REGULATING THE GENETIC REVOLUTION: WHAT IS AND ISN’T HAPPENING IN CANADA

Timothy CAULFIELD

SUMARIO: I. Regulatory environment. II. Regulatory challenges. III. Existing regulations. IV. Genetic research. V. Conclusion.

In Canada, as in many countries throughout the world, the recent rapid advances occurring in the field of genetics have created a tremendous amount of public interest. Rarely a day goes by without a genetics story appearing in the popular press. This almost constant media coverage has been accompanied by an intensifying call for more regulatory oversight of genetics and new reproductive technologies. However, despite over a decade of almost policy discussions and a significant amount of public debate, Canada has few laws that have been specifically crafted to meet the unique social, legal and ethical challenges associated with the “genetic revolution”.

In this paper, I will briefly review the regulatory environment in Canada, a number of the existing relevant laws, policies and regulations and make some tentative predictions for the future. This piece is not meant to be a comprehensive overview of the relevant law and regulations. There are numerous areas of Canadian law which are clearly important to the fields of genetics and reproductive technology but will not be discussed in this paper, including patent law, informed consent law, insurance law and the emerging provincial privacy laws. The goal of this short piece is merely to give the reader a sense of how Canada has, and has not, regulated in this dynamic area.

1 Health Law Institute, University of Alberta, Canada.
I. REGULATORY ENVIRONMENT

In the context of genetic technologies, Canada could be characterized as a country that has done a lot of talking about regulatory policy but very little actual regulating. For example, in the early nineties, the multi-million dollar Royal Commission on New Reproductive Technologies released a massive report that including a multitude of recommendations regarding the regulation of reproductive genetics. Since then, numerous other working groups and expert advisory committees have been formed - such as the Expert Working Group on Genetic Testing of Late Onset Disease, and, most recently, the Canadian Biotechnology Advisory Committee. There hasn’t, however, been much actual legislative activity. As we will see below, in May of this year, the federal government released “draft” legislation directed at regulating reproductive technologies. However, to date, no laws have been proclaimed.

II. REGULATORY CHALLENGES

To be fair to Canadian regulators, it is worth noting that they face a number of unique regulatory challenges. First, Canada is a country sandwiched between two strong cultural ideals: a European deference for the interests of community and an American reverence for individualism and autonomy. This tension can make it difficult for policy makers to craft regulations that bridge both socio-political approaches.

Second, our proximity to the US can also be problematic. For instance, Canadian companies and citizens have easy access to the US market. This can greatly water down the practical impact of Canadian regulations. Moreover, because the US is viewed as an importance source of venture capital, essential for the growth of the biotechnology industry, Canadian regulators may hesitate to create policies that are viewed as unfriendly
to industry. Indeed, government policy making entities and, even, regulatory agencies, such as Canada’s Therapeutic Products Programme, seem highly sensitive to the impact of industry pressures in this context.  

Third, because of Canada’s constitutional division of powers, there is some uncertainty about which government has legal authority to regulate in the area of genetics and biotechnology. Though there seems to be a desire to have federal oversight in this area, the topic of “health” generally falls under provincial jurisdiction. The federal government does have the power to regulate matters of national concern and the area of criminal law. The latter power has been used, somewhat controversially, as a justification for regulating in the area of reproductive and genetic technologies.

Finally, there remains a lack of consensus about the “genetic issues” that should be the subject of regulatory policy. In fact, there isn’t even agreement about many of the more controversial technologies. For example, a recent survey found that 24.3% of Canadian surveyed thought it would be acceptable to use “genetic engineering” to improve a child’s esthetic or physical features and 18% thought it would be acceptable to use genetic technology to determine the sex of a child. In another survey it was found that 62% of Canadians support the cloning of human embryos to produce organs. Interestingly, despite the relatively high level

