership over such knowledge and commercialize it.

Although typical, the assertion that corporations may claim exclusive ownership over knowledge appropriated from indigenous peoples is inaccurate. Only the particular application of such knowledge, providing that it is itself novel and involves an innovative step (or in patent parlance, is not obvious to a person of ordinary skill in the art) will be protected. The patent holder does not gain thereby an exclusive rights to the common knowledge that underlies the particular technology, nor does the commercial application preclude the continuance of prior noncommercial usages of such knowledge. Nonetheless, patents are being granted that should not be granted based upon a proper application of these legal principles, and threats to enjoin alternative usages are often made by intellectual property holders even when they do not legally have rights of the scope that they assert. The assumption by indigenous peoples that the legal claims made by intellectual property holders are valid ones that the Western legal system supports is, however, part of the problem that needs to be addressed.

²⁸. This form of creativity, it is argued, is likely to continue to be usurped, marginalised and eventually extinguished by plant breeders' rights which do not respect indigenous creativity:

states are prepared to independently protect ITKIP and to limit plant breeders' rights will ITKIP, and the cultural diversity it manifests, survive.

Given the TRIPs obligation to protect plant varieties, it is asserted that any new breeders' right introduced should be subject to a public interest proviso that precludes the granting of such a right when the public interest so requires. This, it is suggested, will be the case "where biodiversity is adversely effected, where the variety poses a possible hazard to the agricultural system and to human, animal and plant life, based on the precautionary principle, where the introduction of the variety might affect the innovative capacity and indigenous technologies of farmers, healers, indigenous peoples, and local communities"(Nijar, *Perspectives*). Moreover, it is suggested that states pass laws to protect and respect the knowledge of indigenous peoples and farming communities with respect to plant varieties that would provide for a proprietary right of such peoples to any variety developed by, or essentially derived from, the knowledge of indigenous peoples or traditional farming communities, recognizing co-

The Union for the Protection of Plant Varieties (UPOV) allows for breeders' rights in respect of plant varieties that are 'improved' modifications of farmers' germplasms. UPOV 1991 extends the gap between source materials and improved varieties in terms of value and ownership rights attached to them. This revised instrument allows for both breeders' rights and patents for plant varieties. Finally, the TRIPs Agreement under the WTO allows for patents over life forms and requires that plant varieties be protected by patents or a *sui generis* system. In all of these instruments, the definitional constructs preclude recognition of innovations that are inter-generational, collective and for the social good—hallmarks of the way indigenous people create and innovate (Nijar, *Perspectives*).

ownership among communities if necessary (Nijar, *Sui Generis*).

All of the Council Parties (with the exception of Luxembourg) currently adhere to the Union for the Protection of Plant Varieties (UPOV). Research is needed to determine if the introduction of a public interest provision would be congruent with UPOV obligations and whether recognition of communally-developed varieties could coexist with a plant breeders' rights regime based upon UPOV principles. If Council Parties were to refuse to grant patents upon plant varieties and to incorporate this definition of the public interest in their national plant breeders' rights legislation (putting the onus of proof upon the applicant for the exclusive right, perhaps supplemented with a right of standing for indigenous peoples or NGOs with a history of activism in this area), then the perceived tendency of the intellectual property system to sanction biopiracy and to promote biotechnology of dubious safety and harmful cultural consequences would be greatly alleviated. Considerable research needs to be done, however, to ascertain how and when the introduction of genetically modified varieties affects local plant life and in what ways the introduction of new varieties affects innovation activities in indigenous and local communities. Such assertions are often made, but are seldom adequately documented.

A strong case can be made that more information about intellectual properties being applied for and granted should be made available digitally and in a form accessible to more of the world's peoples. Indigenous peoples and holders of traditional knowledge should be able to use digital technologies to ascertain if patents, for example, are being granted on technologies which are based on traditional knowledge, involve an "obvious" step in technological development, and/or for subject matter that lacks the necessary

quality of novelty given publication activities known to them. Unfortunately, very few patent regimes enable patents to be challenged on these legitimate legal grounds *before* a patent is issued. More and more information about patents has been recently made available on the Internet and some of these services are free.²⁹ However, the availability of this information may be of only limited value to indigenous peoples and the NGOs that support them. Patent information is opaque (even to lawyers) and patent claims are often written to obscure rather than reveal the scope of the subject matter claimed to deter competitors or to encourage them to license the technology rather than risk infringing it. Even assuming that patent and plant breeders' rights documentation was so clear, adequate, and accessible that indigenous peoples, third world farming communities, and interested NGOs could assess their validity, the cost of challenging these rights is enormous. Further research needs to be done into the benefits and savings of a patent prosecution process that would enable indigenous peoples (and market competitors who might be inclined to support indigenous challenges to monopolies in their fields) to challenge *pending* patent applications on conventional legal grounds and for public interest purposes.

IT IS RECOMMENDED THAT COUNCIL PARTIES UNDERTAKE FURTHER RESEARCH TO CONSIDER:

- How IPR systems can be improved so as not to undermine forms of cultural diversity.
- The possibility of introducing a public

interest proviso that precludes the granting of plant breeders' rights when the public interest so requires.

- Whether the introduction of a public interest provision would be congruent with UPOV obligations and whether recognition of communally authored varieties could coexist with a plant breeders' rights regime based upon UPOV principles.
- Means to provide for a proprietary right of indigenous peoples and farming communities to any variety developed by or essentially derived from the knowledge of indigenous peoples or traditional farming communities, recognizing co-ownership among communities if necessary.
- How and when the introduction of genetically modified varieties affects local species and ecosystems.
- How the introduction of new varieties is likely to affect innovation activities in indigenous and local communities.
- How information about intellectual properties being applied for (or granted) may be made digitally available in a form accessible to more of the world's peoples.

- The benefits and savings of a patent prosecution process that would enable indigenous peoples (and market competitors who might be inclined to support indigenous challenges to monopolies in their fields) to challenge pending patent applications on conventional legal grounds and for public interest purposes, and/or *before* a patent is issued.

²⁹. For a list of patent sites, see Newton, *How to Find Information*. The British Library also offers access to this information at <<http://www.bl.uk/services/bsds/pxp/overview.html>>.

Indigenous Peoples, Cultural Diversity, and the Internet

Indigenous peoples have been active users of the Internet, using it to communicate amongst themselves and to others, to gain access to resources, to publish and access databases, and to provide alternative perspectives on issues that are not covered in mainstream media (Cisler 1998). Apple Computer's Library of Tomorrow project, for example, funded several library, networking, and language preservation projects with American Indian tribes and similar initiatives are now underway around the globe.³⁰

In some indigenous communities, elders have rejected new information technologies, but others see the Internet as a tool for cultural survival. Unfortunately, in many areas of the world, electronic communications systems tend to reinforce traditional hierarchical social structures which isolate and marginalise many indigenous peoples (Donaghy 1998). Whereas in the U.S. and Canada, indigenous networks have received extensive technical support from universities, in areas like Latin America such collaboration is rare (Donaghy 1998). European states and regional governments can assist in these efforts.³¹

³⁰. As Delgado and Becker write: "Computer technology has been taught in a manner which makes indigenous peoples recall the way their languages work. Most of these languages work on an 'agglutinative' principle; a root word provides the base and an infinite number of suffixes are added according to the situation. Computer technology, listservs, newsgroups, and web sites work in this way as well" (1998).

³¹. The "Inkarri" information centre on indigenous issues, sponsored by the Basque county of Vitoria-Gasteiz, illustrates this possibility (*Inkarri Site*). Similarly, a web site functioning from Geneva has enabled a team of indigenous peoples to concentrate on Andean issues (*Pueblo Indio Site*). Within Europe, EU funds created for cultural and economic development in sparsely populated areas have been used by the Sami to adopt digital technology to further the marketing of traditional crafts. However, the failure of the Swedish government to recognize Sami other

Although many sites on the World Wide Web are effective in advocating on behalf of international reforms and mobilizing support amongst Northern activists unless these sites broadcast simultaneously in indigenous languages they not serve as organizing tools for indigenous peoples in the South. For many indigenous languages, however, new fonts must be developed for use in digital environments.³² This is a first and fundamental step in the drive to realize the potential of new information technologies for preserving cultural diversity. The maintenance, use, sharing, and recognition of ITKIP is also dependent upon the revitalization and reevaluation of indigenous languages.

Media experts in Canada's Northwest Territories are optimistic that the Internet will help to preserve Dene, Inuit, and Métis identities and prevent the further erosion of aboriginal languages. Contemporary research indicates that language maintenance and revival tend to be accompanied by a reaffirmation of cultural traditions, a revitalization of ITKIP, and a renewal of traditional relationships with the environment (Maffi 2000). The isolation of many indigenous communities may be overcome by the Internet because it

than those engaged in reindeer husbandry as having indigenous identity, has limited the extent of computer and Internet education. Only one Sami language has digital type fonts, moreover, and without support for font development, the potential of the Internet to assist in the survival of these endangered languages will not be realized (Forsgren 1998).³² For instance, even though most people in Burma are not permitted to use the Internet, Burmese in exile have taken advantage of it to spread information about repression in Burma and to organize resistance activities. Members of an indigenous human rights and environmental organization have traveled through border areas to teach computer skills to Mon and Karen peoples who have now developed digital fonts for use in communications that document military abuses (Fink 1998).

arguably provides an ideal medium for aboriginal communications.³³

³³. Northern News Services copy editor, James Hrynshyn, believes that "the Internet is an ideal match for Aboriginal tribes, providing the necessary economy of scale to support electronic publishing for such small constituencies...because the Internet can support an admixture of audio, video, and text, transcending the print medium, it is ideally suited to the oral story-telling traditions of the Aboriginal Community" (Zellen 1998). Indeed, the small town of Inuvik has one of the fastest public Internet connections and the Gwich'in and Inuvialit globally market traditional art from their home pages. The Oneida Nation had a web page before the White House did and through it has educated an entire Chinese high school on Oneida culture, attracted visitors from Europe to its cultural centre, and created interest in the Middle East in the dissemination of Oneida design (Polly 1998). In the South, interactive electronic conferencing has enabled indigenous peoples living in remote areas to share common concerns and exchange information about their shared problems in relation to nation states. The Zapatista uprising against the Mexican government upon the ratification of NAFTA marked the beginning of the political use of Internet technology by indigenous groups. The Maya in Guatemala are attempting to electronically retrieve any and all information pertaining to their cultures to revive their traditional languages and to legitimate their claims to their ancient territories. The Kuna in Panama have become international advocates of indigenous peoples' stewardship over biodiversity and its relationship to indigenous rights of self-determination.

Digital video camcorders will enable indigenous peoples to share cultural performances and practices, making ITKIP globally available, or at least available to other indigenous peoples if that is the more desirable end. Stories told by elders and traditional practices can both be filmed and recorded so that they can 'speak' to their descendants for eternity. This is only valuable, however, insofar as their descendants can speak their languages and have viable opportunities to use these practices in a context where they are respected and supported.

Indigenous peoples who no longer reside on ancestral lands have used the Internet to revitalize their indigenous identities while those who did not formally belong to indigenous groups have rediscovered their ethnic heritage through Usenet group. The Internet has afforded them opportunities to trace their own histories.³⁴ The Hawaiian indigenous language, long outlawed and facing extinction, has been reintroduced in the school system through the use of computer technology, the development of fonts, the Internet linkage of peoples learning the language, and the authorization of Microsoft to create a Hawaiian language version of the Internet Explorer programme (Donaghy 1998). This example suggests some inherent limitations on the potential of new information technologies to aid in the preservation of cultural diversity. To the extent that most Internet browsers, email programmes, web page designs, existing fonts, html authoring programmes, and Internet multimedia applications are proprietary technologies, indigenous peoples are put at a profound disadvantage when attempting to adapt them for indigenous language use. Intellectual property holders are under no obligation to license these technologies, or even to license them at less than market rates, regardless of whether these new language versions are being put exclusively to nonprofit usages that further international legal norms and human rights commitments. The possibility and feasibility of introducing new exemptions

³⁴. Indigenous Assyrians, forbidden to teach their own language, develop their cultural identity, or refer to themselves as a people in many Middle Eastern countries, have used the Internet to reconnect with Assyrians in exile all over the world and to educate the global community about their culture, persecution, and aspirations (Gabrial 1998). Continued and renewed usage of the Syriac or Aramaic language through the World Wide Web, however, will only be possible if compatible fonts are developed.

into domestic copyright, trademark, and patent regimes to further indigenous use of such technologies is a topic that requires further research.

The lack of women's involvement in indigenous digital culture is a serious shortcoming and, given that indigenous women are often custodians of language and tradition as well as major holders of ITKIP (particularly with respect to traditional medicine and agricultural techniques), this remains a significant obstacle to realizing the full potential of Internet technology for preserving cultural diversity. Further research needs to be done exploring effective means for involving more indigenous and rural community women in indigenous use of digital technology for biodiversity and cultural preservation purposes.

When asked whether he had any advice for "those who would follow in your footsteps and try to preserve their culture using a web page," the Oneida Indian Nation's Internet coordinator, Dan Umstead, advocated caution in sharing cultural knowledge: "Remember, if you put it up, people will use it. So carefully plan it all out beforehand" (Polly 1998). To the extent that there are cultural precautions and prohibitions concerning the use and reproduction of particular knowledge, imagery, stories, or texts, these are unlikely to be known or respected in cyberspace. The Internet could become a means of educating others about such indigenous systems of intellectual property and online license agreements based upon indigenous cultural principles could also be devised. Further research on the prospects for recognizing and enforcing indigenous customary law in cyberspace is needed.

IT IS RECOMMENDED THAT COUNCIL PARTIES UNDERTAKE FURTHER RESEARCH TO CONSIDER:

- Developing fonts for indigenous

languages to maximize use of new information technologies for preserving cultural diversity and the maintenance, use, and compensation for ITKIP upon which global biological diversity depends.

- The feasibility of devising online licensing agreements based on indigenous cultural principles.
- The possibility and feasibility of introducing new exemptions into domestic copyright, trademark, and patent regimes to further indigenous use of digital technologies for cultural preservation and revitalization purposes.
- New and effective means for involving more indigenous and rural community women in the use of digital technology for biodiversity and cultural preservation purposes.
- Prospects and opportunities for recognizing and enforcing indigenous customary law in cyberspace.

Digital Technology, Biodiversity Preservation, and the Protection of Indigenous Knowledge

Digital technology is widely used for biodiversity preservation purposes and many state and NGO initiatives are underway to develop electronic storage and communications media to meet CBD objectives. National contacts exist in each of the Council Parties for the 'clearing house' mechanism being established under the CBD to promote and facilitate technical and scientific cooperation (Article 18.3) with respect to the sustainable use of biodiversity (Article 10), the sharing of benefits derived from the use of biodiversity (Article 19.2), and the involvement and equitable sharing of benefits with indigenous and local

communities (Article 8(j)). Many of these clearing houses are in their infancy and currently operate more as catalogues or inventories. Most have been launched on the Internet.³⁵

Work is underway to create a single international facility for information on biodiversity—the Global Biodiversity Information Facility or GBIF—that will link the clearing house mechanisms with other “databases on the distribution of plants, animals, and microbes around the globe, detailed genome maps, compilations of the physiological functions of organisms, and information about the behaviour and function of species within ecosystems” (Environment News Service). Such international maps, however, are not necessarily conducive to the goal of preserving cultural diversity to the extent they presuppose a singular knowledge of

³⁵. The Belgian Institute of Natural Sciences, for example, launched the web site of the Belgian Clearing House on October 7, 1996. It was the second to be added to the official list of National Focal Point Clearing-Houses on the Internet and provides several options for searching for information on biological diversity in Belgium and elsewhere. Like other such sites, it provides hyperlinks to other national, regional, and thematic clearing houses as well as linking to the CBD, and the United Nations Environmental Programme. The site also houses the CBD clearing houses for Niger, the Congo, Chad, Mauritania, and Burkina Faso. Within the framework of the Belgian Research Network (BELNET), the Workgroup on Biodiversity has launched a two-part initiative. The first part is an inventory of biodiversity resources in Belgium—not limited to biodiversity in Belgian territory—that refers to universities, research institutes, botanical gardens, zoos and aquaria, museums, nature education centres, associations, libraries and nature reserves. The second part of the initiative will create an inventory of the content of the databases on biodiversity kept in Belgium. The linkage between biodiversity and cultural diversity could be made more explicit in such projects.
<<http://www.naturalsciences.net/bch-cbd/homepage.htm>>.

the properties of biodiversity that might be universally shared. For instance, a key feature of the GBIF will be a database containing the names of all known organisms which, it is envisioned, will “ensure a single global nomenclature for all named living organisms” (Environment News Service). It is, however, precisely the continued existence of multiple systems of knowledge about natural organisms and their culturally specific classification systems, nomenclatures, and linguistic relations to ecosystems that is key to maintaining the cultural diversity upon which biodiversity depends.³⁶

Other government departments may also use the World Wide Web for public education purposes with respect to ITKIP. The federal environmental ministry in Canada, for instance, posts commissioned reports on indigenous and traditional knowledge to its web site (Lambrou 1997; Mann 1997; Brockman 1997) as well as more general examples of the Canadian government’s acknowledgment of the value of ITKIP in environmental policies (Blanchet-Cohen 1996). The government of India is producing CD-ROMs of its traditional medicinal plant knowledge

³⁶. Most of the world’s linguistic diversity is carried by small communities of indigenous and minority peoples. Indigenous and minority languages encode distinct forms of knowledge and cognitive maps of local ecosystems that cannot simply be translated into dominant languages. Nor can such diversity be reduced to nomenclature. Ethnobiologists now recognize that traditional ecological knowledge is not about entities per se, such as natural kinds, but about natural processes and relations among entities, such as the relationships among plant and animal species or between humans and the ecosystem. Moreover, this knowledge is not carried simply in linguistic terms but in grammar and speech formulas and culturally conventionalized ways of expressing spatial, temporal and causal relations. The relationship between landscapes and languages is in many cases mutually constitutive. See the extensive discussion in Maffi (2000).

which will be distributed to patent offices worldwide to provide a database of prior art. This database may serve to prevent the issuing of patents such as U.S. Patent 5,401,504 which claimed the use of turmeric for promoting wound healing when the practice had been known for centuries and published in India for over thirty years. Few developing countries have the resources to document and digitally disseminate ITKIP in this fashion. For many indigenous peoples facing pressures of assimilation and territorial encroachment, the governments of the states in which they are resident are not bodies that can or will be entrusted with such knowledge. There is a need then, to support indigenous peoples' own efforts and those of supportive NGOs to develop and provide such databases as well as protocols for access to data and benefit sharing. Research is necessary, however, to ascertain the extent to which some forms of knowledge should be kept confidential and for what purposes. Indeed, a concern with confidentiality has resulted in the deployment of a trade secret model in one Ecuadoran project (Bodeker 12). In this project, local and indigenous communities are invited to participate in depositing and cataloguing traditional knowledge in a restricted access database, a determination of the public domain status of the knowledge will be made by the database administrators and, to the extent that more than one community shares potentially proprietary knowledge, a cartel of communities will be established to negotiate Material Transfer Agreements with the CBD state government and those interested in exploiting the knowledge for commercial use. Further research needs to be done to ascertain the viability of similar trade secret models in other regions, the degree to which violations of database confidentiality give rise to legal recourse, the extent to which such agreements should be respected and recognized in national and regional patent regimes, and

the desirability of amending patent law to do so.

