
Reflections: The Challenge of Biotechnology and Public Policy

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Rapid developments in the area of biotechnology within the next decade are likely to have a significant impact on Canadian society. This article outlines the practical and ethical issues that will need to be addressed in the face of scientific advances, and contemplates the development of an appropriate policy framework in this regard. Surveying the approaches to policy development taken thus far, the author notes the underlying need for greater transparency and public participation. Rational and effective policies will only result from additional basic scientific data being made available to a more informed and engaged Canadian public.

Les développements dans le domaine de la biotechnologie qui surviendront au cours de la prochaine décennie auront vraisemblablement un impact important sur la société canadienne. Le présent article expose les questions pratiques et éthiques qui seront soulevées par ce progrès scientifique, et envisage le développement, pour y répondre, d'un cadre de politique approprié. En passant en revue les différents modèles d'élaboration de politiques en la matière, l'auteure souligne la nécessité d'une plus grande ouverture ainsi que de la participation du public. Des politiques rationnelles et efficaces ne pourront naître que d'une diffusion plus large de l'information scientifique élémentaire à un public canadien plus informé et engagé.

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Introduction

The next decade will be characterized by three major developments: the proliferation of genetic choice, the emergence of complex systems pertaining to genetics,¹ and an increasing public concern and interest in the definition of what is "human". While it appears that future genetic choices will largely be private, prospective, and preventive, their cumulative effect will not be without public implications. Furthermore, rapid progress in the genomic life sciences (animal, plant, and human) and in informatics are contributing to the emergence of highly dynamic yet complex systems of information gathering, storage and management that are difficult to characterize and control. These developments have raised a certain sense of public unease with the deciphering of the genomes of all living organisms (animal, plant, and human) and a perceived transgression of our humanness, if not humanity, in this new technocracy.

To understand and analyze the need for a public policy framework (which is as epigenetic as the subject matter and the social trends the policy would seek to address) requires a preliminary understanding of how the three developments (*i.e.*, choice, complexity, and concepts of humanness) will emerge. Developments in both genetics (part I) and genomics (part II) have attracted a tremendous amount of media attention. Less immediately evident but equally important are the effects on future generations (part III).

I. Human Genetics

Current sequencing and mapping efforts in the human genome project will likely be completed by the year 2003.² Creating much hope in the power of sophisticated diagnostic and prognostic tools and of informatic capabilities within medicine, the new "post-mapping" genetic medicine promises: 1) genetic screening of asymptomatic populations for carrier status and prevention of the onset of genetic conditions; 2) knowledge of susceptibility status for specific and individualized drug targeting; and 3) genetic testing for individual treatment, reproductive, and lifestyle choices. Ultimately, it will be possible to obtain genetic information prior to embryo implantation, or during infancy, adolescence, and adulthood. However, until specific genetic markers are found for a given condition, most genetic information in the post-mapping era will still come from the contribution of familial pedigrees. This requires the reconstruction of the biological "genetic" family, partially abandoned today in favour of consensual, social family forms.³

¹ R.C. Strohmman, "Five Stages of the Human Genome Project" (1999) 17 *Nature Biotech.* 112.

² See F. Collins, "Shattuck Lecture—Medical and Societal Consequences of the Human Genome Project" (1999) 341 *New Engl. J. Med.* 28 at 28.

³ See B.M. Knoppers, "Towards a Reconstructing of the 'Genetic Family': New Principles?" (1998) 9 *Int'l Dig. Health Leg.* 241 at 242.

In short, the exercise of personal genetic choices, currently based largely on risk estimates, will only become more certain and thus personally significant as basic genetic epidemiological research advances.⁴ Paradoxically, there are often obstacles set up to such population data research due to fear of possible misuse or misunderstanding of this enterprise. While perceived to be protective of personal privacy and intimacy, these obstacles in fact undermine transparency and public oversight in that they drive informatics and genetic research into the private sector. While the public has accepted DNA data banking as useful for criminal surveillance of morally reprehensible activities, no such acceptance as yet exists for the creation and promotion of population data banking (be it of genetic samples or of genetic information).⁵ It is precisely the lack of publicly available, basic scientific data at the level of populations that will exacerbate current discriminatory attitudes towards genetic research.

Indeed, the use of inaccurate and thus unscientific information will have several untoward effects. First, workplace and insurance screening based on actuarial data will be inaccurate. The lack of large population data bases will result in an inability to prove such inaccuracies, thereby inadvertently fostering illegitimate uses of the existing data. Second, any decision to integrate genetic information into government programs for public health, planning, promotion and prevention purposes will either be thwarted for fear of negative public reaction, or (as said before) will be unscientific and thus unethical. Yet, these population database systems could, if promoted and used in a transparent way, not only be subject to public surveillance but also contain the very checks and balances needed to conform to modern privacy goals (*i.e.*, legitimacy, authentication, transparency, finality, etc.). Thus, there is a need to prepare new ethical frameworks for genetic epidemiology that, while inspired by individualistic ethics and sensitive to communitarian ethics (the concerns and cultural concepts of "collectivities"), address the urgent need for an appropriate methodology specific to population health.