---

5 For example, a recent amendment to Canada’s Food and Drug Regulations governing the approval process for drugs used in clinical trials was done, in part, to avoid “discouraging the development of human drugs in Canada”. See, Canada Gazette, part 1, Regulations Amending the Food and Drug Regulations (1024-Clinical Trials), January 22, 2000 at 227. It is worth noting that this issue raises some interesting concerns about promoter/regulator conflicts of interest. That is, should the government entity that is charged with protecting the public be concerned about economic development?


of comfort that the public seems to have with therapeutic embryo cloning, it may become a criminally prohibited activity in the near future.\textsuperscript{11}

III. EXISTING REGULATIONS

Though Canada has yet to enact any broadly applicable “genetic” laws or policies, there are a number of existing regulations that are relevant to this area. Below is a review of some of the regulatory environments relevant to genetic testing, reproductive technologies and genetic research.

1. Genetic testing

At the current time, neither the federal government nor any of the provinces have formal regulations which are specifically designed to deal with the issues associated with genetic testing technologies.\textsuperscript{12} For instance, unlike many US and European jurisdictions, no Canadian province has an “anti-genetic discrimination” law,\textsuperscript{13} though the concern about the impact of predisposition testing on insurability and employment has been noted by a variety of commentators.\textsuperscript{14} In fact, individuals who are referred for testing often receive a letter warning of the possible adverse implications of genetic testing on insurability.\textsuperscript{15} Nevertheless, as no juris-
diction has taken even preliminary steps to enact anti-discrimination regulations, it seems unlikely that we will see legislation in this area any time soon.

Of course, there are regulatory frameworks that are relevant to the provision of genetic testing services. The federal government, through Health Canada, can and does oversee the development and dissemination of genetic test kits (e.g., the test kit for cystic fibrosis). However, as in the US, \textsuperscript{16}, \textit{feb. 2, 2000.} the majority of genetic tests are provided as in-house laboratory services or “home brews.” As such, the federal government does not currently have systems established to monitor the validity, quality or marketing of the emerging technologies.

The laboratories which provide testing services also receive a degree of oversight through, for example, an accreditation process provided by provincial College of Physicians and Surgeons. \textsuperscript{17} The goal of these provincial schemes, however, is merely to ensure sufficient staff training and the quality of laboratory techniques rather than evaluate a specific test’s validity or use. \textsuperscript{18} It has been noted that a more comprehensive regulatory system is required in order to protect, and maintain the confidence of, the public. \textsuperscript{19}
Malpractice law is another regulatory force that is relevant in this context. In fact, many have predicted that the anticipated growth in genetic testing technologies will result in new “genetic malpractice” law suits. Specifically, it has been suggested that we may soon witness a dramatic rise in the number of wrongful birth/wrongful life law suits. In general, a wrongful life or wrongful birth lawsuit is brought against a physician as a result of the birth of a child with a disability. The allegation in such a case is that but for the negligence of the physician the child would not have been born. Though wrongful life cases remain tremendously controversial, there seems little doubt that wrongful birth law suits can succeed in Canada.

2. Reproductive genetics

Because of the high degree of media attention recently given to stories about human cloning and stem cell research involving embryos and fetal tissue, the issue of federal regulation of reproductive genetics has been a tremendously hot topic in recent months. Though there are currently no Canadian laws governing human cloning, germ line therapy, and the creation of and research on human embryos, the federal government recently released a “Proposal for Legislation Governing Assisted Human Reproduction”. In the proposed law, which is currently being debated, a number of activities are criminally prohibited, including human clo-


21 Wrongful life actions have always been controversial. The very nature of the action seems intuitively wrong. This is because, at some level, the plaintiff must claim that non-existence is more desirable than a particular state of disability. In Canada, a number of recent cases have explicitly rejected wrongful life actions Arndt v. Smith, 1997, 148 DLR (4th) 48 (SCC); Lacroix (Litigation guardian of) v. Dominique, 1999, M. J. num. 397 (Man. Q. B.); Jones v. Rostvif, 1999, BCJ, num. 647 (BCSC).