The Sociedad Peruana de Derecho Ambiental has proposed that all patent applications in the future should include a sworn statement as to the genetic resources, as well as the associated knowledge, innovations and practices of indigenous peoples and local communities utilized directly or indirectly in the research and development of the subject matter of the patent application. This proposal could also be extended to plant breeders' rights applications (Bodeker 12) and would entail the submission of evidence of prior informed consent from the country of origin and the local community.³⁷ Further research needs to be done to determine if such a requirement is compatible with the TRIPs Agreement (and preliminary research indicates that it is, if characterized as an aspect of the novelty requirement) but such an amendment is widely urged. In 1997 the Indian government submitted a paper to the WTO's Committee on Trade and Environment that criticized TRIPs on the basis that patent applicants were not asked to make such disclosure. Facilitators of both the People's Biodiversity Registers³⁸ and the Local Innovations Database³⁹ initiatives in India argue that the documentation of community knowledge will only be

³⁷. For a longer discussion of making prior informed consent a condition precedent for receiving a patent see Coombe.

³⁸. This project is sponsored by the World Wildlife Federation India and is co-ordinated with the Centre for Ecological Sciences of the Indian Institute of Science and the Foundation for Revitalization of Local Health Traditions in Bangalore. For more information on People's Biodiversity Registers, see Gadgil et al.

³⁹. This project has been developed by the Society for Research and Initiatives for Sustainable Technologies and Institutions in Ahmedabad and is managed by Professor Anil Gupta of the Indian Institute of Management.

successful if intellectual property regimes are so modified.

Other electronic databases and digital networks are being established in developing countries with support by Council Parties and Council Party NGOs.⁴⁰

⁴⁰. For example, the Swiss Agency for Development and Cooperation supports The Farmer's Rights Information Service (FRIS) developed by the M.S. Swaminathan Research Foundation to educate the public about India's heritage of biodiversity and current issues of significance in the preservation of agro-biodiversity, including the need for incentives to support ongoing activities of genetic stewardship. As the founder's introduction explains, "exchange of information, technical and scientific cooperation, research and training, public education and identification of suitable financial resources are all important for arresting the loss of agro-biodiversity"(FRIS Website).The web site operates as part of an emerging network that links local and indigenous communities in conservation efforts:

With the emergence of democratic systems of governance worldwide and with the onset of the information superhighway, the widespread involvement of grassroots level peoples' organizations in the conservation movement is becoming feasible. In addition to information dissemination through printed and electronic media, 'awareness through action' programmes will have to be fostered in schools and colleges (Introduction, FRIS Website).

The website's founder believes that "the information age has provided tools such as the Internet and GIS mapping to promote a learning revolution in agriculture" and uses the site to participate in this revolution. The site operates as a tutorial and teaches that: entitlements, asset reform and technological empowerment of the poor will be essential in ensuring economic access; and, that gender perspectives must be integrated into the development of appropriate technology transfers and the information dissemination process if agriculture is to serve as an instrument of income and livelihood opportunity. The site is linked to videos of

"experts" espousing the importance of traditional and tribal peoples and their knowledge in preserving biodiversity and to a set of "field videos" that take web visitors to sacred groves whose genetic diversity is maintained by tribal peoples as places of worship, to an interview with a local farmer, and to local peoples engaged in traditional methods of seed storage.

From the site, web surfers may "visit" tribal communities in the Indian states of Tamil Nadu, Kerala, and Andhra Pradesh, where they will gain information on the social customs, agricultural practices, and knowledge of medicinal and other useful plants held by tribal peoples. Such information, however, is described in general rather than disclosed in specificity.

More specific information is provided for Orissa, a centre of origin for traditionally cultivated varieties (landraces) of rice assumed to contain many valuable genes particularly for resistance/ tolerance to various biotic and abiotic stresses and thus to hold promise for utilization in future plant-breeding programmes. The multimedia database contains details on the morphological and agronomical characters of the rice variety, the donor farmers' name and the community, and location and date of collection for landraces from five areas inhabited by tribal peoples who continue to grow these varieties. Visitors will find pictures of the individual who cultivated the variety, his or her tribal affiliation, and the location of the gene bank in which the landrace has been deposited.

More problematic, from the perspective of preserving cultural diversity, are the Orissa site's detailed descriptions of the sacred groves located in tribal areas. Not only does the site name and locate these, it describes the species found there, and the particular taboos that local peoples observe. To what extent does such a practice operate as an invitation to those who would appropriate local knowledge about species which, by virtue, of local cultural prohibitions, are likely to have unique genetic properties? What protection has been afforded to these peoples against biopiracy? Is cultural diversity maintained by practices that expose local belief systems to such international and indiscriminate scrutiny?

Such databases may have consequences for the future potential of peoples to benefit from this cultivation activity. To the extent that such publication does create a record in the public domain, it may operate so as to prevent the appropriation of such knowledge and resources in patent claims and plant breeders' rights asserted by others. Again, this will depend upon the willingness of patent offices to recognize this as "prior art". However, the option of local peoples' profiting from such knowledge as a trade secret may also be foreclosed by such publications. Further research needs to be done on the likely legal and cultural consequences of such publications before knowledge of a sensitive, sacred, or potentially proprietary character is posted on the Internet. Protocols for local peoples' prior informed consent to govern such postings need to be established.

Traditional systems of medicine and local knowledge of plant genetic resources are especially diverse in India. In order to counter the general public devaluation of the traditional knowledge of those in marginalised communities and to ensure compensation to communities and individuals for the commercialization of such knowledge, community knowledge databases are being created. Such decentralized databases may serve a number of local cultural and ecological purposes and are networked to a national database that promotes the use of such knowledge for the benefit of local communities. Access to the contents of such registers is therefore restricted to communities of origin who, it is anticipated, will be able to charge fees to others, create tariffs, and negotiate contractual arrangements. Further research on the implications of various forms of confidentiality for local peoples needs to be carried out. On the one hand, access restrictions no doubt lessen misappropriations. On the other hand, to the extent that such knowledge is acquired and used, the fact that such information

was not in the public domain could make any patent based upon it difficult to challenge because prior art in many jurisdictions does not encompass private databases (Dutfield, *Protecting*, 122). Ultimately, a global linkage of such databases might enable individual and collective innovators to receive both acknowledgment and compensation for commercial applications of their KIP while enabling small investors, entrepreneurs, and local innovators and communities to locate each other for the purposes of business development. Such a system could maintain linkages with regional and national patent offices which would universalize prior art so that traditional knowledge is respected and acknowledged.

In terms of their capacity to preserve cultural diversity, however, it is important to remember that ITKIP thrives to the extent that it is used in ongoing human practices to meet new challenges, not to the extent that it is archived. As Agrawal argues, "divorced in archives from their cultural context, no knowledge can maintain its vitality or vigour" (Agrawal 429). The danger of the archival approach is that it "may deflect attention from the far more important priority of protecting traditional knowledge *in situ* which of course requires that attention be given to the cultural, spiritual, and physical well-being of the knowledge holders and their communities" (Dutfield, *Protecting*, 109). Some indigenous peoples are concerned that the effort to document traditional knowledge indicates that outsiders value traditional knowledge much more than they respect those who generate it. Many indigenous peoples have made it clear that concern for the protection of IKP should be subsidiary to the recognition of indigenous peoples' rights to self-determination and territorial rights.

Linked database initiatives—like the Honeybee Network which documents and puts onto the Internet actual video

demonstrations of sustainable agricultural technologies in several languages— provide a means for local and indigenous communities around the world to share traditional knowledge; they may be considered a form of technology transfer. Again, such postings pose particular problems to the extent that they may be legally deemed to be anticipations that will preclude the issuance of patents for such technologies in the future.⁴¹ To the extent that the sharing of ITKIP helps to meet the health and food needs of other local communities, it seems inequitable that such disclosures should preclude innovating communities from later

⁴¹. As I have argued previously: “because the law [of patents] encourages secrecy and the privatization of knowledge until its potential commercial application becomes clear, third world innovators cannot share knowledge with others who may desperately need it, nor can they seek to attract investors who may be able to transform it into a better source of revenue for local communities. A group like the Honeybee Network is therefore in a difficult position. Prior to the publication of knowledge in the newsletter, the network must attempt to aid either the community or the individual in establishing a legal right. In most cases, however, the innovation will not have reached the point of patentability because the capacity for industrial application remains to be ascertained, and there is little investment capital available to explore the possibility. In the meantime, the knowledge may be valuable in alleviating poverty amongst other indigenous and local peoples and enriching their livelihoods. Third World networks and networks of indigenous peoples face an untenable choice between not publishing in order to maintain the potential for future patent benefits, in which case they withhold useful information from those in dire need of it, or publishing it with the knowledge that in assisting others, one risks forfeiting the fruit of one’s labors. Such a choice violates human rights norms that encourage the sharing of benefits, the flow of information, the right to share in progress in the arts and sciences, cross cultural exchange, and the right to sustainable development and a healthy environment” (Coombe 113).

benefitting from its commercial exploitation. Further research needs to be done on the potential for distinguishing between kinds and forums of publication as modes of “anticipation” and the viability of introducing exemptions for indigenous knowledge registers and database linkages in current patent regimes.

It is imperative that local cultural norms with respect to distinctions between sacred, secular and sensitive knowledge are respected in any and all digital use of traditional knowledges. The Indigenous Peoples’ Biodiversity Information Network (IPBIN), which was developed as a mechanism to help indigenous peoples to communicate and build capacity in implementing the indigenous and traditional knowledge provisions of the CBD, advises against the posting of any ITKIP on the Internet, keeps several of its online discussion forums closed to the general public, monitors links to ensure ethical relationships to posted material, and is developing protocols to govern clearinghouse mechanisms to ensure that these do not operate to the detriment of indigenous peoples’ cultures. Further research into the protocols developed by indigenous peoples and respect for such protocols in all Internet activities supported by Council Parties would assist efforts to preserve cultural diversity.

IT IS RECOMMENDED THAT COUNCIL PARTIES UNDERTAKE FURTHER RESEARCH TO CONSIDER:

- The viability of trade secret models for protecting ITKIP in digital environments, the degree to which violations of database confidentiality give rise to legal recourse, the extent to which such agreements will be respected and recognized in national and regional patent regimes, and the desirability of amending patent law to respect the norms and agreements of confidentiality developed by indigenous peoples and traditional communities.

- The compatibility of the TRIPs Agreement with the suggested requirements that: 1) all patent applications include a sworn statement as to the origins of genetic resources, as well as any associated knowledge, innovations and practices of indigenous peoples and local communities utilized directly or indirectly in the research and development of the subject matter of the patent application; 2) evidence of prior informed consent from the country of origin and the local community be submitted with patent and plant breeders' rights applications that involve genetic resources and ITKIP.

- The legal and cultural consequences of Internet postings before ITKIP of a sensitive, sacred, or potentially proprietary character is posted.

- The emergence and development of protocols for indigenous peoples' and local communities' prior informed consent for Internet postings of ITKIP and means of respecting such protocols in all Internet activities directly or indirectly supported by Council Parties.

- Implications of various forms of confidentiality for local communities and indigenous peoples' biodiversity and cultural diversity preservation needs.

- The potential for distinguishing between kinds and fora of publication in ascertaining whether patentable subject matter has been "anticipated" and the viability of introducing exemptions for restricted access indigenous knowledge registers and database linkages between local communities as permissible forms of technology transfer in current patent regimes.

Conclusion

In conclusion, Council Parties' international legal obligations under environmental and human rights regimes provide opportunities to ensure that digital technologies are utilised in a way that serves to preserve biological diversity in a fashion that simultaneously preserves and revitalizes the world's cultural diversity. The recommendations for future research contained herein are designed to ensure that these efforts are undertaken with full awareness of the complexities posed by the need to balance intellectual property, trade, and environmental considerations with cultural diversity objectives.

References

Agrawal, A. "Dismantling the Divide Between Indigenous and Scientific Knowledge." Development and Change 26 1995. 413-439.

Australia. Commonwealth of Australia. Biological Diversity and Indigenous Knowledge, Research Paper 17. 1997-78.
<<http://www.aph.gov.au/library/pubs/rp/1997-98/98rp17.htm>>.

Australian Institute of Aboriginal and Torres Strait Islander Studies, Our Culture, Our Future: Proposals for the Recognition and Protection of Indigenous Cultural and Intellectual Property. Canberra: 1997.

- - - . Our Culture, Our Future: Report on Australian Indigenous Cultural and Intellectual Property Rights. Canberra: 1998.

Austria. Federal Ministry for the Environment, Youth and Family. First Austrian National Report on the Convention on Biological Diversity. June 1997.
<<http://www.biodiv.org/natrep/index.html>>.

Belgium Clearinghouse Web Site for the Convention on Biodiversity.
<<http://www.naturalsciences.net/bch-cbd/homepage.htm>>

Belgian Research Network. Workgroup on Biodiversity. <<http://www.belspo.be/biodiv>>

Blanchet-Cohen, N. "Strategies for a Living Earth: Examples from Canadian Aboriginal Communities" Biodiversity Convention Office, Environment Canada. 1996.
<http://www.bco.ec.gc.ca/DocumentPublications_e.cfm>.

Bodeker, G. "Indigenous Medical Knowledge: The Law and Politics of Protection." Oxford Electronic Journal of Intellectual Property Rights. WP03/00. Jan 2000.
<<http://www.oiprc.ox.ac.uk/EJWP0300.pdf>>.

Brockman, A. "When All Peoples Have the Same Story, Humans will Cease to Exist; Protecting and Conserving Traditional Knowledge." Biodiversity Convention Office, Environment Canada. Sept. 1997. <http://bco.ec.gc.ca/documentpublications_e.cfm>.

Brush, Stephen B., ed. Genes in the Field: On-Farm Conservation of Crop Diversity. Boca Raton, London, New York, Washington: Lewis Publishers, 2000.

Bulgaria. Ministry of the Environment and Waters. National Report for Biological Diversity in Bulgaria. 1998. 6 June 2000 <<http://www.biodiv.org/natrep/index.html>>.

Canada. Environment Canada; Canadian Biodiversity Convention Office. Canadian Biodiversity Information Network. <http://www.bco.ec.gc.ca/Jump_e.cfm>.

Cisler, S. "The Internet and Indigenous Groups; An Introduction." Cultural Survival Quarterly. 21:4 (1998). <<http://www.cs.org/CSQ/csqinternet.html#Cisler>>.

Coombe, R. "Intellectual Property, Human Rights and Sovereignty: New Dilemmas in International Law Posed by the Recognition of Indigenous Knowledge and the Conservation of Biodiversity." Indiana Journal of Global Legal Studies 6 (1998). 59-115.

Correa, Carlos M. "Beyond TRIPs." United Nations Environment Programme, Cultural and Spiritual Values of Biodiversity. London: Intermediate Technology Publications, 2000. 533-534.

Council of the European Union. Document 394R1467: Council Regulation (EC) No 1467/94 of 20 June 1994 on the conservation, characterization, collection and utilization of genetic resources in agriculture. 5 July 2000. <http://europa.eu.int/eur-lex/en/lif/dat/1994/en_394R1467.htm>.