II. Genomics

Genomics goes well beyond human genetics in that it concerns all living organisms. New life-sciences companies manipulate "life" for therapeutical and environmental properties. Their work includes basic research, the clinical and industrial applications of DNA-based technologies, the culture and reproduction of plants and animals, and the study of pharmaceutical properties. Such biotic endeavours place all living organisms into research and permit the study of homologies and differences between the species. Ultimately, transgenic "pharming" will not only produce plants and animals that carry vaccines and have therapeutic properties, but will also enable the development of tissues or even organs transferable to humans (xenotransplants).

⁴ See *e.g.* N.J. Schork, L.R. Cardon & X. Ku, "The Future of Genetic Epidemiology" (1998) 14 *Trends in Genet.* 266.

⁵ See *e.g.* A.J. Wilcox *et al.*, "Genetic Determinism and the Overprotection of Human Subjects" (1999) 21 *Nature Genet.* 362.

These life-science industries suggest future "biotic" possibilities of increased productivity, resistance to disease and other adverse events, and the development of nutraceuticals. Concerns for the preservation of species integrity and biodiversity, however, have placed these life sciences at the forefront of public debate. Classical approaches to the safeguarding of ecosystems may no longer be sufficient. Furthermore, as humans co-evolve and co-adapt with the plant and animal species, the natural environment itself presents new viruses for which there is no treatment available (*e.g.*, BSE in animals; the new variant of Creutzfeld-Jakob in humans).⁶

Together, genetics and genomics will transform life in its pure biological form and in its lived human forms. Will humans, then, be just another form of living matter in this new biotic universe?

III. The "Humanity" of Future Generations

The acquisition of this knowledge and its possible (ab)uses will affect future generations as well. Personal and collective ethics will need to reflect an understanding of the transgenerational effects and the accompanying new and different obligations. Such obligations may include, for example, deliberate interference in the germ line in order to avoid the transmission of a given disease to the next generation. The globalization of science, economies, and information all elevate transgenerational concerns beyond the domestic scale to an international one. Similarly, bioethics must move from the realm of individual concern to that of collective concern, and must ultimately be considered at a truly universal level.⁷ A complex systems approach that recognizes the dynamic and epigenetic nature of a new BIOethics at the very level of the cell in all living organisms needs to be encouraged.

The last half of this century has seen the development of bioethics as a forum for questioning personal values and the relationship of humans to each other and to the environment, particularly in relation to quality-of-life issues. In the face of new biotechnological and informatic possibilities, bioethical debates continue to stress respect for individual autonomy and privacy. In the medical setting, the principles against causing harm and favouring the maximization of benefit over risk have predominated decision-making. Only in the last few years has attention turned to questions of distributive justice, equity, and, more recently, relational or communitarian ethics (but not yet to transgenerational ethics). Likewise, questions regarding human rights have moved beyond individual claims (civil or economic rights) to encompass the concerns of groups, populations, and communities. Confronted with the new genomic revolu-

⁶ See Bayer Advisory Council on Bioethics, "Creutzfeld-Jakob Disease, Blood and Blood Products: A Bioethics Framework" (Working Paper, 13 October 1998) online: Bayer Advisory Council on Bioethics <<http://www.bayer-bioethics.org/bioFrames.html>> (date accessed: 8 February 2000).

⁷ See *e.g.* *Universal Declaration on the Human Genome and Human Rights*, UNESCO Gen. Conf., 29th Sess. (11 November 1997), online: United Nations Educational, Scientific and Cultural Organization <<http://unesdoc.unesco.org/images/0010/001096/109687eb.pdf>> (date accessed: 22 February 2000).

tion and the personal and collective choices it presents, what shall be the direction of public policy?

IV. Policy Framework^{*}

Over the last two decades, whether in relation to organ transplants, reproductive technologies, or human genetics, four approaches to policy development have been emerging. The first is a constitutional, human rights approach which through its broad ambit serves to circumscribe the applications of new technologies that otherwise might encourage discriminatory or stigmatizing practices. In contrast, a "statutory-specific" approach crafts laws issue by issue to address the implications of scientific advances through prohibitions, constraints, or moratoria. A third approach is administrative and regulatory in nature, concentrating on quality assurance, standardization, and monitoring either through governmental or professional bodies. Finally, a liberal, market-driven approach theorizes that proper, professional practices will ultimately "win out" and, in any event, all new technologies will be subject to the restraining impact of litigation.

There are advantages and disadvantages to each of the four approaches. The constitutional approach relies on existing human rights instruments to interpret the applications of new technologies. The policy-oriented decisions of high-ranking courts are strengthened by the intervenor status often afforded to public interest groups, and so serve to express public values, clarify issues, and set far-reaching precedents. However, the process of reaching these decisions is both costly and lengthy; furthermore, it is *ad hoc* in nature and achieved after a given technology has already been integrated into research and health-care programs. Lastly, if a court is timorous and refuses to go beyond the basic facts or issues, this approach is of limited usefulness.

