MCGILL HEALTH LAW PUBLICATION / PUBLICATION EN DROIT DE LA SANTÉ DE MCGILL

MHLP PDSM

Montreal 2007 Montréal

EDITORS' NOTE

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We are delighted to present the inaugural issue of the McGill Health Law Publication (MHLP).

The term "health law" is highly charged. For us, it refers to the legal challenges presented by an increasingly intricate interweaving of health, technology, and medical research as it is brought to bear on public policy and social concerns. Founded over two years ago, the Publication has sought to turn a critical lens on the dialogue between governmental agencies and the legal and medical professions. Our contributors—an eclectic group of scholars in law, medicine and allied health fields, lawyers, policy analysts, and judges—have been encouraged to venture beyond purely regulatory or legalistic analysis.

Eschewing a designated theme, we have assembled an intentionally diverse anthology of peer-reviewed articles on a broad range of contemporary issues, including commercialization of biomedical research, prenatal care, stem cell research, animal-human combinations, the public/private health care debate, and research ethics. Bookends are provided by Dean Nicholas Kasirer of the McGill Faculty of Law and eminent health law jurist Mr. Justice Jean-Louis Baudouin.

We wish to express our profound gratitude to each and every supportive member of the McGill community, with special thanks to the MHLP team, our Advisory Board, and our Faculty Advisor, Professor Angela Campbell. As the need for efficient and just health care policy grows ever more acute, we hope that this volume will offer new perspectives on constructive solutions to emerging legal quandaries.

À votre santé!

[*] Co-Editor-in-Chief.

FOREWORD / AVANT-PROPOS

Nicholas Kasirer[*]

The advent of a scholarly journal, particularly in a context where public funding for higher education and research is so severely challenged, is an occasion to celebrate. The travails associated with developing a mission statement, soliciting articles and mounting a first issue are often enough to contain the most well-meaning enthusiasms. The Faculty could not be prouder of the students who have conceived and brought to fruition this important new institution in the intellectual life of McGill University. But two further reasons give special meaning to the celebrations connected to the appearance of this first McGill Health Law Publication. First, it is a student-run journal, and as such allies itself with a powerful and vigorous tradition at McGill and in legal letters generally. Second, the journal fixes on an emerging body of ideas—health law—and gives it, as a structure of legal knowledge, new visibility and new substantive shape. This inaugural issue of the McGill Health Law Publication is thus important as an achievement for the editors and authors here, but also as part of broader narratives relating to the history of legal literature, on the one hand, and the sociology of legal ideas on the other.

La création d'une nouvelle revue juridique est certes un événement dans l'évolution de la documentation juridique vue comme objet d'étude[1]. Ici la forme est plus que garante du fond — outre le soin qu'apporte le comité de rédaction à la confection de cette revue, le fait de la placer dans un environnement électronique aura des avantages quant à son accessibilité et sa rentabilité[2]. Ceci permettra à la Publication en droit de la santé de McGill d'intégrer, avec une facilité relative, une banque de données en droit de la santé qui offre une contribution originale à la communauté des chercheurs. On note aussi que la PDSM s'inscrit dans une tradition canadienne de bijuridisme et de bilinguisme qui est particulièrement bien établie à la Faculté de droit. Mais c'est sans doute le fait que la PDSM est une entreprise étudiante que l'on doit retenir comme son trait marquant dans un paysage disciplinaire où les revues gérées par des étudiants jouent un rôle décisif[3]. Tout comme la Revue de droit de McGill fondée il y a plus que cinquante ans, ainsi que la Revue internationale de droit et politique du développement durable lancée à McGill il y a 24 mois, la caution intellectuelle de la PDSM provient non seulement de son comité de lecture indépendant, mais d'abord de l'énergie et du dévouement des étudiants de la Faculté de droit. Tout comme les Jacques-Yvan Morin, Fred Kaufman, James Robb, Derek Guthrie et Melvin Rothman qui, lors des premiers balbutiements de la Revue de droit de McGill, avaient jeté les bases d'une institution qui a marqué le droit d'ici, dix-neuf étudiants actuellement inscrits à la Faculté ont investi de longues heures dans la préparation du premier numéro de la PDSM. Ils se donnent ainsi une expérience de vie intellectuelle qui leur sera précieuse, quelle que soit la longévité de cette revue qui se veut une « anthologie » et, par précaution peut-être, adopte le nom moins engageant de « publication » pour l'instant. Grand expert en droit de la santé, M. le juge Jean-Louis Baudouin, B.C.L. 1958 — lui-même un ancien rédacteur de la Revue de droit de McGill — leur offre un parrainage en signant la postface de ce premier numéro, un geste hautement symbolique et apprécié de continuité. On notera, comme signe de fraternité entre la Revue de droit de McGill et la PDSM, qu'une ancienne rédactrice en chef du volume 51 de la Revue, Kristin Ali, et une ancienne membre du comité de rédaction du volume 24, la professeure Bartha Knoppers, LL.B. 1978, B.C.L. 1981, figurent parmi les premiers auteurs de la PDSM.

But if the form of the McGill Health Law Publication is a matter deserving of the attention, it is the substance that will win it a place on the law library's virtual shelf. By fixing on health law as their focus,

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[1] Voir André Dunes, *La documentation juridique*, Paris, Dalloz, 1977 et, pour ses indications méthodologiques pertinentes au Québec, Sylvio Normand, « L'histoire de l'imprimé juridique : un champ de recherche inexploré » (1993) 38 R.D. McGill 130.

[2] Voir, pour une évaluation de la façon dont le support électronique désarçonne la doctrine présentée sous forme de revue, Bernand Hibbits, « Last Writes? Re-Assessing the Law Review in the Age of Cyberspace » (1996) 71 N.Y.U. L. Rev. 615, reproduite à <http://www.law.pitt.edu /hibbitts/lw_p1.htm> (consultée le 31 mars 2007).

[3] Voir notamment « Special Issue : Law Review Conference » (1995) 47 Stanford L. Rev. 1147 dans lequel plusieurs textes évoquent l'importance, pour le droit américain notamment, de la « student-edited law review ».

the editors have contributed to the consolidation of this field as a free-standing category of legal ideas. Health presents a transversal theme for law, as the articles that make up this first number make plain, in that it draws on areas of scholarship and teaching that range from the law of persons and obligations in private law to the complexities of administrative and constitutional law in public law. This broad erudition required for a scholarly journal in health law is to be found in the student body at McGill, especially as seconded by the varied research interests of my colleagues Angela Campbell, Pierre Deschamps, Derek Jones, Lara Khoury, Marie-Claude Prémont, and Margaret Somerville who compose the Faculty Advisory Board. At McGill and beyond, there can be little doubt that health law is an emerging field of interest and concern for society and its lawyers, but it is also taking shape as an organizing category of legal ideas.[4] The appearance of a first number of the MHLP is thus also part of a phenomenon of reconfiguring structures of knowledge for law — studied under the sometimes daunting tag of "legal epistemology" — whereby the ways of knowing law are themselves recognized as influential on how law may be effective in regulating human behaviour.[5] It bears mentioning that this scholarly publication is self-consciously multidisciplinary, as the mission statement of the MHLP underscores. It is launched at a moment when this university and many others have designated "health" as a sector that doesn't just belong to the doctors, just as "law" is one that the jurists have to share with colleagues in other disciplines. In this sense, McGill students may be offering a further understanding of the locally famous "trans-systemic" ideal which, in addition to evoking the McGill project of multiple legal traditions as relevant to teaching and research in law, should also remind us that multiple disciplines are engaged in pursuits that the lawyers once thought they had to themselves.[6]

Tous mes collègues de la Faculté de droit se joignent à moi pour souhaiter longue vie à la PDSM et pour remercier l'équipe éditoriale pour sa contribution importante à la vie intellectuelle de la Faculté.

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[4] See, for a compelling argument in favour of the recognition of health law at McGill, Angela Campbell and Lara Khoury, eds., *Report on Concerted Research in Health Law*, McGill U., Faculty of Law, unpub., Feb. 2007, 29 pp. (report on file in the Dean's Office).

[5] See, generally, Geoffrey Samuel, "Epistemology and Legal Institutions" (1991) Int'l J. Semiotics L. 309.

[6] See Harry Arthurs, "Madly Off in One Direction: McGill's New Integrated, Polyjural, Transsystemic Law Programme" (2005) 50 McGill L.J. 707, esp. 717–9.

THE PRIVATE SALE OF CANCER DRUGS IN ONTARIO'S PUBLIC HOSPITALS: TOUGH ISSUES AT THE PUBLIC/PRIVATE INTERFACE IN HEALTH CARE

Colleen M. Flood[*]
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As increases in health care spending outpace economic growth, governments increasingly face tough choices. One significant cost driver is the influx of new technologies, particularly expensive drug therapies. In response, provincial governments are increasingly scrutinizing the costs and benefits of new drugs and determining that despite having some therapeutic benefit, they are not sufficiently beneficial to receive public funding. These choices raise complex legal, economic, political, and ethical issues.

This paper explores these issues as they pertain to Ontario's recent decision not to publicly fund three cancer drugs—Velcade, Alimta, and Zevalin. To be clear, although not considered sufficiently cost-effective to warrant public funding in Ontario, these drugs are of some therapeutic benefit; indeed, a physician may strongly recommend one or more of these drugs to extend a patient's life by a few months. This is illustrated by the fact that the provinces of Quebec, Alberta, and British Columbia have all elected to fund these drugs in their public hospitals. That they have chosen public funding, when Ontario has not, illustrates that no sharp distinctions can be drawn about what is "medically necessary" (and thus publicly funded) and what is not.

Ontario's decision has resulted in pressure from patients who want to buy the drugs but have the drugs administered within *public hospitals. For safety reasons, these drugs need to be provided in hospital-like settings. Patients who can afford to pay for the drug still find it difficult to access them because there is only one private cancer clinic in Ontario (downtown Toronto). The Ontario government is considering whether or not to allow private-pay drugs to be administered within public hospitals—so that people who can afford to pay for the drugs can access them more readily. We explore Ontario's dilemma in three parts. First, we address how Ontario's statutory context permits or acts as a bar to the sale of drugs in public hospitals. Second, we discuss the myriad of policy concerns the government faces in deciding whether to permit the sale of cancer drugs in public hospitals: fairness, equality, sustainability, compassion, safety, and the effects of such a policy on the public system. Finally, given the difficulty in obtaining these drugs safely in a private setting, we address whether the government could be compelled to allow patients access to privately purchased drugs in public hospitals via a successful challenge under section 7 of the* Canadian Charter of Rights and Freedoms.

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We thank Sujit Choudhry, Jocelyn Downie, Carolyn McLeod, Kent Roach, Lorne Sossin, Pamela Spencer, Terry Sullivan, Michael Trebilcock, and Sujith Xavier for their comments. All errors are our own.

INTRODUCTION

Health care systems in developed countries around the world are concerned with their future sustainability as increases in health care spending outpace economic growth. Canada is no exception. For example, if health care spending continues at its present pace, more than 50% of Ontario's total public budget will soon be spent on health care.[1] There is general agreement that a significant cause of cost increases is the influx of new technologies, particularly expensive drug therapies.[2] In response, publicly funded insurance schemes, including Canada's ten provincial systems, are increasingly scrutinizing the costs and benefits of new drugs and may increasingly decide that a drug, although of therapeutic benefit, is not sufficiently beneficial given its price to warrant public funding. The drug is thus not considered "medically necessary" for the purposes of the public plan, although a physician may recommend it in treating a patient.

Electing to leave an increasing number of drugs and therapies out of public Medicare raises many complex legal, economic, political, and ethical issues. Here we explore some of these issues as they pertain to a recent decision in Ontario not to fund certain cancer drugs,[3] particularly Velcade, Alimta, and Zevalin.[4] Velcade, Alimta, and Zevalin are not publicly funded in Ontario[5] because they are viewed as not sufficiently cost-effective; given their high cost and relatively small benefits (extending patients' lives by months as opposed to years), the money can be used for other pressing demands. For example, Velcade, a last-resort medication for multiple-myeloma blood cancer, costs approximately $55,000 for a full course of treatment.[6] However, to reiterate, these drugs are of *some* therapeutic benefit; indeed, a physician may strongly recommend one or more of these drugs to extend a patient's life by a few months. This is illustrated by the fact that the provinces of Quebec, Alberta, and British Columbia have all elected to fund these drugs in their public hospitals. That they have chosen public funding, when Ontario has not, illustrates that no sharp distinction can be drawn between what is "medically necessary" (and thus publicly funded) and what is not. Consequently, it is not surprising that many cancer patients in Ontario still wish to access the drugs in question, although a determination has been made that the drugs are not

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[1] Ontario government projections indicate that health care's share of provincial program spending could rise from 45% in 2004–2005 to nearly 55% in 2024–2025. Ontario Ministry of Finance, News Release, "Toward 2025: Assessing Ontario's Long-Term Outlook" (4 October 2005), online: Ontario Ministry of Finance <http://www.fin.gov.on.ca/english/media/2005/nr10-ltr.html>. For further discussion on sustainability issues in health care in Canada, see e.g. Commission on the Future of Health Care in Canada, *Building on Values: The Future of Health Care in Canada* (Ottawa: 2002) at 1–44 [*Romanow Report*] and Colleen M. Flood, Carolyn Tuohy & Mark Stabile, "What's In and Out of Medicare? Who Decides?" in Colleen M. Flood, ed., *Just Medicare: What's In, What's Out, How We Decide* (Toronto: University of Toronto Press, 2006) at 15 [Flood, *Just Medicare*]. For international comparisons on variables affecting sustainability, see *OECD Health Data 2006*, CD-ROM (Paris: Organisation for Economic Co-operation and Development, 2006).

[2] See e.g. Andreas Laupacis, Geoffrey Anderson & Bernie O'Brien, "Drug Policy: Making Effective Drugs Available Without Bankrupting the Healthcare System" (2002) 3:1 Healthcare Papers 12 at 16 and Commission on the Future of Health Care in Canada, *Discussion Paper No. 14: Influences on the "Health Care Technology Cost-Driver"* by Steve Morgan & Jeremiah Hurley (Ottawa: 2002), online: Health Canada <http://www.hc-sc.gc.ca/english/pdf/romanow/pdfs/14_Morgan_E.pdf>. For the American context, see also Patricia Seliger Keenan, Peter J. Neumann & Kathryn A. Phillips, "Biotechnology and Medicare's New Technology Policy: Lessons From Three Case Studies" (2006) 25 Health Affairs 1260.

[3] The mechanics of decision-making for funding of a new cancer drug in Ontario are as follows: when a new drug, or a new indication for an existing drug, is brought before the Cancer Care Ontario/Drug Quality and Therapeutics Committee Subcommittee, the Subcommittee obtains external reviews on both pharmaco-economics and clinical considerations and makes a recommendation to the Drug Quality and Therapeutics Committee. This Committee then makes a recommendation to the Ministry of Health and Long-Term Care which, in the case of hospital-based intravenous drugs, decides whether to make these medications available through the New Drug Funding Program.

[4] Velcade is a drug used to treat multiple myeloma, a cancer of the bone marrow: Millennium Pharmaceuticals, Inc., "A Patient's Guide to Velcade" (Cambridge, MA: Millennium Pharmaceuticals, Inc., 2006), online: Millennium Pharmaceuticals, Inc. <http://mlnm.com/patients/cancer/velcade/patient_brochure.pdf>. Alimta is used in the treatment of lung cancer: Eli Lilly and Company, "Home: Determine Your Course", online: Alimta <http://www.alimta.com/index.jsp>. Zevalin is used in the treatment of lymphoma: Biogen Idec Inc., "Welcome to ZEVALIN.com", online: Zevalin <http://www.zevalin.com/>.

[5] This case has been recently highlighted by Catherine Pytel, who received Zevalin free of charge from its manufacturer, Biogen Idec Inc., on a "compassionate" basis. Once the Drug Quality and Therapeutics Committee decided not to fund Zevalin, Ontario hospitals would not provide the drug: see Lisa Priest, "Woman's last hope tied up in red tape" *The Globe and Mail* (16 March 2006) A1. Pytel ultimately travelled to a public hospital in Quebec that was willing to allow the transfusion. Lisa Priest, "An Infusion of New Hope: Hospital Ends Patient's Months-Long Battle to be Treated With Cancer Drug Zevalin" *The Globe and Mail* (31 March 2006) A5.

[6] Carolyn Abraham, "Cancer clinic opens the door for private care" *The Globe and Mail* (22 August 2005) A1.

sufficiently cost-effective to warrant public funding in that province. For example, a 35-year-old mother of three young children or a 65-year-old man who wants to attend his daughter's wedding may consider the chance of even one additional month of life as extremely valuable and might be willing to use his or her savings to pay for the drugs. In addition, patients may have private insurance that covers the cost of these drugs.

I
ONTARIO'S DILEMMA

When a provincial government elects not to fund a drug, the drug is left to be funded by the private sector (either through insurance or by way of an out-of-pocket payment). The situation is complicated in the case of new cancer drugs like Velcade, Alimta, and Zevalin, which may need to be infused—necessitating nursing staff and supervision for proper administration in a hospital environment. However, because of limitations and restrictions on the private health care sector, there is as yet only one private clinic in Ontario capable of providing these cancer drugs to private patients: the Provis Infusion Clinic Inc., located in downtown Toronto.[7] Whether due to confusion about the regulations, an inability or unwillingness to travel to Toronto, a desire to avoid fees associated with provision at a private clinic, or a combination of the above, there have been stories of patients obtaining these drugs and having them administered in family doctors' offices; others have asked staff in public hospitals, who may be inadequately trained in how to administer drugs not listed on their formulary.[8] Some cancer patients are asking that they be permitted to buy these new cancer drugs within public hospitals, saving them the additional cost and stress of having to travel to a private clinic.[9]

Presently, public hospitals in Ontario do not facilitate the private sale of drugs to patients. With respect to in-patients, all drugs provided within public hospitals are free of charge. It would be a significant change to allow patients to pay privately for drugs requiring infusion in a public hospital. With respect to out-patients, hospitals do charge them for drugs, but an exception is made for cancer patients. It would thus also be a significant change in practice for hospitals to sell cancer drugs that are not listed on the hospital formulary to out-patients.

Cancer Care Ontario (an arm's-length agency charged with the administration of Ontario's delivery of cancer services across the province) has recommended to the Ontario government that in-patients be allowed to buy these new cancer drugs in public hospitals. This proposal is motivated by both safety concerns and compassion. A patient dying of cancer who has sufficient private insurance or other means to buy the drug will benefit if a public hospital can sell the drug to her; this policy will ensure better continuity of care with other treatments and will help reduce the unsafe practice of asking family doctors or untrained hospital staff to infuse the drugs. Compassionate concerns have been taken into account in that these private-pay patients will not be required to pay the price of travelling to and accessing a private clinic, whether in Toronto or in another province or country.

Compassion in this regard only goes so far, however, and the situation of a person wanting but unable to buy an uninsured cancer drug remains unclear. It is certainly possible that hospitals may find ways to fund the drug for a needy person or that drug companies may provide some of the drug free of charge for hospitals to distribute. Nevertheless, it is also equally possible that a low-income individual will go without the cancer drug in question. Their perception of this loss will likely be affected by the fact that the drug is considered sufficiently important that public hospitals are able to sell it to those who are able to pay.

The Ontario government is caught in a bind between what it is allowed to do, what it should do, and what it may be made to do. To be more specific, the government is asking—or should ask:

1. What do existing statutes and regulations allow presently in terms of selling private drugs in Ontario's public hospitals?;
2. What should the government's policy be with regard to the preceding question, given that it wants to enhance and to ensure both fairness and sustainability of Medicare?; and

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[7] See Provis Inc., "About Provis", online: The Provis Group Inc. <http://www.provis.ca/index.html>.

[8] This point was made by Terrence Sullivan, President of Cancer Care Ontario. A hospital's formulary is the list of drugs that are available within that hospital.

[9] See Lisa Priest, "Let cancer patients pay for unfunded therapy, study says" *The Globe and Mail* (29 July 2006) A7; Lisa Priest, "Ontario minister supports user-pay plan for cancer drugs" *The Globe and Mail* (6 May 2006) A8; Lisa Priest, "Ontario changes tack on cancer drugs" *The Globe and Mail* (5 May 2006) A1.

3. Regardless of the answers to the previous two questions, could it be forced to change its policy through a successful *Charter* challenge on the part of patients frustrated by public hospitals failing to allow the private sale of cancer drugs?

We address each of these three issues in turn. Although the analysis that follows is limited to Ontario's dilemma, our discussion of this recent policy development in Ontario is illustrative of issues that will continue to arise in the ongoing debate over the appropriate role for public and private financing of health and the protection of the public health care system within all Canadian provinces. Indeed, a recent newspaper article suggests that while some provinces, such as Saskatchewan, permit the infusion of privately purchased drugs in public hospitals, others, such as Manitoba, refuse to do so.[10]

II
WHAT THE ONTARIO GOVERNMENT CAN DO: LEGISLATIVE PROVISIONS PROHIBITING THE SALE OF PRIVATE DRUGS IN PUBLIC HOSPITALS

We turn first to exploring what existing statutes and regulations prescribe in terms of the sale of private drugs within public hospitals, looking both at relevant Ontario statutes and regulations and at the *Canada Health Act* (*CHA*).[11]

A. Ontario Legislation

The *Commitment to the Future of Medicare Act, 2004*[12] seeks to prohibit a number of practices viewed as detrimental to Medicare. For example, the *Act* prohibits extra billing for insured services[13] and payment for preferential access to insured services[14] except where otherwise provided for by regulation. The relevant regulation states that a hospital may charge or accept "payment for private or semi-private accommodation, except where an insured person is entitled to the accommodation without charge" and "co-payments as permitted ... under the *Health Insurance Act*".[15] One interpretation of this regulation is that the only charges a hospital may make to an insured person are for semi-private accommodation or explicitly permitted co-payments; in our view, this interpretation is not persuasive. Subsection 10(5) of the *Regulation* focuses on the status of the service itself (insured or uninsured), saying that private payment is not allowed "for an *insured service* rendered to an insured person".[16] It does not, however, say that a hospital may never sell an uninsured service to an insured person. If hospitals were not entitled to charge insured patients for anything other than semi-private accommodation and permitted co-payments, they would not be able to charge patients for services such as telephones or televisions in their rooms.[17]

The other relevant statute is the *Health Insurance Act*,[18] which provides for the operation and administration of the Ontario Health Insurance Plan (OHIP). The Lieutenant Governor in Council has the power to enact regulations "governing insured services, including specifying those services that are not insured services", and states that any regulation made under this section may provide "[w]hich services rendered in or by hospitals and health facilities are insured services".[19] There is nothing explicit that

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[10] In this regard, Priest notes that Saskatchewan allows patients to purchase Avastin and have it infused in the hospital, with the costs of infusion being absorbed by the public system. In contrast, Manitoba refuses to allow patients to have these drugs infused in the hospital as it "creates inequality amongst patients and generates emotional discomfort for caregivers who are dealing with similar patients, one of whom can pay and one of whom can't." Roberta Koscielny, Director of Communications and Public Affairs, CancerCare Manitoba, cited in Lisa Priest, "Clinics let cancer patients purchase treatment" *The Globe and Mail* (8 December 2006) A1.

[11] R.S., 1985, c. C-6 [*CHA*].

[12] S.O. 2004, c. 5.

[13] *Ibid.*, s. 10.

[14] *Ibid.*, s. 17.

[15] *General Regulation*, O. Reg. 288/04, s. 4. Section 15(1) of the *General Regulation* made pursuant to the *Health Insurance Act* states that ambulance services are insured if they are provided by one of the listed ambulance operators; the hospital is one of a listed class, and the insured pays a $45 co-payment to the hospital.

[16] *Ibid*. [emphasis added].

[17] These are services for which hospitals typically charge through a third party. For example, a number of hospitals in Canada have these services provided through the Hospitality Network: Hospitality Network, "Patient TV and Phone Rental Availability and Pricing", online: Hospitality Network <http://www.hospitalitynetwork.ca/pricing/>.

[18] R.S.O. 1990, c. H-6.

[19] *Ibid.*, s. 45(3.2)(1).

empowers public hospitals to sell uninsured services; however, there is nothing to prevent it. Much turns on the definition of "insured service", which we turn to now, for if all drugs provided in a hospital must be insured, then it is beside the point whether hospitals are entitled to sell uninsured services or products like drugs.

Section 8 of the *Commitment to the Future of Medicare Act, 2004* defines "insured service" by referring to the *Health Insurance Act*, where we find the following definition: "prescribed services of hospitals and health facilities rendered under such conditions and limitations as may be prescribed". "Prescribed" is defined as "prescribed by the regulations".[20] In understanding "prescribed", we need to consider both in-patient and out-patient services, although most patients will be seeking to have new cancer drugs infused on an out-patient basis. As discussed further below, the regulations do not decisively resolve the issue in the context of in-patient care. With respect to out-patient care, it is reasonably clear that there is no impediment to the sale by hospitals of uninsured drugs.

1. *In-patient Services*

With regard to in-patients, section 7 of the *General Regulation*[21] states that

> ...the in-patient services to which an insured person is entitled without charge are all of the following services:
>
> ...
>
> 2. Necessary nursing service, except for the services of a private duty nurse who is not engaged and paid by the hospital.
>
> 3. Laboratory, radiological and other diagnostic procedures, together with the necessary interpretations for the purpose of maintaining health, preventing disease and assisting in the diagnosis and treatment of any injury, illness or disability.
>
> 4. Drugs, biologicals and related preparations that are prescribed by an attending physician ... in accordance with accepted practice and administered in a hospital....

If the Ontario government wanted to allow the private sale of cancer drugs in public hospitals to in-patients the most problematic provision is subsection 7(4). Its broad wording seems to entitle a patient to any drug administered in a hospital and prescribed by an attending physician. Thus, arguably, as long as a doctor prescribes the drug in question, and the patient is in a hospital, the drug must be publicly insured. In contrast, subsection 7(2) speaks of "necessary" nursing services, opening up the possibility of classifying some nursing services as "necessary" and thus publicly insured, and others as unnecessary and thus not publicly insured.

Our interpretation of the existing regulation (section 7 of the *General Regulation*) supports the argument that residents of Ontario are entitled to full coverage of all drugs prescribed by an attending physician in a hospital. In our view, it is necessary to amend Ontario's *General Regulation* if the government wants to allow public hospitals to charge in-patients for these new cancer drugs.

2. *Out-patient Services*

The situation with respect to the provision of private-pay drugs on an out-patient basis in public hospitals is clearer. Subsection 8(1) of the *Regulation* lists the out-patient services to which an insured person is entitled without charge, but specifically excludes *"visits solely for the administration of drugs, vaccines, sera or biological products*."[22]

If a patient goes to an out-patient clinic solely for the administration of cancer drugs, then there appears to be no barrier to the hospital selling uninsured drugs to her. It could be argued, however, that because these new cancer drugs must be infused, and nursing services are thus required, the patient is not presenting solely for the purpose of receiving a drug. But this interpretation likely will not be persuasive—after all, even providing an out-patient with a tablet to ingest requires some additional services in addition to the drug itself.

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20 *Supra* note 18, s. 1.

21 R.R.O. 552.

22 *Ibid*., s. 8(1)(5)(iv) [emphasis added].