Crucible II Group. Seeding Solutions, Policy Options for Genetic Resources: People, Plants, and Patents Revisited. Vol. 1. Ottawa, Rome, Uppsala: International Development Research Centre, International Plant Genetic Resources Institute, Dag Hammarskjold Foundation, 2000.

- - - . Vol. 2. Forthcoming in 2001.

Dei, George J. Sefa, Budd L. Hall, and Dorothy Goldin-Rosenberg, eds. Indigenous Knowledge in Global Contexts. Forthcoming from the University of Toronto Press in 2000.

Delgado, G. and M. Becker. "Latin America: The Internet and Indigenous Texts." Cultural Survival Quarterly 21:4 (1998). <<http://www.cs.org/CSQ/csqinternet.html#Becker>>.

Donaghy, K. "'Olelo Hawai'i: A Rich Oral History, A Bright Digital Future." Cultural Survival Quarterly. 21: 4 (1998). <<http://www.cs.org/CSQ/csqinternet.html#Donaghy>>.

Dutfield, G. "Protecting and Revitalising Traditional Ecological Knowledge: Intellectual Property Rights and Community Knowledge Databases in India." Intellectual Property Aspects of Ethnobiology. Michael Blakeney, ed. Perspectives on Intellectual Property (Vol. 6) London: Sweet & Maxwell, 1999. 103-122.

- - - . Intellectual Property Rights, Trade, and Biodiversity. London: Earthscan Publications, 2000.

- - - . "Rights, Resources and Responses." United Nations Environment Programme, Cultural and Spiritual Values of Biodiversity. London: Intermediate Technology Publications, 2000. 505-515.

Egziabher, Tewolde Berhan G. "The Inappropriateness of the Patent System for Life Forms and Processes." Working Papers on Biodiversity and Community Rights. Third World Network 1999. Unpublished paper.

- - - . "The TRIPs Agreement of the WTO and the Convention on Biological Diversity: The Need for Coordinated Action by the South." Working Papers on Biodiversity and Community Rights. Third World Network 1999. Unpublished paper.

- Environment News Service. "Biodiversity Merges Online." October 15, 1999. <<http://www.wired.com/news/print/0,1294,31918,00.html>>.
- Fink, C. "Burma: Constructive Engagement in Cyberspace?" Cultural Survival Quarterly. 21:4 (1998). <<http://www.cs.org/CSQ/csqinternet.html#Fink>>.
- Forsgren, A. "Use of Internet Communication Among the Sami People." Cultural Survival Quarterly. 21:4 (1998). <<http://www.cs.org/CSQ/csqinternet.html#Forsgren>>.
- Gabrial, A. "Assyrians: 3000 Years of History, Yet the Internet is Our Only Home." Cultural Survival Quarterly. 21: 4 (1998). <<http://www.cs.org/CSQ/csqinternet.html#Gabrial>>
- Gadgil, Madhav et al. New Meanings for Old Knowledge: The People's Biodiversity Registers Programme. Ecological Applications. Special issue on "Traditional Ecological Knowledge and Wisdom." In press.
- Grenier, Louise. Working with Indigenous Knowledge: A Guide To Researchers. Ottawa: International Development Centre, 1998.
- Ho, Mae-Wan and Terje Traavik. "Patents, Life-Forms and TRIPs: A Scientific Briefing on TRIPs Article 27.3 (B)." Working Papers on Biodiversity and Community Rights. Third World Network. 1999. Unpublished paper.
- Indigenous Peoples Biodiversity Information Network. <<http://www.ibin.org>>.
- Inkarri Web Site. <<http://www.inkarri.net/ingles/indiceng/indiceng.htm>>
- King, Amanda and Pablo B. Eyzaguirre. "Intellectual Property Rights and Agricultural Biodiversity: Literature Addressing the Suitability of IPR for the Protection of Indigenous Resources." Agriculture and Human Values 16 (1999): 41-49.
- Lambrou, Y. "Control and Access to Indigenous and Biological Resources." Biodiversity Convention Office, Environment Canada. Oct. 1997. <http://bco.ec.gc.ca/documentpublications_e.cfm>.
- Lange, D. and M. Mladenova. "Bulgarian Model for Regulating the Trade in Plant Material for Medicinal and Other Purposes." Medicinal Plants for Forest Conservation and Health Care. Volume 11 of the Global Initiative for Traditional Systems (Gifts) of Health. Rome: Food and Agriculture Organization of the United Nations, 1997.
- Louwaars, N.; Engels, J. "Intellectual Property Rights: Patents and Sui Generis Systems?" Almekinders, C.; De Boef, W. Eds. Encouraging Diversity: The Conservation and Development of Plant Genetic Resources. London: Intermediate Technology Publications, 2000. 279-284.
- M.S. Swaminathan Research Foundation. Farmer's Rights Information Service. <<http://www.mssrf.org/fris9809/>>.

Maffi, L.; Skutnabb-Kangas, T. "Linguistic Diversity and the 'Curse of Babel'." United Nations Environment Programme, Cultural and Spiritual Values of Biodiversity. London: Intermediate Technology Publications, 2000.

Mann, H. "Indigenous Peoples and the Use of Intellectual Property Rights in Canada: Case Studies relating to Intellectual Property Rights and the Protection of Biodiversity." Biodiversity Convention Office, Environment Canada. Nov. 1997. <http://bco.ec.gc.ca/documentpublications_e.cfm>.

Muhlhausler, P. "The Interdependence of Linguistic and Biological Diversity." The Politics of Multiculturalism in the Asia/Pacific. Ed. D. Myers. Darwin: Northern Territory University Press, 1995. 154-161.

Newton, D. How to Find Information: Patents on the Internet. Forthcoming from British Library Publications, August 2000.

Nijar, Gurdial Singh. "Legal and Practical Perspectives on *Sui Generis* Options." Working Papers on Biodiversity and Community Rights. Third World Network. 1999. <<http://www.twinside.org.sg/title/generis-cn.htm>>.

- - - . "Sui Generis Law for Plant Varieties: Preserving the Knowledge and Creativity of Traditional Breeders A Third World View." Working Papers on Biodiversity and Community Rights. Third World Network 1999. <<http://www.twinside.org.sg/title/sui-cn.htm>>.

Oh, Cecilia. "IPRs and Biological Resources: Implications for Developing Countries." Working Papers on Biodiversity and Community Rights. Third World Network 1999. <<http://www.twinside.org.sg/title/iprharare.htm>>.

Polly, J A. "Standing Stones in Cyberspace: The Oneida Nation's Territory on the Web." Cultural Survival Quarterly. 21: 4 (1998). <<http://www.cs.org/CSQ/csqinternet.html#Polly>>.

Posey, Darrell Addison. "Introduction: Culture and Nature - The Inextricable Link." United Nations Environment Programme, Cultural and Spiritual Values of Biodiversity. London: Intermediate Technology Publications, 2000. 3-18.

Pueblo Indio Web Site (In Spanish). <<http://www.puebloindio.org/ceacisa.htm>>.

Rovillos, Raymundo D. "Indigenous Peoples' Rights and Sustainable Development; The Contradictions in Philippines Laws." Working Papers on Biodiversity and Community Rights. Third World Network 1999. Unpublished paper.

- - - . "Interphasing Indigenous Knowledge and Western Scientific Knowledge." Working Papers on Biodiversity and Community Rights. Third World Network 1999. Unpublished paper.

Simpson, T. Indigenous Heritage and Self-Determination. Copenhagen: International Work Group for Indigenous Affairs, 1997. 132-158.

Swaminathan, M.S. and Gelia Castillo. "Forward." Encouraging Diversity: The Conservation and Development of Plant Genetic Resources. Ed. Conny Almekinders and Walter de Boef. London: Intermediate Technology Productions, 2000. xi-xii.

Switzerland. Swiss Agency for the Environment, Forests and Landscape (SAEFL), ed. National Report of Switzerland for the Convention on Biological Diversity. 1998. <<http://www.biodiv.org/natrep/index.html>>.

Tauli-Corpuz, Victoria. "Indigenous Peoples and IPRs." Working Papers on Biodiversity and Community Rights. Third World Network. 1999. Unpublished paper.

Third World Network. "Progress Report of the Second Year of Activity." Programme for the Protection and Promotion of Biodiversity and Community Rights. November 1998-October 1999.

UNESCO. Amendment to the Draft Programme and Budget for 1994-5 (27 C/5), Item 5 of the Provisional Agenda (27 C/DR.321). Paris: UNESCO, 1993.

United Kingdom. Department of the Environment, Transport and the Regions Biodiversity Secretariat. The United Kingdom National Report on Biological Diversity. 1998. <<http://www.biodiv.org/natrep/index.html>>.

Wyss, Eric and Cornelia Wiethaler, eds. Final Report on the International Conference on Biodiversity and Organic Plant Breeding. 1999. <<http://www.biogene.org>>.

Zellen, B. "Surf's Up!: NWT's Indigenous Communities Await a Tidal Wave of Electronic Information." Cultural Survival Quarterly. 21:4 (1998).

Appendix – Acronyms

CBD	Convention on Biological Diversity
CGIAR	Consultative Group on International Agricultural Research
Council Parties	Austria, Belgium, Bulgaria, Canada, Luxembourg, Switzerland, United Kingdom
EC	European Community
EU	European Union
FAO	Food and Agriculture Organization
GBIF	Global Biodiversity Information Facility
IPBIN	Indigenous Peoples' Biodiversity Information Network
IPRs	Intellectual property rights
ITKIP	Indigenous and traditional knowledge, innovations and practices
KIP	Knowledge, innovations and practices
NGOs	Non-governmental organizations
TRIPs	Trade Related Aspects of Intellectual Properties Agreement
UPOV	Union for the Protection of Plant Varieties
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Stepping into the Breach: Provincial Funders Replace Federal Regulators in Defense of Public Priorities and Safety

Ken Bassett

About the Author

Ken Bassett is a cultural anthropologist, practising physician, and university-based provincial health policy consultant. He is the Senior Medical Consultant at the BC Office of Health Technology Assessment, and the Chair of the Drug Assessment Working Group of the Therapeutics Initiative for the province of BC. Bassett's central academic interest is the relationship between scientific evidence and public policy as these relate to gender, class, ethnicity and geography. Currently, Bassett's primary concern is the erosion of science into a marketing tool.

About the Article

From his perspective as an academic active on the 'front line' of health-care policy in BC, Ken Bassett describes the opportunities which are available in the province to challenge corporate influence on health-care. According to Bassett, if the Canadian Biotechnology Strategy (CBS) is left uncontested, provincial health services are likely to be overwhelmed by the activities of the pharmaceutical and device industries, whose agendas place profits ahead of need, promoting remedies that are usually expensive, often useless, and sometimes dangerous. Bassett's paper offers direction for provincial payment agencies and university research review committees on how to fill what he sees as the void left by federal de-regulation of the industries involved in the health sector.

Introduction

Science has made magnificent achievements across several centuries in the understanding of nature, in controlling it and sometimes even overcoming it. The very power of science has enabled its use as a tool for society to challenge dogma, particularly religious doctrines designed to maintain political and economic dominance of church over state.

In the modern age, however, the seemingly dominant power of science has itself become a resource for the corporate agenda. In as much as commercial interests appropriate science to advance their political and economic programs, science risks losing its independence and becoming co-opted as part of the new dogma in the theology of corporate profiteering.

Using the language and the very institutions of science, manufacturers have adopted a liturgy of product promotion in which effectiveness claims are exaggerated and safety concerns minimised. For scientists, academics and researchers who cherish the neutrality of science, it is of the greatest importance that this developing pattern of 'belief' should be challenged.

My primary activist work is in two formal roles. I am Senior Medical Consultant at the BC Office of Health Technology Assessment (BCOHTA). Health technology assessment is a discipline which conducts systematic reviews of clinical efficacy and effectiveness evidence. I am also Chair of the Drug Assessment Working Group of the Therapeutics Initiative. The Working Group is responsible for systematic reviews of all new drugs submitted to Pharmacare, the Ministry of Health Department responsible for the Provincial Drug Benefit Plans in BC.

From these evaluative perspectives, I have been able to recognise that the problem areas faced by women and society as a whole in relation to the CBS do not differ in substance from a long list of health-related initiatives directed at women throughout the second half of the 20th century.

I begin by looking at reciprocal federal and provincial responsibilities in health: as the federal role diminishes, the provincial role grows. Then I describe two provincial strategies which have proved more or less successful in countering commercial interests, by promoting social interests in health. I cite almost exclusively our (BCOHTA's) reports, not because they are either unique or definitive in these areas, but because they provide additional details of our provincial social advocacy. I end with a description of the osteoporosis 'disease management model', a disturbing example of how commerce has moved to dominate health-care.

1. Federal De-regulation

Federal regulation of food and drugs developed in the wake of the thalidomide disaster in order to restrict market access until safety was proven and, in the case of drugs, efficacy established. Manufacturers explicitly bore the burden of proof. More recently, however, Canadian federal policy has favoured Industry Canada over Health/ Agriculture/ Environment Canada, primarily through de-regulation of most sectors of the economy. In the case of the Health Protection Branch (HPB), de-regulation has meant non-enforcement of current regulations and the introduction of new, less-stringent legislation. In keeping with this less stringent legislation, the burden of proof in product licensing is gradually reversing. Manufacturers need to meet lower and lower standards of proof of safety and efficacy. Researchers,

publicly or privately-funded, more and more, must prove harm.

The CBS reflects these federal de-regulatory, pro-industry trends. The CBS is strong on supporting an internationally competitive industrial strategy, but weak on making the case for safety requirements. In this sense, I see the position of the CBS as not just indicating the future direction, but as showing the current realities of federal policy.

Others know much more than I do about the potential costs and benefits of providing input to federal policy-making processes such as the CBS. My suggestions, therefore, are limited to the provincial level: how best to support social interests within the federally de-regulated, pro-industry context.

2. Provincial Mandate

Diminishing HPB regulation could not have occurred at a worse time. The past decade has seen phenomenal growth in the economic power, and with it the political influence, of the drug and device industry. In addition, during the same time period, the drug and device industry has sought a more insidious mechanism to control the health-care sector: by influencing how people and professionals think and behave in relation to health, and to what are termed healthy and un-healthy lifestyles.

This industry now has the power and capability to create its own need. It can promote certain tests (predictive and diagnostic); therapeutic strategies (which may include genetically-engineered drugs) and massive 'educational' strategies for administrators, medical professionals, and patients. As I shall later describe in relation to the management of osteoporosis, the marketing strategy forms a package, including a 'disease management model' that supports an

immensely profitable market structure. This package is readily – in fact specifically – suited both to a population primed to accept pharmaceutical 'solutions' to social problems, and to physicians trapped in busy, fee-for-service clinical care settings.

Without federal policy to effectively limit the market's access to the health sector, provincial purchasers and regulators of health services, devices, and drugs take on an increasingly important role. They must mediate between individuals seeking health care, and manufacturers seeking to provide goods for the marketplace. They must select which services to fund, for whom, and to what extent, all within capped, global budgets. This task is not just difficult, it is all but impossible, requiring meaningful prioritisation among items as diverse as housing for people with disabilities, life-saving techniques, sophisticated diagnostic imaging-technology, and numerous other interventions demanded by an increasingly 'informed' population. All this within a 'capped' or finite budget.

To add to their burdens, diminishing HPB standards for proof of effectiveness and safety have greatly increased the responsibilities of provincial purchasers. They, rather than Health Canada, must now determine the scientific validity of effectiveness and safety data, and interpret competing claims of benefit versus harm.

3. Provincial Strategy

The strategy we have used to balance commercial with social interests at the provincial level is based on one principle: focus upstream on key decision-makers.

'Upstream' means early attention to the purchasing-funding process where decisions are made about what is to be made available to communities, hospitals

and clinics. The corollary is 'Downstream', the points where these programs, tests or technologies are used.

'Upstream' or province-wide decisions regarding funding and regulation are preferred because they involve fewer individuals, usually in senior management or executive positions, and acting according to relatively strict rules of conduct within standing committees having explicit mandates. They can therefore be identified and reached by independent researchers, publicly-funded assessment institutes, and by social activists working with limited budgets and small staff.

Downstream utilisation in local medical clinics, by contrast, involves diverse settings and numerous individuals with different values and expectations. Clinical settings are the areas most strongly influenced by the drug and device industry through clinical practice guidelines and direct-to-consumer advertising. Similarly, downstream utilisation in local hospitals varies widely and is equally vulnerable to direct commercial control.

For example, in BC, only one hospital has a Technology Assessment process able to consider the medical necessity of new technology. Instead, most hospitals encourage new technology because it is an important source of prestige and, in the case of diagnostic technology, desperately-needed funds. Hospitals in BC can use diagnostic technology as a funding source because they are able to bill the provincial payment plans for services provided to 'out-patients' visiting their facility. Meanwhile, all 'in-patient' costs, including diagnostic tests, must be paid from the global hospital budget.

Given this situation, concerns over a given technology, however legitimate, are unlikely to be most effectively presented downstream. In consequence, "Focus Upstream" is the best strategy.

Two upstream provincial opportunities that we have used to counter the commercial dominance of health (defined broadly) are:

- 1) University and Hospital Ethical Review Committees, under a duty to ask not only if research meets ethical standards, but also if it is valid science and serves public interests;
- 2) provincial and regional committees charged with purchasing tests or drugs.