A statutory-specific method has the advantage of bringing immediate certainty, clarification, and precision, and is also an expression of political consensus. The danger remains, however, that highly focused statutes will be of limited scope and impact beyond the immediate issues, and that they will close public debate thereby encouraging complacency. Finally, if such statutes are adopted in rapid succession, there is a risk of enacting contradictory positions and definitions.

A regulatory-standardization approach, however, allows for the gradual development of professional codes of conduct as well as licensing, monitoring, and quality assurance standards (where necessary) through regulations made pursuant to existing broad health legislation. Professionally and procedurally oriented, it ensures ready acceptance of the gradually imposed changes by those affected, resulting in greater effectiveness and integration into practice. This incremental approach however has its own drawbacks: it "administers" technologies and fails to explicitly enunciate the value-choices underlying their acceptance, or to explain why certain constraints are

^{*} This section is largely abstracted from: B.M. Knoppers, M. Hirtle & K.C. Glass, "Commercialization of Genetic Research and Public Policy" (1999) 286 *Science* 2277.

placed on access or use of certain forms of research in the codes or standards themselves.

Lastly, the liberal, market-driven approach has been seen as the one which is most flexible and facilitative of scientific research. Technological development depends on investment, and support is either public or private. Investment is subject, however, to lobbying by narrow interest groups, including those who stand to gain financially from public investment (and/or a lack of public control), and those who, for a variety of reasons, see certain technologies as potentially harmful or in conflict with their particular values. The inability of these groups to achieve compromise in the broader public arena inhibits the consensus necessary for successful government-initiated oversight, thus leaving development of any given technology to the vagaries of the market, the chilling effect of litigation, and consumer choice.

The choice between these approaches, or a combination thereof, depends not only on the degree of public trust in the credibility and effectiveness of such research, but on the state of the debate.

Conclusion

Currently, the state of the debate in Canada is that there is *no* debate, at least no public debate. While not usurping the legitimate role of politicians and governmental policymakers in the framing of policy and in leading the decisional process, it must be asserted that the current lack of visibility and transparency on the contentious fundamental issues constitutes an affront to Canadian citizens. The collective moral failure of Canadian society to address these issues in a structured and rational process is the ultimate proof of tunnel vision.

The failure to actively inform and consult the public cannot be remedied simply by providing more information. Scientists themselves, while responsible for the production of the knowledge, cannot be solely accountable for the (ab)uses of ensuing technologies. Although increasingly sensitive to the social implications of their work, scientists must nevertheless be free to actively and creatively pursue knowledge. Furthermore, greater public trust in the outcomes and direction of scientific research and in the regulatory system is severely hampered by the "dread factor"—that is, a perceived lack of public control and of ongoing oversight of the consequences of such scientific freedom and innovation. Public perception of risk, even when not objectively substantiated, should not be ignored. The intermingling of facts and values can only be legitimately recognized and given direction by putting into place procedural mechanisms (such as regional fora, media debates, websites, and public referenda, etc.) that are both participatory and consultative. It has been argued that the failure of Bill C-47 on reproductive and genetic technologies was due to its highly prohibitive

and criminal law approach.⁹ This is but one example of why a more consultative approach to policy development in relation to such issues needs to be adopted.

The personal and political costs of engaging in an ongoing open dialogue with the nation will be high.¹⁰ There is no doubt that much courage and patience will be necessary, especially in the early stages when the public will be adjusting to a more democratic process and strident advocates will likely polarize the initial debate. Abdicating the responsibility for managing this debate to the scientists, however, or simply legislating and attempting to resolve misunderstandings *post hoc*, will only further undermine public trust in the political process and erode credibility of the nation's leaders and governments.

Public policy should be, as the term implies, both *public*- and *policy*-oriented. If it is accepted that the great majority of citizens are morally responsible beings with an interest in their society, the prospect of "exposing" scientific advances to that same public should not be frightening. After the first round of polemic and phobia subsides, there will be clarification of the facts at hand. After such clarification will come a more sensible and balanced debate respecting diversity and difference, especially in a multicultural nation such as Canada. After a more public and transparent airing of the facts and issues, and the provision of information by neutral government sources and the media, two options will remain: the Swiss model of public *referenda* (free from party politics) when public opinion considers it necessary, or a healthy parliamentary debate culminating in a free vote. Biotechnology and BIOethics cross party lines and provincial and national boundaries, to say nothing of genomes and generations. The challenge is to construct a framework and a process that is equally dynamic.

⁹ See T.M. Caulfield, M. Hirtle & S. Le Bris, "Regulating NRGTS: Is Criminalization the Solution for Canada?" (1997) 18 Health L. Can. 3.

¹⁰ In September 1999, the Federal Government created the Canadian Biotechnology Advisory Commission ("CBAC"). Its mandate is to advise Ministers on the full range of policy issues related to the development and applications of biotechnology in Canada. It will also address ways to enhance public awareness and facilitate public debate.