B. The *Canada Health Act*

If Ontario's legislation is interpreted to allow the sale of private drugs in public hospitals or amendments are made to facilitate this sale, then we must address whether these changes will comply with the *CHA*. The *CHA* protects and requires first-dollar public coverage for "insured health services". If a province chooses not to provide public coverage then the federal government may withhold payment. The *CHA* defines "insured health services" by reference to "hospital services", which are:

> ...any of the following services provided to in-patients or out-patients at a hospital, if the services are *medically necessary* for the purpose of maintaining health, preventing disease or diagnosing or treating an injury, illness or disability, namely,
>
> ...
>
> (b) nursing service,
>
> (c) laboratory ... and other diagnostic procedures, together with the necessary interpretations,
>
> (d) drugs, biologicals and related preparations when administered in the hospital,
>
> (e) use of ... case room ... facilities, including necessary equipment and supplies,
>
> (f) medical and surgical equipment and supplies....[23]

The *CHA* thus requires that all "medically necessary" drugs be provided when administered in a hospital. However, "medically necessary" is not defined, with the result being that whatever is covered in a province's insurance plan is typically regarded as medically necessary. In other words, the term "medically necessary" does not substantively drive coverage decisions but rather is a label applied *ex post* to coverage decisions.[24]

Because Ontario has chosen *not* to insure the cancer drugs at issue, then it is likely that these drugs will *not* be considered "medically necessary" for the purposes of the *CHA*. However, although it largely lies with a provincial government to determine what is and is not "medically necessary", it is still possible that the federal government could contest a classification of one or more of these cancer drugs as not medically necessary and thus not publicly insured. It is feasible that the federal government, given evidence of effectiveness and the fact that other provinces and other countries fund these same cancer drugs, could claim the drugs are in fact "medically necessary" for the purposes of the *CHA*. But rare indeed are examples where the federal government has challenged a provincial government's decision-making in this regard and, as Choudhry notes, provinces are frequently not penalized for what seem to be more blatant breaches of the *CHA*.[25]

We also note that the sale of these drugs in public hospitals will reinforce public perception that the drugs truly are "medically necessary", which in turn will put pressure on both the federal and provincial governments to treat the drugs as medically necessary and to publicly insure them.

In conclusion, it seems that under existing Ontario legislation it is not permissible to sell cancer drugs to in-patients, but it is permissible to sell cancer drugs to out-patients. With respect to the *CHA*, all turns on the definition of "medically necessary". If the drugs are considered medically necessary, they must be publicly funded within public hospitals; if not, then there is nothing in the *CHA* that would prevent their sale in a public hospital. There is no established process for deciding what is and is not medically necessary, and there is a large grey area in which a judgment has to be made; further, the federal government has historically been wary of trumping provincial decision-making in this regard. It is unlikely, except in circumstances where Ontario is a clear outlier from other provinces in terms of a decision not to insure a drug publicly, that a federal government would object to a province's own assessment of what is or is not "medically necessary". If a drug is not considered medically necessary, there is nothing in the *CHA* that would seem to prevent the private sale of such a drug within a public hospital.

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23 *Supra* note 11, s. 2 [emphasis added].

24 See Flood, *Just Medicare*, *supra* note 1.

25 Sujit Choudhry, "Bill 11, the *Canada Health Act* and the Social Union: The Need for Institutions" (2000) 38 Osgoode Hall L.J. 39 at 51–59.

III
WHAT THE ONTARIO GOVERNMENT SHOULD DO: POLICY CONSIDERATIONS FOR AND AGAINST ALLOWING THE PRIVATE SALE OF CANCER DRUGS IN ONTARIO'S PUBLIC HOSPITALS

Having discussed what the Ontario government is presently permitted to do under statute and regulation vis-à-vis the sale of private drugs in public hospitals, we now turn to what it should do. We do this through exploring the policy arguments for and against the sale of private drugs in public hospitals. First, we look at arguments against such sale, including concerns about unequal treatment within public hospitals and the possibility of negative effects on the public system. We then turn to look at favourable arguments, particularly concerns for safety of those who are attempting to buy cancer drugs in inappropriate venues, given that they are not permitted to purchase them in public hospitals.

Both the *CHA* and Ontario's *Commitment to the Future of Medicare Act, 2004* speak to important values underlying the health care system: in particular, a commitment to access on the basis of need rather than ability to pay, and a commitment to one-tier Medicare through bans on extra billing and user charges. The difficulty with these governing pieces of legislation is that it is not clear *why* they prohibit extra billing and user charges. There are two possibilities. The first is that it is always wrong for there to be unequal treatment vis-à-vis health care (or at least "medically necessary" hospital and physician services). The second possibility is that these governing pieces of legislation are in place because they are necessary to ensure a robust and reasonable standard of care for all in the public health care system (for example, by ensuring sufficient doctors working in the public system).[26] One's stance with regard to this central question of justification significantly affects how one will respond to the government's proposal to allow public hospitals to sell uninsured drugs.

A. Unequal Treatment in Health Care

Let us look at the first argument, namely, that it is wrong for there to be unequal treatment vis-à-vis health care. Access on the basis of need rather than ability to pay is a defining principle of Medicare, and equality *within* Medicare is an extremely important value. However, there are necessary limits to Medicare and thus to the extent of the equality principle. Equality under the *CHA* is only with respect to "medically necessary" hospital and physician services. Provinces are not required to provide other kinds of services although they may be "medically necessary"—prescription drugs outside of hospitals, home care, long-term care, dentistry, etc.[27] Even with respect to medically necessary services, there are no outright provincial prohibitions vis-à-vis their purchase by private-pay patients. There are, instead, many indirect regulations that suppress the flourishing of a private tier for "medically necessary" hospital and physician services (for example, regulations that require doctors to opt out of the public system if they wish to bill privately for "medically necessary" care and regulations that limit what doctors can charge private-pay patients).[28] The end result is that there is, across Canada, a very small private sector for medically necessary hospital and physician services. Compared to many other jurisdictions, there is a sharper division between the privately and publicly financed sectors. The privately financed sector stands somewhat separate from the public sector. This isolation is both symbolic and value-oriented in nature, as well as having substantive implications that we address further below.

The argument that unequal treatment is always wrong, taken to its extreme, would mean that if a treatment is not publicly funded for every Canadian, then it cannot be provided at all. There would be few, if pressed, who would agree that this notion could be the foundational basis for our (public and private) health care system. For example, a provincial government, having decided that it will not publicly fund a particular treatment like *in vitro* fertilization services, would not conclude that because of the need for equality the provision of these treatments should also be banned in the private sector. In other words, there is a limit to equality, and equality is only required within Medicare. The problem is that the boundary or limits of publicly funded Medicare are determined by the vague and often unsatisfactory process for deciding what is and is not "medically necessary".[29] The social consensus has been that

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[26] For a general summary of some of the manners in which the private sector can impact the public sector negatively, see e.g. *Romanow Report*, *supra* note 1 at 6–8.

[27] However, with the deinstitutionalization of medical care and the corresponding increase in the importance of pharmaceuticals and home care, some advocate for the inclusion of these services within the *CHA*. See e.g. *ibid*. at 171–210.

[28] See Colleen M. Flood & Tom Archibald, "The illegality of private health care in Canada" (2001) 164 Canadian Medical Association Journal 825.

[29] See Flood, *Just Medicare*, *supra* note 1.

services left to the private sector are not as important as those that are publicly funded. This consensus will be increasingly challenged as new technologies—judged to be not sufficiently cost-effective to be publicly funded, but still of value—are left to private markets. The boundary of what should be public and should be private will, to many people, start to seem much less clear.

If we accept that equality is limited to the extent that we speak of allocation of publicly funded health care within Medicare (i.e., care that has been determined to be "medically necessary"), should public hospitals be able to sell private services? Accepting the existence of limits on equality and the fact that services not defined as medically necessary may be sold in private markets, should we be concerned if public hospitals sell these services too?

In terms of symbolic values, Canadians view public hospitals, although technically privately owned, not-for-profit institutions, as public institutions benefiting all citizens, rich or poor. Although Canadians may access private services, they generally do so in facilities that are independent of the public system, in clinics that are in separate locations, and from physicians that are not employed in the public system. One claim may then be that although some unequal treatment is tolerated within the system broadly, such inequality is not acceptable within public hospitals. This claim is linked to the symbolic notion of the public hospital as a community facility for the benefit of all. The power of this argument is diminished by the fact that private payment is allowed in public hospitals for some services (for example, private nursing staff). On the other hand, the fact that the drugs in question are life-prolonging might be viewed as sufficient to distinguish them from the caring or comforting types of nursing that are allowed to be provided on a private basis in public hospitals. Another argument in favour of allowing private payment is that presently there is unequal access within public hospitals to the drugs in question. For example, as we understand it, Alimta is already provided to qualifying patients within a hospital through the Workplace Safety and Insurance Board, if their cancer is related to workplace exposure.[30] However, pointing out the existing inequalities in the provision of cancer drugs risks falling into the fallacy of arguing that one form of inequality can justify another. Also, let us recall that an important principle of Medicare is access on the basis of need and not of ability to pay. All patients, whether rich or poor, qualify for workplace safety coverage. Their coverage depends on how they acquired the cancer from which they suffer and not on their ability to pay.

The issue of unequal treatment within a public hospital likely engages ethical issues that are beyond the scope of this paper. We would note, however, that regardless of whether such unequal treatment is theoretically tolerable (on the grounds that the drug in question has been deemed "not medically necessary"), Ontarians may not view it as acceptable. While they may tolerate different treatment across the system as a whole, they may be unwilling to tolerate it within public hospitals particularly with respect to life-prolonging treatments.

B. Impact on the Public System

Legislation limiting the private health care sector is also rooted in concerns about the potential impact of the private tier on the public system. A commonly expressed concern (for which there is an evidentiary basis) is that in a two-tier system, the private tier will pay physicians more to do less arduous work (treating less needy patients), resulting in a migration of manpower from the public to the private tier.[31] For example, the New Zealand Medical Council reports that in New Zealand (which has a two-tier system and allows doctors to work simultaneously in both the public and private sectors) specialists spend just 48.9% of their time in public hospitals. Most of the rest of the time is devoted to their private medical activities.[32]

The supply of drugs in a two-tier system does not raise this kind of capacity concern because it is usually possible to manufacture more drugs in a short time-frame. By comparison, it is never possible to manufacture doctors in a short time-frame. If a private-pay patient buys a hip operation, then it is more

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30 Personal discussion with Terrence Sullivan, President and CEO, Cancer Care Ontario [April 2006].

31 Charles Wright, "Different Interpretations of 'Evidence' and Implications for the Canadian Healthcare System" in Colleen M. Flood, Kent Roach & Lorne Sossin, eds., *Access to Care: Access to Justice: The Legal Debate over Private Health Insurance in Canada* (Toronto: University of Toronto Press, 2005) 220 at 221–222 discusses a number of studies which outline these concerns. See also Colleen M. Flood, "*Chaoulli*'s Legacy for the Future of Canadian Health Care Policy" (2006) 44 Osgoode Hall L.J. 273 at 289–293.

32 Medical Council of New Zealand, *The New Zealand Medical Workforce in 2000* (Wellington: Medical Council of New Zealand, 2000) at 14, online: Medical Council of New Zealand <http://www.mcnz.org.nz/portals/0/publications/workforce%202000.pdf>.

likely that a surgeon will be spending time treating the private-pay patient, time that could have otherwise have been spent with a public patient. In contrast, imagine a patient in a private clinic being infused with cancer drugs. Because there is no shortage in the supply of cancer drugs, buying cancer drugs in private markets will not detrimentally affect the ability of public patients to access drugs. The consumption of uninsured drugs (whether in private clinics or in public hospitals) has no direct effect on the availability of drugs for public patients. Thus, the strongest argument in favour of one-tier medicine (i.e., that allowing a second tier will divert scarce human resources from the public to the private tier) does not apply in the case of drugs.

This is not to say that allowing hospitals to sell uninsured drugs may not have some negative effect on human resources within the public system, as the time spent by doctors or nurses in the prescription or administration of uninsured drugs is time that may have been spent supplying "medically necessary" services to public patients. The resources devoted to blood work and imaging are also resources that could have been used for other public patients requiring medically necessary care. The extent of this harm is an empirical question that has yet to be answered; the effect may not be particularly large if the cancer patients in question would use other public resources in substitution. If a hospital could charge the patient for the other costs of treatment associated with administering a private-pay drug,[33] concerns about cross-subsidization from public patients to private-pay patients would be negated. There may, however, be barriers—not the least of which are political—to such an approach, as it would seem that the government was treating cancer patients even more harshly than it would if it simply did not allow public hospitals to sell the drugs in question.

There are two further arguments against allowing the sale of cancer drugs within public hospitals. First, the sale by public hospitals of uninsured cancer drugs may further undermine confidence in publicly funded Medicare. It may be hard for Ontarians to accept that these drugs are not important and are not "medically necessary" if public hospitals sell them to patients who are able to pay, particularly if other provinces are publicly funding the drug. Allowing public hospitals to sell these cancer drugs may be viewed as an implicit endorsement of the true importance of these drugs and may undermine trust in the process of decision-making about what drugs to publicly fund and what drugs not to, and more broadly undermine trust that Medicare is really covering that which is "medically necessary". Second, and more importantly, allowing the sale of uninsured drugs in public hospitals may erode political support for ensuring a high standard of care in the public system and make it easier to delist (or not list in the first place) services or drugs from the universal public plan. The middle-class and the wealthy—able to pay privately for the drugs they want within public hospitals—may not use their political clout to lobby for public funding of new drugs. Potentially, this situation makes it easier for future governments not to add new therapies and technologies to the basket of services that attract universal public funding. This stasis may be a good thing from the perspective of ensuring sustainability but of concern from the perspective of ensuring a robust standard of care in the universal public system.

Although this concern of diminished political support in a two-tier system is one that is often expressed in the literature, it is not one that has yet been conclusively proven on an empirical basis. Some work has suggested that increases in private spending will result in overall reductions in public spending over time, providing some basis for the concerns expressed here.[34] It should be noted that in the *Chaoulli* decision, a majority of the Supreme Court did not find a sufficient evidentiary basis for the concern that allowing a two-tier system would degrade political support for a robust publicly-funded system;[35] this decision, however, has been severely criticized.[36]

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[33] This charge could include, for example, the cost of the nursing services required to administer the drug, of blood work, of occupying the room where the drugs are administered, and of needles and tubing through which the drugs are administered. It could also include charges for more ancillary services, such as post-drug imaging to evaluate whether the drugs were effective in reducing the tumor, and anti-nausea or other medications required to counteract the side-effects of the intravenous cancer drugs.

[34] See Carolyn Hughes Tuohy, Colleen M. Flood & Mark Stabile, "How Does Private Finance Affect Public Health Care Systems?: Marshalling the Evidence from OECD Nations" (2004) 29 J. Health Pol. 359.

[35] *Chaoulli v. Quebec (A.G.)*, 2005 SCC 35, [2005] 1 S.C.R. 791 at paras. 68, 83–84 [*Chaoulli*].

[36] For a more detailed discussion in this regard, see e.g. Christopher P. Manfredi, "Déjà vu All Over Again: *Chaoulli* and the Limits of Judicial Policy-Making" in Colleen M. Flood, Kent Roach & Lorne Sossin, eds., *Access to Care, Access to Justice: The Legal Debate over Private Health Insurance in Canada* (Toronto: University of Toronto Press, 2005) 139 and the other chapters in this volume; Joan M. Gilmour, "Fallout from *Chaoulli*: Is It Time to Find Cover?" (2006) 44 Osgoode Hall L.J. 327; Marie-Claude Prémont, "L'affaire *Chaoulli* et le système de santé du Québec: cherchez l'erreur, cherchez la raison" (2006) 51 McGill L.J. 167; and Amélie Quesnel-Vallée *et al.*, "In the aftermath of *Chaoulli v. Quebec*: Whose opinion prevailed?" (2006) 175 Canadian Medical Association Journal 1051.

C. Patient Safety and Access

To be balanced against the concern over erosion of the public system is the issue of patient safety and the emotional distress caused by having to travel for private treatment. There are dangers associated with being treated by multiple practitioners and having multiple sets of medical records at different locations.[37] There are stories about desperate patients trying to get these drugs infused in a family doctor's office or by untrained staff in a public hospital. Such situations are of concern, as the attendant risks require the drugs to be infused in a hospital setting by appropriately trained staff.[38] Another issue may arise when patients require the administration of both an uninsured and an insured drug. Despite the fact that it may be recommended that the two drugs be infused simultaneously, under the current regime, patients are receiving them separately—the uninsured drug at a private clinic and the insured drug at a public facility. With respect to distress, cancer patients may simply not be well enough to travel to the only private clinic in Toronto or to another jurisdiction. Even if a patient is well enough, there will be hardships involved in having to make this kind of journey for treatment, including possible separation from her family and supports.[39] If public hospitals sell uninsured cancer drugs, patients will be able to access the drugs they wish (if they have the resources to pay for them or have private insurance) at any of the 14 regional cancer centres in Ontario.

D. Balancing the Arguments For and Against Funding Cancer Drugs

The Ontario government has made a decision not to publicly fund some of these new cancer drugs; this is obviously a tough call, given the fact that at least three other provinces have elected to fund these drugs. In our view, the Ontario government must either uphold their tough decision, or contradict it and fund the cancer drugs. The middle-ground option of allowing the sale of private-pay drugs in public hospitals for those who are insured or able to fund the drug from their private resources would, in our view, likely cause political backlash on equity grounds (even though inequity has always been tolerated to some degree within the system). Moreover, allowing the sale of private cancer drugs in public hospitals further legitimizes the drug treatments in question—undermining the government's stance that these drugs are not sufficiently beneficial to be publicly funded. In addition, we have concerns in the longer term about how private payment may compromise the decision-making process about what is in and out of Medicare. However, these arguments are not cut and dried and, frankly, we find it difficult to decide between the two opposing viewpoints on this particular issue. There is not here the same strong argument that exists against two-tier medicine in the case of physician services, where there are incentives for scarce medical manpower to be diverted from the public to the private sector. There is more robust supporting evidence against a two-tier system for physician services than there is against a two-tier system for drugs.

We turn now to explore if a frustrated patient could launch a successful section 7 *Charter* claim against the Ontario government for refusing to allow the sale of new cancer drugs in public hospitals.

IV
WHAT THE ONTARIO GOVERNMENT MAY BE FORCED TO DO: CHALLENGES UNDER THE *CANADIAN CHARTER OF RIGHTS AND FREEDOMS*

Do patients have a constitutional right to pay privately for cancer drugs in public hospitals? Recall that we are addressing cancer drugs that are unquestionably of some therapeutic benefit but that are not considered sufficiently beneficial given their cost to warrant public funding. However, because of a lack of private hospital and clinic facilities in Ontario, it is difficult for a patient wishing to purchase the drugs to access a private facility for their administration. Could the Ontario government be effectively forced

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[37] An inquiry into a number of paediatric cardiac surgical deaths in Britain is perhaps the best illustration of the concerns with multi-site treatment: U.K., *Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984–1995* (London: Secretary of State for Health, 2001), online: The Bristol Royal Infirmary Inquiry <http://www.bristol-inquiry.org.uk/final_report/the_report.pdf>.

[38] Personal discussion with Terrence Sullivan, President and CEO, Cancer Care Ontario [April 2006].

[39] However, as will be discussed at greater length in the section addressing the *Charter*, this psychological stress would have to be severe in order to invoke section 7 legal protections. We would differentiate between the emotional distress discussed in this case, namely the difficulties private-pay patients would have in accessing the cancer drugs at any other venue apart from a public hospital, and the psychological stress discussed in *Chaoulli*, *supra* note 35. In the latter case, the stress in question resulted from long wait times in the public sector coupled with an inability to purchase private insurance. However, as discussed below, this differentiation would not necessarily bar a section 7 claim relating to cancer drugs.

through a *Charter* challenge pursuant to section 7, which guarantees the right to life, liberty and security of the person, to allow patients to access private-pay cancer drugs in public hospitals?

A. Section 7

Section 7 of the *Charter* provides that "[e]veryone has the right to life, liberty and security of the person, and the right not to be deprived thereof except in accordance with the principles of fundamental justice".[40] There are three elements to this provision: a life, liberty, or security interest must be engaged; an individual must suffer a deprivation of this interest as a result of governmental action; and this deprivation must be contrary to the principles of fundamental justice. We address these elements in turn below.

To clarify, we are not considering whether the government's failure to *insure* these drugs publicly constitutes a breach of section 7, but rather whether Ontario's laws or other governmental action that prevents public hospitals from selling uninsured cancer drugs to patients are in breach of section 7 (for further details as to the existing laws, see section II(A) above). The courts have been very clear that there exists at present no positive right to publicly funded health care under section 7.[41] For example, the majority in *Chaoulli* found that "[t]he *Charter* does not confer a freestanding constitutional right to health care".[42] More recently, the Ontario Superior Court of Justice, Divisional Court, in *Flora* found that provision of health care does not require that the "government must do everything possible to save the lives of the citizens in every circumstance".[43] To put it bluntly, section 7, to date, has been used to prevent governments from taking actions that affect individual rights, but not directly to require governments to spend money.[44] If the government chooses to fund a health service or other treatment, then it cannot do so on a discriminatory basis under section 15 of the *Charter*. However, there is, to date, no free-standing constitutional right to health care in the context of section 7.

1. *Life, Liberty, Security*

As discussed, the cancer drugs in question are of some therapeutic benefit and may extend life by several months. As such, deprivation thereof would seem clearly to engage one's life or security interests. More specifically, being forced to travel to a private clinic may be found to violate the psychological aspect of security of the person. For example, in *R. v. Morgentaler*, the Supreme Court took the view that administrative procedures causing a delay in the provision of abortion services constituted a violation of both the physical and the psychological aspects of security of the person. Dickson C.J.C. specifically dealt with the issue that abortion services are available in other jurisdictions, finding that notwithstanding this option "the emotional and financial burden"[45] of travelling long distances and the potential for increased risk of complications, meant that security of person was engaged.[46]

2. *Governmental Action*

A claimant will have to demonstrate a clear nexus between the inability of a public hospital to sell private cancer drugs and a breach of a section 7 right. A claimant's difficulty is that section 7 does not generally protect economic rights;[47] thus she would need to show a connection between the prohibition on public hospitals selling cancer drugs and her suffering.

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40 *Canadian Charter of Rights and Freedoms*, Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (U.K.), 1982, c. 11 [*Charter*].

41 *Supra* note 35 at para. 104 and para. 173; *Flora v. Ontario Health Insurance Plan*, 2007 CanLII 339 at 200 (Ont. Sup. Ct. Div. Ct.) [*Flora*].

42 *Supra* note 35 at para. 104.

43 *Flora*, *supra* note 41 at para. 227.

44 This is subject to the possible exception of the Court's decision in *New Brunswick (Minister of Health and Community Services) v. G. (J.)*, [1999] 3 S.C.R. 46, in which the Court imposed an obligation on the state to provide legal aid in a custody hearing.

45 *R. v. Morgentaler*, 1988 1 S.C.R. 30 at 71 [*Morgentaler*].

46 Stanley H. Hartt & Patrick J. Monahan, "The *Charter* and Health Care; Guaranteeing Timely Access to Health Care for Canadians" in *C.D. Howe Institute Commentary* (May 2002) at 9–23, online: C.D. Howe Institute <http://www.cdhowe.org/pdf/commentary_164.pdf>.

47 For example, the dissent in *Chaoulli*, *supra* note 35 notes: "The argument that 'liberty' includes freedom of contract (in this case to contract for private medical insurance) is novel in Canada, where economic rights are not included in the *Canadian*

In *Chaoulli*, a majority of the Court accepted the nexus between the prohibition of the purchase of private health insurance and long waiting times in the public system.[48] For people who could not travel to the U.S. for treatment or pay out-of-pocket to opted-out physicians, a majority of the Court (in the context of the Quebec *Charter)* found a deprivation of their life and security interests. The sale by public hospitals of uninsured cancer drugs raises different issues from those at stake in *Chaoulli*. With respect to the sale of drugs, there is no issue of a governmental ban on private insurance or otherwise on private financing. Legislative barriers focus on the inability of patients to pay privately for the drug *within* a public hospital. The facts are more in line with those in the *Morgentaler* case where administrative barriers prevented women from accessing timely abortions.[49] As in *Morgentaler*, there is theoretically the option of getting treatment elsewhere—at a private clinic or in another jurisdiction—but the stress associated with accessing those options is high. The obvious difference between *Morgentaler* and the facts under discussion is that in *Morgentaler*, abortion services were publicly funded. Here Velcade, Alimta, and Zevalin are specifically not publicly funded in Ontario. It is not clear whether this difference is substantive vis-à-vis a section 7 analysis although the fact that in the present discussion we are speaking of a right to buy drugs (as opposed to a right to have administrative impediments to public treatment removed) underscores the economic aspects of this claim.

In order to be able to demonstrate a sufficient nexus between government policy and a deprivation of a section 7 right, a claimant would have to show that being required to buy the treatment at a private clinic rather than in a public hospital jeopardizes a life and/or security interest. This hurdle would be much more difficult to cross than that crossed in *Chaoulli*. A patient *may* be able to demonstrate a connection between the prohibition on the sale by public hospitals of uninsured drugs to in-patients and an infringement of life or security by the government in two circumstances. In the first, there would be serious safety concerns associated with requiring a patient to travel from a public hospital to a private clinic for infusion of a cancer drug. In the second, a patient would have to rely upon demonstrating serious psychological stress associated with having to travel unreasonably long distances to receive treatment (as the only private clinic providing the drug is in Toronto) or show that, as was recently the case for Zevalin, only public hospitals were able to provide the drug in question.[50] McLachlin C.J.C. and Major J. in *Chaoulli* quoted *Rodriguez v. British Columbia*, stating that "security of the person encompasses 'a notion of personal autonomy involving, at the very least, control over one's bodily integrity free from state interference and freedom from state-imposed psychological and emotional stress.'"[51] Being effectively forced to travel to a private clinic and the psychological stress associated with such travel, in conjunction with safety concerns, might create the necessary nexus to engage section 7.

3. *Principles of Fundamental Justice*

The third requirement under section 7 of the *Charter* is for a claimant to prove that any deprivation of his or her rights is not in accordance with the principles of fundamental justice.[52]

In *Chaoulli*, the three judges who determined that there was a breach of section 7 found that one of the principles of fundamental justice was a requirement that the law not be arbitrary.[53] In order to establish arbitrariness, a claimant would have to show, on a balance of probabilities, that preventing

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Charter...." at para. 201.

48 Moreover, the majority judgment is only in respect of the Quebec *Charter of Human Rights and Freedoms*, R.S.Q. c. C-12 [Quebec *Charter*] and not with respect to the Canadian *Charter*. With respect to the latter, the court was split 3:3 on whether the prohibition on the sale of private health insurance in Quebec was in breach of section 7. Consequently, the extent to which the *Chaoulli* decision will serve as a precedent is questionable, but we can nonetheless extrapolate from some of the findings in that decision to inform our analysis here.

49 *Supra* note 45.

50 This is because the administration of Zevalin requires a nuclear medicine licence, which, until recently, no private facilities had been granted.

51 *Rodriguez v. British Columbia (A.G.)*, [1993] 3 S.C.R. 519 at 587–88 [*Rodriguez*], cited in *supra* note 35 at para. 122.

52 Although there are a number of definitions of what constitutes a principle of fundamental justice, one of the broader definitions is: "principles which have been recognized by the common law ... and by the very fact of the entrenchment in the Charter, as essential elements of a system for the administration of justice which is founded upon the belief in the dignity and worth of the human person and the rule of law". *Reference Re B.C. Motor Vehicle Act*, [1985] 2 S.C.R. 486 at 512.