1) University and Hospital Research/Ethics Committees

Most drug and device research in Canada requires approval by a research ethics committee, usually associated with a university or health-care institution or program. Strengthening these committees and expanding their mandates to review scientific validity as well as ethics could provide a significant opportunity to counter the CBS, at the provincial and community levels.

Although these committees have not customarily considered issues of scientific validity or social relevance of research, this role is gaining increasing importance in the absence of alternative forums to raise these issues. Moreover, assessing scientific validity fits with the Helsinki Agreement which states that research must have "a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research." Our Technology Assessment Office has helped some committees in the effort to examine whether proposed research is scientifically valid or a marketing tool.

A scientifically-valid study would enrol a sufficient number of reasonably representative patients to answer a question regarding benefit or harm. Marketing studies, by contrast, enrol

relatively few patients from as many settings as possible, and measure short-term changes in body parameters such as blood pressure or cholesterol, known to favour the proposed test or clinical intervention.

The strategy of focussing on study validity has had some success in slowing the introduction of new, virtually unstudied treatment technology in the province (Bassett et al 1998).

We have also worked with the larger Health Regions in BC to strengthen their research and ethical review processes. Device manufacturers often target regional hospital systems to familiarise a medical community with their equipment and service personnel.

For example, manufacturers interested in introducing a new laser treatment in urology approached several regional hospitals for participation in a clinical study (Bassett and Kazanjian 1996). The laser technology was rejected when the research review committee noted that the study, although ethical, was too small and too poorly designed to result in scientifically-valid findings. A different region in the province accepted the research study because the manufacturer offered the technology at reduced cost at the end of the study period.

2) Provincial Purchasers and Regulators

A second opportunity to support social as opposed to commercial interests occurs with provincial regulation and purchase. Since 1995, the Drug Assessment Working Group of the Therapeutics Initiative has produced approximately 200 reports assessing the effectiveness and safety of new drugs submitted to the Provincial Drug Benefit Plans for payment. The reports have influence public drug plan funding policy in BC.

Our Health Technology Assessment Office has also had some success at influencing diffusion of diagnostic imaging technology into the province. Diagnostic technology can only be provided in an accredited facility which must obtain a specific licence to bill the provincial fee-for-service plan.

Licensing is the jurisdiction of a joint BC Medical Association-BC Ministry of Health committee, where government representatives have shown themselves prepared to challenge assumptions regarding patient benefit from a new technology. Working with these government individuals, one-on-one, we have been able to successfully support their challenges on the state of scientific knowledge. In the case of bone mineral-density testing, for example, a moratorium on licensing in BC effectively blocked diffusion of this unproven technology for 3 years (Green et al 1997).

Laboratory tests, similar to diagnostic devices, need a 'fee code' within the provincial health insurance payment plan. Establishing a fee code and payment conditions can take several years alone, because fee codes are fought over in a very competitive environment within the BC Medical Association itself. The BCMA is dealing with a capped global budget. The fee code must also be approved by the provincial government which again provides an opportunity for raising issues of social concern. Our work on prostate specific antigen screening is an example of the successful use of this approach. We argued effectively that the scientific evidence did not support mass screening as providing greater benefit than harm (Green et al 1993).

4. Disease Management Models: The Ultimate Public Advocacy Challenge

Disease management models promoted by drug and device manufacturers are crafted with great sophistication, and

aimed at the long-term medical management of health issues across the life-span. They develop measurements, and propose specific drug therapies designed to alter those measurements. The goal of the disease management model is to have drug prescription based on and assessed in terms of the measurements.

Disease management models have seen phenomenal marketing success: blood pressure testing and treatment (Kawachi and Conrad 1996), cholesterol testing and treatment (Savoie et al 2000), glucose testing and treatment for adult onset diabetes (Management 1998). In all instances, the issue is not whether the drug alters the test result; it may do so unequivocally. Nor is the issue whether the test can identify a risk factor for an actual clinical event such as a heart attack or stroke. All these indicators are accepted as population-based risk factors for clinical events. The issue with disease management models is that they exaggerate the treatment benefit both to individuals who achieve some benefit and to others, by extrapolating findings beyond those people in whom a benefit has been found. In other words, for individuals, disease management models focus attention away from problems of diet, exercise, lifestyle, poverty, unsafe environments, and onto specific measurable, alterable physiological components. For populations, disease management models divert limited funds from alternative, often more cost-effective programs.

Genetic disease management models are not yet as sophisticated as other disease management models. While genetically-manufactured drugs and hormone and enzyme replacement products are in current use, there is not as yet an example of a treatment that alters a test result for a genetic disease parameter. Genetic disease management models are proceeding, however, with treatments

such as 'herceptin' (see Batt, this volume). Herceptin does not itself alter the original genetic characteristics. It is, however, dependent on genetic tests to determine a woman's suitability.

Nevertheless, whether considered a genetic or non-genetic disease, the problem remains the same for provincial policy-makers and regulators. The drug and device industry presents disease management models within a carefully-orchestrated marketing strategy. The ability of provincial governments to respond effectively has been diminished by fragmentation over different departments, with isolated individuals with different mandates.

5. The Osteoporosis Disease Management Model: Upstream Success, Downstream Failure

We believe the upstream focus is both necessary and appropriate for our limited resources. However, we recognise that it is the downstream activity which determines who is the ultimate winner, public or corporate.

The most recent and dramatic example of an upstream success, but downstream failure is provided by the osteoporosis disease management model. Destined to become the most successful disease management model to date, it is designed to medically manage bones and bone health across the life-span. The model brings together bone mineral density (BMD) measurements with specific drug-therapy designed to alter those measurements.

BMD testing is an x-ray technique used to assess bone structure and to predict future fracture risk. The problem is that BMD is a very poor test for predicting which women will and will not suffer future fractures (Green et al 1997). Nevertheless, low BMD is very actively promoted to well

women. This despite the fact that drug treatment of low BMD (necessarily offered for long-term use) has not been shown to reduce the fracture rate of well women, the group targeted for BMD testing (Kazanjian et al 1999).

From the early 1990s, numerous researchers, women's activist groups and the provincial Women's Health Bureau argued that the osteoporosis disease management model diverts attention away from problems of diet, exercise, lifestyle, unsafe walking, shopping environments, and focuses instead on the specific, measurable, alterable component of bone structure - which is not necessarily connected to disease outcome.

Our technology assessment office showed provincial policy makers that this disease management model diverts funds from effective programs shown to reduce fracture rates (NHS 1996). The Therapeutics Initiative argued that available hormone and bisphosphonate (Fosomax) therapy was of very limited, and likely transient, benefit. The latter drugs remained as restricted drug benefits in the province. As mentioned above, support for individuals in the Ministry of Health resulted in a 3 year moratorium on BMD diffusion in the province (Bassett 1999).

In the end, however, no one person and no committee could adequately argue for social needs or consequences, nor solicit sufficient public or expert opinion to counter the disease management models being rolled out by the drug and device industry. In short, once BMD technology became available to clinical care, it was 'game over'. Unsubstantiated clinical guidelines and protocols in the use of the technology were rolled out as part of drug and device industry sponsored 'educational' strategies.

The failure to control the osteoporosis disease management model was

facilitated by providing it a fee code within the provincial health insurance payment plan, albeit an old code not using the x-ray technique. Furthermore, with a fee code in place, individual hospitals exercised no control over utilisation. For example, when BMD was considered by the Greater Victoria Hospital Society, Technology Assessment Committee, they did not consider the medical necessity of new technology.

BMD remains as a dark moment in the history of the Greater Victoria Hospital Society TAC. It is a clear example of the inducement mentioned earlier, the opportunity to bill for hospital services provided to 'out-patients' outside the global budget. The committee could not bring itself to adequately evaluate BMD because it was such an important source of sorely-needed funds.

6. Genetic Testing and Treatment

Decoding the human genome and understanding the role of genes in health and disease holds great promise and challenge for the future. Genetic research promises to provide greater understanding of the origin and mechanism of disease, possibly treatment and, at times, cure. Genetic research also promises very significant financial reward for a rapidly growing, national and international, biotechnology industry. The challenges faced by society include maintaining privacy, ensuring access of individuals to health insurance, and countering discrimination based on disability and eugenics.

Public purchase of genetic tests and treatments and the ethical review of genetic research provide important opportunities to weigh costs and social consequences against potential health benefits. My recommendation is that decision making regarding public purchase and ethical review should include very clear and unbiased assessments of the

scientific validity of effectiveness and safety claims. With unbiased assessments, science remains a very powerful social tool. With biased assessments, science risks further absorption into the commercial enterprise.

kind to combat the re-modelling of health-care into a commercial market place.

With the advent of genetics-based medicine, these strategies may serve to help individuals and committees at the provincial level who are soon to face the incoming tide of genetic testing and treatment options.

Summary

I have described what provincial opportunities exist to provide social direction to the federal, pro-industry CBS policy, at the points of purchasing and research review. Few objective observers will doubt the need for strategies of this

Social interests could also be greatly furthered by co-ordinating ethical and research review committees with one another, and with provincial purchasers and regulators.

References

Bassett KL. 1999. Using diagnostic tests to sell drugs: the case of bone mineral density testing in BC. Centre for Health Services and Policy Research, Annual Health Policy Conference, University of BC, Vancouver November 26.

Bassett KL, Morris V, Chambers K, Fry P, Foerster VA, Fatin N. 1998. Endovascular graft treatment of infrarenal aortic aneurysms. Joint Health Technology Assessment Series, BCOHTA 98:5J.

Bassett KL, Kazanjian A. 1996. Incorporating clinical effectiveness debates into hospital technology assessment: the case of laser treatment of benign prostatic hyperplasia. BCOHTA 96:1D.

Green CJ, Bassett KL, Foerster V, Kazanjian A. 1997. Bone Mineral Density Testing: Does the Evidence Support its Selective Use in Well Women? BCOHTA 97:2T.

Green CJ, Hadorn D, Bassett KL, Kazanjian A. 1993. Prostate specific antigen in the early detection of prostate cancer. BCOHTA 93:6D.

Kawachi I and Conrad P. 1996. Medicalization and the Pharmacological Treatment of Blood Pressure. In Peter Davis, editor, *Contested Ground*. New York: Oxford University Press. 26-41.

Kazanjian, A., Green, C.J., Bassett, K., Brunger, F. 1999. "Bone Mineral Density Testing in Social Context." *International Journal of Technology Assessment in Health Care*. 15(4):679-685.

Management of Type 2 Diabetes. 1998. Therapeutics Letter 23, Jan/Feb/Mar. Full text available through www.ti.ubc.ca

NHS Centre for Reviews and Dissemination and Nuffield Institute for Health. 1996. Preventing falls and subsequent injury in older people. *Effective Health Care*. 2(4):1-16.

Savoie I, Kazanjian A, Bassett KL. 2000. Cholesterol Testing Clinical Practice Guidelines and the Clinical Expert Paradox. *Journal of Health Services Research and Policy*. 5(2):76-82.

Science Education for a Science Dependent Culture

Ellen Larsen

About the Author

Ellen Larsen is a Professor in the Department of Zoology at the University of Toronto. Her interest in science education has led her to develop courses aimed at understanding "science as a way of knowing". She has served on the Council of the Royal Canadian Institute, an organisation devoted to making science accessible to the general public, and has also served on a Science for Peace committee which examined Canada's compliance with its international treaty obligations with respect to chemical and biological warfare.

About the Article

Ellen Larsen addresses a fundamental question about the democratization of knowledge. How, she wants to know, can people be empowered to engage seemingly abstruse issues, such as biotechnology? As a teacher of science to undergraduate university students, Larsen sees both limitations and promises in the ways many students trained in the liberal arts conceive of science. She recommends a shift in the cultural understanding of science, from its characterization as an elite-based tool for the few professionals who use it daily, to a common cultural artifact – a tool of the masses as we interpret and explore our world.

As an academic geneticist interested in the arcane mechanisms of development, I spend my days trying to understand how a fruit fly's genes determine whether it will have a leg or an antenna growing from its head. The vocabulary and techniques I use daily are often poorly understood by colleagues in other biological disciplines, let alone most lay people. Nevertheless, the motivation for doing this research, and my particular approach, should be accessible to anyone. Unfortunately, the lack of comprehension of science goes far beyond problems of communicating the essence of one's research to a broader community.

My concerns in the area of women/ health/ genetics stem from the conviction that for citizens to be empowered to make decisions with respect to their health, and that of their families, they should understand the issues involved. As an instructor in 1st year seminar courses serving as the only science course that many Arts students will encounter, I have been startled by the inability of these students to read newspaper and magazine articles on genetics with comprehension. This inability extends to recreational media like the movies Jurassic Park and GATTACA. Part of the problem is that the vocabulary, and some of the concepts, are not part of their knowledge base.

Another part of the problem is an antipathy to "science as a way of knowing". When asked what kinds of information they would like to have before they decided to use a new type of medical treatment, it was astonishing to hear that if a relative recommended it, that would be good enough. These are bright, articulate students for whom risk-benefit analyses

hold no charm and double-blind experiments no hope. It would not be surprising, therefore, that a few years later, if issues of new reproductive technologies or genetically modified foods became important to them, they would be incapable of doing more than putting their trust in someone else's analysis.

I do not understand the cultural dynamics responsible for the disaffection with science among many of our educated citizens. It occurs to me, however, that scientists may be looked upon as belonging to a priesthood which has access to information stored in Temples (libraries) which is incomprehensible to the lay public. This is not true for many aspects of the science-based issues in the health/ genetics areas, since a 1st year university student with a grade 10 science education can search out articles on specific, technical subjects and understand their key points. Web based tools have the power to remove barriers to such technical information because the cyber library is open to the increasing number of people with Internet access.

Yet the Web represents a double-edged sword since one has to be able to evaluate the information one is getting. The challenge for the educational system at both the high school and university level is to integrate science into curricula as part of our culture much as music, drama, dance and the graphic arts. This will only happen if the demand for such integration exists in the community so that science as a way of exploring our world and understanding technology replaces the notion of science as the province of the relatively few who will use it professionally.

A Gender Critique of Forensic DNA Evidence: Collection, Storage and Applications.

Patricia Lee

About the Author

Patricia Lee is a Research Associate in the Department of Anthropology and Sociology, University of British Columbia and Research Associate to the BC Centre of Excellence for Women's Health (BCCEWH). For the last two years she has represented BCCEWH on the Working Group for Women, Health and the New Genetics. Lee tutors in the Faculty of Medicine at UBC, and works as an Independent Health Research Consultant. She is the second author on the report on triple marker screening for the BC Office of Health Technology Assessment entitled "Triple-marker Screening in British Columbia: Current Practice, Future Options." (BCOHTA 00:14T. June 2000)

About the Article

Patricia Lee approaches biotechnology from a particular vantage point: the development, use and storage of DNA forensic information. By posing the question, what specific effects will these seemingly generic technologies have on women? Lee unpacks a wealth of crucial insights. DNA forensic technologies, her analysis reveals, are inserted into existing social systems, with all the problems and inequities that exist therein. Recounting the discouraging statistics on the percentage of sexually assaulted women willing and able to gain legal redress, Lee asks "Will DNA collection and storage become a further reason for victims to remain silent about their assaults?" In addition, she points to the place of DNA evidence in an expansive network of state surveillance, with especially harsh consequences for members of marginalised communities. A considerable amount of further research, Lee argues, is warranted.

Introduction

As Canada enters the 21st century, many DNA¹-based biotechnologies are developing rapidly. Among these are the collection, analysis, storage and use of DNA for the purposes of forensic evidence in the legal system. Indeed there is almost daily media coverage about the significance of forensic DNA.² Yet there has been little analysis of the potential negative consequences and effects of collected forensic evidence on Canadian society. Also missing is a thorough gender critique.³

Forensic evidence is commonly derived from the DNA in human fluids and tissues – blood, semen, saliva, skin cells, hair, nail clippings, finger prints, deposits found in bodily orifices. This evidence is generally substantiated with photographic or diagrammatic and textual descriptions of attack sites, bodily wounds and the instruments of assault. Such evidence is generally found in and on the bodies of women.

It is becoming commonplace for police investigators to obtain as much information as possible from a crime

scene in order to reconstruct the crime and to identify a known assailant, or archive information that could lead to identification of the unknown attacker at a future time. Forensic DNA analysis, sometimes referred to as “fingerprinting” technology, is commonly performed in cases of violent physical assault, including sexual assault, homicides, and hit-and-run accidents. By checking the suspect’s DNA against DNA samples found at a crime site, usually in the form of semen, saliva, skin cells or hair follicles, charges can be laid, court proceeding initiated and convictions made.

While these potential case-solving aspects of DNA forensics have been widely publicized, the ways in which the evidence is used once it is available have received virtually no public attention. I argue that, before we allow wholesale use of this expensive and time-consuming DNA biotechnology we ensure that women’s rights⁴ to privacy, security and confidentiality, and their proprietary interests in their bodily parts, are protected. Furthermore, women victims of violent crime must have their right to consent to their DNA being stored enshrined, and enforced with medical, ethical and legal standards of disclosure. If this is not ensured, tracing the genetic material once alienated from the body may be impossible. Some would argue that this happens all the time when one gives a blood or tissue sample, and hospitals do retain the samples for later reference.⁵ However, the concern with alienated DNA resides in its potential use for surveillance

¹ DNA is the acronym for deoxyribonucleic acid, the genetic composition of all higher living organisms.