23 It is somewhat unusual for the government to release a “proposed law” instead of a draft Bill. Obviously, the government feels it would benefit from more public commentary on the issue.
The proposed legislation will undoubtedly generate a substantial amount of commentary, both for and against. Though most commentators believe that some form of regulation is badly needed, others, myself included, have concerns about the use of criminal law in this area. Regardless, the government has committed to enacting some form of legislation in the first half of 2002.

There has also been some regulatory activity in the area of stem cell research. In March 2001, the Canadian Institutes of Health Research, the primary public funding agency for health care research, released draft guidelines for stem cell research. The draft guidelines support the public funding of stem cell research on spare embryos and fetal tissue, but suggest that, at this time, the creation of embryos for research and embryo cloning cannot be justified.

IV. GENETIC RESEARCH

As with many jurisdictions, the issue of research on human genetic material has been the subject of a good deal of controversy - be it clinical research involving individual patients or population research involving the participation of large communities. To some degree, genetic research in Canada is governed by the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, a document which governs all federally funded research involving human subjects. The Tri-Council Policy has a specific section devoted to genetic research. There are a number of provisions worth noting. For example, the Policy

---

24 For example, section 3 reads: “No person shall knowingly create or participate in the creation of a human clone or transplant or participate in the transplantation of a human clone into a human being”.

25 For example, I have been critical of the rationale used to justify the criminal prohibition of cloning. See T. Caulfield, “Commentary: Cloning and Genetic Determinism: A Call for Consistency”, 2001, Nature Biotechnology (accepted for publication).

26 Canadian Institutes of Health Research, Human Stem Cell Research: Opportunities for Health and Ethical Perspectives, Ottawa, 2001.


mandates that subjects involved in genetic research should be provided, as part of the informed consent process, with specific information about the protocol - including information about the commercialization of the research. Section 8.7 reads as follows:

At the outset of a research project, the researcher shall discuss with the REB and the research subject the possibility and/or probability that the genetic material and the information derived from its use may have potential commercial uses.29

Another interesting guideline in the Tri-Council Policy Statement recommends that families participate in the consent process. Section 8.2 states:

Because genetic research involves the family and/or the community... a potential tension exists between the individuals in the study and the families who are thereby implicated. Therefore, free and informed consent shall also involve those social structures, as far as is practical and possible.

Because Canadian consent law - as manifested in the common law - has yet to embrace the idea of “family consent,” this provision remains somewhat controversial. Canadian consent law is built on the ethical principle of individual autonomy and has little room for processes that mandate the participation of third parties. So while the notion of “group consent” is gaining a degree of acceptance in the genetics literature,30 it is an area where Canadian law and ethics policy diverge.

V. CONCLUSION

As noted above, the goal of this paper is merely to provide the reader with a few examples of Canada’s “genetic regulatory policy.” There are, of course, many other relevant laws and policies—such as the emerging provincial health information laws that govern the use and access to health data. Moreover, despite over a decade of legislative inaction, it

29 Ibidem, at 8.8.
30 R. Chadwick and K. Berg, “Solidarity and Equity: New Ethical Frameworks for Genetic Databases”, 2001, 2 Nature Reviews Genetics 318 at 318: “It has become clear that some principles of biomedical ethics, such as individual informed consent, ...might not be ideally equipped to deal with the issues that arise in large-scale population genetic research”.

DR © 2002. Instituto de Investigaciones Jurídicas - Universidad Nacional Autónoma de México
seems likely that we will see new genetic policies and regulations in the near future. The Canadian Biotechnology Advisory Committee is poised to release major reports on the patenting of human genetic material and higher life forms. The Canadian Institutes of Health Research will likely remain involved in policy development in this area, as exemplified by the recent release of the stem cell policy. And, perhaps most important, the federal government is poised to legislate in the area of reproductive genetics.