53 As mentioned above, this is not a majority decision, so its value as a precedent is limited. However, in another case the court stated that "[w]here the deprivation of the right in question does little or nothing to enhance the state's interest (whatever it may be), it seems that a breach of fundamental justice will be made out, as the individual's rights will have been deprived for no valid purpose." *Rodriguez*, *supra* note 51 at 594.

public hospitals from selling uninsured drugs did not achieve the government's goal of protecting the public health care system. A claimant could argue that the sale of uninsured drugs in public hospitals does not affect the supply of drugs to public patients. She could also argue that hospitals are free to charge for any ancillary nursing services and blood work, thus negating any concern with diverting public resources to private patients. In fact, a claimant might argue that allowing these services to be provided within public facilities would help retain nurses in the public system by not increasing demand for their services in private clinics. Claimants could also suggest that the legislation allowing the sale of cancer drugs on an out-patient basis but not on an in-patient basis is arbitrary (the reader is referred back to section II(A) above for a discussion of the different approaches to funding treatment on an in-patient as opposed to an out-patient basis).

The Ontario government, in response, would have to point to at least some evidence that to allow the sale by public hospitals of uninsured drugs would either undermine support for the public health care system or result in untenable inequities. For example, the government could argue that the sale by public hospitals of uninsured drugs depleted resources from the public system that should be directed to patients in need of "medically necessary" care. Additionally, the government may argue that such sale could open the floodgates to privatization of public hospitals, undermine public trust in decision-making about what is and is not "medically necessary", and erode political support for single-tier Medicare. As *Chaoulli* illustrates, however, arguments in principle or political theory will not be sufficient alone, and the government would have to compile strong comparative evidence from other jurisdictions in order to be successful.[54]

B. Section 1

If the court is satisfied that there has been a breach of section 7, then it must consider whether the breach is a reasonable limit "prescribed by law as can be demonstrably justified in a free and democratic society".[55] Although the burden of proving a section 7 violation is on the claimant, once this burden has been met, the state must prove that the breach is justified pursuant to section 1. This burden is rarely met where a section 7 right has been violated.[56] We will be brief in our discussion of section 1, as this discussion involves many of the same considerations contemplated under the "principles of fundamental justice" and our policy discussion in section III above.

The test for considering whether the government's burden under section 1 has been discharged is set out in *R. v. Oakes*: the legislative objective must be pressing and substantial; the means chosen must be rationally connected to the objective; the legislation must be minimally impairing; and the means chosen must be proportional to the resultant breach of rights.[57]

1. *Pressing and Substantial Objective*

It will be relatively easy for the government to meet this part of the test by arguing that the objective of the impugned legislation is to create an insurance plan that fosters equality regardless of ability to pay. This objective is furthered through protecting the public system. These types of broad objectives were accepted in *Chaoulli*, for example, with Deschamps J. finding the legislative objective was "to promote health care of the highest possible quality for all Quebeckers regardless of their ability to pay".[58]

2. *Rational Connection*

This part of the test will prove more difficult for the government to meet. Although the courts have traditionally deferred to governments, particularly in areas of complex social policy, *Chaoulli* may signal a shift in this attitude. In *Chaoulli*, faced with competing and inconclusive policy and social science evidence, three of the seven members of the Court who ruled on section 7 refused to defer to the Quebec government's chosen means of protecting public Medicare. The defendant government will, as discussed earlier, have to provide evidence supporting well-established theories about the negative impact of public

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54 *Supra* note 35 at para. 64, Deschamps J., and at para. 136, McLachlin C.J.C. and Major J., dissenting.

55 *Supra* note 40, s. 1.

56 Patrick J. Monahan, *Constitutional Law*, 2d ed. (Toronto: Irwin Law Inc., 2003) notes at 426 that out of 35 successful section 7 claims between 1991 and 2001, only two were saved under section 1.

57 [1986] 1 S.C.R. 103 [*Oakes*].

58 *Supra* note 35 at para. 49.

hospitals providing private-pay drugs; it will not be sufficient merely to lay out these theories. There is presently a paucity of empirical evidence on the effects of the sale of uninsured drugs within public hospitals.[59] If the claim reaches this stage before a court, then the government will be in a difficult position. In addition, patients could argue that any drain on the public system could be compensated by patients paying for the nursing time and other costs ancillary to the administration of the drugs. Most importantly, as discussed above, if a court concludes that the provisions are "arbitrary", then, as noted in *Chaoulli*, it is questionable whether an arbitrary provision would ever meet the rational connection test.[60]

As discussed above, if the government allows the sale of cancer drugs to out-patients and does not allow such sale to in-patients, it will strengthen the claim that the provisions are arbitrary. In turn this claim will strengthen the argument against the existence of a rational connection between the objective (protecting the public system) and the measures taken.

3. *Minimal Impairment and Proportionality*

The last two parts of the test may also prove difficult for the government to meet. Arguably, there are alternative means by which the government could protect the public system, such as charging cancer patients who buy uninsured drugs a fee for nursing, administration, diagnostic, and other services. In addition, a claimant may argue that provinces, such as Alberta, that allow for the sale of enhanced services within public hospitals arguably do so without jeopardizing the integrity of the public system.[61] Patients who have to travel unreasonably long distances for treatment as a result of the prohibition on the sale of uninsured drugs at public hospitals may argue that minimally impairing legislation would generally prohibit charging for uninsured services within hospitals, except in cases where it would effectively deny patients living in remote and rural areas the ability to obtain treatment because of a lack of access to private facilities.

Given the foregoing analysis of minimal impairment, the government would also have difficulty meeting the fourth requirement of proportionality. The underlying purpose is to ensure that there is "proportionality between the effects of the measures which are responsible for limiting the *Charter* right or freedom, and the objective which has been identified as of 'sufficient importance'".[62] The objective of the regulation requiring all drugs be funded publicly that are provided within public hospitals is to ensure equality in treatment within public hospitals. The effect of the measures on some patients may be viewed as onerous and therefore might not be proportional. The court in *R. v. Oakes* notes that "[t]he more severe the deleterious effects of a measure, the more important the objective must be if the measure is to be reasonable and demonstrably justified in a free and democratic society."[63]

C. Conclusion on section 7

We think it unlikely that a claimant will establish a *prima facie* breach of section 7, *but if* such a breach is proven, the government will then have an uphill battle. First, it will need to show that the breach is in accordance with the principles of fundamental justice. Second, if the government fails in this first step, then it will need to demonstrate that the breach is justified under section 1 as being a reasonable limit demonstrably justified in a free and democratic society. As we have already illustrated in our discussion of the relevant policy options, the evidence of a negative effect on the public system is relatively weak as it lacks a strong empirical base. Consequently, proving these adverse policy consequences to the satisfaction of a court may, as in *Chaoulli*, be difficult.

CONCLUSION

There are increasingly tough choices for governments to make in the face of an influx of expensive new health care technologies, particularly of new drugs. In Ontario, a decision has been made not to fund publicly a number of new cancer agents on the basis that they are not sufficiently cost-effective. These drugs are, however, of therapeutic benefit, and many patients and their physicians will consider these

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59 Because of the novelty of the issue of selling uninsured drugs in public hospitals in Canada, there has been no opportunity to collect data on the effects of such a policy. In addition, we were unable to find international data on this point that is important.

60 *Supra* note 35 at para. 155, McLachlin C.J.C. and Major J., dissenting.

61 For a discussion of Alberta's legislation in this regard, see Choudhry, *supra* note 25.

62 *Oakes*, *supra* note 57 at 139 [emphasis in original].

63 *Ibid.* at 140.

drugs crucial to cancer treatment. Accordingly, patients with means (and/or private insurance) will want to buy these drugs.

Having made a decision not to publicly fund these drugs, the Ontario government now faces pressure from those who can afford to pay privately to facilitate their access to these drugs in public hospitals. The reason for this pressure is that presently there is only one private clinic in Ontario at which these cancer drugs can be safely accessed outside of a public hospital. This paucity in private delivery options results in safety concerns, with patients anxious to receive these new cancer drugs approaching untrained staff in inappropriate sites (for example, urging their family doctor, untrained in the complexities of these drugs and their administration, to provide the infusion).

The resolution of this problem is extremely difficult and fraught with political complexities. In this paper, we explored the Ontario government's dilemma in three parts: what it could do (in terms of what statutes and regulations limited the private sale of cancer drugs in public hospitals); what it should do (considering the pros and cons of this policy); and what it may be made to do (if a frustrated patient, who wanted to buy cancer drugs in public hospitals, could successfully bring a section 7 *Charter* challenge).

First, with respect to what it can do, it seems that under existing Ontario legislation, it is not permissible to sell cancer drugs to in-patients, but it is permissible to sell cancer drugs to out-patients. Turning to federal legislation, with respect to the *CHA*, all turns on the definition of "medically necessary". If the drugs are "medically necessary", then in order to qualify for federal funding, a province must ensure that such drugs are fully publicly funded within public hospitals. The catch is that there is no established process for deciding what is and is not medically necessary, and there is a large grey area in which a judgment call has to be made. The federal government has historically been wary of trumping provincial decision-making in this regard. It is therefore unlikely, except in circumstances where Ontario is a clear outlier from other provinces, that the federal government would object to a provincial government's own assessment of what is "medically necessary". If a drug is not classified as medically necessary, there is nothing in the *CHA* that would seem to prevent the private sale of such a drug within a public hospital.

Second, with respect to what it should do (i.e., the advantages and disadvantages from a policy perspective), the Ontario government is in an unenviable position. There are real concerns about the sustainability of Medicare and the threat that the cost of new drugs pose. However, having made the tough call not to publicly fund a new cancer drug, there is the question of how to respond to cancer patients who have sufficient private financing to buy the drug but cannot readily access a private provider. Although the cancer drugs in question may be judged cost-ineffective and thus not "medically necessary" from the perspective of the public plan, many patients and many doctors will nonetheless view them as necessary. Resolution of these issues turns on how one justifies the various regulations prohibiting a two-tier system. We argue that there are two basic approaches to answering this question. The first is that it is wrong for there to be unequal treatment vis-à-vis health care. The second is that unequal treatment is acceptable, provided that it does not result in derogation from a robust and reasonable standard of care for all in the public health care system. We reject the first approach and accept the second approach; it is acceptable to allow others to buy private care *provided that* it does not undermine achieving the goal of a reasonable standard for all in the public health care system.

Looking first at the equality argument, there has always been inequality in our system to the extent that every publicly funded system has limitations and beyond those limitations patients are free (if able) to access private markets. However, this acknowledgment does raise the question of whether *within* public hospitals there should be equality in treatment. There may be more sophisticated ethical answers to this question than we are able to provide here; we would simply note that allowing patients to access cancer drugs on a private-pay basis within public hospitals will likely be viewed by the public to be in breach of a commitment to equality in Medicare even if such permission can be justified in theory.

Turning to consider the impact on the public system, we raised the concern that over time if patients with means (or private insurance) are able to buy private-pay drugs in public hospitals, they will no longer be as committed to ensuring a robust (in terms of access, quality, and timeliness) universal public system. This result may be good from the perspective of cost containment and perhaps the fiscal sustainability of Medicare; however, it is of concern from the perspective of ensuring a robust standard of quality in universal public Medicare. Another potential negative impact on the public system is that the sale of these drugs in public hospitals may undermine the government's position that these drugs are not sufficiently beneficial to warrant public funding. If they are not sufficiently beneficial, the public may question why the government is taking steps to facilitate access on the part of patients who can afford to pay for them. However, the arguments against the sale of uninsured drugs in public hospitals are not as strong as the

arguments and supporting evidence against two-tier medicine in the case of physician services, where there are incentives for scarce medical manpower to be diverted from the public to the private sector. In contrast, there is little empirical data addressing the concerns associated with the sale of uninsured drugs by public hospitals.

Balanced against concerns of increased inequalities within public hospitals and the flow-back effect on the universal public system is the fact that patients who wish to access these cancer drugs presently have very few private delivery options and that travelling to the one private clinic that exists in Toronto may further compromise patients' health and add to the financial and other burdens they already face.

The decision not to publicly fund some cancer drugs was likely a difficult one, given that at least three other provinces fund these same drugs in their respective public plans. In our view, weighing the pros and cons, the Ontario government should either continue not to publicly fund these drugs for all or change its policy and fund the drugs for all. The government should eschew the temptation to take the middle ground of facilitating access on the part of private-pay patients in public hospitals.

Notwithstanding our view of what the right policy choice is, the government may be forced to take action as a result of a section 7 *Charter* challenge. The first hurdle for a claimant is that section 7 does not protect economic rights and so one needs to show a nexus between the inability to purchase private care (seemingly an economic claim) and the suffering endured (as was done in *Chaoulli*). Here, in contrast to the circumstances of *Chaoulli*, a patient is at liberty to carry private insurance to cover the cost of the cancer drugs and to go to a private clinic in Canada to be infused with uninsured cancer drugs. Thus, a claimant would likely need to demonstrate that the physical and/or psychological stress of having to go to a private clinic, rather than to a public hospital, is such that one's life or security of the person is engaged. Such a case was made in *Morgentaler* vis-à-vis access to abortion services. The key difference between *Chaoulli* and the fact scenario under examination here is the claim to be able to pay privately for drugs in public hospitals. The claim to be able to privately pay for drugs in public hospitals is economic in nature compared to the claim in *Morgentaler*.

We envisage only two situations where a successful section 7 challenge *may* be possible. The first would arise when having to go to a private clinic for infusion would demonstrably jeopardize a patient's safety. The second category of potentially successful claimants would be those who would suffer significant psychological stress as a result of having to travel an unreasonably long distance to receive treatment in Toronto, the location of the only private clinic. However, assuming the number of private clinics increases, this second category of potentially successful claimants could diminish.

Although we think a plaintiff's chances of establishing a *prima facie* section 7 violation are limited, if such a breach is proven, we argue that the government will have a difficult battle demonstrating that the breach is in accordance with the principles of fundamental justice, or justifying the breach under section 1 of the *Charter*. Due to the lack of empirical evidence on the negative effect of selling drugs in the public system, proving adverse policy consequences may prove difficult, as in *Chaoulli*.

We conclude that, provided limits are drawn in a fair and transparent way, it is difficult to challenge conceptually a decision not to publicly fund a particular drug or treatment even if the drug or treatment is of some clinical benefit; it is also difficult to contest that such a drug should not be subsequently available in private markets, given the limits on what the public system can insure. The only real issue that arises is whether there are any negative effects on allowing the private sale of these drugs or treatments *within* the public system (i.e., within the walls of a public hospital). In the case of cancer drugs, the pressing concern is whether, over time, decisions not to fund new drugs and therapies will be taken more lightly, given that those with means and insurance will still be able to access these drugs in a public hospital. Will this policy ultimately erode a high standard of care for all Ontario citizens in the public system? This is a tough call. Allowing this policy may make future political decision-making about the limits of public-funding easier but this outcome should cause government to pause, as arguably these decisions should *not* be easy. Decision-makers should agonize over such close calls. The potential for this policy to lead to more unprincipled decision-making is the tie-breaker for us in resolving this extremely difficult dilemma, but, as discussed, at least some readers of this article and a court in a *Charter* challenge may not be so persuaded.

REFLECTIONS ON THE COMMERCIALIZATION OF RESEARCH CONDUCTED IN PUBLIC INSTITUTIONS IN CANADA

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We are presently witnessing a remarkable emphasis upon the commercialization of research in public institutions around the world. The issue is polarizing within the academic community, but the commercialization of research in public institutions has, in itself, largely failed to capture the public imagination. Nothing suggests that a large-scale debate on this issue is forthcoming in Canada or elsewhere. The purpose of this paper is therefore to build the case for why large-scale debate is necessary and to set the stage for that debate by providing an account of all of the alleged benefits and harms of commercialization. Our review of these benefits and harms exposes the fact that there is much that we simply do not know about the impact of commercialization, which provides support for the claim that much greater caution is warranted on the part of public institutions currently embracing this phenomenon with enthusiasm. Therefore, to ensure that this social experiment proceeds safely, ethically, and democratically, we must start gathering and sharing all of the relevant information pertaining to effects of this commercialization phenomenon, engage all those with relevant expertise and those whose interests are at stake in discussions about the values involved and the relative merits of various courses of action, and then ground policies and practice in the arena of commercialization in these discussions.

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The authors would like to thank the members of the Novel Tech Ethics research team at Dalhousie, Brad Abernethy, and the anonymous reviewers for helpful comments on earlier drafts of this paper. We would also like to note that this paper is a Canadianized, updated, and revised version of Jocelyn Downie, "The Power of Money: Commercialisation of Research Conducted in Public Institutions [in Australasia]" (2006) 11:2 University of Otago Law Review 305-325.

INTRODUCTION

Against a backdrop of increased operating costs and decreased support for universities from government and other traditional non-commercial sources,[1] as well as a transition to "knowledge-based" economies, we are witnessing the remarkable commercialization of research in public institutions around the world. Academic scholarship on the topic of commercialization has begun to explode—predominantly in relation to biomedical research, although a few treatments have been more encompassing.[2] The issue is polarizing, with critics of commercialization seemingly becoming more strident on the one hand and government officials (of all political stripes) and university administrations more deeply embracing commercialization goals on the other. Yet, the commercialization of research in public institutions has, in itself, largely failed to capture the public imagination. Nothing suggests that a large-scale debate on this issue is forthcoming in Canada or elsewhere. Thus, rather than undertaking an in-depth scholarly analysis of a few specific examples of the impact of commercialization upon specific research areas, our approach in this paper is decidedly broad: we seek to build the case for why large scale debate is necessary and to set the stage for that debate by providing an account of all of the alleged benefits and harms of commercialization. Our review of these benefits and harms will, of necessity, be summary in nature but will nevertheless expose the fact that there is much that we simply do not know about the impact of commercialization. By demonstrating that the push in favour of commercialization is in turn largely responsible for this paucity of evidence, we hope that our overview will add persuasive force to more detailed critiques of discrete aspects of the commercialization phenomenon and support the claim that much greater caution is warranted on the part of public institutions currently embracing this phenomenon with enthusiasm.

There are three parts to our paper. First, we define our object of inquiry, the commercialization phenomenon, by briefly situating it in historical terms, charting current related statistical indicators, and describing some of the consequences it has already had upon places of research, research priorities, and researchers. In the second part, we present the alleged benefits and harms of the commercialization phenomenon, deferring a consideration of the relative weighting of these benefits and harms until the third and final part of the paper.

I
DISSECTING THE PHENOMENON

For the purposes of this paper, we stipulate a set of definitions. First, "commercialization of research" means "the conversion of research results into products, services, and processes that can be the object of commercial transactions". "Public institutions" means "post-secondary institutions, government-funded Networks of Centres of Excellence, public hospitals, and government research organizations". In discussing the commercialization of research in public institutions, we focus on two often-related, but nonetheless distinct, features of the phenomenon: first, the harnessing of intellectual property by public institutions (through, for example, the patenting or licensing of research results); and, second, the partnering of public institutions with the private sector.

There are, of course, historical precedents for patenting, licensing, and public-private partnerships. In the early 1920s, for instance, University of Toronto researchers F.G. Banting and C.H. Best patented a method of making synthetic insulin. Donations from private corporations and individuals then helped to

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[1] "[G]overnment grants and contracts make up only 56.6% of all university revenues, down from 67% as recently as 1992". Canadian Association of University Teachers, "Public or Private? University Finances 2002-2003" 6:3 CAUT Education Review 1 at 3. "In the past two decades, government operating grants to public universities have fallen by 30 per cent per student." University of Waterloo, "Building a talent trust", online: University of Waterloo <http://www.campaign.uwaterloo.ca/brochure/building.html>. "At precisely the time when the 'knowledge-based' economy is crying out for better educated workers—people who can think and solve problems—we have seen a shocking decline in education spending." A. Charles Baillie, Chairman and Chief Executive Officer, Toronto Dominion Bank (Address to the Canadian Club, Toronto, 26 February 2001), online: <http://www.canadianclub.org/static/speeches/13.pdf>.

[2] Derek Bok, *Universities in the Marketplace: The Commercialization of Higher Education* (Princeton: Princeton University Press, 2003) [Bok]; Neil Tudiver, *Universities for Sale: Resisting Corporate Control over Canadian Higher Education* (Toronto: James Lorimer and Company Ltd., 1999) [Tudiver]; Jennifer Washburn, *University, Inc.: The Corporate Corruption of American Higher Education* (New York: Basic Books, 2005) [Washburn]; Sheila Slaughter & Gary Rhoades, *Academic Capitalism and the New Economy: Markets, State, and Higher Education* (Baltimore: The Johns Hopkins University Press, 2004) [Slaughter & Rhoades].

create the Banting Research Foundation in 1925,[3] the same year in which Canada's first public-private research institute, the Pulp and Paper Research Institute of Canada (PAPRICAN), was founded at McGill University.[4] As we show next, however, patenting, licensing, and public-private partnerships are now occurring at unprecedented rates. In Banting and Best's era, the commercialization of research was more grass-roots and not always condoned by public institutions or well received by the academic community.[5] Today, public institutions explicitly embrace the commercialization of research as a core goal and actively attempt to steer research in that direction through a variety of mechanisms.[6] We therefore start from the position that the present commercialization phenomenon represents a fundamental shift in values and direction.

A. Harnessing Intellectual Property

Public institutions in Canada are certainly harnessing their intellectual property (IP). For example, public institutions reported the following IP harnessing activities for 1998, 1999, 2001 and 2003:[7]

TABLE 1

Harnessing Activity	**1998**	**1999**	**2001**	**2003**
# of new patent applications	379	656	932	1252
# of patents held	*	1915	2133	3047
# of spin-off companies	366	471	680	876

* An exact figure for this year is unavailable.

Earlier data about levels of patenting are difficult to obtain or simply unavailable. According to the U.S.-based Association of University Technology Managers (AUTM), whereas only 59 new U.S. patent applications were filed by 10 Canadian institutions in 1991 (i.e., an average of 5.9 applications per institution), 572 new applications were filed in 2004 by 34 institutions (i.e., an average of 16.8 applications per institution).[8] The rate of "start-up" company formation is also accelerating according to AUTM: of the 712 start-up companies accounted for in 2004, 556 were formed after 1993.[9]

Through the harnessing of IP, public institutions are generating considerable and continually increasing income. For example, public institutions reported the following income from IP harnessing in 1998, 1999, 2001 and 2003:[10]

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[3] See Banting Research Foundation, "About Us: Proud Of Our History", online: Banting Research Foundation <http://www.utoronto.ca/bantresf/>.

[4] Jorge Niosi, *Flexible Innovation: Technological Alliances in Canadian Industry* (Montreal: McGill-Queen's University Press, 1995) at 33 [Niosi].

[5] For an interesting account of early instances of patenting publicly funded inventions in the U.S. and the ensuing public controversies, see Charles Weiner, "Patenting and Academic Research: Historical Case Studies" (1987) 12:1 Science, Technology, & Human Values 50.

[6] Again, we do not mean to suggest that historical examples of government-sponsored programs to encourage university-industry collaboration do not exist. The federal government implemented the Program for the Advancement of Industrial Technology (PAIT) and the Industrial Research Institute Program in 1965 and 1966, respectively: see Janet Atkinson-Grosjean, Dawn House & Donald Fisher, "Canadian Science Policy and Public Research Organisations in the 20th Century" (2001) 14:1 Science Studies 3 at 12-13ff. [Atkinson-Grosjean]. Nevertheless, as detailed below, the number of, and emphasis placed, upon these programs have increased dramatically in recent years.

[7] Statistics Canada, *Survey of intellectual property commercialization in the higher education sector, 1998* by Michael Bordt & Cathy Read (Ottawa: Minister of Industry, 1999), online: Statistics Canada <http://www.statcan.ca/english/research/88F0006XIE/88F0006XIB1999001.pdf> [Statistics Canada, *1998 Survey*]; Statistics Canada, *Survey of intellectual property commercialization in the higher education sector, 1999* by Cathy Read (Ottawa: Minister of Industry, 2000), online: Statistics Canada <http://www.statcan.ca/english/research/88F0006XIE/88F0006XIB2000001.pdf> [Statistics Canada, *1999 Survey*]; Statistics Canada, *Survey of intellectual property commercialization in the higher education sector, 2001* by Cathy Read (Ottawa: Minister of Industry, 2003), online: Statistics Canada <http://www.statcan.ca/english/research/88F0006XIE/88F0006XIE2003012.pdf> [Statistics Canada, *2001 Survey*]; Statistics Canada, *Survey of intellectual property commercialization in the higher education sector, 2003* by Cathy Read (Ottawa: Minister of Industry, 2005), online: Statistics Canada <http://www.statcan.ca/english/research/88F0006XIE/88F0006XIE2005018.pdf> [Statistics Canada, *2003 Survey*].

[8] Association of University Technology Managers, *AUTM Canadian Licensing Survey: FY 2004, Survey Summary* (AUTM, 2006) at 10, online: AUTM <http://www.autm.net/events/File/AUTM%20PUBLICATIONS/FY04AUTMCanLicSurvSum-public.pdf>.

[9] *Ibid.* at 18.

[10] Statistics Canada, *1998 Survey*, *supra* note 7 at 22-23; Statistics Canada, *1999 Survey*, *supra* note 7 at v; Statistics Canada,

TABLE 2

Income (in millions)	**1998**	**1999**	**2001**	**2003**
Income from IP commercialization	*	*	$52.5	$55.5
Equity held in public spin-offs	$22.5	$54.6	$45.1	$52.4
Royalties from licensing	$15.6	$21.1	$47.6	$55.4

* Exact figures for these years are unavailable.

This harnessing of IP is driven, in large part, by significant financial incentives. First, and most obviously, public institutions are permitted to keep profits from the commercialization of their research (even where that research is funded by the public purse).[11] With no governmental strings attached, then, income from commercialization is becoming increasingly prized. Second, significant funding is available specifically for commercializable research, as the federal government is creating funds to support commercializable research in public institutions. Examples include:

- The NSERC Idea to Innovation Program ("provides funding to college and university Faculty members, through defined stages, for research and development activities leading to technology transfer to a new or established Canadian company");[12]
- The CIHR Proof of Principle Program ("Grants will fund proof of principle research projects of up to 12 months duration designed to advance discoveries/inventions towards commercializable technologies, with a view to attract new investment and create new science-based businesses.");[13] and
- Industry Canada's new program for "Commercialization Funds" ($75 million over the next five years: "One of the Funds will provide $50 million ... to further strengthen the commercialization capacity of universities and research hospitals. The other $25 million Fund will encourage the commercialization of research conducted in federal government labs.").[14]

Later in this paper, we will discuss additional reasons for the commercialization of research in public institutions.

B. Partnering with the Private Sector

Public institutions in Canada are also partnering with the private sector. For example, investment by business in Canadian universities is significant. "Canadian firms contract out over 6% of their R&D to universities (well above levels in other G-7 countries) and this represents 16% of university research funding."[15] "Business enterprise" R&D expenditures in the higher education sector have gone from $115.1 million in 1988–89 to $643.1 million in 2002–03, increasing by more than 500%.[16]

As with the harnessing of IP, this partnering is driven, in large part, by financial incentives. Governments clearly see partnering as beneficial:

2001 Survey, *supra* note 7 at 25, 28; Statistics Canada, *2003 Survey*, *supra* note 7 at 12-13, 23.

[11] Cathy Read, "Commercializing the results of research in Canadian universities and hospitals: an update for 2003" (2005) 7:3 Innovation Analysis Bulletin 11 at 11.