² The terms “DNA evidence”, “forensic DNA”, “forensic evidence” all apply to the physical collection of bodily, usually human, tissues and substances, the analysis of the DNA contained therein, and the subsequent storage of the physical record and/or the reports based on that evidence, and the use by the police and courts of that information. The human materials are called forensic because they are specifically collected for legal purposes in the pursuit of social justice. Otherwise they are medical evidence collected expressly for diagnostic and treatment purposes.

³ In the mid-1990s two strongly feminist commentaries were published on this topic by Kubanek 1997 and Miller 1996.

⁴ I would include under this umbrella the rights of children and other vulnerable minorities. This discussion paper focuses specifically on women’s interests.

⁵ Recall the case of Moore v. Regents of the University of California, where a man (John Moore) being treated for cancer had his cell line used for commercial purposes without his knowledge.

– purposes other than medical diagnosis and treatment.

DNA Forensics in Canada

In 1995 DNA warrant legislation made it possible for Canadian police to seize DNA samples for a wide range of offences included under thirty sections of the Criminal Code. The expectation at the Department of Justice was that this legislation would diminish violent assaults through deterrence and enhance convictions (Canada, Solicitor General 1996). Consequently, it has become routine for a finger prick blood sample to be taken from a crime suspect, whose DNA is typed in at least nine identifiable ways, then checked against DNA found at the crime site⁶, or filed for future reference. As this practice has increased, a central place to store DNA has become vital.

In 1996 a bill was introduced by the Federal Government to establish a National DNA Databank. Presently, under federal government legislation a bank is being set up in Ottawa housed on RCMP premises. DNA samples along with crime scene data will be stored for future reference. Over time it is expected that large numbers of Canadians will have their DNA profile and a biological sample on file in this costly bank.

The RCMP in 1996 projected that the cost for DNA studies would be \$6 million per annum, plus \$5.8 million to build the new facility (Miller 1996:2). These estimates pale in contrast to those of similar banks already in existence in Britain, Australia and the U.S. In Britain, the reported cost of

⁶ Site may include not only a place, but also a human body, usually female, living or dead. The Vancouver Police Department is accelerating now their systematic search for possibly in excess of 30 women missing without trace from the Downtown Eastside. Mitochondrial DNA evidence is beginning to be used in the case of human remains found in remote parts of the Province.

their data bank in the first five years of operation for the storage portion alone was \$300 million Canadian. The British government introduced databanking as part of a move to increase police and state power, particularly in response to curtailing terrorism from the IRA (Kubanek 1997:3). Its motive was less about the issue of public safety.

The perceived focus of DNA collection and storage for the Canadian public has been the identification of criminals, predominantly male perpetrators, who are responsible for the greatest proportion of crimes (common assault, sexual assault and hit and run road accidents). However, there has been little discussion of the repercussions of DNA evidence collection, storage and analysis on Canadian women's experiences, or for marginalized/minority populations in Canada. There is minimal awareness of how pervasive and extensive is the state's surveillance capacity in the analysis of individual and collective DNA once it is collected and stored.

DNA Surveillance: Implications for Immigrants and First Nations

There has been some preliminary research on the use of genetic information in the immigration and refugee context in Canada. Critics argue that the use of genetic tests to establish or confirm familial ties is premised on the assumption that consanguineous links, as opposed to culturally determined social relations, are paramount in determining which significant "family" members may be sponsored for immigrant status. Therefore using genetic testing as the standard tool to determine legal residency in Canada compromises the rights of applicants whose families are based on non-genetic kinship models.

Moreover, the storage and use of the DNA information from applicants, either within Canada or in countries of origin, could

have serious consequences. Employing genetics as a gatekeeper strategy to enter Canada has sinister reminiscences of socio-biological techniques to preclude entry into Canada and the United States in the early part of the twentieth century. At that time new immigrant hopefuls were subjected to physical and psychological examination in order to assess their worthiness for residency. Determinants such as low IQ, small head size, diseases such as tuberculosis, or being a member of certain minorities (gypsies, Jews) resulted in many travellers arriving exhausted and sick from long journeys on the immigrant ships from Europe only to be sent back to their homelands.

Currently, DNA technology is being used in the international context to analyze, store and make available the genetic blueprints of specified ethnic groups. This data will be available in perpetuity, should certain peoples become extinct. The Human Genome Diversity Project (HGDP) originally aimed to bank the DNA of 722 indigenous peoples globally. Despite the fact that the Indigenous Women's Caucus at the UN Fourth World Conference on Women unanimously declared the project unacceptable, the project's sponsors have continued their efforts with the approval of the international scientific community (Kubaneck 1997:4). The HGDP proper has never actually started, largely because of these protests. Yet bio-prospecting continues. Canada has not been immune to this investigation, as isolated communities in the Canadian north, composed of First Nations and Inuit people have been the objects of commercial and intellectual property interests. Recently, the Icelandic government agreed to collect and submit the profiles of all their nationals to HGDP.

There is a clear need for more research in this area.

DNA Surveillance: Implications for Women Survivors of Sexual Assault

The remainder of this discussion focuses on a narrower spectrum of DNA use in Canada. It addresses some of the ways in which the growth of medico-legal examinations resulting in the collection DNA evidence may affect women adversely in their dealings with law enforcement agencies and the courts. It challenges the prevailing assumption that identifying an assailant based on DNA will help protect women in general against assault, and ensure that the courts rightly identify and convict known offenders. I question whether DNA databanking is any more than a new genetically based form of state surveillance, where ethnicity, disability and deviance are labelled and manipulated by state practices which evoke memories of past eugenic policies. New areas of research are suggested which can begin to address some of these issues.

From the hospital setting, through to the courts and extending into the realm of federal policy, women's health, safety and well-being may be affected in unforeseen ways by the perceived need to collect and store evidentiary materials and release pertinent information in sexual assault trials. While I do not dispute that in certain instances forensic evidence has great value for bringing assailants to trial, convicting them of heinous crimes and compensating to some degree the innocent victim, the discussion that follows takes a cautionary approach. It questions the degree to which the exponential growth and concomitant validation of DNA evidence serves the best interests of specifically identified women, and by extension, all women.

The first point I address concerns privacy, confidentiality and the ethics surrounding informed choice in the collection of forensic evidence. At issue is whether women realize that when they submit to a

forensic examination following a sexual assault that their own DNA will also be identified and documented, and potentially may end up in the National DNA Databank. The second point involves inappropriate stereotyping. Although sexual assault (not to be confused with domestic violence) is indiscriminate throughout society, there is a misplaced assumption that certain types of women are the targets of sexual assault and thus they deserve what they get. The third point, which follows on from the second, is that there is very little research as yet about the relationship between admissibility of forensic evidence in the courts and women's experience in court.

Privacy, confidentiality and the ethics of informed consent in the collection of forensic evidence

Patient autonomy (or self-direction or self-determination) is a central value in all approaches to health care ethics as Sue Sherwin has pointed out. Yet her concept of relational autonomy also calls attention to the context within which decisions are made, the situational ethics. Protection of autonomy is particularly difficult in health care settings because sick patients are dependent on the care and goodwill of their caregivers. The tendency towards paternalism in medical care "reduces patients' power to exercise autonomy and it also makes them vulnerable to manipulation, and even to outright coercion, by those who provide them with needed health services" (Sherwin 1998:20).

In the situation where medical/forensic evidence is collected, it is particularly important that patient autonomy is respected and that the patient/victim's care is in the context of experienced, sensitive assistance from trained sexual assault examiners, counsellors and victims service workers. BC Women's Sexual Assault Service (SAS), for example,

actively promotes a woman-centred approach, which ensures that a patient/victim will be given all the time and information necessary to understand precisely what she is consenting to. SAS has a clear mandate that the physical, psychological, emotional and security needs of the woman following a sexual assault are primary. The forensic examination, while available on consent, takes second place to health services and then only following stringent rules and safeguards at every stage of consent.

Allied with the issue of consent is the obligation for patient confidentiality and privacy. Lack of consent to engage in sexual activity, as occurs in sexual assault, and limited understanding of the consequences of the invasive medical procedures which occur in a forensic examination both relate to extreme abuse of power. They are associated with the violation of bodily integrity and acts of disempowerment which undermine the dignity and control that women need for self-determination, agency and autonomy. A patient/victim's right to confidentiality, like consent, is a cornerstone of medical ethics. Unfortunately if women fear that evidence taken from their bodies may be misappropriated by the law enforcement and court systems, then their confidence is shaken with respect to frontline health care. Consequently, some women, who are often the most vulnerable, are unlikely to seek the medical and psychological help they require for the effects of sexual assault.

Although legal reform and other social changes have brought about greater efforts to eradicate biases that confront those who press complaints of sexual assault (Johnson 1996:36), it is well documented that most women who are sexually assaulted never involve the police or seek medical care. It is estimated that about 70% of women utilizing sexual assault services do not report to the police. In fact, only 1 in 10 women who are

sexually assaulted report the incident to the police, and in the case of date rape, the number rises to 1 in 100. According to the Statistics Canada victimization survey (1993) more than one in three adult women have been sexually assaulted since the age of sixteen, and 94% of these cases never come before the criminal justice system. Moreover, when SAS tracked service records they found that only 10 out of 100 cases where evidence had been collected for the police had led subsequently to a trial with a conviction (personal communication).

Many women have valid concerns about disclosure of an assault for fear of repercussions from an abuser if they report. Other women, as documented by victim services workers, have legitimate concerns about how they will be treated in court. This rightful wariness of the medical, law enforcement and judicial systems raises the question: Will DNA collection and storage become a further reason for victims to remain silent about their assaults? Therefore at the outset assurances of confidentiality and non-disclosure are critical for victims who do seek victims services or medical supports.

Recommendations for research

While issues of consent, confidentiality and disclosure of personal records in sexual assault cases⁷ are beginning to be recognized and addressed in the health care context unexamined to date are proprietary rights to DNA in the broader context. Should women be concerning themselves with what happens to their own DNA profile that is collected as part of the forensic evidence following a sexual assault? One way to investigate this would be to evaluate studies conducted at DNA databanks that have been operational for

a number of years. What kinds of analyses, if any, have been conducted on those records? What is the demographic profile of those who have their DNA stored in these banks? Furthermore, what kinds of safeguards are in place to protect the privacy and proprietary interests of any given individual? In the short term it is important to track the development of the DNA databank as it is implemented in Canada and the legislation surrounding both its own internal operations and its linkages with DNA forensic laboratories under various police jurisdictions across Canada, including the practices of private laboratories.

Inappropriate stereotyping of sexual assault victims.

DNA banking has the potential to feed into the hierarchies and inequities already in existence in the prosecution process. There is an unfounded assumption that certain men's and women's accounts have more credence than others. Recall how white, well-groomed, educated rapist and murderer Paul Bernardo evaded prosecution for sometime, and did not have his DNA collected, while other men, such as those who are poor, Native and/or substance abusers are more likely to be targeted immediately.

This section will discuss how certain types of women are stereotyped as more likely to be sexually assaulted, for example poor women, sex trade workers, substance abusers and certain ethnic groups e.g. First Nations women. In Vancouver, this assumption is based partly on the backgrounds of women living in the Downtown Eastside who tend to fall into these categories and are identified as being subject to frequent abuse. Women who agree to evidence collection after a sexual assault could unwittingly be providing evidence that may be used against them in an unrelated criminal investigation.

⁷ See papers by Addison, Busby, Robinson and Sampson in Metrac publication 1998. Also unpublished confidential paper by Lee 1999.

The Downtown Eastside scenario exists in other inner cities in Canada, where the destitute congregate and crime is rampant. There is national evidence that native men, men of colour and poor men are jailed in Canada at a rate disproportionate to the Canadian demographic profile. Therefore the DNA of marginalized groups is more likely to be retained in the National Databank. The logical consequence is that the DNA of sexually assaulted women, who become labelled as “bad girls”, will fall into the same categories as their male counterparts and thus are more likely to show up in this bank. We now know that there is greater discrimination and a higher incidence of physical and sexual abuse among women “whose lives are compounded by oppression, including aboriginal women, women of colour, lesbians, and disabled women. Race, ability, age, class and their intersections are known to impact on the quality of health care service [and legal services] a woman received” (Rodgers 1995:164). There is much to be learned from the critical insights of women of colour about the perpetuation of hierarchies of power within the medical institution, and the forms of resistance that are transforming medical ethics and health care systems (Roberts 1996:117). These socio-economic lessons also apply to law enforcement and legal institutions.

In the near future, readily accessible genetic data such as that retained by the DNA Databank may well become a rich resource for studies which seek to identify certain genetic traits e.g. the propensity for substance abuse, or violence, the inability to become and remain employed, homosexuality etc. There are alarming privacy issues wrapped up in this type of surveillance through the one-way mirror of scientific observation. The institutionalized deviant is seen in passive isolation, leaving no recourse for the latter to act in her/his own interests.

Legislation must ensure that a person retains rights over future research and statistical use of her/his banked DNA. It is unlikely that women, traumatized or not, would be aware of the long term consequences of the medical/forensic examination. The immediate and subsequent trauma for women who have been sexually assaulted (including date rape) makes them particularly vulnerable to often well meaning health care workers and police investigators, who encourage them to submit to evidentiary examination in order to aid the justice system or legal proceedings.

Recommendations for research

It is important to assess and develop strategies that provide all women with adequate information about a range of aspects relating to sexual assault. This is particularly critical for victims faced with the collection of forensic evidence. Additionally, research needs to be done to educate police officers and the courts concerning the misplaced myths about who gets sexually assaulted, and about how women fare in the justice system. Woman-centred approaches, particularly feminist oriented work (where possible conducted in conjunction with police departments and various offices of the Attorney General) is vital to ensure that there are safeguards written into police protocols and public policies such that victims’ DNA will never become available for subsequent analysis without their informed consent.

The imperative to collect DNA samples and its arbitrary use in sexual assault trials

Paradoxically, despite increased pressure on Sexual Assault Services and medical examiners to collect forensic evidence for the police, there is relatively little use of that evidence in the courts. Examination of court practices reveals that defense

lawyers often focus on negative stereotyping of victims, on the meaning of consent and the significance of the complainant's past sexual history, rather than the difficult to dispute facts of the forensic evidence.⁸ The assailant is constructed as the maligned victim, while the victim is re-victimized by being characterized as unstable, unreliable and a seductress of innocent men.

Research in British Columbia on court proceedings demonstrate both the limited number of sexual assault cases that actually gain a court hearing, and the limited percentage of these for which DNA evidence was available, or useful, in obtaining convictions.⁹ Kee's (1996) report for the B.C. Ministry of the Attorney General verifies the minimal use of collected evidentiary data in court, while Herbert and Wiebe's (1989) earlier study for the BC Women's Sexual Assault Service found that more than half the cases for which DNA evidence was available did not proceed to trial. Recently, McGregor et al (1999) conclude that "It is important to have good evidence that the time spent on the forensic part of the examination does indeed influence the legal outcome of the case" (1568-9). In other words good documentation of

⁸ Contamination of forensic evidence samples is now being given as a reason for its inadmissibility in the courts. Since 1985 survival of DNA in evidence samples in sufficient quantity and quality has made it possible for genetic analysis directly at the gene level. In relation to sexual assault, specimens in the vagina may last up to seven days, in the mouth for several hours and in the anal canal for twenty four hours (Sensabaugh and Blake 1994:417). In August 1999 for the first time in a Canadian criminal trial, mitochondrial DNA evidence, which makes identification of older remains possible, was used to implicate Shannon Murrin in the Mindy Tran murder trial.

⁹ See research by Herbert and Wiebe 1989, Kee 1996, McGregor et al 1999; also a recent Ontario publication by DuMont and Parniss 1999.

moderate and severe physical injuries which can be made available at the time of charge laying may outweigh relying on the often delayed laboratory report of DNA typing to identify an assailant. The McGregor report also identified the need for more research into other variables that predict laying of charges and even more importantly the securing of convictions. These variables included socio-economic factors, and the possible bias of the justice system towards certain characteristics of victims, who are poor, sex trade workers, substance abusers and uncooperative with the police.

In spite of more cases of sexual assault coming before the courts since the reform legislation of 1983, when Parliament reviewed the Criminal Code revision related to assault, and *R. v Chase* (1987) provided guidelines as to what constituted sexual assault, the courts remain hostile places for women pressing sexual assault charges. Throughout the 1980s and 1990s, the courts have been a minefield for female sexual assault victims. Some judges continue to enforce old patriarchal practices, legislation enforces production of a complainant's prior sexual history records,¹⁰ while defense counsellors strategize to discredit complainants by producing discriminatory stereotypes of women as fabricating allegations of rape and as sufferers from "false memory syndrome".

Efforts by feminists to create a more hospitable climate through legislation¹¹ protecting women from in-trial exposure of past sexual histories has been only sporadically successful. So the scales of justice continue to teeter, a balancing act which leaves women unsure about their

¹⁰ See decisions in *Seaboyer* (1991), *O'Connor* (1996) and the ongoing challenges to the constitutionality of Bill C-46 in two Alberta cases, *Mills* and *Ewanchuk*.