[12] National Sciences and Engineering Research Council of Canada, "Idea to Innovation (I2I) Program", online: NSERC <http://www.nserc.ca/professors_e.asp?nav=profnav&lbi=b4>.

[13] Canadian Institutes of Health Research, "Operating Grant: Proof of Principle", online: CIHR <http://www.cihr-irsc.gc.ca/e/25487.html>.

[14] This statement previously appeared at Industry Canada, "University and Government Research Commercialization Funds", online: <http://strategis.ic.gc.ca/epic/internet/incf-fc.nsf/en/h_tg00003e.html>, but is no longer available. However, this commitment was originally made in the federal government's 2004 budget: "Budget 2004: Building an Innovative Economy for the 21st Century", online: Ministry of Finance <http://www.fin.gc.ca/budget04/pamph/paecoe.htm> at 4.

[15] Canada, "Innovation in Canada: The Canadian University Sector: Innovation Profile" (2002), online: Government of Canada <http://www.innovation.gc.ca/gol/innovation/site.nsf/en/in02596.html> [Canada, "Innovation in Canada"].

[16] Statistics Canada, *Estimation of Research and Development Expenditures in the Higher Education Sector, 2002-2003* (Ottawa: Minister of Industry, 2004), online: Statistics Canada <http://www.statcan.ca/english/freepub/88-001-XIE/88-001-XIE2004010.pdf>.

> Universities play an important role in stimulating innovation ... but their ties to the private sector make them a particularly important player in Canada.... [U]niversities need to ... more aggressively seek out commercial applications for publicly funded research.[17]

One of the Canadian government's current priorities is to "support academic institutions in identifying intellectual property with commercial potential and forging partnerships with the private sector to commercialize research results".[18] Government programs clearly encourage industry/university collaboration. Some funding programs include:

- NSERC's Collaborative Research and Development Grants Program ("intended to give companies that operate from a Canadian base access to the unique knowledge, expertise, and educational resources available at Canadian postsecondary institutions ... the mutually beneficial collaborations are expected to result in industrial and/or economic benefits to Canada..."));[19]
- CIHR's Innovation and Industry Programs ("designed to help the academic community interact with Canadian companies with an interest in health research and development");[20]
- Networks of Centres of Excellence ("...fosters powerful partnerships between university, government and industry. Networks of Centres of Excellence funded by the program are designed to develop Canada's economy and improve the quality of life of Canadians.");[21]
- Canada Foundation for Innovation ("an independent corporation created by the Government of Canada to fund research infrastructure which consists of the state-of-the-art equipment, buildings, laboratories, and databases required to conduct research. The CFI's mandate is to strengthen the capacity of Canadian universities, colleges, research hospitals, and non-profit research institutions to carry out world-class research and technology development that benefits Canadians.... [CFI] normally funds up to 40 percent of a project's infrastructure costs which are invested in partnership with eligible institutions and their funding partners from the public, private, and voluntary sectors who provide the remainder");[22] and
- Genome Canada (provides funding to support "large-scale projects of strategic importance to Canada, which are beyond current capacities by bringing together industry, government, universities, research hospitals and the public").[23]

In addition, benchmarks of success for public institutions (and the concomitant rewards) now include commercializable and commercialized research. The total number of patent applications filed, licensing agreements secured, and spin-off companies created are closely tracked as primary indicators of commercialization by technology manager organizations such as AUTM and by governmental bodies such as Statistics Canada and the federal funding agencies alike. The metrics used by other organizations are cruder. Research Infosource, for example, rates the top 50 Canadian research universities each year based strictly on their sponsored research income. The more sponsorship a university attracts, the more favourable a rating they will receive.[24] Finally, while an awareness of the limits of all of these metrics is

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17 Canada, "Innovation in Canada: Section 5: The Knowledge Performance Challenge: Canada's Innovation Strategy", online: Government of Canada <http://www.innovation.gc.ca/gol/innovation/site.nsf/en/in04160.html>.

18 Canada, "Executive Summary: Achieving Excellence", online: Government of Canada <http://www.innovation.gc.ca/gol/innovation/site.nsf/en/in02425.html> [Canada, "Achieving Excellence"].

19 Natural Sciences and Engineering Research Council of Canada, "Collaborative Research and Development (CRD) Grants", online: NSERC <http://www.nserc.ca/professors_e.asp?nav=profnav&lbi=b3>. Other collaborative funding programs from NSERC include Research Partnerships Agreements, Strategic Network Grants, and Strategic Project Grants: Natural Sciences and Engineering Research Council of Canada, "Partnerships Programs Overview", online: NSERC <http://www.nserc.ca/professors_e.asp?nav=profnav&lbi=toc_b>.

20 Canadian Institutes of Health Research, "What We Do: CIHR Innovation and Industry Programs", online: CIHR <http://www.cihr-irsc.gc.ca/e/4569.html>. Other collaborative funding programs from CIHR include Industry Partnered Operating Grants, Industry Partnered Randomized Controlled Trials, Industry Partnered New Investigator Salary Awards, and Industry Partnered Research Chairs: Canadian Institutes of Health Research, "Master List of all CIHR Current Funding Opportunities", online: CIHR <http://www.cihr-irsc.gc.ca/e/27194.html>.

21 Networks of Centres of Excellence, "Welcome to the Networks of Centres of Excellence (NCE) Program", online: NCE <http://www.nce.gc.ca/index.htm>.

22 Canada Foundation for Innovation, "CFI Policy and Program Guide", online: CFI <http://www.innovation.ca/programs/index.cfm?websiteid=253>.

23 Genome Canada, "About Genome Canada: Mandate and Objectives", online: Genome Canada <http://www.genomecanada.ca/xcorporate/about/objectives.asp?l=e>.

24 Research Infosource Inc., "Canada's Top 50 Research Universities 2005", online: Research Infosource <http://

beginning to emerge,[25] Canadian universities have explicitly promised to treble the commercialization of research by 2010;[26] this target is based exclusively on gross financial income.[27]

C. Consequential Changes

A number of changes in the research landscape largely facilitate, maximize, and respond to this harnessing and partnering. These changes include: creating new structures; collaborating across sectors; intermingling of people across sectors; and shifting the roles, missions, and mandates for researchers, research institutions, research regulators, research funders, hospitals, and universities.

1. *New Structures*

In universities, new offices have been created. Many universities now have a Business Development Office, Technology Transfer Office, or similarly named office aimed, at least in part, at commercializing the research results of the institution.[28] The staff members of these offices include commercialization managers, as well as lawyers specializing in contracts and IP. In Australia, New Zealand and the US, titles and portfolios at the highest levels of university management have also evolved to include Pro or Deputy Vice Chancellor (Research and Innovation), Pro Vice Chancellor (Research and Development), Deputy Vice Chancellor (Research and Commercialization), and Deputy Vice Chancellor (Research, Enterprise and International).[29] We are also starting to witness this evolution in Canada through the development of positions such as the Vice-President of Research and Innovation at York University.[30]

New companies attached to universities have also been created. For example, Queen's University's PARTEQ Innovations is an independent corporation "founded in 1987 to commercialize intellectual

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www.researchinfosource.com/media/2005-top50.pdf>.

25 The Association of Universities and Colleges of Canada (AUCC), for example, has acknowledged that commercialization is but one aspect of innovation and knowledge transfer, and has attempted "to push the measurement of commercialization to a broader discussion of the economic and social benefits". Statistics Canada, "Summary: Meeting on Commercialization Measurement, Indicators, Gaps and Frameworks, Ottawa" (Working paper) (Ottawa: Minister of Industry, 2005) at 10, online: Statistics Canada <http://www.statcan.ca/english/research/88F0006XIE/88F0006XIE2005007.pdf>. Statistics Canada, too, has recognized that the goals of obtaining patents and generating licensing revenues may conflict with training highly qualified personnel. *Ibid*. at 14.

26 "Universities should seek to triple the intellectual property revenues generated by commercialization by 2010. This target has been adopted by the federal government as part of the national innovation strategy." Association of Universities and Colleges of Canada, "The Commercialization of University Research", online: AUCC <http://www.aucc.ca/_pdf/english/reports/2002/innovation/commercial_e.PDF>.

27 A 2005 report explains this tripling target:

> To measure universities' collective progress in meeting their target of tripling commercialization performance, AUCC developed an indicator called *Total Income from the Commercialization of Intellectual Property*. This measure is based on data reported every two years in the *Survey of Intellectual Property Commercialization in the Higher Education Sector* conducted by Statistics Canada. The tripling indicator is an aggregate of gross income earned as a result of royalties from licences, equity disposed of by institutions, dividends paid to institutions and reimbursement of patent costs.... In 1999, the base year for the tripling target, total income derived from the commercialization of university intellectual property was estimated at $23.4 million. To triple this income from 1999 to 2010, universities and their affiliated institutions will need to earn more than $70.2 million from their commercialization activities by 2010. Universities have made significant progress and are on track to achieve the tripling target, possibly in a shorter timeframe than initially predicted. The most recent results of the Statistics Canada survey show that between 1999 and 2003, universities more than doubled their total gross income from commercialization, from $23.4 million to $51 million.

Association of Universities and Colleges of Canada, *Momentum: The 2005 report on university research and knowledge transfer* (2005), online: AUCC <http://www.aucc.ca/momentum/en/_pdf/momentum_report.pdf> [footnotes omitted].

28 A few universities had established so-called "Research Offices" in the 1970s. Starting in the 1980s, however, the federal government's financial assistance enabled every major research institution in Canada to establish an "industry liaison office" mandated to protect and licence intellectual property, to administer research contracts, and sometimes even to create "spin-off" companies: see Donald Fisher & Janet Atkinson-Grosjean, "Brokers on the boundary: Academic-industry liaison in Canadian universities" (2002) 44 Higher Education 449 at 453.

29 Australian Vice-Chancellors' Committee, "Deputy/Pro Vice-Chancellors – Research", online: AVCC <http://www.avcc.edu.au/database/report.asp?a=show&committee=283>.

30 York University, "Vice-President Research & Innovation", online: York University <http://vpacademic.yorku.ca/directory/findadm.php?id=5001>.

property ... arising from university-generated research".[31] Univalor is an independent company whose mission is "to commercialize discoveries made by researchers at the Université de Montréal".[32]

Universities have also developed new degree and diploma programs. For example, the University of Waterloo's Masters in Business, Entrepreneurship and Technology (MBET) is described on its official website as follows:

> MBET's vision is to be recognized as an entrepreneurship program of local and international [renown], where the exceptional talents of graduates in identifying, developing and marketing breakthrough opportunities are widely recognized. By providing visionaries with a unique set of business skills and hands-on opportunities in a nurturing, real-time technological environment, the MBET program will supply the leaders who will build tomorrow's businesses.[33]

While the University of Waterloo has long taken an approach that integrates education with employment (e.g., through its co-op programs), the emphasis on identifying commercial opportunities *ex ante* rather than *ex post* in the technology development process represents a subtle but arguably significant development.

2. *New Collaborative Entities*

Groups of individuals and institutions are also collaborating on the commercialization of research. Consider, for example, the following ways in which new entities present themselves on their websites:

- TR Labs ("Creates innovative technologies and trains students to enhance ICT expertise and improve Canada's competitiveness.... Industry seasons the research program by setting direction and priorities...."); [34]
- Westlink Innovation Network ("We connect skilled professionals in academia and industry to collaborate and move Canadian expertise and innovations from the lab and minds of researchers to final products in the marketplace."); [35]
- MaRS ("is building a closely connected commercialization community that will bring together research, capital and industry to improve the productivity of technology transfer, increase capital flow and grow the number of Canadian companies achieving global success"); [36] and
- Leaders' Roundtable on Commercialization ("is a blue-ribbon panel of 46 CEOs, university presidents and deputy ministers ... with the self-declared mandate: *to establish a shared commercialization vision for Canada and an action plan that recognizes the unique challenges facing various sectors and regions*.") [37]

3. *Intermingling of People across Sectors*

Industry has long sought to have greater influence on research performed at public institutions, securing positions in university administrations and creating foundations in order to advance that goal.[38] In the past, many of these efforts sparked intense controversy and resistance from members of the academic community and from an outspoken former President of the National Research Council.[39]

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31 PARTEQ innovations, "about PARTEQ", online: PARTEQ <http://www.parteqinnovations.com/about.html>.

32 Univalor, "Home", online: Univalor <http://www.univalor.ca/researchers/home.htm>.

33 University of Waterloo, "What is the Master of Business, Entrepreneurship and Technology (MBET)?", online: University of Waterloo <http://cbet.uwaterloo.ca/Prospective_Students/MBET.html> [University of Waterloo, "What is the MBET?"]. See also University of Alberta, "MBA: Technology Commercialization", online: University of Alberta <http://mba.bus.ualberta.ca/Degrees/TC.htm>.

34 TRLabs, "A Thread in Western Canada's ICT Fabric", online: TRLabs <http://www.trlabs.ca/trlabs/about/>.

35 Westlink Innovation Network, "About Westlink", online: Westlink Innovation Network <http://www.westlink.ca/about.php>.

36 MaRS, "Explore MaRS: About MaRS", online: MaRS <http://www.marsdd.com/>.

37 The Conference Board of Canada, "Leaders' Roundtable on Commercialization", online: The Conference Board of Canada <http://www.conferenceboard.ca/CRTBL/> [emphasis in original].

38 In 1956, a national nongovernmental organization designed to foster university-industry cooperation called the Industrial Foundation on Education was formed, wholly financed by the private sector: see Tudiver, *supra* note 2 at 142. Also, industry-sponsored research chairs, research contracts and consulting arrangements with universities date as far back as the latter part of the nineteenth century: see Niosi, *supra* note 4 at 33.

39 Influential university officials' plans to build on-campus "institutes" solely for industrial research, for instance, ended when a Parliamentary subcommittee learned that faculty at the University of Toronto were "adamantly opposed to 'bargaining with manufacturers'": see Canada, *A Science Policy for Canada: Report of the Senate Special Committee on Science Policy*, vol. 1

However, following a rash of programs and measures introduced by various federal governments, reaching back as far as the 1960s and accelerated through the 1980s and 1990s,[40] the intermingling of the public and private sectors is now much more profound and less subject to comment, let alone controversy. Most Boards of Directors of Canadian universities include Directors of a variety of companies. The President of GlaxoSmithKline, a major pharmaceutical company, is on the Board of Directors at Queen's University.[41] The Chancellor of the University of Waterloo board is Mike Lazaridis, President and CEO of RIM[42] and a major donor to the university.[43] In some universities, industry even represents the majority at the board level, while at the University of Alberta, Concordia University, and the University of Calgary, nearly 50% of the members of the Boards of Directors have corporate affiliations.[44] But industry's presence also permeates the institution as a whole, with "industry scholars" appearing on peer review committees and with industry employees using space in university/hospital labs and holding appointments on university/hospital staff. At the same time, public institution researchers now commonly appear in the private sector, where they can be found serving as board members, consultants, authors, and speakers. University administrators are also serving on corporate boards. For instance, the President of Dalhousie University, Tom Traves, is a director at Clearwater Seafood, The Greater Halifax Partnership, and InNOVAcorp.[45]

This intermingling is not only in roles but also in space, through "co-location" of industry and academic researchers. Since the 1980s, several urban centres have built "science parks" near university campuses, zoning sizeable plots of land for spin-off company tenants in the hope of stimulating technology transfer.[46] In 2002, the Canadian government took this idea a step further, officially endorsing co-location of government, academia, and industry not only within the same geographical region but within the same building.[47] Consider, for example, the MaRS Centre in Toronto: "The MaRS Centre—both as a physical complex and as the hub for an extended virtual community—is designed to accelerate the commercialization of Canadian innovation by uniting the disparate worlds of science and technology with industry and capital."[48] Interestingly, the chair of the board of directors at MaRS, Dr. John Evans, is also Chair of the Torstar corporation, former vice-chair of NPS-Allelix Inc., and President *emeritus* of the University of Toronto.[49] Industry and the academy are both literally and figuratively coming together through the commercialization of research in public institutions.

(Ottawa: Queen's Printer for Canada, 1970) at 31 (Chair: Maurice Lamontagne). Under the direction of E.W.R. Steacie between 1952 and 1962, the NRC continued to see its task as developing a "critical mass" of university-based scientists. Although indirect, Steacie fervently believed that this approach was the optimal way to support industry: Atkinson-Grosjean, House & Fisher, *supra* note 6 at 10–11. Bureaucratic organization was, in his view, the "enemy" of laboratory science. Steacie once stated the following: "The important thing is that in any well run laboratory there must be a conscious and continuing effort to reduce organisation and planning to a minimum, to have as few committees as possible, to write reports as infrequently as possible, and to regard 'coordination' as a dirty word!" E.W.R. Steacie, *Science in Canada: Selections from the Speeches of E.W.R. Steacie*, ed. by J.D. Babbitt (Toronto: University of Toronto Press, 1965), cited in *ibid*. at 11.

40 See Atkinson-Grosjean, *supra* note 6.

41 Canadian Association of University Teachers, "Directory of University and College/Corporate Board Linkages 2005-2006" (2005), online: CAUT <http://www.caut.ca/en/publications/linkages/db.asp> [CAUT, "Directory"].

42 *Ibid.*

43 See University of Waterloo, Media Release, "RIM Founder increases donation to $50 million for Quantum Computing and Nanotechnology Engineering Research at UW" (2 May 2005), online: University of Waterloo <http://newsrelease.uwaterloo.ca/news.php?id=4463>.

44 CAUT, "Directory", *supra* note 41.

45 *Ibid.*

46 Various other terms are used to describe these areas, including "research parks", "technology parks", "technopoles", and "innovation centres". By the year 2000, there were 17 such areas, mostly built during the 1980s, although the Sheridan Science and Technology Park in Mississauga opened in 1965. All science parks are intended to serve essentially three sorts of objectives: "economic development objectives" (e.g., "[s]timulate the formation of start-up new-technology-based firms"); "transfer-of-technology objectives" (e.g., "[f]acilitate technology transfer from academic institution to firms on park"); and "local benefit objectives" (e.g., "[c]reate new jobs for the region"). Proponents of science parks may, however, stress different objectives when speaking to different audiences: see Richard Shearmur & David Doloreux, "Science parks: actors or reactors? Canadian science parks in their urban context" (2000) 32 Environment and Planning A 1065 at 1066–67, 1071–72 [Shearmur & Doloreux], citing, amongst others, Doreen Massey, Paul Quintas & David Wield, *High-Tech Fantasies: Science parks in society, science and space* (New York: Routledge, 1992).

47 Canada, *Achieving Excellence: Investing in People, Knowledge and Opportunity* (Ottawa: Industry Canada, 2001), online: Government of Canada <http://innovation.gc.ca/gol/innovation/site.nsf/vDownload/Page_PDF/$file/achieving.pdf>.

48 MaRS, "Explore MaRS: The MaRS Centre", online: MaRS <http://www.marsdd.com>.

49 MaRS, "Leadership: Board of Directors", online: MaRS <http://www.marsdd.com>.

4. *Shifting Roles, Missions, and Mandates*

A researcher in a public institution may now be not only a researcher but also a graduate student supervisor, teacher, clinician, consultant, peer reviewer, author, speaker, license holder, patent holder, and equity holder. Similarly, a public institution may now be not only a research institution but also an educational institution, clinical care provider, license holder, patent holder, and equity holder. The role of public universities has shifted from the provision of education and the conduct and dissemination of research to the provision of education, the conduct and dissemination of research, and entrepreneurial engagement in the market economy.[50] Universities have long struggled to balance competing demands for utilitarian, vocation-oriented education with fundamental inquiry and the pursuit of knowledge for its own sake. However, this shift towards economic entrepreneurialism signals a new era in higher education.[51]

II
THE POTENTIAL BENEFITS AND HARMS OF COMMERCIALIZATION

Quite clearly, there is significant commercialization of research in public institutions in Canada (as elsewhere in the world). The question that must be addressed is whether this phenomenon should be embraced and promoted or resisted. In order to begin to answer this question, a thorough canvass of the potential benefits and harms of commercialization is needed.[52] Potential benefits and harms of commercialization of research in public institutions can be seen for research itself as well as for individual researchers, students, public institutions, industry, and society. We will consider each in turn and, of necessity, in brief.

A. For Research

1. *What Is Researched*

The phenomenon of the commercialization of research in public institutions may result in less non-commercializable research being undertaken. Research with commercial potential may be prioritized over research with no commercial potential.[53] For example, research into the treatment of diseases disproportionately affecting the poor (in countries without government-funded drug coverage),[54] research into the treatment of diseases affecting only a small number of people, and research into prevention rather than pharmaceutical treatments may all be less likely to be undertaken.[55]

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50 The historical shifts in the university's missions or roles have been studied and variously characterized by a number of commentators. In the American context, Etzkowitz argues that universities had two primary missions, teaching and research, until the early twentieth century, when events at the Massachussets Institute of Technology, Stanford University, and a few other institutions helped legitimize a third mission, the university's role as an enterprise of economic development: see Henry Etzkowitz, "Research groups as 'quasi-firms': the invention of the entrepreneurial university" (2003) 32 Research Policy 109.

51 See Tudiver, *supra* note 2; see also Washburn, *supra* note 2.

52 It must be acknowledged here that some readers may disagree about whether some effects are potential harms or potential benefits. For example, some may find the shaping of research to be a positive rather than a negative result of commercializing research. We have deliberately chosen not to offer a justification of a normative position in relation to the effects, firstly because doing so would require far more space than we have available to us, and secondly because justification is not necessary for the point we wish to make in regard to the need for informed debate (which requires information that we do not have). Where possible, we have directed the reader to relevant literature that explores the potential benefits or harms in detail.

53 In the United Kingdom, "[a]pproximately 90% of clinical drug trials and 70% of trials reported in major medical journals are conducted or commissioned by the pharmaceutical industry. As it does most of the research, inevitably the industry not only has a major effect on what gets researched, but also how it is researched and how results are interpreted and reported." U.K., House of Commons Health Committee, *The Influence of the Pharmaceutical Industry: Fourth Report of Session 2004-2005*, vol. 1 (London: The Stationary Office Limited, 2005) at para. 160 [Pharma Industry].

54 This is especially true of diseases affecting populations in developing countries such as "tropical diseases". In fact, because the commercial model of drug development fails completely "in the developing world, where few patients can afford to pay patented prices for drugs" some advocates are actively promoting alternate models of drug development to aid those populations. Stephen M. Maurer, Arti Rai & Andrej Sali, "Finding Cures for Tropical Diseases: Is Open Source an Answer?" (2004) 1 PLoS Medicine 183 at 183.

55 Examples of industry shaping can be found in Sheldon Krimsky, *Science & the Private Interest: Has the Lure of Profits Corrupted Biomedical Research?* (Lanham, MD: Rowman & Littlefield Publishers Inc., 2003) at 223 [Krimsky]. A committee in the U.K. recently heard evidence of this fact, with people arguing that drug innovation was aimed at the affluence rather than health needs, and that it was directed at established and emerging mass markets. Also, it was claimed that there was little research into non-drug intervention. The committee received evidence that "more money is now invested in research into the prevention of

2. *How Research Is Conducted*

When the emphasis is on the commercialization of research, we may see cheaper but more dangerous methods being used. For example, a placebo-controlled trial is usually cheaper and faster than a trial using an active-control arm. Yet, a placebo-controlled trial can be more dangerous in some situations than an active control trial, as some of the participants are, by definition, on a placebo rather than on a known safe and effective, or possibly safe and effective, treatment.[56] In addition, research may be designed to achieve favourable results and avoid negative results. For example, with respect to favourable results, the following methods might be employed:

- Conducting a trial of one drug against another treatment known to be inferior;
- Testing one drug against too low a dose of a competitor drug;
- Conducting a trial of one drug against too high a dose of a competitor drug (making the former drug seem less toxic);
- Conducting trials that are too small to show differences from competitor drugs;
- Using multiple endpoints in the trial and selecting for publication those that give favourable results;
- Doing multi-centre trials and selecting for publication results from centres that are favourable;
- Conducting subgroup analyzes and selecting for publication those that are favourable; and
- Presenting results that are most likely to impress (for example, reduction in relative rather than absolute risk).[57]

With respect to avoiding negative results, for example, if a liver biopsy is not conducted in a trial of a drug for the treatment of thalassemia (a disease causing damaging iron loading in the liver), liver fibrosis may not be discovered and an unsafe drug may appear safe. [58]

3. *How Research Is Interpreted*

There may be a bias towards positive results in the interpretation of research results in research funded by industry. It has been reported that, in the U.K., "[f]ive out of six systematic reviews published in the last two years have shown that research that is sponsored by a drug manufacturer is more likely to yield a positive result for the company's product than research that is independently sponsored."[59] For example,

> one survey investigating the wide divergence of views on the health effects of passive smoke found that 74 percent of the studies finding no adverse effects were written by authors with ties to the tobacco industry. Of the authors with tobacco ties, 94 percent found that passive smoke was not harmful to health, while only 13 percent of those without tobacco ties reached the same conclusion.[60]

Similar results are being reported in meta-analyses of clinical trials.[61]

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disease, such as drugs to reduce cholesterol, than into its treatment, which serves to divert investment away from the sick towards the well, away from the old towards the young and away from the poor towards the rich." It also heard arguments that "'there is little incentive for industry to conduct research aimed at small patient populations', and that there is little industry funding for research to determine the subgroups of patients that benefit from particular therapies". Pharma Industry, *supra* note 53 at para. 165.

56 Susan S. Ellenberg & Robert Temple, "Placebo-Controlled Trials and Active-Control Trials in the Evaluation of New Treatments: Part 2: Practical Issues and Specific Cases" (2000) 133 Annals of Internal Medicine 464 at 464.

57 Richard Smith, "Medical Journals Are an Extension of the Marketing Arm of Pharmaceutical Companies" (2005) 2 Public Library of Science Medicine 364 at 365.

58 Jon Thompson, Patricia Baird & Jocelyn Downie, *The Olivieri Report: The complete text of the report of the independent inquiry commissioned by the Canadian Association of University Teachers* (Toronto: James Lorimer and Company Ltd., 2001) [*Olivieri Report*].

59 Pharma Industry, *supra* note 53 at para. 177.

60 Deborah A. Barnes & Lisa A. Bero, "Why Review Articles on the Health Effects of Passive Smoking Reach Different Conclusions" (1998) 279 Journal of the American Medical Association 1566 at 1566, cited in Bok, *supra* note 2 at 76.

61 Justin E. Bekelman, Yan Li & Cary P. Gross, "Scope and Impact of Financial Conflicts of Interest in Biomedical Research: A Systematic Review" (2003) 289 Journal of the American Medical Association 454 at 456-459; Joel Lexchin *et al.*, "Pharmaceutical industry sponsorship and research outcome and quality: systematic review" (2003) 326 British Medical Journal 1167.

4. *How Research Is Reported*

Industry sponsorship of research may affect the way that research is reported. First, research reporting may be shaped through "ghost authorship" and "ghost journalism". "Ghost authorship" describes a practice wherein an individual employed by the corporate sponsor writes up the results of research and then the company (or a second company hired by the first) casts about for an academic to sign on as the "author" or "co-author" on the paper.[62] "Ghost journalism" describes a practice wherein the corporate sponsor of the research (or a second company hired by the first) produces a video that looks like a news report. It is sent to a television or radio station complete with, for example, a report by an individual who appears to be a journalist and interviews with "experts", individuals suffering from whatever disease the new treatment is for, and a script for the local anchor to read as voiceover for the story. Yet, the entire package has been created by or paid for by the company.[63] The problem of bias is obvious.

Second, research results may be suppressed. This can occur when a sponsor or university prevents a researcher from publishing the results of research (e.g., by issuing legal threats).[64] For example, Dr. Nancy Olivieri was threatened with legal action by her research sponsor, Apotex, if she disclosed information in any manner to a third party about the negative results of her study.[65] The University of Toronto and the Hospital for Sick Children, involved in the negotiations for a substantial donation from Apotex, failed to support Dr. Olivieri in her efforts to disclose the research results.[66] More recently, the University of Manitoba prevented the release of a film made as part of a research project on genetically modified crops. The video is "explicitly critical of crop genetic modification technology as a whole and, of biotech giant, Monsanto.... Monsanto has a long and intimate relationship with the University of Manitoba...."[67]

Suppression of research results can also happen when a researcher self-censors because of the risk of harm to his own profits where, for example, he is an owner of a company holding the patent for the intervention he is testing.[68] Self-censorship can also occur because the research sponsor does not want the results reported at all or wants negative results misreported; the researcher complies in order not to compromise future research funding or other financial rewards.

As the British House of Commons Health Committee's *The Influence of the Pharmaceutical Industry, Fourth Report of Session 2004-05* notes: "Studies comparing all clinical trials have shown that, overall, pharmaceutically sponsored trials are less likely to be published than trials commissioned by other organisations."[69] While reforms directed at this problem are being implemented,[70] there is a long way to go before the problem of suppression of results is resolved.

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62 See David Healy & Dinah Cattell, "Interface between authorship, industry and science in the domain of therapeutics" (2003) 183 British Journal of Psychiatry 22; Melody Petersen, "Whistle-Blower Says Marketers Broke the Rules to Push a Drug" *New York Times* (14 March 2002) C1; Erica Johnson, "Inside the Business of Medical Ghostwriting", CBC Marketplace (25 March 2003), online: CBC.ca <http://www.cbc.ca/consumers/market/files/health/ghostwriting/>; Annette Flanagin *et al*., "Prevalence of Articles With Honorary Authors and Ghost Authors in Peer-Reviewed Medical Journals" (1998) 280 Journal of the American Medical Association 222.

63 See Daniel Price, "Doctor Doctor, Give Me the News" (2005) 12:2 PR Watch 1, online: PR Watch, <http://www.prwatch.org/files/PRW12Q2.pdf>. For an Australian example, see transcript of Liz Jackson, "A marketing breakthrough" *Media Watch* (13 June 2005), online: ABC <http://www.abc.net.au/mediawatch/transcripts/s1390967.htm>.

64 *Olivieri Report*, *supra* note 58 at 5.

65 Dr. Olivieri conducted a clinical trial for a new drug to treat patients with thalassemia. However, when she began to observe unfavourable results, her efforts to report those results both to the patients in the trial and the scientific community at large were undermined by the University of Toronto and the Hospital for Sick Children, which were in the midst of negotiating a large donation from Apotex Inc., the producer of the drug being tested in the trial. For a detailed account of this case, see *Olivieri Report*, *supra* note 58.

66 *Ibid.* at 8.

67 Seeds of Change, "University of Manitoba, Monsanto, and the Battle for Academic Freedom: Background to the controversy surrounding the *Seeds of Change* film" (2005), online: Seeds of Change <http://seedsofchangefilm.org/?p=the_film_censored>.

68 See e.g. the Tseng case described in Bok, *supra* note 2 at 67.

69 *Supra* note 53 at para. 203.

70 Clinical trials registries are being widely discussed and implemented. For example, the GSK register can be seen at GlaxoSmithKline, "Clinical trial register", online: GlaxoSmithKline <http://ctr.glaxowellcome.co.uk/welcome.asp>. ICMJE statements can be found at "Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors" (2004) 141 Annals of Internal Medicine 477. The NIH provides a registry at <http://www.clinicaltrials.gov>.

5. *Public Trust in Researchers, Research Institutions, and Research*

As the shaping of research and research results becomes public, it is possible that public trust in researchers, research institutions and the research enterprise as a whole may be eroded.[71] This erosion could have significant negative effects on research as the public may withdraw its support for government funding of research and research institutions and reduce its willingness to participate in research.

B. For Researchers

1. *Employment Prospects*

If commercialization brings more money into public institutions, more jobs for researchers might be created and these (and existing jobs) might have higher salaries. Closer links between industry and universities might result in greater job prospects for students upon graduation if they are seen as better prepared for careers in industry and if they take advantage of increased networking opportunities. If commercialization results in benefits to society (see below), researchers' job satisfaction may increase as they feel that they have made a positive contribution to society. Their job satisfaction may also be higher if their work is valued more by universities and by society.

2. *Financial Rewards*

Individual researchers might find additional personal income through industry funding for conducting research, writing papers, allowing their name to be listed as a paper's author,[72] giving presentations, consulting, and serving on advisory boards. They might also enjoy additional personal income through holding the IP in their own research results (e.g., from the profits realized through patenting).[73]

C. For Students

1. *Funds Available for Educational Purposes*

Through the commercialization of research, public institutions may have access to more unrestricted funds from industry partners. These funds could either come out of the profits from harnessing the IP of their own research or from industry partners (directly as unrestricted gifts or indirectly through overhead on research contracts).[74] While these funds could be used for educational purposes, it is also possible that

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[71] Ulrich Beck, for instance, argues that public distrust of the scientific-political complex has markedly increased: see Ulrich Beck, *Risk Society: Towards a New Modernity*, trans. by Mark Ritter (London: Sage Publications, 1992).

[72] David Healy, "Conflicting Interests in Toronto: Anatomy of a controversy at the interface of academia and industry" (2002) 45 Perspectives in Biology and Medicine 250 at 261.

[73] In most institutions, researchers own the intellectual property rights to their inventions, educational material, industrial designs and trade marks. Statistics Canada, *2003 Survey*, *supra* note 7 at 20.

[74] Overhead costs for research vary among universities, but in research contracts are usually calculated as a percentage of the direct costs of research. Some examples:

Dalhousie University	30%	"Research Contracts", online: Dalhousie University <http://researchservices.dal.ca/research_1487.html>.
Memorial University of Newfoundland	40%	"Policy and Procedures on Indirect Costs of Contract Research", online: Memorial University <http://www.mun.ca/research/overhead_policy.php>.
University of Calgary	typically 40%	"Research Overhead & Indirect Costs Policy", online: University of Calgary <http://www.ucalgary.ca/UofC/research/html/policies/over_indcosts.html>.
University of Prince Edward Island	30% min.	"Contract Research Policy", online: UPEI <http://www.upei.ca/research/research/researchpolicies/contract_policy/contract_policy.html>.
University of Toronto	40% standard	"Policy on Research Contracts and the Recovery of Indirect Costs of Research: Appendix A", online: University of Toronto <http://www.utoronto.ca/govcncl/pap/policies/recontapp.html>.
Wilfred Laurier University	20-50%	"WLU Policy on Research Contracts", online: Wilfred Laurier University <http://www.wlu.ca/page.php?grp_id=1445&s_id=1603>.

universities will spend less money on teaching and more money on research.[75] It is already the case that they are spending more money on professional managerial staff.[76]

2. *Financial Support for Students*

Increased funds might become available to support graduate students through unrestricted funds from the commercialization of research being redirected to scholarships, through new scholarships being funded for commercializable research,[77] and through direct employment on research projects.

3. *Teachers*

If it is true that active researchers are better teachers,[78] and if the phenomenon of commercialization results in more active researchers on university campuses, the educational environment might be enriched. However, in the profiles and activities of educators may change as they redirect their preferences, strengths, and time from teaching to research.[79]

4. *Curricula*

Students may learn more business and entrepreneurial skills and develop attitudes which may prove very useful in knowledge-based economies. With the commercialization of research, we may see the creation of new, commercially oriented degrees and/or diplomas (e.g., the University of Waterloo Masters in Business, Entrepreneurship and Technology).[80] We may also see the emergence of new, commercially oriented courses in established degree programs. For example, the Engineering Department at the University of Western Ontario now offers a course on Technological Entrepreneurship and Innovation.[81]

5. *Student Research Areas and Topics*

Student research areas and topics may be shaped as more funding is available or funding is more readily available for research with commercial potential.[82] In addition, changes in the costs of research tools may also affect student choices of areas and topics.

6. *Space*

Insofar as students are learning in a research environment, their education may be enriched by the increasing amount of research space and the allocation of more resources to research. However, this may reduce the amount and quality of teaching space. A Canadian survey recently found that "for new

Lakehead University	30% min.	"Research: Recovery of Overhead (Indirect Costs) on University-Administered Research Funds", online: Lakehead University <http://policies.lakeheadu.ca/policy.php?pid=29>.

75 This was recognized in an American study by the National Science Board: "As all public institutions increased expenditures devoted to research by roughly four percentage points [in the period of 1977–1996], they decreased expenditures for instruction by approximately six percentage points." Slaughter & Rhoades, *supra* note 2 at 313.

76 In 2003, Canadian hospitals and universities spent over $36 million on intellectual property management. $17 million went to salaries for people devoted strictly to IP management, a 31% increase from $13 million in 2001. Statistics Canada, *2001 Survey*, *supra* note 7 at 5; Statistics Canada, *2003 Survey*, *supra* note 7 at 17.

77 For example, Canadian Institutes of Health Research (CIHR) has some masters and doctoral awards that are available only for industry-partnered research: Canadian Institutes of Health Research, "Graduate Training Award: Master's: Industry Partnered (2005-2006)", online: CIHR <http://www.cihr-irsc.gc.ca/e/27916.html>. NSERC awards Industrial Postgraduate Scholarships which require a student to pursue their postgraduate studies in partnership with industry: online: Canadian Institutes of Health Research, "MD/PhD Studentships: Industry-Partnered (2005-2006)", online: CIHR <http://www.cihr-irsc.gc.ca/e/22425.html>.

78 Sue Wuetcher, "UB prof's book says active researchers are better teachers" (1996) 28:11 State University of New York at Buffalo Reporter, online: State University of New York at Buffalo <http://www.buffalo.edu/reporter/vol28/vol28n11/n6.html>.

79 "In response to surveys, faculty indicated that they preferred teaching to research until the mid-1980s, after which an increased preference for research began to emerge." Slaughter & Rhoades, *supra* note 2 at 312.

80 University of Waterloo, "What is the MBET?", *supra* note 33.

81 University of Western Ontario, "Academic Calendar 2007", online: University of Western Ontario <http://www.westerncalendar.uwo.ca/western/web/2007(new)/Courses_UWO_ES.html#466a/b>.

82 See e.g. the funding available for industry-partnered research: Canada, "Achieving Excellence", *supra* note 18.

academic space on campus, research labs trump teaching space at 15 of the 20 universities surveyed—with ratios as high as eight square metres of new research space to one square metre of new teaching space."[83]

This development may be the result of more money becoming available for research space. It may also be because the funds available for research space require matching funds, and so funds and fundraising resources that might otherwise be directed to teaching space are instead directed toward matching for research space. The same Canadian study found that space may be disproportionately allocated between disciplines. For example,

> of the 164 new academic buildings or additions built or planned at 20 universities, just nine involve faculties of arts and social science, and four involve the fine arts or contemporary arts. These projects carry a price tag of $341.2 million. Three new libraries and five multi-use academic building projects, at a cost of $312.8 million, will also benefit students in the arts and humanities. But this represents a fraction of the total $4.73-billion cost of the new academic buildings captured in the survey.[84]

Some of the new research buildings can be directly linked to commercializable research. At the University of Saskatchewan in Saskatoon, where "the building boom is skewed heavily in favour of research over classrooms",[85] the Canada Foundation for Innovation contributed over 30% of the funding for the Canadian Light Source research lab.[86] According to the University, this project "represents an unprecedented level of collaboration among governments, universities and industry across Canada".[87]

7. *The Free Flow of Ideas*

With the commercialization of research can come a significant reduction in the sharing of information, yet education is enhanced by the free flow of ideas. Students learn, in large part, by sharing their ideas with others and by discussing other people's ideas. All other things being equal, policies and practices that promote secrecy (as are found in the commercial arena) inhibit education.

Furthermore, when research is sponsored by industry or is being commercialized by a university, the disclosure of the research results can be delayed and can seriously harm students' educational progress. Clauses in research sponsorship contracts and time delays related to patenting by the university may hinder student publication and thesis approvals.[88]

8. *Trust between Students and Supervisors and between Students*

Trust between students and supervisors as well as between students can be undermined, as they may worry that the other will steal potentially valuable ideas or will intentionally or accidentally disclose them to others before the IP in the research is harnessed.

D. For Public Institutions

1. *Retention of Faculty*

The commercialization of research in universities may make it easier to retain researchers who would otherwise work for much greater financial rewards in the private sector (e.g., in pharmacology or electrical engineering). They may instead stay in the universities if they are able to benefit from commercialization of their research. On the other hand, this development may lead to the loss of faculty. For some, an increased emphasis on the commercialization of research and the pressure to conduct commercializable research may make working in public institutions less appealing.

2. *Competition and Morale within Universities*

If faculties with more commercializable or commercialized research are seen to obtain more resources from the university or from external sources, or if faculty members with more commercializable or

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83 Sarah Schmidt, "Universities choose labs over classrooms: Survey of 20 universities: Federal funding partly to blame for imbalance" *National Post* (13 January 2005) A4.

84 *Ibid.*

85 *Ibid.*

86 Canadian Light Source, Media Release, "Canadian Light Source Partners Celebrate Building Completion and Full Capital Funding" (26 February 2001), online: Canadian Light Source <http://www.lightsource.ca/media/celebrate.php>.

87 Peter MacKinnon, President, University of Saskatchewan, cited in *ibid.*

88 Such delays can range up to three years: see Slaughter & Rhoades, *supra* note 2 at 110.

commercialized research earn higher salaries or receive other benefits, competition between faculties and faculty members may increase and morale within the university may be undermined.[89]

3. *Public Support for Universities*

The reputation of public universities and hospitals may improve if they are seen as less like "ivory towers". This might translate into growing public support for funding of these institutions, either for a particular university or hospital or for universities or hospitals in general. If research comes to be seen as more relevant and useful, there may be an overall increase in public support for research, researchers, and research institutions, as well as more public participation in research. However, if the negative consequences of the commercialization of research come to dominate public opinion, there may be less public support for the amount of government funding of universities and funds available for education may ultimately drop.[90]

E. For Industry

Through increased government support for commercializable research in public institutions, industry may realize increased growth in revenues, net income, and number of employees. This could in turn benefit the companies' employees and shareholders. The requirements for partnering with industry may increase the number of academics willing to work with industry, which may ultimately lead to more and better research results and, through these results increased industry profits. Finally, the public reputation of industry may be enhanced by its partnership with public institutions and contribution to economic growth.

F. For Society

1. *Consumer Health and Safety*

Advances in research brought about by commercialization may result in the better health and improved quality of life of Canadians. We may witness the emergence of certain health and safety products, services, and processes that, without commercialization, would never have been developed, would have been developed more slowly, or would have been developed but never put on the market.[91]

As we have seen, however, increases in commercialization cause researchers in public institutions to become increasingly involved with industry. Some of these researchers, in turn, become involved with or advise on the regulation of products (e.g., through the United States Food and Drug Administration (US FDA)).[92] These conflicts of interest may result in more dangerous products being placed or kept on the market. This may happen through improper approvals or failure to restrict use, require warnings, or withdraw products. Recent experiences with Vioxx, Celebrex, and Bextra illustrate such risks.[93]

Competition among drug companies can lead to the development of a number of similar drugs for a single condition. This could increase the risk or decrease the efficacy of treatment because "it is difficult for non-specialists to stay well-informed about more than two or three drugs in any one therapeutic class. Moreover, comparative studies would be needed to assess the relative efficacy and safety of the available drugs, but these are not usually done."[94]

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89 Some university professors' salaries are public in some provinces: see e.g. the Ontario *Public Sector Salary Disclosure Act*, s. 2(1), being Schedule A to the *Savings and Restructuring Act, 1996*, S.O. 1996, c. 1.

90 Slaughter & Rhoades, *supra* note 2 at 334.

91 "In order to maximize the development of effective health products and services from health research, CIHR is developing a comprehensive proactive commercialization strategy.... CIHR will continue to work closely with the research community, universities, research institutions and industry partners to enhance the commercial viability of research so that research moves effectively from laboratories and offices to the marketplace and clinics for the benefit of Canadians." Canadian Institutes of Health Research, *Report on Plans and Priorities for the fiscal year 2003-2004*, online: CIHR <http://www.tbs-sct.gc.ca/est-pre/20032004/cihr-irsc/cihr-irscr34_e.asp>.

92 David Healy, *Let them Eat Prozac* (Toronto: James Lorimer, 2003) at 116-119 and Marcia Angell, *The Truth About The Pharmaceutical Industry: How They Deceive Us and What To Do About It* (New York: Random House, 2004) at 210, cited in Trudo Lemmens, "Leopards in the Temple: Restoring Scientific Integrity to the Commercialized Research Scene" (2004) 32 J.L. Med. & Ethics 641 at 652.

93 See Lemmens, *ibid.*, for descriptions and analysis of recent controversies.

94 *Pharma Industry*, *supra* note 53 at para. 175.

Moreover, if the range of research being done is narrowed and less research is done for health promotion and prevention and for interventions or products for diseases or needs that affect few people or the poor, any health benefits of research will be disproportionately distributed. The potential health consequences of this process are obvious.

2. *Participant Safety*

The increasing commercialization of research may generate a growing number of risks for research trial participants. For example, when researchers have personal financial interests in the enrolment and retention of trial participants, these participants may be inadequately informed, improperly enrolled, and unduly kept in trials. The Jesse Gelsinger case from the United States amply illustrates this point: a participant in a gene transfer study (in which the researcher and the research institution had financial interests) was not given full information about the risks of participating in this study. These risks included adverse results in previous animal studies involving the same protocol. The participant died a few days after receiving the adenovirus vector intended to correct his genetically based metabolic disorder, called ornithine transcarbamylase (OTC) deficiency.[95]

The growing phenomenon of "marketing research" may also put trial participants at risk. The real purpose of this so-called "research" is to introduce patients and their physicians to a particular drug in the hope that the patient will continue to use that drug after the "study" has ended. The focus is on increased sales rather than increased health benefits.[96] These patients may be unnecessarily put at risk because they undergo potentially harmful tests aimed at safety monitoring to give the appearance of a research study, but the results of the monitoring may not actually be used for the advancement of knowledge.

3. *Rate of Advancement of Knowledge and Knowledge Translation*

The protection of IP in research results through the use of the patent regimes may result in more sharing of information.[97] This sharing could, in turn, lead to the faster advancement of knowledge, as researchers are then able to build upon the shared research results. With the intermingling and collaborating of various research sectors, complementary skills may be brought together (e.g., basic research and business development skills), and this may lead to the faster translation of knowledge.

Alternatively, the sharing of information may be delayed by the use of patent regimes. For example, universities may introduce a screening process during which information cannot be released while its potential commercial value is being assessed.[98] The sharing of information may be further delayed while patents are being processed.[99]

A more ominous development may be that the advancement of knowledge is not merely delayed, but entirely blocked. A company might buy a research result (e.g., a research tool) and then withhold it because it is in competition with the company's own product.[100] Furthermore, if key elements of research are kept secret, the reproduction of results may be rendered impossible. The advancement of knowledge dependent on the reproduction of results (particularly the case in the physical sciences) may be blocked.[101] Scientists may also be, in effect, prevented from lawfully pursuing a particular research project because

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95 Josephine Johnston & Françoise Baylis, "What Happened to Gene Therapy?: A Review of Recent Events" (2004) 4:1 Clinical Researcher 11; Sally Lehrman, "Virus treatment questioned after gene therapy death" (1999) 401 Nature 517; Rick Weiss & Deborah Nelson, "Gene Researchers Apologize for Lapses in Teen's Fatal Treatment" *The Washington Post* (10 December 1999) A06; Deborah Nelson & Rick Weiss, "Hasty Decisions in the Race to a Cure? Gene Therapy Study Proceeded Despite Safety, Ethics Concerns" *The Washington Post* (21 November 1999) A01; Tim Beardsley, "Gene Therapy Set Back: A Tragic Death Clouds the Future of an Innovative Treatment Method" (2000) 282 Scientific American 21.

96 American Academy of Family Physicians, "Research Policies", online: AAFP <http://www.aafp.org/online/en/home/policy/policies/r/research.html>.

97 See Ann Louise Monotti & Sam Ricketson, *Universities and Intellectual Property: Ownership and Exploitation* (Oxford University Press, 2003) at 47 [Monotti].

98 Slaughter & Rhoades, *supra* note 2 at 115-116.

99 Getting a patent in Canada can take anywhere from 18 months to three years: see Western Economic Diversification Canada, "The Inventors Guide: Obtaining a Patent in Canada & USA", online: Western Economic Diversification Canada <http://www.wd.gc.ca/tools/inventors/protect_c_e.asp> [WEDC].

100 Slaughter & Rhoades, *supra* note 2 at 331.

101 *Ibid.* at 120–121: "They asked scientists whether at least one of their requests for information, data, or materials related to published research results was denied in the past three years. Of the geneticists that responded, 47 percent did so in the affirmative. Because they were denied information, 28 percent of the geneticists reported that they were unable to confirm the accuracy of published results." See also Krimsky, *supra* note 55 at 83.

they are unable to secure all the necessary licenses from the multiple patent-holders implicated by the project's protocol.[102]

4. *Amount and Rate of Access to Useful Products, Processes, and Services*

Through commercialization, we may see more and faster access to useful products, processes, and services.[103] We may have access to products that would otherwise not have been developed because they are not a medical or government priority:

> [T]he industry explores therapeutic areas that have been overlooked by the medical profession, perhaps due to a feeling that "lifestyle" problems rather than medical issues are involved. An area such as impotence, for example, was not traditionally investigated or treated to any extent by the medical profession, despite being of great concern to the individuals affected. In large part due to industry promotion and awareness campaigns, the issue is now more likely to be broached by patients with their GPs, and patients are more likely to receive treatment.[104]

Commercialization potential may also cause products to be developed more quickly by encouraging competition among researchers. Researchers might try to improve their research and come out with newer and better products so that they can reap their financial benefits. This could result in more and better products being available to consumers. Furthermore, competition may cause a number of similar drugs to be available from competing companies and researchers, allowing doctors to choose a specific treatment with the most favourable harm/benefit ratio for each patient's unique circumstances.[105]

However, rather than speeding up access to treatments and products, it is possible that access will be delayed as treatments and products are kept confidential and off the market while applications are made for patents. This process can last from 18 months to three years.[106] In addition, some treatments and products may become less accessible as the costs are increased due to the harnessing of IP.

5. *Amount of Research Funds*

There may be more funding available for research in public institutions through the sponsorship of research from partners (e.g., industry and government), and through the profits realized from public institutions harnessing IP.[107] However, as a result of the commercialization of research in public institutions, research may become more expensive as research tools are patented and have access fees attached to their use.[108]

6. *Use of Research Funds*

Research funds may be used more efficiently as research becomes subject to the discipline of the market. Furthermore, when working towards commercializable results, researchers may maintain a narrow, more efficient focus rather than pursuing non-profitable tangents that they find interesting. Alternatively, research resources may be wasted as researchers duplicate the work of others either because they do not know that it has been done (e.g., it has not been published) or they cannot gain access to the results (the costs may be prohibitive or the research may simply not be shared). In this case, research is inadvertently repeated.[109]

If the market reflects usefulness in the public's mind, and if the research agenda in public institutions is driven by commercial incentives, then commercializable research may be seen as more responsive to public demands and thus a more useful application of research funds.

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102 This hypothetical scenario in which the fact of multiple ownership causes valuable resources to be underused has been dubbed the "tragedy of the anticommons". Multiple sequences of DNA patented by multiple individuals present the classic example of the anticommons problem: see Michael A. Heller & Rebecca S. Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research" (1998) 280 Science 698.

103 See Monotti, *supra* note 97 at 47, 524, 529.

104 *Pharma Industry*, *supra* note 53 at para. 161.

105 *Ibid.* at para. 173.

106 See Monotti, *supra* note 97 at 432-433, 522; on the time required to process patents, see also WEDC, *supra* note 99.

107 See discussion above, "Dissecting the Phenomenon".

108 See e.g. Arti K. Rai & Rebecca S. Eisenberg, "Bayh-Dole Reform and the Progress of Biomedicine" (2003) 66 Law & Contemp. Probs. 289 at 295ff.

109 *Ibid.* at 112.

7. *Wealth*

The commercialization of research may have a number of economic implications. Not only will individuals, public institutions, and companies directly involved in research profit from commercialization, but consumers may enjoy lower prices resulting from greater competition in the marketplace. We may also witness more general economic growth as a result of the commercialization of research, leading to lower taxes leading to greater individual wealth overall. In addition, research-led improvements in technology may increase productivity, in turn boosting the general standard of living and per capita income.

Wealth created by the commercialization of research might shift the burden of research costs from the public sector to the private sector (as the private sector becomes more involved in sponsorship) and shift the benefit of research from the private sector to the public sector (as public institutions enjoy the profits from harnessing IP in research results).

It might also be argued that the commercialization of research represents an unjust enrichment of researchers and industry. Researchers who form companies in order to harness the IP of their research are like venture capitalists. However, these researchers run no financial risk and reap the benefits, with the capital coming from the public.[110] Similarly, sometimes industry joins forces with researchers in public institutions on publicly funded research, either reaping all of the profits from the products, processes, or services developed or sharing them with the researchers involved. In such cases, the public funds the research, has no share in future profits, and must ultimately pay for the results.[111]

8. *Jobs*

The commercialization of research may result in an increased number of jobs for skilled workers. Where jobs in "knowledge industries" are considered preferable, these new jobs may be of a higher quality.

9. *Competitiveness for Country*

Commercialization could lead to an improvement in a country's competitive position, for example, in the World Economic Forum Global Competitiveness Report and in the OECD rankings.[112]

10. *Costs for Publicly Funded Health Care Systems*

Research results may lead to cost savings for Canada's publicly funded health care system (e.g., safer products may result in fewer expensive hospital stays). However, as more research results are commercialized, drugs and tests may cost more. This would be particularly harmful to a publicly funded health care system that provides drug coverage, as Canada's system does for some members of society.[113]

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[110] For example, the Stem Cell Network, a Network of Centres of Excellence, *supra* note 21, recently created a company called Aggregate Therapeutics: "Aggregate Therapeutics will gather intellectual property from institutions across Canada, add value to it over a period of three to five years, secure investment and then spin it off into the marketplace.... With agreements in place with eight key research institutions across Canada, Aggregate Therapeutics will serve as an incubator, helping accelerate the development of stem cell therapies and technologies.... Industry Canada sees this process as a potential solution to a problem that has plagued biotechnology." Stem Cell Network, "Catalyzing: Commercialization", online: Stem Cell Network <www.stemcellnetwork.ca/success/commercial.php>. There is an argument that while the researchers are investing intellectual capital, they are using public capital to fund their research.

[111] This is sometimes referred to as the "double payment problem". For an argument as to why the general Canadian public should receive some form of direct return from its substantial investment in the resources expected to be pooled together under the umbrella of Aggregate Therapeutics, as well as a discussion of other concerns relating to this corporation, see Matthew Herder & Jennifer Dyck Brian, "Canada's Stem Cell Corporation: Aggregate Concerns and the Question of Public Trust", Journal of Business Ethics [forthcoming].