¹¹ For example, Bill C-49 (1992), the rape shield legislation.

survival in the courts. This distrust is well voiced by victims' service workers who frequently attend court with victims.

Recommendations for research

Further research to follow up on the few feminist studies which have started to track some aspects of the collection, admissibility and lack of use of DNA evidence in the courts would be valuable. If it is found that forensic evidence is not consistently considered beneficial information in sexual assault trials, then the time of sexual assault examiners would be better spent on medical and psychological services to victims rather than on legally based medical services. Studies focussing on the various ways in which women resist collection of forensic evidence, and their experiences with police investigators and defense counsels in sexual assault trials would also serve to illuminate women's responses to a biotechnology which seems to have questionable value for women's health and security.

Summary

The above discussion encompasses the ethical, social and cultural context within which certain categories of women are often served poorly by the very institutions which purport to assist them. In both the health care context and the courtroom, as

well as on the streets, women continue to be vulnerable to oppression and control by dominant hierarchies. This critique also moves into the speculative realm of whether women can trust what happens to their genetic material if it is captured through DNA banking. Here other forms of surveillance and analysis may construct and re-construct stereotypes of the types of women who are sexually assaulted. As Canadian society advances into a new deterministic genetic age in which the genetic blueprint of each person may be investigated, it is important to examine the new loci of power and control that are emerging currently, which are sanctioned by federal policies and regulations. At the very heart of the matter is the need for voiceless, violated women who are the targets of sexual assault to be protected from further violations by institutions that do not always and fully respect fundamental rights to confidentiality, privacy and proprietary ownership of personal bodily tissues and substances. These rights underpin basic ethical standards of health care, and in the case of collection of forensic evidence, what happens to the data after it has been acquired. Within the Canadian Biotechnology Strategy, there is urgent need to ensure that those ethical, social and cultural values principally affecting women be given priority over the predominant concern with commercial issues.

References

Addison, Mary. 1998. The Damage to the Sexual Assault Survivor of Disclosing Personal Records. In *Can Confidentiality Survive: A Day of Study on Disclosure of Personal Records in Sexual Assault Cases*. Toronto:METRAC

Busby, Karen. 1998. An Examination of the Constitutionality of Bill C-46. In *Can Confidentiality Survive? A Day of Study of Disclosure of Personal Records in Sexual Assault Cases*. Toronto:METRAC

Canada, Solicitor General. 1996. *Establishing a National DNA Data Bank*. Consultation Document. Minister of Supply and Services Canada.

- Du Mont, J., and D Parnis. 1999. Sexual assault and legal resolution: Querying the medical collection of forensic evidence. Manuscript accepted for publication in *Medicine and Law*.
- Herbert, Carol P. and Ellen Wiebe. 1989. That Notwithstanding Clause Again. *Canadian Medical Association Journal*. July 15th:141:97-98.
- Johnson, Holly. 1996. *Dangerous Domain. Violence against Women in Canada*. Toronto: Nelson Canada
- Kee, Janet. 1996. Collection, Storage and Use of Medical Forensic Evidence in Sexual Assault Investigations in British Columbia. A Research Paper. B.C. Ministry of Attorney General, Community Justice Branch, Victims Services Division.
- Kubaneck, Julie. 1997. DNA Evidence under Feminist Scrutiny: Myths and Dangers Exposed. Kinesis.
- Lee, Patricia M. 1999. *Sexual Assault and Collection of Forensic Evidence: The Role of Consent in the Case of the Unconscious Victim* A discussion paper prepared for the BC Women's Sexual Assault Service and the BC Centre of Excellence for Women's Health, BC Women's Hospital and Health Centre. Unpublished.
- McGregor, Margaret J., Grace Le, Stephen Marion and Ellen Wiebe. 1999. Examination for sexual assault: Is the documentation of physical injury associated with the laying of charges? A retrospective cohort study. *Canadian Medical Association Journal* June 1st 160(11):1565-1569.
- Miller, Fiona. 1996. *The DNA Data Bank – A Feminist Critique*. Document presented at 1996 consultation of women's groups by the Justice Department. Ottawa. June 11-13.
- Roberts, Dorothy E. 1996. Reconstructing the Patient: Starting with Women of Colour. In *Feminism and Bioethics: Beyond Reproduction*, editor Susan M. Wolf, New York: Oxford University Press.
- Robinson, Gail. 1998. Disclosure of Psychiatric Records In *Can Confidentiality Survive? A Day of Study of Disclosure of Personal Records in Sexual Assault Cases*. Toronto:METRAC
- Rodgers, Sandra. 1995. Health care Providers and Sexual Assault: Feminist Law Reform? *Canadian Journal of Women and the Law*. Vol.8,159-189.
- Schneider, David. 1968(1980). *American Kinship: A Cultural Account*. Second Edition. Chicago and London. The University of Chicago Press.
- Sampson, Fiona. 1998. Production and Disclosure of complainant's Personal Records in Sexual Assault Trials In *Can Confidentiality survive? A Day of Study of Disclosure of Personal Records in Sexual Assault Cases*. Toronto:METRAC.

Sensabaugh, George F. and Edward T. Blake. 1994. DNA Analysis in Biological Evidence: Application of the Polymerase Chain Reaction. *Forensic Science Handbook*. Third Edition.

Sherwin, Susan. 1998. *The Politics of Women's Health: Exploring Agency and Autonomy*. Philadelphia: Temple University Press.

Statistics Canada. 1993. *The Violence Against Women Survey*. Ottawa.

Tibbetts, Janice. 1999. Constitutionality of privacy shield to be debated by Supreme Court, *The Vancouver Sun*, January 18th: A1-2.

The Human Genome Project and the Issue of Biodiversity

Priscilla Settee

About the Author

Priscilla Settee is a Cree Indian from northern Saskatchewan. She is Director of the Indigenous Peoples Program with the Extension Division at the University of Saskatchewan. Ms Settee is associated provincially, nationally and internationally with several boards and organizations. She has worked as an advisor to the International Development Research Centre (Ottawa) and helped produce the book *Seeding Solutions, Policy Options for Genetic Resources*. Settee works with NGO's in the South Pacific in building strategies for preserving biodiversity and Indigenous Knowledge. She has written a chapter called "The Issue of Biodiversity, Intellectual Property Rights, and Indigenous Rights" in the new Native Studies Textbook" *Expressions in Canadian Native Studies* (2000), of which she is a co-editor.

About the Article

Priscilla Settee outlines the work of Aboriginal peoples around the world to mobilise against biopiracy – the appropriation of Indigenous knowledge, and Indigenous bodies. The focus of much of this mobilising has been the Human Genome Diversity Project – a DNA sequencing project proposed as a complement to the international Human Genome Project. The HGDP is distinct in being intended as a way to gather the DNA of 'diverse' or 'endangered' peoples and thereby to 'map the migration history of humankind.' While the official HGDP has been derailed by the protests of its many critics, biopiracy is alive and well and commercially lucrative. As Settee here explains, Indigenous peoples have organised around the HGDP to articulate their own priorities, and to formulate agendas for tackling the large and growing problem of biopiracy.

The Human DNA of identified Indigenous groups is the focus of curiosity and activity among an international consortium of scientists, universities, governments, and other interests in North America and Europe.¹

Over 700 Indigenous groups world-wide have been identified to have samples collected from them. Indigenous communities targeted for DNA collection include Africa (165), Asia (212), South America (114), Oceania (101) North America (107 tribes) and Europe (23). Established in 1992, the Human Genome Diversity Project (HGDP) will take blood, tissue samples (cheek scrapings or saliva), and hair roots from hundreds of Indigenous communities throughout the world. Through the Human Genome Organization (HUGO) the project is mandated to map the entire genetic structure of the human race

HUGO seeks to sequence the DNA information in all 100,000 genes in the human body and is expected to cost 3 billion dollars over the span of the fifteen year project; HUGO is now nearing completion significantly ahead of schedule; a 'rough draft' has already been completed. While HUGO intends to uncover the norm of the human genome as a composite model, the Human Genome Diversity Project seeks to map and sequence genetic diversity. The project is specifically mandated to take blood, tissue, and hair samples from

¹ This article draws on the following source material: Indigenous Women Address the World. *Indigenous Woman Magazine*. Special Beijing Edition, Rapid City, South Dakota, U.S.A. 1996; *Indigenous Woman Magazine*, Rapid City, South Dakota, U.S.A., Vol, 2, No. 3, 1996; Dukepoo, F., & Harry, D. Indigenous Peoples Coalition on Biopiracy, 1998; "Voice of Native Grassroots for Environmental Justice." *Indigenous Environmental Network News*. Vol.3 No. 2, 1997; *Western Shoshone Defense Project Newsletter*, 1997.

"endangered" indigenous communities around the world.

The HGD project was formally adopted in 1994 by the Human Genome Organization. It has sought massive funding. This multi-billion dollar initiative by scientists has plans to sequence the DNA in the entire human genetic structure. The HGDP seeks to map the genetic difference of groups from the monotype genome that will be identified by the HUGO effort.

Scientists believe that many of the world's Indigenous people are in danger of becoming extinct and refer to them as 'isolates of historic interest'. Scientists hope to gather DNA samples from the living before they disappear forever, and so avoid the irreversible loss of precious genetic information. Indigenous peoples find it reprehensible that scientists' interest is purely to document scientific genetic information rather than to preserve tribal groups. In effect, the scientists are asking endangered tribal groups to submit personal samples before their group disappears. The scientists' actions revive out-dated and oppressive attitudes, and their actions instil self-fulfilling pessimism. Such actions are simply unethical.

Blood samples taken from Indigenous peoples will become immortalized for future study. A technique called "cell conservation" will keep certain cells of an organism alive and capable of multiplying. Unlimited amounts of the organism's DNA will be stored at various gene banks, mostly in the United States.

Indigenous peoples have many concerns with the HGDP. One is the issue of informed consent. Although the HDGP claims that it will seek the consent of the individuals and populations concerned, many people doubt whether this will, in fact, happen. Some questions that remain unanswered are:

- Can tribal leaders give consent for the whole tribe?
- Can one person give consent while others don't?
- How can some of these concepts be explained in ways and languages for people who have no concept or words for these confusing terms?
- What are the benefits for the local communities?
- Will decisions to refuse consent be fully respected?

The HGDP North American Committee secured a grant to develop a model protocol or rules for the collection of samples from Indigenous groups. It is felt by Indigenous people that this protocol will primarily be used to seek project co-operation.

The HGDP states that the research will help reconstruct the history of the world's populations, address questions about the history of human evolution and migration patterns, and identify the origins of existing populations. While the HGDP is looking for answers about human evolution, Indigenous peoples already possess strong beliefs and knowledge regarding their creation and histories.

Danny Billie, traditional spokesman for the Independent Seminole Nation of Florida, stated in 1997

“The white people are trying to play God. If they continue to do what they are doing the impact to the human species, insects, plant and animal life is going to be devastating. They think that they can get away with it, but they'll also suffer the consequences.”

In response to the HGDP research Indigenous peoples from various parts of the world have mobilized against the project. Documents such as the Ukupseni Declaration from Panama and the National Congress of American Indians Resolution No. 93-118 have been signed. These documents represent hundreds of communities who declare their opposition to the HGDP.

Karioca Declaration. In the early 1980's, the Karioca Declaration was signed by a group of Indigenous people who were opposed to the HGDP and who met prior to the 1993 United Nations Conference at the Earth Summit in Rio de Janeiro.

Mataatua Declaration. The Karioca Declaration was followed ten years later by the Mataatua Declaration and signed by over 150 participants from 14 United Nations countries. The Declaration calls for an immediate halt to the ongoing HGDP until all aspects of it could be understood by Indigenous peoples.

Article 29. In 1994 The United Nations' working group on Indigenous populations, along with the Sub-Commission on the Prevention of Discrimination and Protection of Minorities approved Article 29 of the Declaration of the Rights of Indigenous Peoples which stated:

“Indigenous Peoples are entitled to the recognition of the full ownership, control and protection of their cultural and intellectual property. They have the rights to special measures to control, develop and protect their sciences, technologies and cultural manifestations including human and other genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, and visual and performing arts.”

New Zealand. In 1993 an assembly of representatives of the tribes from the

North and South Islands of Aotearoa (New Zealand) passed resolutions condemning the HGDP and the patenting of life-forms.

National Congress of American Indians. In that same year the National Congress of American Indians (the oldest and largest national organization, comprised of representatives from 671 American Indian tribal governments in the United States) passed a resolution condemning the HGDP and called upon all related activities to cease immediately.

Central Australian Aboriginal Congress. Coined as the "Vampire Project" by the World Congress of Indigenous Peoples, the Central Australian Aboriginal Congress Position Paper stated in 1993:

"The Vampire Project is legalized theft. The Vampire scientists are planning to take and to own what belongs to Indigenous People. We must make sure that our people are not exploited once more by corporations, governments, and their scientists."

Maori Congress. In 1994 at the Maori Congress Indigenous Peoples Roundtable, Indigenous participants from the World Council of Indigenous Peoples, Greenland Home Rule Government, COICA (Peru), Treaty Six Chiefs of Alberta, and governmental representatives from Vanuatu, Papua New Guinea, and Fiji declared that:

"The collection of genetic samples from Indigenous peoples such as the Human Genome Diversity Project, is unethical and immoral and must be brought to an immediate halt."

Patents on Indigenous Peoples. Also in 1994 in Panama, the Guaymi Indians, along with citizens of Papua New Guinea and the Solomon Islands, discovered that the United States government had taken patent claims out on the cell lines from

some of their people. Through effective campaigning they were able to have the patent claim abandoned.

Workshop on "Intellectual Property Rights". In August 1994, the International Academy of the Environment, along with the World Wildlife Federation and the United Nations Centre for Human Rights, organized an information workshop on "Intellectual Property Rights and Indigenous Peoples" stating:

"The issue of HUGO, and others related to human genes, is a serious violation of our peoples' rights. Without consultation with the indigenous communities, several projects are now taking blood, hair, tissue and other samples for purposes that are not clear. This practice of collecting samples without our approval is very dangerous because in this way our genetic material can be patented or used for other purposes. Such practices not only violate ethics and human rights, but also violate nature, our spirituality, and our knowledge of creation that connects us with all forms of life."

Latin and South American Consultation. In Bolivia in September 1994, the Latin and South American Consultation on Indigenous Peoples Knowledge rejected the HGDP and human genetic research.

Asian Consultation. Similarly in Malaysia in 1995, the Asian consultation on the Protection and Conservation of Indigenous Peoples Knowledge rejected the HGDP.

Declaration of Indigenous Organizations. In Arizona, at the same time, Indigenous leaders from US, Canada, Panama, Ecuador, Peru, Bolivia, and Argentina, formulated a Declaration of Indigenous Organizations of the Western Hemisphere. It considered the responsibility to future generations:

“We have a responsibility to speak for all life forms and to defend the integrity of the natural order. We particularly oppose the HGDP which intends to collect, and make available our genetic materials which may be used for commercial, scientific and military purposes. We oppose the patenting of all natural genetic materials. We hold that life cannot be bought, owned, sold, discovered or patented, even in its smallest forms.”

PAHO. In April 1995 the Pan-American Health organization passed a resolution opposing the HGDP, and stated:

“This type of research will have a negative impact on future health programmes and projects in indigenous communities, by undermining indigenous peoples' trust in the medical and health professions.”

The Pacific Consultation. The Pacific Consultation on the Protection and Conservation of Indigenous Peoples Knowledge developed a Treaty declaring a Life-Forms Patent Free Pacific, with specific objections directed to the HGDP.

North American Indigenous Peoples' Summit. In August of 1997, several hundred Indigenous peoples representing many tribes and over 60 organizations met to discuss the impact of the new biotechnology on their homelands and their people. This meeting was called "the North American Indigenous Peoples' Summit on Biological Diversity and Biological Ethics" It established the "Heart of the People Declaration". The preamble "expresses our profound concern for the well being of our Mother Earth and the Indigenous circle of Life known as 'biological diversity'." The Declaration further states:

“We wish to add our voices to ongoing global discussions regarding the protection of biological diversity, the

safeguarding of traditional knowledge and sustainable development practices, and the ethical use and treatment of all forms of life in harmony, respect and the spiritual interconnectedness of the natural world.”

Ukupseni Declaration. In November of 1997, Indigenous people representing 25 organizations from 15 countries met in Panama to discuss the HGDP and the issue of human genetic piracy. This meeting was one the first opportunities for Indigenous people from Latin America to meet with North American Indigenous people who were working on the HGDP issue. The Ukupseni Declaration on the Human Genome Diversity Project was established as a result of the two-day meeting. The Declaration condemns the HGDP:

“It calls for a moratorium on the collection of genetic samples from indigenous peoples, and demands the repatriation of genetic samples and data already obtained by unethical measures. It opposes the application of intellectual property law, and patents, to human genes. It calls upon scientists to denounce any research conducted in a manner that violates the protocols that protect the human rights of human subjects. Finally it calls upon allies to work with Indigenous Peoples to demand protection for the human and collective rights of Indigenous Peoples.”