[112] See e.g. discussion in OECD, Committee for Scientific and Technological Policy at Ministerial Level, *Final Communique: Science, Technology and Innovation for the 21st Century* (2004), online: OECD <http://www.oecd.org/document/15/0,2340,en_21571361_21590465_25998799_1_1_1_1,00.html>; OECD, Directorate for Science, Technology and Industry, *Main Science and Technology Indicators (MSTI), 2006/2 edition* (Paris: OECD, 2006), online: OECD <http://www.oecd.org/document/26/0,2340,en_2649_34451_1901082_1_1_1_1,00.html>. See also Xavier Sala-i-Martin, ed., *The Global Competitiveness Report 2003-2004* (New York: Oxford University Press, 2004).

[113] Although it is not required by the *Canada Health Act*, most provinces provide some prescription drug coverage to specific groups of people. British Columbia, Saskatchewan and Manitoba provide coverage to all residents, while residents of Alberta can purchase coverage through the government. There are high deductibles in these plans. Quebec sponsors drug insurance for people who do not have a plan with their employer. The Atlantic provinces and Ontario provide some coverage to seniors and welfare

11. *Socially Valuable Institutions*

With the commercialization of research in public institutions, we may see the erosion of some socially valuable institutions. The threat to an independent press is illustrated through the phenomenon of "ghost journalism" described earlier. The threat to a protective regulatory arm is illustrated through the prevalence of conflicts of interest in the US FDA. The threat to universities as disinterested critics and trusted advisors of sources of knowledge is illustrated through the prevalence of connections between researchers and industry and the prevalence of researchers and research institutions in commercial enterprises.[114] Undermining the university's role as a place for social criticism, cultural transmission, and knowledge generation for public consumption may even threaten democracy as a whole.[115]

III
WEIGHING THE POTENTIAL BENEFITS AND HARMS

Having canvassed the potential benefits and harms of the commercialization of research in public institutions, we would normally now turn to an attempt to weigh them against each other. However, doing so is, to quote Derek Bok in *Universities in the Marketplace: The Commercialization of Higher Education*, "much like asking whether an indeterminate number of olives, figs, and grapes should count more than an unknown quantity of apples, pear, and plums. The uncertainties involved cast a fog over the problem and invite personal bias into the calculations of those who make the decisions."[116]

Which of the potential benefits or harms have been or are likely to be realized? Will products, processes, and services reach the public more quickly? Will jobs and wealth be created? Will the advancement of knowledge be hindered? Will research participants be harmed? Will universities cease to be trusted, disinterested sources of knowledge and advice? Unfortunately, these questions are not easily answered. Some data available about job creation are available,[117] and a growing number of studies are examining the impact of commercialization (and the attendant emphasis placed upon IP) with respect to scientists' ability to conduct research.[118] But overall, there is far too little evidence in relation to many of the potential effects outlined above.[119]

Even more unsettling is the fact that we simply cannot know (or more precisely, that we are not doing that which is needed in order to know) the effects of this commercialization phenomenon. That is, much of the information we need in order to analyze the effects of these developments is not being gathered. For example, when benchmarking the effects of commercialization of research in public institutions, many of the potential effects outlined above are not being monitored. While the economic benefits of commercialization are commonly traced,[120] and while benchmarks are sometimes used in relation to

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recipients. All provinces provide assistance to people with illnesses that require high-cost drugs: see Colleen M. Flood, "The Anatomy of Medicare" in Jocelyn Downie, Timothy Caulfield & Colleen M. Flood, eds., *Canadian Health Law and Policy*, 2d ed. (Toronto: Butterworths, 2002) at 31-32.

114 For a helpful discussion of models of the role of a university, see Michael Robertson, "Research and Academic Freedom" in John Dawson & Nicola Peart, eds., *The Law of Research: A Guide* (Dunedin: University of Otago Press, 2003) 27.

115 See Jon Alexander & Charles Davis, "Democratic Theory and the Political Incorporation of Higher Education" (1991) 19 Mondes en Developpement 17.

116 Bok, *supra* note 2 at 118.

117 For instance, Shearmur & Doloreux, *supra* note 46 demonstrated that science parks, contrary to expectations, did not foster "high-tech employment" in Canadian cities, remarking at 1076 that

> [t]he proportion of the workforce in high-tech sectors did not grow faster in cities which opened a park: indeed, it can be observed that the significance level of the difference between the 9 agglomerations which opened a park and the 18 which did not actually decreased monotonically between 1971 and 1996. Thus, at the very least, opening a park in the 1980s did not lead these 9 cities to shift their employment structure towards high-tech employment, and an argument could be made that the opposite occurred.

118 The empirical evidence is, even in this limited respect, ambiguous and complex. For example, Blumenthal *et al.* recently found that data withholding is common in biomedical science and takes many forms, but attributed this situation to the "growing commercialization of U.S. universities": David Blumenthal *et al.*, "Data Withholding in Genetics and the Other Life Sciences: Prevalences and Predictors" (2006) 81 Academic Medicine 137. More narrowly, Walsh, Cho and Cohen reported that material transfer agreements typically pose greater problems than IP *per se* in terms of researchers' difficulties in obtaining research inputs: John P. Walsh, Charlene Cho, & Wesley M. Cohen, "View from the Bench: Patents and Material Transfers" (2005) 309 Science 2002 at 2003. See also Christine Vogeli *et al.*, "Data Withholding and the Next Generation of Scientists: Results of a National Survey" (2006) 81 Academic Medicine 128; Lori Pressman *et al.*, "The licensing of DNA patents by US academic institutions: An empirical survey" (2006) 24 Nature Biotechnology 31.

119 Bok, *supra* note 2 at 60-61. See also Slaughter & Rhoades, *supra* note 2 at 330-331.

120 See e.g. Statistics Canada, *2003 Survey*, *supra* note 7.

scientific reputation (e.g., number of papers published and cited)[121] or health standards (e.g., improvements in mortality and morbidity),[122] it is rare to have benchmarks relating to the shaping of what is researched, how research is carried on, and how it is interpreted and reported. Nor do there exist benchmarks relating to the shaping of curricula, profiles of educators, spending, and space in universities. The potential effects on valuable social institutions are not mentioned, let alone considered.[123]

Still more unsettling are recent developments in the reporting of information, ones that actually make it more difficult to assess the phenomenon of commercialization. For example, the definitions of the different kinds of research (e.g., basic, applied, strategic, and experimental) have been changed over time by Statistics New Zealand. This renders it difficult to assess changes in the amount of each kind of research being undertaken, both as a percentage of all research carried out, and as a percentage of research conducted at universities.[124] In addition, the categories of external sources of funding for university research have been collapsed, so that it is no longer possible to determine the percentage of university research that is funded by industry.[125] Similar changes might happen in Canada.

Generalizing somewhat from available documents on indicators, it appears that the realization of potential benefits is being monitored, while the realization of potential risks is not. To start with objectives and then outline outcomes, targets and benchmarks tests only for positive results. Such an approach is like running a clinical trial and testing for efficacy, but not for safety. This would not be allowed in the assessment of a new drug. Should we accept this approach in the realm of social policy? We would argue that we need to monitor for safety and, like clinical trials, we need something analogous to independent data that monitors committees with appropriate expertise (including, for example, the social costs related to the potential effects outlined above).

It must also be noted that even if much of the information were gathered, it might not be shared. As research is commercialized, more and more information about it may become cloaked in claims of "commercial in confidence" and less information may be made available to the public. For example, Statistics New Zealand changed its reporting of external funding for universities "[d]ue to confidentiality reasons" and explained, "we were prohibited to release comparable data for the University sector in 2004 R&D HoTP for source of funds."[126] Again, similar changes could happen in Canada.

A great deal of information is required to make informed decisions about whether this grand social experiment in the commercialization of research in public institutions is a good idea, and is being conducted well. If we never gather and gain access to the information about the realization of potential benefits and harms, we may never get from indeterminate to determinate and from uncertain to certain.

There are still further problems with respect to weighing the potential harms and benefits of the commercialization of research in public institutions. There is both a lack of public debate about the relative value of the various potential harms and benefits, and a lack of independent expert advice in relation to public policy and practice regarding commercialization. In relation to independent expertise, it is revealing to look at the composition of the groups most actively involved in the commercialization of research. It would not be surprising (or inappropriate) for industry organisations to consist solely of those engaged in the industry. However, it is surprising (and arguably inappropriate) for government bodies

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121 See e.g. Milken Institute, "Mind to Market: A Global Analysis of University Biotechnology Transfer and Commercialization: September 2006", online: Milken Institute <http://www.milkeninstitute.org/pdf/mind2mrkt_2006.pdf> at 75-86.

122 Statistics Canada, "Health Indicators" 82-221-XIE (2004), online: <http://www.statcan.ca/english/freepub/82-221-XIE/2005001/pdf/framework.pdf>. See also Andrew Sharpe & Jeremy Smith, "Measuring the Impact of Research on Well-being: A Survey of Indicators of Well-being" (2005), online: Centre for the Study of Living Standards <http://www.csls.ca/reports/csls2005-02.pdf>.

123 Very few people are discussing the potential dangerous effects of commercialization of university research. In a 1999 article, Gary Matkin comments on this issue but tries to use some recent, small-scale examples to predict what could happen in the future. Gary W. Matkin, "University Intellectual Property Management in the 20th Century: How Did We Get Here and Where Are We Going?" (Paper presented to the Conference on Research and Development Investment and Economic Growth in the 20th Century, University of California, Berkeley, 26-28 March 1999), online: University of California Berkeley <http://cshe.berkeley.edu/events/randdconference1999/papers/matkin.html>.

124 Of course, it might be argued that the definitions of "basic", "applied", "strategic", and "experimental" are not appropriate, and that more meaningful definitions for different kinds of research should be adopted. We do not dispute this possibility, but rather seek to highlight the implications for comparative analysis over time with respect to the effects of commercialization that accompany changes in definitions in statistical reviews.

125 See Statistics New Zealand, online: Statistics New Zealand <http://www.stats.govt.nz> (definitions changed, reporting categories collapsed).

126 Email from Daniel Martin, Statistical Analyst, Statistics New Zealand, to Jocelyn Downie (2 June 2005).

and bodies charged with policy-making or advising tasks to be similarly limited in their membership. Yet, consider some past and present examples of such bodies:

- The Council of Science and Technology Advisors (advises the federal Cabinet on the management of the government's science and technology activities);
- The Advisory Council on Science and Technology (aims to "review Canada's performance in research and innovation, identify emerging issues of national concern, and advise on a forward-looking agenda with a view to positioning Canada in an international context"); and
- The Governing Council of the Canadian Institutes of Health Research.

None of these bodies as presently constituted appears to include anyone with expertise in ethics, the sociology of higher education, or other areas relevant to the potential risks of the commercialization of research in public institutions.[127]

If we are to ensure that the social experiment in the commercialization of research in public institutions is consistent with public values, there needs to be more public discussion and debate about the values that we want to see pervade the public research institution sector. Unfortunately, the nature, extent, and impact of the commercialization of research in public institutions is not widely known or understood by the public. Furthermore, some of the government's engagement with the public is problematic, as it seems directed toward advocacy rather than education (and truly seeking the public's opinions on appropriate directions for policy and practice).[128]

So what are we to do? We would argue that we must start by gathering and sharing all of the relevant information pertaining to this phenomenon. We must then involve all those whose interests are at stake in discussions of the relative values, policies, and actions. We must also involve those with expertise relevant to all of the potential effects outlined earlier. We must then ground policies and actions in the arena of commercialization in these discussions (tempered, as needed, with core values found in the *Canadian Charter of Rights and Freedoms* and with surveys of Canadians regarding core values for the health care system).[129] We must then hold the policies and actions to benchmarks directly related to all of the objectives. Brendan Nelson, the Australian Government Minister for Education, Science, and Training said recently: "[W]e should never be frightened of turning knowledge back into money."[130] Perhaps not—but, quite clearly, we should be much more careful.

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127 See Council of Science and Technology Advisers, "Members", online: CSTA <http://www.csta-cest.ca/section.php?ID=3&Lang=En&Nav=Section>; Advisory Council on Science and Technology, "Members", online: ACST <http://acst-ccst.gc.ca/member_e.html>; Canadian Institutes of Health Research, "Who We Are", online: CIHR <http://www.cihr-irsc.gc.ca/e/7263.html>.

128 See e.g. Canada, "Innovation in Canada", *supra* note 15; Advisory Council on Science and Technology, "Public Investment in University Research: Reaping the Benefits", online: Advisory Council on Science and Technology <http://acst-ccst.gc.ca/comm/rpaper_html/report_toc_e.html>.

129 *Canadian Charter of Rights and Freedoms*, Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (U.K.), 1982, c. 11; "Values Working Group Synthesis Report", in National Forum on Health, Canada Health Action: Building on the Legacy: Synthesis Reports and Issue Papers, vol. 2 (Ottawa: Health Canada, 1997), online: Health Canada <http://www.hc-sc.gc.ca/hcs-sss/pubs/care-soins/1997-nfoh-fnss-v2/legacy_heritage2_e.html>.

130 Brendan Nelson (Address to the National Press Club, Canberra, 24 March 2004), online: <http://www.dest.gov.au/Ministers/Media/Nelson/2004/03/ntscript240304.asp>.

SANTÉ PUBLIQUE ET NOUVEAUX RÔLES DU MÉDECIN EN FRANCE

Christine Noiville[*]
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Dans une société gagnée par la médicalisation et la judiciarisation, il incombe de revenir sur une question classique, celle du rôle et des responsabilités du médecin, dans un contexte totalement renouvelé par la publicisation de la santé. Au-delà de la préoccupation classique des pouvoirs publics pour la santé des populations, apparaît en effet un concept nouveau, l'ordre public sanitaire, qui exerce une influence indéniablement perturbatrice sur l'activité médicale. Le présent article montre ainsi comment le médecin, bien qu'affaibli par l'effritement du traditionnel pouvoir médical, est investi de rôles de plus en plus variés. Soignant, il est également éducateur de santé, gestionnaire, conseiller, expert et, au bout du compte, apparaît comme un relais plus que jamais indispensable des politiques publiques.

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INTRODUCTION

Syndrome d'alcoolisme fœtal, dépistage précoce des troubles du comportement, lutte contre le tabagisme et l'obésité : nul n'ignore le spectaculaire renforcement de la santé publique et l'emprise croissante que celle-ci exerce sur les choix politiques des sociétés occidentales contemporaines[1].

Moins connue, en revanche, est l'influence profonde et indéniablement perturbatrice de cette publicisation de la santé sur la profession médicale et, partant, sur l'acte médical. Pourtant, il est clair qu'elle aboutit à assigner au médecin des rôles de plus en plus nombreux et variés et, tout en amenuisant le traditionnel pouvoir médical, paraît contribuer à un alourdissement global de ses responsabilités.

On pourra certes aisément objecter qu'inévitablement, toutes les professions changent. De fait, tout comme la profession de juge a sensiblement évolué ces dernières décennies[2], la profession de médecin[3] a d'ores et déjà connu des mutations radicales. C'est d'abord l'art médical qui a profondément évolué, à la fois quant aux techniques employées — PMA, chirurgie de pointe, imagerie, etc. — et quant à ses performances — prolongement de l'espérance de vie et éradication d'une grande partie des épidémies infectieuses, même si parallèlement, de nouvelles pathologies émergent[4]. En tant que profession, ensuite, la médecine a également profondément changé, tant sur le plan économique que social, puisqu'en même temps que la démographie médicale s'est accrue et spécialisée, la figure traditionnelle du médecin s'est banalisée, son autorité sociale fragilisée[5]. Enfin, cela fait déjà longtemps que l'on ne peut plus dire du métier de médecin, envisagé de façon concrète[6], qu'il est enfermé dans un rôle unique, celui de soignant : le médecin est aussi chercheur, expert, arbitre de conflits privés ou publics, conseil, conciliateur, etc.

Le métier a donc sans aucun doute profondément changé et de façon qui plus est très spécifique, en raison des considérations collectives imposées par la protection de la santé publique et avec lesquelles il a été, de longue date, contraint de s'articuler. Champ de prédilection de l'action publique, la santé a

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1 Sur la notion de santé publique, sa polysémie et son extension, voir Dominique Lecourt, dir., *Dictionnaire de la pensée médicale*, Paris, Quadrige, Presses Universitaires de France, 2004, *s.v.* « santé publique ». L'expression désigne une réalité épidémiologique — l'état de santé d'une population, un mode de gestion — caractérisé le plus souvent par l'administration étatique de la santé, un domaine d'activité — correspondant à une spécialisation professionnelle et institutionnelle, de même qu'un champ disciplinaire. Jusqu'alors dénuée de définition juridique, la santé publique est désormais définie par l'article 2 de la *Loi n° 2004-806 du 9 août 2004* relative à la politique de santé publique, J.O., 11 août 2004, 14277 [*Loi n° 2004-806 du 9 août 2004*], comme concernant :

> 1° La surveillance et l'observation de l'état de santé de la population et de ses déterminants ; 2° La lutte contre les épidémies ; 3° La prévention des maladies, des traumatismes et des incapacités ; 4° L'amélioration de l'état de santé de la population et de la qualité de vie des personnes malades, handicapées et des personnes dépendantes ; 5° L'information et l'éducation à la santé de la population et l'organisation de débats publics sur les questions de santé et de risques sanitaires ; 6° L'identification et la réduction des risques éventuels pour la santé liés à des facteurs d'environnement et des conditions de travail, de transport, d'alimentation ou de consommation de produits et de services susceptibles de l'altérer ; 7° La réduction des inégalités de santé, par la promotion de la santé, par le développement de l'accès aux soins et aux diagnostics sur l'ensemble du territoire ; 8° La qualité et la sécurité des soins et des produits de santé ; 9° L'organisation du système de santé et sa capacité à répondre aux besoins de prévention et de prise en charge des maladies et handicaps ; 10° La démographie des professions de santé.

2 Voir par ex. la *Loi n° 2002-1138 du 9 septembre 2002* d'orientation et de programmation pour la justice, J.O., 10 septembre 2002, 14934 et la *Loi organique n° 2003-153 du 26 février 2003* relative aux juges de proximité, J.O., 27 février 2003, 3479, qui ont créé des juges de proximité. Plus récemment, voir aussi la proposition formulée par la Commission parlementaire sur l'affaire d'Outreau d'adjoindre deux citoyens jurés au juge des libertés et des détentions : France, *Commission d'enquête chargée de rechercher les causes des dysfonctionnements de la justice dans l'affaire dite d'Outreau et de formuler des propositions pour éviter leur renouvellement*, Rapport n°3125 à la p. 343 et s. (6 juin 2006 ; président : André Vallini).

3 Voir art. L4131-1 Code de la santé publique, qui fait référence à la « profession de médecin » et la rattache désormais à la catégorie plus large des « professionnels de santé », qui désigne l'ensemble des professionnels médicaux et paramédicaux (médecins, chirurgiens dentistes, sages femmes, infirmières, pharmaciens, etc.) (voir par ex. art. L1110-1-1 Code de la santé publique).

4 Les causes de morbidité et de mortalité ont radicalement changé depuis 50 ans : la mortalité par cancer est 15 fois plus élevée que celle liée aux maladies infectieuses — qui représentaient 10 % des causes de mortalité en 1945 — et ce malgré l'apparition du sida. Parallèlement, les affections de longue durée ont explosé, comme l'asthme et les allergies, qui progressent dans chaque tranche d'âge, et ont doublé en trente ans. Par ailleurs, les pathologies mentales se diversifient et augmentent : 15 % de la classe d'âge 25–45 ans sont aujourd'hui atteints de dépression. Voir Marie-Hélène Aubert, Martine Billard et André Cicolella, « La santé publique mérite une deuxième révolution », *Libération* (15 juillet 2004) Rebonds 32.

5 Georges Tchobroutsky et Olivier Wong, *Le métier de médecin*, 2e éd., Que sais-je?, Paris, Presses Universitaires de France, 1996. Jean de Kervasdoué, *La crise des professionnels de santé*, Paris, Dunod, 2003.

6 Dans son sens classique, le terme « métier » revêt une connotation plus mécanique, manuelle et économique que le terme « profession », à connotation plus prestigieuse et souvent associée à l'idée de carrière. Voir *Le petit Robert*, 2006, *s.v.* « métier » et « profession ».

toujours donné prise, en effet, à de multiples interventions de l'autorité publique, ici pour prévenir les maladies — il suffit d'évoquer l'ancienneté des mesures d'hygiène publique — et définir la direction des politiques de santé, là pour gérer les institutions hospitalières ou surveiller les professions de santé[7]. Depuis lors, la santé publique n'a pas cessé d'être au cœur des préoccupations du législateur, y compris dans des dispositifs qui semblent les plus individualistes. Ainsi, la loi de 1975 dépénalisant l'avortement[8] poursuivait-elle autant un but individuel — satisfaire les revendications des femmes sur leur corps — qu'un objectif de santé publique — éviter les nombreux décès dus à des avortements pratiqués clandestinement.

Surtout, comme on le sait, l'État s'est fait garant de la santé en consacrant un droit à la santé[9] par ailleurs rendu possible par la *socialisation de la santé*, c'est-à-dire la prise en charge collective du coût engendré par cette dernière. Avec cette place croissante de l'État en tant que contrôleur, financeur, garant, s'est alors imposée une conception presque planificatrice de la santé, qui a inévitablement bouleversé l'organisation de la médecine et les principes dont elle s'était initialement dotée — paiement à l'acte, libre entente du prix entre médecin et patient, liberté totale des prescriptions[10]. La santé étant ainsi devenue un « triptyque État, patient, médecin », les incidences étaient évidemment décisives sur le statut et le rôle de ce dernier[11].

Pourtant, de la santé publique à la « publicisation de la santé », un véritable basculement s'est encore opéré. Il faut dessiner les contours de cette notion nouvelle (I), avant d'en examiner les conséquences les plus notables sur la profession médicale (II).

I
DE LA SANTÉ PUBLIQUE À LA PUBLICATION DE LA SANTÉ

Une chose est d'observer que la santé, préoccupation continue des pouvoirs publics, est prise en charge dans un cadre public[12], autre chose de constater d'une part, que son champ s'accroît de façon quasi infinie (A), d'autre part, qu'elle se formule en termes politiques (B), enfin, qu'elle se traduit notamment par l'émergence d'une notion-clé, l'ordre public sanitaire (C).

A. L'extension illimitée du champ de la santé

On ne peut comprendre cette première réalité que si l'on rappelle que la santé est une construction sociale, au sens où le rapport à la maladie, à la mort, à ce qui ressortit au normal ou au pathologique est très lié à des représentations culturelles[13]. Or le sens que notre société contemporaine attribue à la santé

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7 Bien avant que l'État ne joue le rôle principal dans la définition et la direction des politiques de santé (par exemple en créant un Ministère de la santé en 1920), les interventions publiques en matière sanitaire ont toujours existé sous trois formes : la gestion des institutions hospitalières ; la surveillance des professions de santé ; la police sanitaire destinée à empêcher la propagation des maladies contagieuses pour lutter contre l'insalubrité — c'est le mouvement classique *d'hygiène publique* — puis à lutter plus activement contre les fléaux — c'est la *prévention sanitaire*. Voir Jean-Michel de Forges, *Le droit de la santé*, 5e éd., Que sais-je?, Paris, Presses Universitaires de France, 2004, à la p. 4 [de Forges, *Le droit de la santé*]. Voir aussi Antoine Leca, « Introduction historique au droit de la protection de la santé publique » R.G.D.M., 2005.n° spécial.12.

8 *Loi du 17 janvier 1975* relative à l'interruption volontaire de la grossesse, J.O., 18 janvier 1975, 739.

9 Alinéa 11 du préambule de la *Constitution du 27 octobre 1946*. Pour le commentaire d'une décision du Conseil d'État déniant la qualification de liberté fondamentale à ce principe constitutionnel, voir Xavier Bioy, note sous Cons. d'État, 8 septembre 2005, Rec. 2005.

10 En témoigne la profonde évolution de la *Charte de la médecine libérale* de 1927, progressivement vidée de sa substance. Sur l'articulation entre l'exercice libéral et individuel de la médecine et les considérations collectives en jeu, voir notamment Louis Dubouis, « La réforme de la médecine libérale : le statut des médecins » Revue de droit sanitaire et social. 1996.743 ; Noël-Jean Mazen, « Le médecin libéral : un homme sous haute surveillance » Gaz. Pal. 1997.Doctr.1383 ; Didier Truchet, « L'intervention publique dans le domaine de la santé. La décision médicale et le droit » A.J.D.A. 1995.611.

11 Sur la question de l'intervention étatique dans le domaine de la santé, voir Jean-Marie Auby, « L'intervention publique dans le domaine de la santé. La légitimité de l'intervention publique » A.J.D.A. 1995.588.

12 Sur l'intensification de l'intervention publique dans le domaine de la santé, qui « fait naître à la vie juridique un corpus de normes, de principes juridiques capables de faire plier les autres branches du droit et de les contraindre à respecter les normes qu'il édicte », voir Emmanuel Cadeau, « Sur l'autonomie du droit de la santé... publique » dans Jacques Fialaire et Eric Mondielli, dir., *L'homme, ses territoires, ses cultures : mélanges offerts à André-Hubert Mesnard*, Paris, LGDJ, 2006, 309.

13 Voir École nationale d'administration (Groupe 10), Rapport « Santé et société », Séminaire « Les politiques de santé », Paris, juillet 2003, en ligne : École nationale d'administration <http://www.ena.fr/index.php?page=ressources/rapports/sante/santesociete>. Voir aussi Jean-Pierre Dozon et Didier Fassin, dir., *Critique de la santé publique. Une approche anthropologique*, Paris, Balland, 2001, qui montrent que la santé publique a beau prétendre œuvrer de façon neutre au bien-être de tous, le sens qui lui est attribué varie profondément selon les cultures et empêche toute approche universaliste en la matière.

laisse apparaître une donnée très nette. Non seulement constate-t-on une extraordinaire extension de l'objet de la protection — en vertu de la définition qu'en donne l'OMS, la santé recouvre aussi le bien-être[14] —, mais une multitude de questions est désormais traduite en langage sanitaire et prise en charge à travers le prisme de la santé.

Les exemples de questions sociales ou morales reformulées en langage médical abondent, allant de la santé mentale[15] à la sexualité[16] en passant par l'échec scolaire[17]. De cette extension de la santé publique, c'est toutefois une récente expertise de l'Institut national de la santé et de la recherche médicale (INSERM) qui s'avère la plus emblématique[18]. Elle préconise le dépistage précoce des « troubles de conduite » chez le petit enfant, entre autres pour aider à mieux prévenir la délinquance ; quelle que puisse être sa validité scientifique, elle illustre alors très bien la médicalisation d'un phénomène pourtant largement social et éducatif et, au-delà, la façon dont notre société tend à traduire ses maux en langage sanitaire.

B. La santé, un enjeu politique majeur

Que la santé constitue parallèlement un enjeu politique majeur est un constat qui s'impose de lui-même : en dix ans, le législateur français a voté plus de textes en santé publique qu'il n'en avait adopté depuis le début du dernier siècle[19] ; par-delà l'offre de services cliniques et curatifs, toujours plus sophistiqués, il s'est doté d'un mandat plus vaste orienté vers la promotion de la santé, la prévention, la recherche, la formation professionnelle. C'est dire si la déontologie médicale n'est plus aujourd'hui qu'une petite facette d'un droit de la santé dont les règles sont de plus en plus définies dans un cadre public.

Mais il faut prendre soin d'affiner encore l'analyse. Un double mouvement s'impose alors. D'une part, les questions de santé se politisent. Tabagisme, obésité, alcoolisme sont érigés en enjeux politiques ; saturnisme ou handicap servent désormais de justification à la mise en œuvre d'une politique sociale[20] ;

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[14] *Constitution de l'Organisation mondiale de la Santé*, 22 juillet 1946, Actes off. Org. mond. Santé, 2, 100, (entrée en vigueur : 7 avril 1948), préambule : « La santé est un état de complet bien-être physique, mental et social, et ne consiste pas seulement en une absence de maladie ou d'infirmité ».

[15] Voir Alain Ehrenberg, « La santé mentale », *Cahiers français*, n°324 (janvier–février 2005) 14 : la santé mentale est caractéristique d'une réorganisation des rapports entre maladie, santé et société, le souci actuel pour les « troubles de masse de la subjectivité individuelle » imprégnant aujourd'hui l'ensemble de la vie sociale. Voir aussi Entrevue du Dr. Daniel Zagury par Delphine Saubaber (18 juillet 2005) dans *L'Express* à la p. 58. Pour Zagury, la psychiatrie est devenue la « bonne à tout faire de la société », à qui l'on demande non plus de soigner les malades, mais d'apaiser un corps social en souffrance, ce qui conduit à un paradoxe terrible : « tout le monde a son psy, sauf les fous, vu l'état d'abandon de la psychiatrie publique ».

[16] Voir *Laskey, Jaggard et Brown c. Royaume-Uni* (1997), 29 Cour Eur. D.H. (Sér. A) 120 (la Cour européenne des Droits de l'Homme (CEDH) a condamné les pratiques sado-masochistes sur le fondement de la santé). Voir toutefois K.A. et A.D. c. Belgique, n° 42758/98 (17 février 2005), en ligne : Cour européenne des Droits de l'Homme <http://cmiskp.echr.coe.int/tkp197/view.asp?item=2&portal=hbkm&action=html&source=tkp&highlight=&sessionid=11380945&skin=hudoc-fr> (La Cour a substitué à ce fondement celui de l'absence de consentement de la victime).

[17] Voir la prolifération des orthophonistes et autres orthoptistes luttant contre dysgraphie, dyslexie, etc., ou encore la croissance des prescriptions de *Ritaline* aux enfants agités, autant d'exemples qui indiquent que l'on confère une nature médicale à des réalités qui n'étaient jusqu'alors pas appréhendées socialement en ces termes.

[18] Institut national de la santé et de la recherche médicale, Dossier de presse, « Trouble des conduites chez l'enfant et l'adolescent », (22 septembre 2005), en ligne : site officiel de l'INSERM <http://www.inserm.fr/fr/presse/dossiers_presse/att00000407/DPTroubledesconduites.pdf>. Sur ce rapport, voir l'avis du Comité consultatif national d'éthique pour les sciences de la vie et de la santé (CCNE), *Problèmes éthiques posés par des démarches de prédiction fondées sur la détection de troubles précoces du comportement chez l'enfant*, Paris, 6 février 2007 <http://www.ccne-ethique.fr/francais/pdf/avis095.pdf>.

[19] Après la loi fondatrice du début du siècle dernier — la *Loi du 15 février 1902* relative à la protection de la santé publique —, les progrès significatifs en matière de santé et l'efficacité croissante des techniques de soins ont réduit l'intérêt porté à la santé publique par l'État et le corps médical. La prévention et l'épidémiologie sont passées au second plan des préoccupations, les pouvoirs publics et les médecins se concentrant davantage sur les aspects curatifs et les soins. C'est l'objet des grands textes adoptés ces 15 dernières années que de procéder à un rééquilibrage en la matière. Voir : *Loi n° 93-5 du 4 janvier 1993* relative à la sécurité en matière de transfusion sanguine et de médicament, J.O., 5 janvier 1993, 237 [*Loi n° 93-5 du 4 janvier 1993*] ; *Loi n° 98-535 du 1er juillet 1998* relative au renforcement de la veille sanitaire et du contrôle de la sécurité sanitaire des produits destinés à l'homme, J.O., 2 juillet 1998, 10056 [*Loi n° 98-535 du 1er juillet 1998*] ; *Loi n° 2002-303 du 4 mars 2002* relative aux droits des malades et à la qualité du système de santé, J.O., 5 mars 2002, 4118 ; *Loi n° 2004-806 du 9 août 2004*, *supra* note 1; *Loi n° 2004-810 du 13 août 2004* relative à l'assurance maladie, J.O., 17 août 2004, 14598. Sur les racines historiques et sociologiques du « mal français » jusqu'alors caractéristique en la matière et que cet ensemble de textes a pour objet de surmonter, voir Aquilino Morelle, *La défaite de la santé publique*, Paris, Flammarion, 1996.

[20] S'agissant du handicap, on est passé d'un modèle individuel et médical à un modèle social, où le handicap ne renvoie plus aux caractéristiques d'un individu mais aux obstacles s'opposant à sa pleine participation sociale. Voir en effet la *Loi n° 2005-102 du 11 février 2005* pour l'égalité des droits et des chances, la participation et la citoyenneté des personnes handicapées, J.O., 12 février 2005, 2353, et la récente condamnation de l'État pour non-scolarisation d'un jeune handicapé, Trib. admin. Lyon, 29 septembre

exemple plus emblématique encore de cette politisation de la santé, la sécurité sanitaire, face à une attente sociale exigeante et critique, a dépassé le champ médical pour devenir une priorité politique[21] et judiciaire, comme en témoigne l'instauration des pôles de santé publique.

D'autre part, on constate un mouvement de « sanitarisation » du champ politique et social, au sens où de multiples questions ayant traditionnellement peu ou pas à voir avec la santé acquièrent désormais une dimension sanitaire[22]. Immigration, politique carcérale, politique de la ville : toujours plus nombreux sont en effet les sujets d'importance politique qui intègrent une composante santé, soit parce qu'ils peuvent constituer un levier — la politique de la ville sera par exemple conçue à l'appui des politiques de santé[23] —, soit tout simplement parce que la santé, bonne ou mauvaise, constitue un critère de reconnaissance de tel ou tel droit — elle est ainsi devenue un mode de régulation de l'immigration.

Avec cet enchevêtrement de sphères jadis largement étanches — le politique et le social d'un côté, la santé de l'autre —, la santé se décline plus que jamais en termes collectifs, parallèlement, voire concurremment, avec le rapport traditionnellement privé entre médecin et patient.

C. La naissance d'un ordre public sanitaire

Très corrélé aux deux précédents, un troisième constat conforte cette tendance. Il tient à la naissance d'un ordre public sanitaire. Si l'expression est nouvelle, son contenu l'est certes moins puisque historiquement, dans un but d'hygiène publique notamment, l'État a largement usé de mesures de police sanitaire — vaccinations obligatoires, examens médicaux prénuptiaux constituent ainsi autant de mécanismes de contrainte imposés dans l'intérêt supérieur de la société[24].

Toutefois, le fait marquant actuel consiste en un véritable envahissement du corps social par divers impératifs de santé publique. Un simple survol du *Code de la santé publique* le confirme : la lutte contre le dopage, la toxicomanie ou le tabagisme et les restrictions qui en découlent pour la liberté individuelle se marquent par un arsenal répressif croissant ; les obligations qui pèsent sur les personnes privées au titre de la santé publique se multiplient — propriétaires vendeurs d'un bien immobilier contraints de procéder à un « diagnostic amiante »[25], industriels obligés à renforcer l'information sur les risques sanitaires de leurs produits[26], etc. Prévention, incitation, contraintes ou répression : quel que soit le mode adopté, on

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2005, 1ère chambre, n° 0403829. Voir aussi Jean-François Ravaud et Isabelle Ville, « Le handicap comme nouvel enjeu de santé publique » *Les cahiers français* n°324 (janvier–février 2005) 21. Concernant le saturnisme, voir le volet « saturnisme » de la *Loi n°98-657 du 29 juillet 1998* d'orientation relative à la lutte contre les exclusions, J.O., 31 juillet 1998, 11679, et la lutte contre « l'habitat indigne » prévue par la *Loi n°2000-1208 du 13 décembre 2000* relative à la solidarité et au renouvellement urbains (loi SRU), J.O., 14 décembre 2000, 19777.

21 La notion est née avec l'affaire du sang contaminé mais aussi avec l'efficacité croissante de la médecine qui, paradoxalement, rend plus présentes les préoccupations de sécurité sanitaire. Elle s'est définitivement imposée avec la *Loi n° 93-5 du 4 janvier 1993*, *supra* note 19, et la *Loi n° 98-535 du 1er juillet 1998*, *supra* note 19. Voir Didier Tabuteau, *La sécurité sanitaire*, 2e éd., Paris, Berger-Levrault, 2002 à la p. 20 et s.

22 Voir Didier Fassin, « Les nouvelles frontières de la santé » *Sciences humaines* n°141 (août–septembre 2003) 16.

23 Depuis la fin des années 1990, la politique de la ville mise en place par l'État français a développé un nouvel outil, les « ateliers santé-ville », qui visent à réduire les inégalités et à améliorer l'accès aux soins et à la prévention des personnes vulnérables. Notons qu'une quantité croissante de textes, tant à l'échelle nationale qu'européenne, imposent un tel croisement entre politiques sectorielles et santé. Voir notamment CE, *Traité instituant la Communauté européenne (version consolidée Amsterdam)*, [1997] J.O. C 340/03 à la p. 173, art. 152, lequel requiert la prise en compte « d'un niveau élevé de protection de la santé humaine dans la définition et la mise en œuvre de toutes les politiques et actions de la Communauté ».

24 De Forges, *Le droit de la santé*, *supra* note 7 à la p. 79 et s., à la p.92 et s. Sur les notions d'ordre public, de démocratie et de citoyenneté sanitaires analysées du côté du patient, voir Benjamin Pitcho, *Le statut juridique du patient*, Bordeaux, Études Hospitalières, Thèses n° 15, 2004.

25 Art. R1334-24 Code de la santé publique.

26 Par exemple, les baladeurs doivent porter un message de caractère sanitaire précisant que, à pleine puissance, l'écoute prolongée du baladeur peut endommager l'oreille de l'utilisateur. Voir *Décret n° 98-858 du 22 septembre 1998* relatif aux sanctions en cas d'infraction aux dispositions concernant les baladeurs musicaux et modifiant le code de la santé publique, J.O., 25 septembre 1998, 14623. Au sujet de la lutte contre l'obésité, les messages publicitaires en faveur de certaines boissons doivent contenir une information à caractère sanitaire (les annonceurs peuvent déroger à cette obligation sous réserve du versement d'une contribution au profit de l'Institut national de prévention et d'éducation pour la santé et destinée à financer des actions d'information et d'éducation nutritionnelles). Également, les distributeurs automatiques de boissons et de produits alimentaires payants et accessibles aux élèves sont désormais interdits dans les établissements scolaires. Voir les articles 29 et 30 de la *Loi no 2004-806 du 9 août 2004*, *supra* note 1. Enfin, une mention sur les bouteilles d'alcool doit informer les femmes enceintes des risques encourus. Voir *Arrêté du 2 octobre 2006* relatif aux modalités d'inscription du message à caractère sanitaire préconisant l'absence de consommation d'alcool par les femmes enceintes sur les unités de conditionnement des boissons alcoolisées, J.O., 3 octobre 2006, 14626.

constate que comme l'ordre public économique ou environnemental[27], l'ordre public sanitaire gagne du terrain et conduit à un véritable maillage sanitaire du corps social, au point que certains ont pu voir dans la loi de santé publique le retour d'un « État policier »[28].

Ce maillage est par ailleurs soutenu par une myriade de structures qui, elles aussi, illustrent un profond renouvellement. Voilà en effet un domaine où les institutions et acteurs foisonnent : État, Haute autorité de santé, agences, assurance maladie, observatoires régionaux de santé, institut d'éducation pour la santé, associations de patients, etc. forment un ensemble, assez peu lisible du reste, comparable à un véritable « gouvernement de la santé », où se redéfinissent les rapports entre les différents acteurs du système de santé, ainsi que l'indiquent diverses innovations sémantiques telles « usagers du système de santé » ou « démocratie sanitaire »[29].

Ordre public sanitaire, publicisation de la santé : il ne s'agit certes pas de nier que derrière ces notions se joue une réalité plus nuancée et souvent plus subtile que celle qui vient d'être brossée à grands traits.

On sait ainsi qu'en même temps qu'elle se publicise, la santé n'échappe pas au phénomène de marchandisation qui marque la société tout entière : certaines pathologies sont purement et simplement construites par une logique marchande — il en est ainsi du dysfonctionnement sexuel féminin, qui démontre la facilité avec laquelle l'industrie pharmaceutique suscite de nouveaux besoins et une consommation médicale supplémentaire[30] ; la question des conflits d'intérêts se pose par ailleurs de façon exacerbée en matière de santé[31].

Il convient également de nuancer et d'affiner le concept d'ordre public sanitaire. D'abord, quant à sa portée — pensons au refus de soin, conforté par la loi du 4 mars 2002[32] ou aux réticences que suscite encore le projet d'interdiction totale de fumer dans les lieux publics. Quant à ses sources, ensuite, puisque au-delà de l'action de l'État, l'ordre public sanitaire s'alimente partiellement à l'offre de services du corps médical lui-même : à travers la multiplication des tests — génétiques, de grossesse, etc. —, les pratiques de procréation médicalement assistée ou le diagnostic préimplantatoire se diffusent en effet une offre et des usages dont il faut reconnaître que, *de facto*, ils finissent par se nover en obligations, au moins sociales.

Quelles que soient les nuances à lui apporter, toutefois, la publicisation de la santé, telle qu'elle vient d'être décrite, constitue assurément un renouvellement profond de la façon dont a été classiquement appréhendée la santé publique. Aussi bien ses répercussions sur le rôle du médecin constituent-elles un véritable basculement.

II
RECONFIGURATION D'UNE PROFESSION

La plupart des conséquences de la publicisation de la santé sur le rôle du médecin sont invisibles à la seule lecture des textes vu le cloisonnement encore trop souvent de mise entre droit de la santé et droit médical. Si l'on fait un effort pour le dépasser, on constate que si le médecin est un indispensable rouage du système (A), son pouvoir, au sens classique du terme, est de plus en plus contesté tout en étant corrélé à de nouvelles responsabilités pesantes mais incertaines (B).

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27 Marguerite Boutelet et Jean-Claude Fritz, dir., *L'ordre public écologique : Towards an Ecological Public Order*, Bruxelles, Bruylant, 2005.

28 *Loi n° 2004-806 du 9 août 2004*, *supra* note 1. Jean-Michel Lemoyne de Forges, « Rapport de synthèse : le droit des politiques publiques de protection sanitaire » R.G.D.M. 2005.n° spécial.134. Sur les incidences de cet ordre public sur le patient, devenu « citoyen sanitaire », voir Pitcho, *supra* note 24.

29 S'agissant de cette redéfinition, il faut en effet noter qu'autant la révolution hygiéniste était une révolution centralisée et parfois autoritaire, autant les récentes réformes de santé publique sont plus régionalisées, tendent à remettre de nombreuses compétences aux instances locales et sont fondées sur une participation active des citoyens (associations de malades et d'usagers, associations de victimes du travail, etc.). Voir Gérard Mémeteau, *Cours de droit médical*, 2e éd., Bordeaux, Études Hospitalières, 2003 à la p. 19 et s.

30 Voir Boris Hauray, *L'Europe du médicament. Politique, expertise, intérêts privés*, Paris, Presses de Sciences Po., 2006.

31 Voir les travaux de la mission parlementaire d'information sur le médicament instituée en 2005 à la demande du sénateur François Autain : France, Sénat, Commission des Affaires Sociales, « Mission d'information de la commission des affaires sociales sur les conditions de mise sur le marché et de suivi des médicaments ».

32 *Loi n°2002-303 du 4 mars 2002* relative aux droits des malades et à la qualité du système de santé, J.O., 5 mars 2002, 4118. Voir toutefois Cass. civ. 1e, 15 novembre 2005, J.C.P. 2005.II.10045, obligeant le médecin à veiller à ce que le refus de soins soit éclairé.

A. Le médecin, rouage essentiel

Parce qu'il est celui qui est en contact le plus étroit avec le corps du patient et peut ainsi influer sur les comportements de ce dernier, parce qu'il est ordonnateur des dépenses de santé, en tant que prescripteur, transformateur d'informations, etc., le médecin, de concert avec les autres professionnels de la santé, est l'un des vecteurs privilégiés des réformes touchant la santé publique.

Plus précisément sa tâche ne cesse de se complexifier, les rôles qui lui incombent de se multiplier. D'une part, au nom de l'ordre public sanitaire le médecin est de plus en plus sollicité pour soutenir des mesures qui à travers la prise en charge de l'individu protègent le groupe. Certes, l'article R4127-2 du *Code de la santé publique* relatif au code de déontologie médicale énonce déjà que le médecin exerce sa mission « au service de l'individu et de la santé publique » mais les choses vont désormais plus loin. C'est ainsi qu'en tant que médecin traitant il doit gérer le dossier de ses patients, coordonner leur parcours et surtout se faire l'instrument de l'équilibre financier de la sécurité sociale[33]; en tant qu'acteur de la prévention, et parce qu'il doit comme l'énonce la loi de santé publique, concourir « à la politique de réduction des risques », et « mettre en œuvre les objectifs quantifiés adoptés par la représentation nationale »[34], le médecin est sollicité pour participer par exemple à la lutte contre le tabagisme ou l'alcoolisme. Cette mission de réduction des risques l'installe parfois dans une posture inconfortable et inédite, par exemple quand il doit convaincre un patient de transmettre une information génétique utile à des apparentés ou encore quand il doit se faire éducateur de santé en façonnant les comportements de ses patients.

D'autre part, et inversement, bien que toujours au nom de l'ordre public sanitaire, on lui demande, au-delà du colloque singulier, d'assumer toujours plus de tâches d'intérêt général (déclarations, certifications, transmission d'informations), parfois au moyen de nouvelles structures tels les réseaux de santé ou de soins, ou de nouveaux instruments comme les contrats de santé publique. On voit qu'avec cette croissance de la facette « intérêt public » de sa mission, le médecin est plus que jamais un relais de choix de société, qui s'exprime de manière particulièrement nette dans le domaine de la santé ou qui comporte de plus en plus une composante relative à la santé. Exécutant de premier ordre ou simple maillon ? L'analyse de la réalité du pouvoir qu'il exerce devrait fournir quelques éléments de réflexion.

B. Un pouvoir contesté doublé de responsabilités mal identifiées

L'analyse de l'évolution du pouvoir médical dans un contexte de publicisation de la santé met au jour un phénomène indéniable, à savoir l'extension de son rôle politico-social du fait de la délégation croissante d'un certain nombre de décisions au corps médical. Ce pouvoir, réel mais décalé par rapport à la mission classique du médecin, contesté par ceux-là même qui en sont dotés (1) est redoublé de responsabilités dont il est difficile de mesurer la portée (2).

1. *Un pouvoir de décision inconfortable*

Ce phénomène, devenu classique dans un certain nombre de domaines, est aujourd'hui renouvelé. Que le médecin assume un rôle de décision croissant n'est certes pas nouveau à proprement parler. Un telle tendance a depuis un certain temps déjà été bien mise en relief s'agissant de l'expérimentation biomédicale ou de l'assistance médicale à la procréation dont les réglementations successives confèrent indéniablement au médecin le pouvoir d'apprécier la légitimité de la demande à laquelle il est confronté. On peut alors se risquer à qualifier les médecins de « petits législateurs » au sens où ils finissent par exercer un pouvoir normatif consistant à élaborer à leur propre usage, dans le cadre législatif ou réglementaire, une « doctrine » justifiant des décisions qui ne sont pas toujours prises au regard de

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33 Voir Odile Plichon, « Les médecins contrôleurs de la Sécu payés au mérite » *Le Parisien* (7 avril 2006) 10 : il semblerait que la Confédération française de l'encadrement — Confédération générale des cadres (CFE-CGC), Force Ouvrière (FO) et la Confédération française démocratique du travail (CFDT) aient avalisé la convention collective des praticiens conseil, ces médecins de la sécurité sociale chargés de vérifier que les assurés n'abusent pas des arrêts maladie et que les médecins libéraux n'en prescrivent pas trop. Non seulement le salaire de base de chaque praticien serait réévalué de 300 euros mais de nouveaux éléments de rémunération au mérite entreraient en ligne de compte. *Quid* alors de l'indépendance de la profession vis-à-vis de son employeur (l'assurance maladie) ? Et des droits des malades ? Si, par exemple, en fin d'année, l'objectif fixé par la sécurité sociale de réduire de 10 % le nombre d'arrêts maladie n'est pas atteint, certains médecins conseil ne seront-ils pas tentés de remettre au travail des assurés afin de toucher leur prime ? Le Conseil national de l'ordre des médecins a exprimé ses plus vives inquiétudes. Le dossier est entre les mains du ministre de la santé qui doit agréer le texte.

34 *Loi n° 2004-806 du 9 août 2004*, *supra* note 1.

critères médicaux[35]. Deux domaines illustrent particulièrement le propos, la procréation médicalement assistée et la fin de vie.

Plus étonnant est sans doute que ce phénomène de délégation de pouvoir se produit de plus en plus souvent dans des domaines *a priori* indifférents à la santé et sans que le médecin l'ait en quelque façon sollicité, contrairement à ce qui se passe dans les champs comme l'euthanasie et la reproduction, où les médecins — quoique souvent critiques par rapport à la législation qui le leur confère — sont souvent à l'origine, de façon directe ou indirecte, de la délégation de cet embarassant pouvoir de décision. En effet, à mesure que s'accroît l'*imperium* de la santé, devenant un critère d'attribution de tel droit ou de refus de tel autre, les cas de figure se multiplient dans lesquels le médecin se trouve fortement impliqué dans une décision non médicale, du fait même qu'il a établi tel certificat ou donné tel avis. Le phénomène est particulièrement net en matière de séjour des étrangers et de droit d'asile.

Pourtant, il serait trop simple de corréler de façon systématique ce pouvoir décisionnel lourd de conséquences sociales à un accroissement de pouvoirs. En effet, il est difficile d'ignorer le discours de médecins se plaignant de devoir assumer de plus ou plus de tâches qui ne sont pas les leurs[36] ou, de manière plus pertinente, d'être insidieusement transformés en agents de politiques publiques par des autorités qui se défaussent. Est-ce au médecin du travail de participer à la politique de sélection de travailleurs qui seraient exposés à tel ou tel risque ? Est-ce au médecin de décider qu'il n'y a pas de contre-indication à ce que tel étranger retourne dans son pays d'origine ? Est-il suffisamment armé et bien placé pour juger des cas de dopage en matière sportive ?

D'où un paradoxe : c'est par ceux-là même qui l'exercent — les médecins — que ce pouvoir d'un nouveau genre, plus administratif ou politique que médical, est contesté. Au fond, qu'il s'agisse de participer à la prise de décisions politiques qui ne le regardent pas ou de s'instituer en expert de telle ou telle condition sociale ou psychologique, le médecin est mal à l'aise avec le pouvoir dont il est investi, parce qu'il s'exerce dans un cadre autre que celui du classique paternalisme médical, borné par le colloque singulier et la compétence technique indiscutable du médecin. Dès lors on est conduit à se demander si, en refusant de s'engager résolument dans ces voies nouvelles, le médecin, sous couvert de manque de moyens et de compétence, s'enferme dans une conception technicienne et désuète de son rôle. À tout le moins faudra-t-il, à l'avenir, que soient redessinés plus fermement les contours de la notion d'acte médical.

Sans doute cet inconfort trouve-t-il également sa source dans la difficulté d'identifier les conditions de mise en œuvre et les effets de la responsabilité médicale.

2. *L'identification malaisée des responsabilités*

Si la publicisation de la santé affecte à coup sûr l'identité sociale du médecin, ses effets sur sa responsabilité sont plus difficiles à mesurer : est-il plus ou moins responsable ? L'est-il autrement ? La synthèse est difficile car une tendance chasse l'autre : la responsabilité civile est globalement marquée par un recentrage autour de la faute, parfois même caractérisée, sans parler des dispositifs indemnitaires d'où est évacuée toute notion de faute ; la mise en cause de plus en plus fréquente de l'État dans des affaires de santé publique semble mettre le médecin au second plan mais en même temps, c'est bien parce que ces hypothèses concernent la santé, et qu'à un moment donné ou un autre il y a eu défaillance de prévention ou de soin, qu'elles surgissent au contentieux ; enfin, le droit pénal étant, en dépit des classifications judiciaires et universitaires, intrinsèquement du droit public, il est logique que la publicisation de la santé affecte la responsabilité pénale du médecin dans une mesure qu'il faudra déterminer.

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[35] Sur ce phénomène, voir Marcela Iacub et Pierre Jouannet, dir., *Juger la vie. Les choix médicaux en matière de procréation*, Paris, La Découverte, 2001.

[36] Il est ici question de la protestation récurrente relative aux tâches administratives croissantes que devraient assumer les médecins. Le constat est indéniable mais d'une part il concerne presque toutes les professions, d'autre part il est parfois piquant de voir ceux-là mêmes qui sont payés par la Sécurité sociale se plaindre de devoir lui envoyer des documents.

WOMEN AT RISK: EMBRYONIC AND FETAL STEM CELL RESEARCH IN CANADA

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In March of 2002, in the absence of explicit Canadian law or policy regulating the burgeoning and ethically controversial field of human embryonic stem cell research, the Canadian Institutes of Health Research (CIHR) published its Guidelines for Human Pluripotent Stem Cell Research. These Guidelines—largely based on the recommendations of CIHR's ad hoc Working Group on Stem Cell Research—aimed to enable the advancement of the stem cell science whilst protecting and promoting the interests of research participants, most particularly women. Unfortunately, as detailed in this paper, some of the ad hoc Working Group's recommendations specifically aimed at shielding women from potential coercion and exploitation were either omitted or amended, absent stated authority, in the 2002 Guidelines as later amended in 2005 and 2006. This paper traces the omissions and amendments to key recommendations on: (i) free and informed consent to research participation; (ii) decision-making regarding the future disposition of unwanted embryos; (iii) potential conflicts of interest; and (iv) the research use of frozen embryos. Concerns are raised about the consequences of the changes made to the protection and promotion of women's interests and the lack of legitimate authority for some of the changes.

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Sincere thanks are owed to Natalie Ram, Jocelyn Downie, Lorraine Lafferty for helpful comments on earlier drafts, and to Tim Krahn for able research assistance.

Competing Interests: Françoise Baylis was a member of the CIHR *ad hoc* Working Group on Stem Cell Research from November of 2000 to December of 2001 and a member of the CIHR Governing Council from January of 2002 to December of 2004. She was a Principal Investigator with the Stem Cell Network from January of 2002 to December of 2005.

INTRODUCTION

In November of 1998, James Thomson[1] and John Gearhart[2] announced their respective successes in deriving human embryonic stem cells (hESCs) and human germ stem cells. Many in the scientific community greeted this news with considerable enthusiasm.[3] Others, however, including some members of the scientific community, were much less optimistic;[4] some expressed concern about the moral status of embryos and fetuses,[5] and others expressed concern about the risks to women and couples who would provide the embryos and fetal tissue for research use.[6] These and other ethical concerns have since been the subject of intense international debate not only in the media and academia, but also in numerous governmental and quasi-governmental reports.[7]

Of particular interest in this paper are concerns about the health and safety of women and more specifically the twin risks of coercion and exploitation. According to some, these concerns are overstated. According to others, they are sufficiently serious as to preclude stem cell research involving embryos or fetal tissues.[8] Between these extremes are those who believe that these concerns are legitimate but that they can be managed effectively with the introduction and implementation of a sound regulatory framework.[9] On this view, rules and regulations can be introduced to protect and promote the interests of women.