The Indigenous Peoples Coalition on Biopiracy. The Indigenous Peoples Coalition on Biopiracy was established in 1998 to address the theft of Indigenous blood, hair, and skin sampling, and as a concerted response to the HGDP. Coalition participants worked on strategies to protect their communities from exploitation. Members disseminated information to the local grass-roots levels. They built alliances for sharing current information as well as for implementing collaborative action and support among

the participating organizations and individuals. An extensive list of key points has been developed by this coalition, the direct quotation from the document is as follows:

“After careful review of HGDP and other independent investigations on the genome of indigenous peoples:

- a.** We declare absolute opposition to the Human Genome Diversity Project, and demand the immediate suspension of any activities to collect genetic samples, cell lines, or genetic data from indigenous peoples, including our deceased ancestors.
- b.** We demand the fullest cooperation of any government agency or independent research institute in the return of all genetic materials, cell lines, and data they may have in their possession to the appropriate governing authorities of the tribal group.
- c.** We oppose any attempt to monopolize or commercialize the genetic samples, cell lines, or data derived from the cell lines of Indigenous peoples through the application of intellectual property law and patent systems.
- d.** We oppose the genetic engineering of Indigenous peoples’ genes and cloning. This includes cloning Indigenous peoples’ genes or gene fragments into bacterial, viral, mammalian cell lines, or other vectors. We demand the immediate suspension of activities that are currently using any Indigenous peoples’ DNA, genes or fragments in any cloning experimentation.
- e.** We demand the international scientific community condemn any research that has been carried out contrary to recognized human values and moral principles, and that violates the international codes of ethics described in the Nuremberg code and the World Medical Association Declaration of Helsinki.

f. We reaffirm the governing entities of Indigenous tribal peoples/nations have the primary authority to deny access to, refuse to participate in, or to authorize any removal of genetic materials from our peoples or territories. The ethical principle of "individual informed consent" is also applicable, and is secondary to tribal governmental consent.

g. We demand that scientific endeavors and resources be prioritized to support and improve social, economic and environmental conditions of Indigenous peoples in their environments, thereby directly improving health conditions and raising the overall quality of life.

h. We demand an immediate moratorium on collections and/or patenting of genetic materials from Indigenous persons and communities by any scientific project, health organization, governments, independent agencies, or individual researchers.

i. We demand that the US government and any governing agencies, to not participate, fund or provide any assistance to the HGDP, or any related research projects which seek to research the genome of indigenous peoples.

j. We denounce the integrity of the report by the Committee on Human Genome Diversity of the National Research Council which gives unethical endorsement to the Human Genome Diversity Project while acknowledging the "lack of a sharply defined proposal that it could evaluate".”

As Indigenous peoples we have many unanswered questions regarding the new biotechnology industry, many of them centre around the issue of respect and some refer to the expropriation of the circle of life or biodiversity. In many of our communities these activities have been referred to as the final act of colonialism against Indigenous peoples. I have

reported the concerns that Indigenous Peoples have not only about the HGDP but about the potential threat to sovereignty and well being that theft of biodiversity has on Indigenous communities in North America and globally.

Obscuring Disability: The Pursuit of Quality” in the Canadian Biotechnology Strategy

Catherine Frazee

About the Author

Catherine Frazee has been involved in the equality rights movement for many years, most notably during her term as Chief Commissioner of the Ontario Human Rights Commission from 1989 to 1992. Ms. Frazee's work as a writer, educator and researcher focuses upon the rights, identity, experience and well-being of persons with disabilities. In addition to her private practice in human rights mediation, she is a part-time instructor in the Disability Studies program at Ryerson University and a Research Associate at the Roeher Institute, Canada's policy research organization promoting the equality, participation and self-determination of people with intellectual and other disabilities.

Ms. Frazee's work has been published in textbooks and academic journals as well as a variety of popular and specialty magazines. Included among her academic assignments are special lectures presented in 1998 at the University of Manitoba as part of the Faculty of Law Distinguished Visitor Series and the Bertha Wilson Visiting Professorship in Human Rights at Dalhousie University during the academic year 2000/2001. In 1998, Ms. Frazee's lecture about the "Untold Harms" of contemporary eugenic ideas was featured in Vision Television's Voices of Vision lecture series commemorating the 50th anniversary of the Universal Declaration of Human Rights. She is currently compiling a collection of essays, speeches and lectures aimed toward deepening societal responses to the experience of disability.

About the Article

Catherine Frazee provides both a critique of how the CBS conceptualizes health, disease and disability, and a commentary on the set of papers in this collection which take biotechnology and community as their theme. In the face of the determined obscurity of the CBS web site, Frazee unpacks the meaning of "health" by interrogating the Strategy's statements of principle. How, Frazee asks, will biotechnology actually contribute to quality of life? And what does "quality of life" really mean? Throughout the CBS, Frazee finds "majoritarian thinking [which] uncritically situates disability disadvantage as intrinsic to individual impairment or nonconformance to physiological and intellectual norms." It is this thinking which masquerades behind the seemingly benign phrase "Canadian values." The papers which Frazee reviews have in common a profound discomfort with these values. All share a concern with the prioritization of biotechnology policy over other social policies, and all identify ways in which specific biotechnologies can be problematic. Ultimately, Frazee suggests, what unites the critics of the CBS's goals and assumptions are a "set of ideas about what constitutes personhood." Frazee challenges us to consider carefully our beliefs about disability, and to imagine a rather different "Ideal citizen."

Introduction

The Internet site to which our attention is directed for information about the Canadian Biotechnology Strategy welcomes me with the Canadian flag, the Industry Canada banner and the greeting, "The Information Site That Means Business!". I am seized by a familiar panic, flashing back to border crossing interrogations of my wayward youth, job interviews from hell, close encounters with hostile canines. I feel the disapproving gaze of my cyberhost. This is not a site for casual browsers. If idle curiosity is my currency, I had best hasten my mouse *BACK* toward the more homely terrain of Yahoo.com. There is nothing for me here.

I take a deep breath and press past the menacing greeting. I do have business here. I am a stakeholder. And I have come seeking purchase.

Purchase:

- *Acquisition through the payment of money or its equivalent.*
- *A grip applied to move something or prevent it from slipping.*
- *A position affording mechanical advantage or the means to move or secure a weight.*
- *A means of increasing power or influence; an advantage used in exerting one's power (American Heritage Dictionary, 1992).*

I am a disabled woman. I feel something slipping away, something integral. I sense the dark approach of an icy glacial drift, its advance propelled by the weight of layer upon layer of values and ideology subtly hostile to my own. I doubt my capacity to influence the inexorable progress of biotechnology's powerful agenda. I need purchase.

I have been invited to bring "a disability rights perspective" to a workshop for the Working Group on Women and the New Genetics. But I cannot come to the table to discuss the CBS strategy with only my gnawing, visceral, unease. I scour the site – the press releases, fact sheets, background papers, consultation documents and committee reports. My browser's find command storms through each document in pursuit of a single fugitive word. But "disability" appears nowhere in the documents that highlight the strategy's features, benefits, guiding principles, goals, development and progress. It is alluded to, in phrases like "recognizable problems attributed to chromosomal, monogenic or multifactorial mutations" or "genetic deficiency" (CBS 1998a). It is implied, surely, in the promise that "Genetic testing will provide a number of diagnostic benefits such as the potential for ... helping potential parents make informed decisions..." (CBS 1998a). But the shadowy foe never quite declares itself.

I find myself remembering Kenzaburo Oe's reference to medieval Zen poetry and its concern with the "linguistic impossibility of telling the truth" (Oe 1995:112). He spoke of words "confined within closed shells", baffling any attempt at full understanding. Perhaps we must plumb for meaning within the closed shell of the strategy's promise "to enhance the quality of life of Canadians in terms of health, safety, the environment, and social and economic development".

A delicate excavation. My quest for meaning will cluster around four phrasings. Each is extracted from CBS documents and appears fundamental to the strategy's health thread. Each states a noble purpose, yet there is an equivocal quality to each when viewed through a disability lens.

Biotechnology as a Key Contributor to Quality of Life (CBS 1998b)

How does biotechnology contribute to quality of life?

It would appear that this is intended in part through the prevention of genetic disease or defect. This presumes first, an identifiable genetic "norm", and second, some social consensus that the "norm" is inherently more desirable than the "deviant" form. It is the latter presumption that is problematic from a disability perspective. Those of us with genetically non-typical characteristics are invariably excluded from any alleged "consensus" about what constitutes desired or acceptable life states.

Implicit in the identification of "genetic disease" (e.g., as applied to conditions such as Down syndrome, Spina Bifida and Muscular Dystrophy) is the assertion that disability is a negative characteristic – "a priori an undesirable trait" (Rioux 1996). I would be the first to concur that disability – like gender and race – correlates strongly with disadvantage. But while it is widely recognized that the disadvantage experienced by women and racial minorities is directly attributable to the social and systemic evils of sexism and racism, the non-disabled majority seems to stumble again and again in applying a similar analysis to the human rights claims of persons with disabilities. Instead, majoritarian thinking uncritically situates disability disadvantage as intrinsic to individual impairment or nonconformance to physiological and intellectual norms.

Disability activists and theorists have emphatically asserted that disability is a social phenomenon, rather than a biological one. Biotechnology's vigorous focus upon disability prevention by genetic methods ignores the deeply embedded and pervasive social, economic and political determinants of disability disadvantage. Disability is located in social

and economic structures, more than it is in genetic ones. How can we "popularize" this inherently unpopular notion?

Of course I cannot deny that living with a non-typical body can and often does add to life a significant dimension of pain, loss and restriction. But as I have argued at length in other fora, the same can surely be said of other states generally accepted as socially desirable – for example, growing up, entry into intimate relationship and parenting. The point is, as Adrienne Asch noted in her recent debate with Peter Singer, that "disability is only one characteristic of any person's life.... Along with disability – whatever that disability happens to be – come a whole range of other characteristics... and redeeming benefits... both intrinsic and extrinsic." (Singer and Asch 1999).

Disability per se cannot be presumed to diminish quality of life. Unless, of course, we are talking about the quality of life (read privilege) enjoyed by non-disabled Canadian citizens. Perhaps encoded in the phrase "quality of life" are forecasts about our national standard of living, and embedded in these, concern for allocation issues arising from escalating costs in health care and health support. This may well be so, but if it is, it must be made explicit. How else can those of us with genetically non-typical bodies find solid footing from which to enter into allocation negotiations?

Helping Potential Parents Make Informed Decisions (CBS 1998a)

For persons with nontypical genetic characteristics deemed undesirable by a non-disabled majority, the very possibility of entry into the human family becomes contingent upon a prospective parent's capacity to resist institutional pressure, reject social stereotypes and withstand the inevitable censure of peers and relations.

Most women over 35 elect to have prenatal diagnosis, and if they are told that their infant will have a "major defect" most of them decide to abort. As Princeton ethicist Peter Singer explains tersely, "If, before life has begun, the prospects are clouded, better to consider starting again" (Singer and Asch 1999). His utilitarian logic, it seems, is irresistible to many.

But what criteria or standards define an "informed decision"?

For those of us with "undesirable" genetic characteristics that could have been detected before birth, the implications of such informed decision-making are genocidal. Had our parents or their physician-advisers been "better informed", how many more of us would have been denied the possibility to experience life, think our own thoughts or form our own opinions and value systems?

The genetic structure of the fetus is such a small piece of the story of who we are and who we will become. Perhaps it is all that is knowable. The gifts and contributions of personhood will forever elude the predictive capacity of biotechnology. It is Singer's argument that some information is better than no information when decisions must be made in conditions of uncertainty. But surely a shred of information – nothing more than a dim flicker, enough only to render the purity of darkness into a labyrinth of shadowy distortions – surely this does not transform a leap of faith into an informed decision. After all, we withhold otherwise relevant evidence from juries when its prejudicial effect outweighs its probative, "informative" value.

Each new reproductive technology challenges us "to think better and harder than we're used to about two mighty pillars of life's foundation: power and love." (Angier 1999) How much power can we have over the outcomes of reproduction? As Angier asks, "Does that power give us greater freedom, or does it deprive us of

one of life's most unsung freedoms: the freedom to have things happen on their own?"

R. Alta Charo, professor of law and medical ethics at the University of Wisconsin in Madison says, "Reproductive technologies cumulatively reduce the range of events that happen by serendipity and increase the range of events that happen by active planning. This changes the texture of life. One of the rights we have is the right to not have to make choices." (Angier 1999)

At the dawn of the Age of Reason, Blaise Pascal observed: "There are two equally dangerous extremes: to shut reason out, and to let nothing else in." (cited in Kumar 2000) We cannot turn back the clock, we cannot suspend the knowledge that biotechnology offers. How then can we ensure that its juggernaut fury is contained? How can we secure a respected place for women's faith and dreams within a discourse so dominated by reason?

Reflecting Canadian Values (CBS 1998b)

What is our recourse when "Canadian values" are at odds with the values of social justice and feminism?

In the era of globalization, what are Canadian values? To what extent will they be shaped by those that dominate contemporary American culture? (Money. Knowledge. Social rank. Sex. Individualism.) Are the courts, the universities or the media our arbiters of cornerstone values? In any case, is the result not likely to have its roots in ideals of wealth, aesthetics, autonomy and power?

"[As we develop] increasingly sophisticated means to detect – and potentially to prevent – difference in

genetic structure, [we find ourselves living in] a time when our public policies reflect an increasingly inhospitable climate for difference. More and more, the Ideal Citizen is seen as the individual who demonstrates self-reliance, efficiency and competitiveness." (Ticoll 1996)

The values and aesthetic preferences that prevail in our society will determine biotechnology's agenda, priorities and presumptions. They will influence not only how questions are answered. More than this, they are the breath with which every question does or does not find utterance. The questions that we fail to ask of biotechnology will be of most profound consequence.

History teaches us that determinations of human worth are always consistent with the qualities that decision-makers have presumed themselves to possess – "the sort that facilitated passage through schools, universities and professional training." (Kevles, cited in Gray 1999) Put in other words, as Eva Feder Kittay has asserted, "The 'relevant' attributes for personhood are invariably abstracted from the lives of the people doing the abstraction." (Montgomery, personal communication)

Feminist economist Marilyn Waring proposes that time, rather than money, is the one commodity of intrinsic value in human society. She argues convincingly that radical transformations in economic policy would flow from the recognition of time and the natural environment in our measurement and distribution of wealth. In the same way, can we reinvent the Ideal Citizen as one with the capacity to form deep relationship, to give or experience joy, to create, to open new pathways for expression of personhood?

Biotechnology for Public Health Advantage (CBS 1998b)

*How can those of us with genetically non-typical bodies reconcile CBS notions of health promotion with our own identity and experience as **healthy** disabled women?*

Contrary to the expectations and preconceptions of non-disabled Canadians, many people with genetically non-typical bodies – once they escape detection and survive gestation and birth – develop well-honed skills in the avoidance of medical "attention," enjoying the quiet and priceless joy of medically uneventful living. By no means the exclusive privilege of the genetically typical, wellness and well-being correlate most strongly with unencumbered access to the major health determinants of adequate money, a clean and safe environment, supportive personal relationships, control over living conditions, etc. Yet people with disabilities are presumed to be unhealthy and overlooked in the establishment of public health standards and programming, having to fight for information, access and services at every turn.

How can we unmask the aesthetic preferences embedded in definitions of health?

School-aged children who are shown pictures of a wide range of "potential friends" and asked to pick the ones with whom they would be most likely to become friends choose children who look like themselves and reject children who look different. Obese children, children with disabilities, children of different racial groups are eliminated quickly, for reasons the children making the selection find difficult to articulate. Regrettably, adult architects and engineers of public policy commonly demonstrate the same inclinations, similarly unconscious and unspoken. The tyranny of designer culture accounts for much of my unease with the CBS and its squeamish reluctance to taint the pretty vistas of our genetically rich future with the nasty business of disability.

How has this group interpreted those pretty vistas? What is our collective assessment of the "public health advantage" of the Canadian Biotechnology Strategy?

A review of the papers presented in this series suggests that contributors share a deep concern that enormous human and economic resources are being directed away from social, economic, cultural and environmental health determinants and used instead to fuel the development of biotechnology and genetic interventions. This point was made explicitly by Madeline Boscoe, Sari Tudiver and Priscilla Settee, it provided a starting point for Ken Bassett, and formed an implicit underpinning for most if not all of the arguments and critiques recorded.

There is also apparent consensus that biotechnology and genetic engineering are fundamentally problematic. The papers collected in the "community" series locate the problem differently – quite naturally, given the impressively diverse range of activist perspectives from which they originate. Fern Brunger and Sue Cox alerted us to ethical issues that may arise for collectives or larger groups when individual members consent to participate in research. Priscilla Settee provided a specific example, identifying the violation of cultural and intellectual property as a colonialist assault upon the identity and spiritual knowing of aboriginal peoples. Patricia Lee warned of possible misuse of DNA biotechnology in forensic contexts, exposing women to state-sanctioned violations of their propriety, privacy, security and confidentiality.

Popular opinion polls – and indeed the official documents of the Canadian Biotechnology Strategy – would suggest that the consensus that we appeared to share is absolutely atypical, perhaps even squarely in opposition to views espoused

by the majority of our friends, neighbours, colleagues and fellow travellers.

This, of course, did not surprise us. But an examination of the thread that linked our various perspectives proved instructive vis-à-vis our efforts to understand and formulate strategies in response to prevailing support for an aggressive investment in biotechnology.

Surely what informs our shared opposition to the Canadian Biotechnology Strategy is a set of common values. I would suggest that these go beyond values about the meaning of health, extending to a shared understanding of justice, and even more profoundly, a set of ideas about what constitutes personhood.

In the paper submitted by Fern Brunger/ Sue Cox, these values are explicitly linked to a feminist understanding of power. They are articulated in the recognition that "genetic testing must be placed firmly in the context of culture in its relation to power. Bioethics, like genetics, is itself culturally (and historically/ politically/ economically) shaped." Similarly, Patricia Lee concludes her paper with reference to "the new loci of power and control" in DNA databanks. Priscilla Settee presents a vivid description of a final act of colonialism against Indigenous peoples. Even Ellen Larsen, whose focus is quite different, introduces the idea of scientists "looked upon as belonging to a priesthood which has access to information stored in Temples". For each of us, the issue at the starting point is one of power in its cultural context.

Concrete suggestions as to where to go from here display a range as broad as the platforms from which the papers were launched. Ellen Larsen proposes a democratization of science – a more fulsome integration of scientific ways of thinking within scholastic contexts and the community at large, rendering science less mysterious, more comprehensible and

accessible to non-scientists, enabling a more informed critique of science as a way of exploring our world and understanding technology.

Ken Bassett proposes the assertion of alternative values in provincial and community settings charged with purchasing social and health services and technology. He suggests that another possible site of similar action is on university and hospital ethical review committees charged with determinations of research validity and conformance with standards of public good.

Fern Brunger and Sue Cox propose that we find the commitment and the resources to engage in genuine community-based research, examining the everyday experiences that shape and are shaped by genetic testing, negotiating standards of collective acceptability and grasping

collective and perhaps foreign value systems.

Finally, I extend a challenge to re-examine even our own attitudes, recognizing that we are a very long way, still, from a collective recognition of disability as an acceptable form of human variation. We are still mostly complicit with the medicalization of disabled women's bodies and the construction of disability as an individual defect or a personal or social tragedy. I urge each of us to attend carefully to the narratives of disabled women who affirm themselves instead as whole and endowed with great strength and beauty. Then perhaps we can arm ourselves for the struggles ahead with a set of values that – to borrow from Nandita Sharma's reference – are radical enough to be worth the fight.

References:

The American Heritage® Dictionary of the English Language. 1992. Third Edition. Houghton Mifflin Company.

Angier, N. 1999. Baby in a Box. *The New York Times Magazine*.

CBS. 1998a. Canadian Biotechnology Strategy Taskforce, CBS Online, *Health Sector Consultation : Health Protection* April 14, available at <http://strategis.ic.gc.ca/SSG/bh00157e.html>

CBS. 1998b. Canadian Biotechnology Strategy Bio-Industries Branch, CBS Online, FactSheet: Key Elements of the Renewed Canadian Biotechnology Strategy, August 6, available at: <http://strategis.ic.gc.ca/SSG/bh00229e.html>

Gray, P. 1999. Cursed by Eugenics. *Time*. 153.

Kumar, S. 2000. Why Science Alone Cannot Satisfy the Soul. *The Globe and Mail*. Toronto.

Oe, K. 1995. Japan, the Ambiguous and Myself -- Nobel Prize Speech, Stockholm, 1994. *Japan, the Ambiguous and Myself -- The Nobel Prize Speech and other Lectures*. Tokyo, Kodansha International: 105 - 128.

Rioux, M. 1996. Reproductive Technology: A Rights Issue. *Entourage* (Summer): 5-7.

Singer, P. and Asch, A. 1999. Ethics, Health Care and Disability, A Debate. Princeton University, October 12. Available at: <http://www.princeton.edu/WebMedia/special/>

Ticoll, M. 1996. The Human Genome Project - A Challenge for the New Millennium. *Entourage* (Summer): 10-12.

Montgomery, Cal, (personal communication). Report on Panel Presentation involving Eva Feder Kittay, American Society of Bioethics and Humanities, Philadelphia, October, 1999.

Communities Constituted through the New Genetics: Actions and Reactions.

Commentary on the Theme of Biotechnology and Community

Margaret Lock

About the Author

Margaret Lock, an anthropologist, is a Professor in the Departments of Social Studies of Medicine and of Anthropology at McGill University. She is a fellow of the Royal Society of Canada, and was awarded the 1997 Prix du Quebec, Leon-Gerin, for the social sciences. She is the author of *East Asian Medicine in Urban Japan: Varieties of Medical Experience* (1980) and *Encounters with Aging: Mythologies of Menopause in Japan and North America* (1993), which won the Wellcome Medal of the Royal Anthropological Institute, the J. I. Staley Prize of the School of American Research, the Eileen Basker Memorial Prize of the American Anthropological Association, The Berkeley Prize, and the Canada-Japan Book Award of the Canada Council. Both books were published by the University of California Press. Lock has co-edited six other books including *Pragmatic Women and Body Politics*, Cambridge University Press, and written over 120 scholarly articles. Her latest book *Twice Dead: Organ Transplants and the Reinvention of Death* is in press.

About the Article

Margaret Lock interrogates received wisdom about technologies in general, and biotechnologies in particular. She provides a critique of the relations between communities and the biotechnology promised by the CBS, and comments on several papers in the collection which take biotechnology and community as their theme. Technologies are neither autonomous nor value neutral, Lock argues. Rather, their constitution and use reflects relations of power, and the complex ways in which they construct the persons and things upon which they act. Genetic biotechnologies, in addition, render the traditional rights of access and informed consent insufficient as arbiters of use, since communities, and not just individuals, are implicated. Finally, Lock notes that, when we talk about 'communities,' "we are dealing with a slippery concept." If individual access and informed consent are insufficient resources for engaging biotechnologies, Lock suggests, adding 'communities' to such processes will not be a panacea, but will necessarily involve debates about which 'communities' are implicated and what 'community' means.

The history of technology, including that of medical technology, is usually told as a narrative of progress, a means to enable us to overcome the limitations that nature places upon us. Dominant arguments, following Heilbroner (1967) and others, are that technology is, in effect, autonomous; that technology itself is value neutral and should be understood as empowering through the production of more freedom and flexibility in the world in which we live.

Emphasis on the rationality of technology and the liberation it brings with it masks at least four things: first that inevitably relations of power are involved in the production and application of all technologies; notably the interests of powerful elites ensure that debate about new technologies does not, without great public outcry, take place in the public sphere; our institutions are designed to be opaque, and protective of those holding the reins. More troubling, is that in contemporary society such elites are located increasingly in the private sector or function in partnerships created between the private sector and universities. Government and universities have less and less say as to what should be invested in and developed and who should have access to the end product once it is placed on the market. An economic imperative has taken hold.

Second, and related to the previous point, while some technologies, in Canada at least, are available to us all, others, notably the new reproductive technologies, and genetic testing and screening do not fall into this category, thus introducing inequities into the system – something which troubled the Royal Commission on New Reproductive Technologies (1993) but about which, as we all know too well, nothing has as yet been done. It is not only the inequities as such that are troubling. Such a system fosters insidious divisions among women to the detriment of everyone except those who are clearly

wealthy. So, questions of access and availability mask more fundamental issues deserving of close attention.

Third, new technologies by their very nature create new entities and populations to be worked upon. As Foucault pointed out, technologies and their associated discourse create the objects on which they operate and are in turn constituted by these same objects. Until BRCA 1 and 2 were isolated, for example, there was no sub-group of women who could be singled out through testing as having the “gene or genes for breast cancer” and who today must face a slew of decisions to which there is no satisfactory resolution, whether the test results are positive or negative. With the availability of genetic testing many people now think of their genes as quasi pathogens and worse yet, as pathogens for which they can be held responsible if passed on to the next generation. Some individuals live their lives as the “pre-symptomatic ill” – having been labeled “at risk” for late onset chronic diseases with a genetic component. In this climate of impending danger, when great value is also placed on control and on creating “normal” populations, pressure mounts daily for people to undergo genetic testing, even when no therapies are available. There is a will to know who we are, genetically speaking. Meanwhile the social and environmental determinants of disease are relegated to the background once again, as they have been in the past decades.

Fourth, half a century ago, in response to medical experimentation and concerns about human rights, the idea of informed consent was adopted and institutionalized over the years, ensuring to a considerable extent the protection of individuals in the face of new biomedical technologies. But protection, and the rights of families and of segments of society in connection with these same technologies, has not thus far been considered necessary, and in any

case individual rights continue to take priority.

The emergence of the powerful combination of population genetics with molecular genetics has upped the ante about the powers of technology and how it can enable us as individuals and as a society. The hype associated with the human genome project and its associated technologies is utopian. We all now have the right, Daniel Koshland (1989) informs us, to a full complement of healthy genes, but it is clear that neither individual informed consent, nor individual desire, or the desire of couples, are adequate to deal with what we are now facing. Each of the papers under discussion makes it clear why.

First, as Ken Bassett points out, we are now clearly in an era of deregulation and less stringent legislation, in large part because funding for these activities has been cut back. Technologies are in effect assumed to cause no harm unless proved otherwise – witness the introduction of GM foods. It takes repeated tragedy before moratoria are instated for interim periods. No standing committees exist that consider the social consequences of what we are doing, suggesting that even today biomedical technologies are thought of as autonomous agents of progress that bring us good. Bassett argues that university and hospital ethical review committees might take on the task of social evaluation. Such committees could indeed spot conflicts of interest, and even encourage communal advocacy, if they could first decide what constitutes a relevant community and who should represent it. But how can the participants in such committees be expected to foresee the larger social consequences, many of which will have effects beyond communities when, for example, genetically engineered foods, patents, xenotransplants, germ-line engineering, and related technologies are involved? Surely we need, in addition to ethical

review committees, national and international bodies with legal clout who can instigate policies that are rigorously enforced? Something like the international court at the Hague perhaps?

Brunger and Cox set out by making the impact of the new genetics on collectivities their prime focus of interest. They are concerned about the non-clinical impact of genetic testing on everyday life and knowledge, something about which we have very little information. They argue, like Bassett, for the inclusion of community representatives in research, and show how the outcomes of research and testing affect not only involved individuals, but families and communities. A heterogeneity of values must be acknowledged, leading to the idea of “negotiating collective acceptability” so that evaluation of the so-called risks and benefits of testing are made communal. This is a forward looking approach, vastly superior to outmoded ideas of informed consent, but in reality large portions of what will be negotiated are things about which no one can predict outcomes, and that in any case, we can do nothing about. One can see how collective acceptability may assist with testing families for Huntingdon’s disease, in that this knowledge can be used to make marriage and reproductive choices, although many people would still not want to know this kind of information. When it comes to late onset diseases with complex and unreliable probability predictions, or worse still, if and when it comes to making decisions about genes erroneously believed to determine behavior, should families and communities be involved? Should we be doing such tests at all? Who should decide what may not go to the table for negotiation at all?

Ellen Larsen is concerned about a dearth of education in connection with genetics because she has been startled by the inability of students to comprehend articles in the media on this subject matter. I am startled about yet other things where the

media is concerned: the relationship of the research community to the media, and the common inability of the media to report with accuracy findings about genetics or predictions of risk. How many times have we heard that 1 in 9 of all women are at risk for getting breast cancer in the next ten years? One of the recommendations made by the committee for Medical, Ethical, Legal, and Social Issues (MELSI), that was part of the now defunct Canadian Genome Analysis and Technology (CGAT) program, was that money be put into the training of science reporters who would then build up close links with research communities. This recommendation should be taken seriously.

The two papers by Patricia Lee and Priscilla Settee take a somewhat different approach to problems raised by the new genetics, namely the collection, storage, and uses to which DNA materials are put. Controls over data banks are almost non-existent in Canada, and this needs to be addressed urgently, but Lee points to a more insidious problem to do with the way in which bodies are “constructed” in connection with DNA analyses. As Ian Hacking (1998) puts it, we are dealing with the problem of how people are “made up” and to what collectivities they are assigned by scientists, lawyers, and government, in this particular case, the way in which victims of violence are re-victimized by characterization in the courts as unstable, bad women. The question of whether the forensic evidence supplied to the court is properly protected is also crucial. If, as Lee suggests, forensic evidence is not in the end used much in trials, then we have to ask two fundamental but related questions: is the very availability of the technology driving what is happening, and should more control be exerted at this point to prohibit its use? Or is there something darker at work: the creation of DNA data banks of marginalized peoples for the testing of hypotheses about stigmatized collectivities? Certainly, as Lee shows so well, the biotechnology has

little value for the health and security of the women in question.

The Human Genome Diversity Project (HGDP) foundered right from its inception, and Priscilla Settee sets out many of its misguided principles in her paper. Responses to the HGDP by indigenous peoples have been mostly of condemnation and with good reason. The project is both unsound scientifically and unethical. Among other things the organizers argue that the project will permit a better understanding of disease in targeted populations. This is not possible because DNA samples are collected in isolation, along with no other data, essential if links are to be made between genotypes, phenotypes, and the expression of disease.

Interest in genetic diversity is hot stuff today, and by raising the issue of who might have rights in, or even make claims to own genetic material, the question is brought to the fore of what exactly is a “community.” While the papers have been grouped together under the heading of “community,” the authors either do not use this concept explicitly or else apply it rather loosely in a variety of ways, suggesting that we are dealing with a slippery concept. The papers group individuals together as collectivities by gender, ethnicity, as First nations, interest groups, risk groups and so on, but we do not know if these units should indeed be conceptualized as communities; nor what being located in a community might mean for involved individuals. Apart from anything else, individual interests usually cut across several “communities.” It is clear that authors are concerned that the particular interests and needs of named collectivities are not being attended to with respect to the several technologies under discussion, most of them related to genetic modifications of one kind and another. It is argued, and I agree, that collectivities should be brought systematically into future discussions and constituted as

actors in decision making, and several of the papers outline ways in which this might be brought about. Parenthetically, several papers argue that limiting attention to individual rights and autonomy is no longer sufficient when it comes to the new genetics. Discourse about genes inevitably presents a paradox: it reinforces associations among people as families and as genealogies having a shared biological heritage, but it also divides people, for individual genomes are unique. Even so, the effects of genes on health and knowledge about genes cannot be thought of as a private matter.

Can body parts be owned? Whether it be by individuals, families, communities, nations, or humankind as a whole? Is it appropriate for individuals or organizations to make such claims? Do we need to find some language other than property law in order to deal with these new dilemmas? In theory, with the abolition of the slave trade we abolished the right to “own” persons, perhaps now is the time to make a move so that parts of the body are made inalienable. At the very least such a move must be debated. At present we live with inconsistencies. It appears that massive public opposition exists to the sale of organs for transplants, on the other hand eggs, sperm, and blood – repositories of genetic material for future generations – are sold daily with few controls in place. In effect we are prepared to make commodities of the stuff that produces children, but not of kidneys that, if procured in humane and sterile surroundings, have the potential to prolong the lives of recipients, sometimes for many years, as productive members of society.

In sum, systematization of the management and monitoring of the collection and commodification of human cells, tissues and organs is extremely urgent and surely is something that cannot be worked out other than by internationally recognized legally binding agreements.

In connection with the new genetics one of the biggest issues to be confronted is that of “individual interest” or what is perceived to be in the interest of individuals, because knowledge about the genes of individuals and their manipulation can place these individuals in potential conflict with the interests of the larger groupings of people of which they are a part – families, communities, societies. If genetic material is understood as belonging entirely to individuals, and if so-called genetic diseases are located entirely in the bodies of individuals, then the social and cultural issues associated with these entities will inevitably be ignored or at the very least set to one side. Depoliticization is the result.

Disputes about disease causation being the result of proximate or final causes – due to external causes or confined to causes internal to the body – are hundreds of years old, and such disputes form the basis for current arguments between health prevention models and those of clinical medicine and the associated basic sciences. Even though we talk today about multifactorial diseases little middle ground has been created between the reductionistic arguments of so many molecular geneticists and those researchers who use the tools of epidemiology and make predictions about human populations. A great deal of talking at cross-purposes persists, permitting obfuscations about the goals and applications of the new genetics to go unexamined.

What is particularly dangerous this time round is that some proponents of the new genetics are trying not simply to institutionalize gene therapy but are moving towards enhancement of the human genome. This will affect not only individuals, but communities everywhere and future generations, and can only be described as neoeugenics – a blatantly political endeavor disguised as scientific benevolence. Efforts at normalization of

the health and well being of individuals through techniques such as preimplantation genetic diagnosis followed by selective disposal of unwanted fetuses are already being put into practice, and will affect the composition and condition of future populations. Rather than limiting our responses as feminists to issues of informed consent and equal access to new genetic technologies, we must at the same

time, I think, vigorously persist in arguments about the social determinants of ill health, including diseases where genetic factors are implicated. At the same time discussion of the social consequences of allowing individual desire and informed consent to shape policy making in connection with the new genetics is urgently called for.

References

Canada. Royal Commission on New Reproductive Technologies. 1993. *Proceed with Care: Final Report of the Royal Commission on New Reproductive Technologies*. Ottawa.

Hacking, Ian. 1998. *The Taming of Chance*. Cambridge University Press.

Heilbroner, Robert L. 1967. Do Machines Make History? *Technology and Cultures* 8:335-345.

Koshland, Daniel. 1989. Sequences and Consequences of the Human Genome. *Science* 146:189.