Canada, as is frequently the case in matters of public policy and public opinion, occupies this middle ground: the concerns of and for women are recognized as legitimate and are addressed in relevant policy and legislative documents. In our estimation, however, the current protections offered to women are inadequate. In this paper we trace the evolution of the Canadian Institutes of Health Research (CIHR) stem cell research guidelines from 2001 to 2006, with particular attention to those parts of the guidelines

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1 James A. Thomson *et al.*, "Embryonic Stem Cell Lines Derived from Human Blastocysts" (1998) 282 Science 1145.

2 Michael J. Shamblott *et al.*, "Derivation of Pluripotent Stem Cells from Cultured Human Primordial Germ Cells" (1998) 95 Proceedings of the National Academy of Sciences 13726.

3 See e.g. Elliott Marshall, "A Versatile Cell Line Raises Scientific Hopes, Legal Questions" (1998) 282 Science 1014; and Davor Solter & John Gearhart, "Putting Stem Cells to Work" (1999) 283 Science 1468.

4 Gretchen Vogel, "Stem Cells: New Excitement, Persistent Questions" (2000) 290 Science 1672.

5 See e.g. Brent Waters & Ronald Cole-Turner, eds., *God and the Embryo: Religious Voices on Stem Cells and Cloning* (Washington: Georgetown University Press, 2003); Richard Doerflinger, "Destructive Stem-cell Research on Human Embryos." (1999) 28 Origins 769.

6 See e.g. Suzanne Holland "Beyond the Embryo: A Feminist Appraisal of the Embryonic Stem Cell Debate" in Suzanne Holland, Karen Lebacqz & Laurie Zoloth, eds., *The Human Embryonic Stem Cell Debate: Science, Ethics, and Public Policy* (Cambridge: MIT Press, 2001) 73; Ingrid Schneider & Claudia Schumann, "Stem Cells, Therapeutic Cloning, Embryo Research: Women as Raw Material Suppliers for Science and Industry" *Proceedings of ReproKult: Women's Forum for Reproductive Medicine; Reproductive Medicine and Genetic Engineering; Women Between Self-Determination and Societal Standardisation, Berlin, 15 - 17 November 2001* 79, online: ReproKult <http://www.reprokult.de/e_forum_3.pdf>.

7 See e.g. American Association for the Advancement of Science & Institute for Civil Society, *Stem Cell Research and Applications: Monitoring the Frontiers of Biomedical Research* by Audrey R. Chapman, Mark S. Frankel & Michele S. Garfinkle (Washington, D.C., 1999), online: <http://www.aaas.org/spp/sfrl/projects/stem/report.pdf>; U.K., Department of Health, *Government Response to the Recommendations Made in the Chief Medical Officer's Expert Group Report "Stem Cell Research: Medical Progress with Responsibility"* by Secretary of State for Health (2000), online: <http://www.dh.gov.uk/assetRoot/04/05/77/34/04057734.pdf>; Australian Academy of Science, *On Human Cloning: A Position Statement* (Cranberra: Australian Academy of Science, 1999), online: <http://www.science.org.au/reports/clone.pdf>; U.S., National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research: Report and Recommendations of the National Bioethics Advisory Commission*, (Rockville, MD: National Bioethics Advisory Commission, 1999), online: <http://www.bioethics.gov/reports/past_commissions/nbac_stemcell1.pdf> [USNBAC, *Report*]; Gretchen Vogel, "Stem Cell Scorecard" (2000) 290 Science 1673.

8 See e.g. Kelly Hollowell, "Federal Stem Cell Research: What Taxpayers Should Know" (Heritage Lecture #888 for the Heritage Foundation: Policy Research and Analysis, 24 June 2005) [unpublished], online: The Heritage Foundation <http://www.heritage.org/Research/HealthCare/hl888.cfm>; Center for Genetics and Society, *Egg Extraction for Stem Cell Research: Protecting Women's Health Fact Sheet* (2005), online: Center for Genetics and Society <http://www.genetics-and-society.org/resources/background/eefactsheet.html>.

9 See e.g. Meredith Wadman, "NIH Stem-Cell Guidelines Face Stormy Ride" (1999) 398 Nature 551; Rick Weiss, "Panel Drafts Ethics Plan for Embryo Cell Studies: Rules Would Guide Federally Funded Research" *The Washington Post* (9 April 1999) A2; Debra Greenfield, "The Impatient Polis: What's Wrong with the California Stem Cell Research and Cures Act?" (Paper presented at the Gender and Justice in the Gene Age conference, New York, NY, 6–7 May 2004) [unpublished], online: <http://www.gjga.org/conference.asp?action=item&source=documents&id=82>; American Society for Reproductive Medicine (Ethics Committee), "Donating Spare Embryos For Embryonic Stem-Cell Research" (2002) 78 Fertility and Sterility 957 (Reviewed June 2006), online: ASRM <http://www.asrm.org/Media/Ethics/donatingspare.pdf> [ASRMEC, "Donating"].

that have been formally incorporated into the *Assisted Human Reproduction (AHR) Act*.[10] This *Act*, in addition to defining and prohibiting assisted reproduction procedures deemed ethically unacceptable, regulates the research use of embryos. Our comparative analysis of relevant documents reveals both substantive and procedural problems with the ways in which key elements related to the protection and promotion of women's interests were eliminated or amended.

I
A BRIEF CHRONOLOGY OF THE CIHR GUIDELINES FOR STEM CELL RESEARCH IN CANADA

In the absence of Canadian laws or explicit research guidelines regulating the rapidly evolving and ethically controversial field of human embryonic stem cell research, CIHR established an *ad hoc* Working Group on Stem Cell Research in late 2000. This was a nine-member committee composed of scientists, clinicians, philosophers, and a lawyer that together possessed national and international proficiency in stem cell research and human reproductive technologies.[11] The mandate of the *ad hoc* Working Group was to determine whether and, if so, under what conditions, individuals and institutions funded by CIHR could undertake stem cell research consistent with the existing ethical framework set out in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Human* (TCPS).[12] On March 29, 2001, CIHR released a Discussion Paper prepared by the *ad hoc* Working Group, initiating a three-month public consultation.[13]

The Discussion Paper was sent to all CIHR-funded organizations and institutions, posted on CIHR's website, and publicized through the media. A total of 116 responses were received: 89 from individuals and 27 from "special interest groups, professional groups, health charities, [and] governmental agencies".[14] Importantly, a number of the ethical issues identified during the public consultation process were also of concern to members of the *ad hoc* Working Group. Chief among the shared concerns was the worry that "an increasing demand for human embryos or fetal material could result in coercion of women involved in fertility treatment or considering therapeutic abortion."[15] The *ad hoc* Working Group's response to this and other ethical concerns was multi-faceted, as explained in Appendix iii of their final report *Human Pluripotent Stem Cell Research: Recommendations for CIHR-Funded Research*.[16]

On January 16, 2002, the CIHR Governing Council unanimously adopted Motion GC-13-5:

> To accept the report of the ad hoc Working Group on Stem Cell Research outlining clear guidelines and prohibitions on stem cell research eligible for CIHR funding, as well as the following recommendations:
>
> - establishment of a National Stem Cell Oversight Committee;
> - establishment of an electronically accessible national registry of human embryonic stem cell lines generated in Canada;
> - collaboration with other Federal funding agencies to ensure the Tri-Council Policy Statement is revised to clarify the ethical guidelines for human stem cell research;
> - the establishment of a new working group to examine the scientific and ethical issues of inter-specific chimeras [organisms with cell populations derived from two different organisms from different species]; and
> - the review of the field of human stem cell research on an ongoing basis with respect to the research guidelines and to review the need for, and process of national research ethics review.[17]

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10 *Assisted Human Reproduction Act*, S.C. 2004, c.2.

11 Canadian Institutes of Health Research *ad hoc* Working Group on Stem Cell Research, *Human Pluripotent Stem Cell Research: Recommendations for CIHR-Funded Research*, (January 2002), online: CIHR <http://www.cihr-irsc.gc.ca/e/1489.html> at App. ii. One of the authors (Françoise Baylis) was a member of the CIHR *ad hoc* Working Group on Stem Cell Research.

12 Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada. 1998. *Tri-Council Policy Statement Ethical Conduct for Research Involving Humans*. Ottawa: Medical Research Council of Canada, online: PRE <http://www.pre.ethics.gc.ca/english/pdf/TCPS%20June2003_E.pdf>.

13 Canadian Institutes of Health Research *ad hoc* Working Group on Stem Cell Research, *Human Stem Cell Research: Opportunities for Health and Ethical Perspectives*, (29 March 2001), online: CIHR <http://www.cihr-irsc.gc.ca/e/pdf_14370.htm>.

14 *Supra* note 11 at App. iii.

15 *Ibid*. [emphasis omitted].

16 *Ibid*. App. iii usefully summarizes the details of the policy response to the public consultation initiative.

17 Canadian Institutes of Health Research 13th Meeting of the Governing Council, *Minutes*, (Ottawa, ON, 16 January 2002), online: CIHR <http://www.cihr-irsc.gc.ca/e/1386.html> at s. 8. One of the authors (Françoise Baylis) was a member of Governing Council.

Of course, a Governing Council can accept the final report of an *ad hoc* Working Group without embracing all of the content of the report. This did not happen in this instance, however. First, the final report of the *ad hoc* Working Group was adopted unanimously and verbatim by the Governing Council. Second, there were no changes initiated by, or proposed to, the Governing Council between the unanimous adoption of the report in January of 2002 and the public release of the CIHR document *Human Pluripotent Stem Cell Research: Guidelines for CIHR Funded Research*[18] in March of 2002. Third, at no time was there any indication in public announcements or documents that the *2002 Guidelines* were different from the *Governing Council Report*. It follows that "accepting the report" did not mean "accepting the report for consideration", but rather meant accepting the guidelines and prohibitions, as well as other recommendations as stated in the final report. In this paper, we therefore refer hereafter to the final report of the *ad hoc* Working Group[19] as the *Governing Council Report*.

On March 4, 2002—with enthusiasm, confidence,[20] and direct reference to the *Governing Council Report*—Dr. Alan Bernstein, President of CIHR, announced "[t]oday, the Canadian Institutes of Health Research is taking a major step in setting guidelines that will enable Canadian researchers to conduct research using human pluripotent stem cells. The guidelines, effective today, will apply to researchers and institutions that receive funding from CIHR."[21]

A few years later, on June 7, 2005, the *Human Pluripotent Stem Cell Research: Guidelines for CIHR Funded Research* (hereafter the *2002 Guidelines*)[22] were officially updated pursuant to a Governing Council decision on March 24, 2005.[23] Consistent with the Governing Council directive to develop a "comprehensive communications plan to inform the research community"[24] of the policy changes, the *2005 Guidelines for Human Pluripotent Stem Cell Research*[25] (hereafter *2005 Guidelines*) were posted on the CIHR website[26] and an email notice was sent to "all CIHR staff, including Institutes, CAURA [Canadian Association of University Research Administrators], Business Officers, University Delegates, Communication Departments within universities, among others".[27] Unfortunately, this notice to the research community did not include a summary of the changes to the *2002 Guidelines* or a summary of the underlying rationale for any of the changes. On June 28, 2006, just over a year later, the *2005 Guidelines* were updated again.*[28]*

A comparative analysis of the *Governing Council Report* and the *2002*, *2005*, and *2006 Guidelines* reveals that several of the articles in the *Governing Council Report* directly relevant to the protection and promotion of women's interests, as well as the presumption in favour of the research use of frozen (not fresh) embryos, were either omitted or significantly amended in one or more versions of the *Guidelines*. In our view, these changes, not only thwart the intent and direction of the CIHR Governing Council, the recommendations of the *ad hoc* Working Group, and the legitimate concerns of Canadians (as identified through the public consultation process), but they also represent a serious threat to the interests of women and a serious threat to the integrity of the CIHR policy-making process. Each of these threats is carefully examined below.

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18 Canadian Institutes of Health Research, *Human Pluripotent Stem Cell Research: Guidelines for CIHR-funded Research,* (March 2002), online: CIHR <http://www.cihr-irsc.gc.ca/e/1487.html>.

19 *Supra* note 11.

20 The characterization of Dr. Bernstein's tone is based on direct observation of the event.

21 Alan Bernstein, "CIHR Guidelines on Human Pluripotent Stem Cell Research" (President's Address at the National Press Theatre 4 March 2002), online: CIHR <http://www.cihr-irsc.gc.ca/e/1203.html>. As CIHR is not a legislative body, its Guidelines only apply to individuals and institutions that receive CIHR funding. The regulation of privately funded stem cell research conducted in privately funded institutions would not occur until the *Assisted Human Reproduction Act* received Royal Assent in March of 2004.

22 *Supra* note 18.

23 Canadian Institutes of Health Research 33rd Meeting of the Governing Council, *Minutes*, (Ottawa, ON, 23-24 March 2005), online: CIHR <http://www.cihr-irsc.gc.ca/e/28683.html>.

24 *Ibid.* at s. 13.

25 Canadian Institutes of Health Research, *Guidelines for Human Pluripotent Stem Cell Research*, (7 June 2005), online: CIHR <http://www.cihr-irsc.gc.ca/e/28216.html>.

26 Canadian Institutes of Health Research, *Funding News and Developments: Application and Funding Policy News*, online: CIHR <http://www.cihr-irsc.gc.ca/e/26626.html>. The direct link to the notice is <http://www.cihr-irsc.gc.ca/e/28267.html>.

27 Personal phone communication between Karen Wallace (CIHR Ethics Office) and Caroline McInnes (5 August 2005), documented in email correspondence to Françoise Baylis.

28 Canadian Institutes of Health Research, *Updated Guidelines for Human Pluripotent Stem Cell Research*, (28 June 2006), online: CIHR <http://www.cihr-irsc.gc.ca/e/31488.html>.

II
THREATS TO THE INTERESTS OF WOMEN

As summarized in Appendix iii of the *Governing Council Report*, there were five articles specifically aimed at promoting the health, safety, and rights of women. First, in an effort to minimize the potentially ever-increasing demand for embryos for research use, the *Governing Council Report* required that successfully derived hESC lines be made available to all Canadian researchers on a cost-recovery basis. Second, in an effort to promote free and informed consent to embryonic and fetal stem cell research, the *Governing Council Report* required full disclosure and a two-part consent process for embryo research. There was to be an initial consent from the gamete providers at the time gametes were collected to make embryos for therapeutic purposes and a second consent from the embryo providers at the time of anticipated research use. Third, to ensure voluntariness and minimize the risk of coercion, the *Governing Council Report* made clear that consent to the research use of embryos or fetal tissue must *never* be a condition of access to treatment. Fourth, it was stipulated that physicians responsible for fertility treatment, persons responsible for securing the initial consent for the future disposition of unwanted embryos, and physicians responsible for therapeutic abortions must *not* be part of the stem cell research team. Last, the *Governing Council Report* called for the creation of a national Stem Cell Oversight Committee to provide national research ethics review of stem cell research (in addition to local Research Ethics Board review) and, as needed, to update the CIHR *Guidelines*. It was assumed that this Committee would continue to attend to the risks of coercion and exploitation of women.[29]

The first and last of these issues are dealt with in the *2002*, *2005* and *2006 Guidelines* in a manner entirely consistent with the *Governing Council Report*—successfully derived hESC lines are to be made available to Canadian researchers on a cost-recovery basis and hESC and germ stem cell research conducted by individuals or institutions that receive CIHR funding must be reviewed by the Stem Cell Oversight Committee.[30] As detailed below, however, the other issues more explicitly linked to the twin risks of coercion and exploitation are not dealt with in a similar manner. They are either omitted or significantly amended in the *2002*, *2005* and/or *2006 Guidelines*.

A. Free and Informed Consent

In an effort to promote free and informed consent, the *Governing Council Report* insisted on the need for "full disclosure of information by the researchers and free and informed consent from the research participants ... at the time that gametes are provided and again when the research use of the discarded embryos is anticipated".[31] Two articles in the *Governing Council Report* are relevant to this aspect of consent—articles 5.1 and 5.4. The first of these two articles stipulated that gamete providers and embryo providers must be informed of all options for the disposition of unwanted embryos, not merely the option of research use, and a decision regarding the future disposition of unwanted embryos must be made prior to the collection of gametes and the creation of embryos for reproductive purposes. The second article detailed the information that must be disclosed.[32]

As regards the requirement for full disclosure, the *Governing Council Report* carefully identified all of the information to be disclosed to prospective research participants in an effort to reduce the possibility of confusion, ambiguity, or misinterpretation, and to promote clarity and consistency.

> 5.4 For the purpose of obtaining free and informed consent to human stem cell research, at a minimum, researchers shall provide prospective research participants or authorized third parties with the following information.
>
> 1) A description of the purpose of the research;
>
> 2) A description of the research procedures;
>
> 3) A description of reasonably foreseeable harms and benefits that may arise from research participation;
>
> 4) An explanation that consent to, or refusal of, research participation will not affect access to treatment;
>
> 5) An explanation of the potential uses of the stem cells including any commercial uses, and the presence of any apparent or actual or potential conflict of interest on the part of researchers, their institutions or sponsors;

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29 *Supra* note 11 at App. iii.

30 *Supra* note 18 at art. 5.0; *supra* note 25 at art. 6.

31 *Supra* note 11 at App. iii.

32 *Ibid*. at arts. 5.1, 5.4.

> 6) An explanation that the research participants will not benefit directly financially from any future commercialization of cell lines; nor will there be any personal benefit in terms of dispositional authority over any cell lines created (i.e., there will be no directed donation of the cells or cell lines to particular individuals), except if the research involves autologous donation;
>
> 7) An explanation that the cell line(s) will be anonymized, except if the research involves autologous donation ...
>
> 8) An explanation that the research could result in the production of a cell line that could be maintained for many years and used for different research purposes;
>
> 9) An assurance that prospective research participants are free not to participate and have the right to withdraw at any time before an anonymized cell line is created.
>
> In the case of stem cell research involving human embryos where "donor" gametes have been used to create the embryos, only a subset of the disclosure requirements will apply because consent will be sought for unrestricted research use.[33]

An amended version of this article in the *Governing Council Report* appeared in article 7.2.3 of the *2002 Guidelines* and article 8.3.3 of the *2005* and *2006 Guidelines*. Of note, the requirements detailed in subsections 1) to 5) were eliminated and replaced with the general description "the usual information". Subsections 6) to 9) appeared with small wording changes and in a different order from that in the *Governing Council Report*.[34]

Though Canadian common law,[35] provincial legislation, legal literature,[36] and the TCPS[37] provided the backdrop against which the requirements for disclosure and consent to stem cell research were elaborated, the novelty of such research presented a unique challenge in defining these requirements, making their details particularly important to the goal of promoting clarity and consistency. Unfortunately, over half of the disclosure requirements in the *Governing Council Report* (articles 5.4.1–5) were replaced in the *2002, 2005* and *2006 Guidelines* with the instructions "in addition to the usual information given", when nowhere in these *Guidelines* is the "usual information" divulged, nor is there a reference to the appropriate authoritative source for the "usual information". This leaves the disclosure requirements for stem cell research seriously under-specific, which increases the risk of uninformed consent.

As the *2002, 2005* and *2006 Guidelines* are to be read in conjunction with the TCPS,[38] which outlines information that researchers must disclose to prospective research participants, the TCPS is at least one potential source of the "usual information". But will stem cell researchers know to consult the TCPS? Will they see these guidelines as authoritative?[39] Might they be confused by the reference to the "usual information" and look to the common law or provincial legislation? To say the least, it would seem unwise to invite guesswork on the part of stem cell researchers who are not legal scholars. In our view, in replacing the specific disclosure requirements with the ambiguous phrase "the usual information" without including a directive to the authoritative source, the *2002, 2005* and *2006 Guidelines* failed to effectively promote clarity and consistency and thereby failed to effectively insulate women from potential coercion associated with uninformed consent.

The second relevant consent issue concerns the requirement for advance planning regarding the future disposition of unwanted embryos prior to the creation of embryos. The *Governing Council Report* stipulated that:

> 5.1 Embryos no longer wanted for reproductive purposes may be donated to another couple, used for research (including research to derive and study human ES cells), or discarded. These options should be discussed with the gamete providers (and the embryo providers if these are different individuals), and *a decision regarding the eventual disposition of unwanted embryos should be made prior to the collection of gametes and the creation of embryos for reproductive purposes.*[40]

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33 *Ibid*. at art. 5.4.

34 *Supra* note 18 at art. 7.2.3; *supra* note 25 at art. 8.3.3.

35 See e.g. *Halushka v. University of Saskatchewan*, [1965] 52 W.W.R. 608 (Sask. C.A.); *Weiss v. Solomon*, [1989] 48 C.C.L.T. 280 (Qc. Sup. Ct.).

36 See generally Kathleen Cranley Glass & Trudo Lemmens, "Research Involving Humans" in Jocelyn Downie, Timothy Caulfield & Colleen Flood, eds., *Canadian Health Law and Policy*, 2d ed. (Markham: Butterworths, 2002) at 479-487. See also Ellen Picard & Gerald Robertson, *Legal Liability of Doctors and Hospitals in Canada*, 3d ed. (Scarborough: Carswell, 1997) at c. 3.

37 *Supra* note 12.

38 *Ibid*.

39 The TCPS applies to individuals and institutions that receive funding from CIHR, SSHRC and NSERC.

40 *Supra* note 11 at art. 5.1 [emphasis added].

The highlighted clause was included, verbatim, in article 7.2.1 of the *2002 Guidelines*.[41] However, it was later amended in article 8.3.1 of the *2005 Guidelines* so that disclosure, but not decision-making, regarding the future disposition of unwanted embryos was required at the time of gamete collection and prior to the creation of embryos:

> 8.3.1 Those who no longer require fresh or frozen embryos for their reproductive purposes may: 1) donate the embryos to others to use for reproductive purposes; 2) donate the embryos for research (including research to derive and study human ES cells); or 3) provide authorization for the embryos to be destroyed. The embryo provider(s) (and the third party gamete provider(s), if applicable) *must be informed of these options prior to the collection of gametes and the creation of embryos for reproductive purposes.*[42]

A few months after the *2005 Guidelines* were published, the proposed regulatory text for the Consent Regulations (section 8), pursuant to the *AHR Act*, was published in the Canada Gazette. [43] As required by law, the draft Consent Regulations were consistent with the *2002 Guidelines* and as such they included a clear requirement for both disclosure and decision-making. The resulting predictable (and predicted) inconsistency between the *2005 Guidelines* and the draft Consent Regulations was brought to the attention of CIHR. The CIHR Ethics Office was provided with a confidential copy of an earlier version of this paper explaining that: (i) the original *2002 Guidelines* were consistent with national and international practice; (ii) the *2005 Guidelines* did not adequately protect and promote women's interests; and (iii) the *2005 Guidelines* would appear to be inconsistent with the law insofar as the consent regulations would have to be consistent with the *2002 Guidelines*. The following year, with the *2006 Guidelines*, the text from article 8.3.1 reverted to the text of article 7.2.1 of the *2002 Guidelines*.

One principled reason for eliciting an initial consent to the future disposition of excess embryos is to ensure that patients not only understand and agree to the purposes of creating IVF embryos, but are also willing to accept responsibility for the associated consequences. A second principled reason for early decision-making is to explicitly recognize and value the dispositional rights of individuals over their reproductive material. In part, patients' understanding and control is evidenced by decision-making regarding the future disposition of embryos no longer wanted for infertility treatment.

An additional pragmatic reason for eliciting an initial consent to the future disposition of excess embryos is to avoid the possibility of no decision being made about the future of embryos created for infertility treatment but no longer wanted for this purpose, and the IVF clinic having in its possession embryos for which there is no advance planning and over which they have no dispositional authority. IVF clinics have no interest in the permanent storage of frozen embryos, hence their interest in making sure that there are disposition plans in place prior to the creation and freezing of embryos. As the time between the creation and possible freezing of embryos is short, there is reason to elicit a choice prior to the creation of embryos. Further, decision-making about the creation and possible freezing of embryos for infertility treatment can be psychologically stressful for women. One way of addressing some of this stress involves assuring women that the future disposition of their embryos is at their discretion (i.e., under their control).

Current practice in Canada (consistent with the Canadian Fertility and Andrology Society and the Society of Obstetricians and Gynecologists of Canada Guidelines,[44] as well as international practice[45]) is to require advance planning for the future disposition of unwanted frozen embryos, recognizing all the while that any advance plans can always be amended (by definition, consent is always revocable). This common practice was reflected in the original consent requirements of the *Governing Council Report* and the *2002 Guidelines*.[46] With the *2005 Guidelines*, however, these consent requirements were amended such that although information about disposition options had to be disclosed, no decision about the future disposition of embryos had to be made.[47]

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41 *Supra* note 18 at art. 7.2.1.

42 *Supra* note 25 at art. 8.3.1 [emphasis added].

43 Department of Health, "*Erratum*: Assisted Human Reproduction (Section 8) Regulations" in *Canada Gazette*, vol. 139 (24 September 2005) at 3181, online: Canada Gazette <http://canadagazette.gc.ca/partI/2005/20050924/pdf/g1-13939.pdf>.

44 Canadian Fertility and Andrology Society and Society of Obstetrics and Gynaecology Canada, "Disposition of Frozen Embryos" (1999) 21:1 Journal of the Society of Obstetricians and Gynaecologists of Canada 19 at 22.

45 See e.g. American Society for Reproductive Medicine (Ethics Committee), "Disposition of Abandoned Embryos" (2004) 82: Suppl 1 Fertility and Sterility S253 (Reviewed July 2006), online: <http://www.asrm.org/Media/Ethics/abandonedembryos.pdf>; ASRMEC, "Donating", *supra* note 9 at 959.

46 *Supra* note 11 at art. 5.1; *supra* note 18 at art. 7.2.1.

47 *Supra* note 25 at art. 8.3.1.

Another pragmatic benefit of decision-making prior to the creation of embryos is that potential problems with clinic practice regarding the disposition of frozen embryos could be rectified before embryos were created and frozen. For example, a 2005 Canadian study of consent documents for embryo freezing revealed that in some circumstances (such as loss of contact), IVF clinics conferred upon themselves decision-making authority for the disposition of frozen embryos.[48] If women were aware of this practice prior to the creation and freezing of their embryos, then they would be in a position to take appropriate measures to preclude this practice.

A third discrete consent issue concerns the explicit requirement that consent to the research use of embryos be renewed at the time of anticipated research use. The *Governing Council Report* stipulated:

> 5.2 At the time when the embryos are to be used for research to derive and study ES cells and other human cells or cell lines of a pluripotent nature, consent of the embryo providers should be confirmed. A renewal of the consent given by the gamete providers (if the gamete providers are not the same individuals as the embryo providers), is not required provided that appropriate consent for the unrestricted research use of the embryos was given at the time of gamete "donation".
>
> 5.6 To help ensure voluntariness, at the time the embryo(s) are to be used for research, a reconfirmation of the original consent to the research use of embryos must be obtained from the embryo providers. This requirement affirms the right to withdraw and is necessary because of the possible lengthy delay between the time at which the original consent is given and the time at which the embryos are utilized for research purposes.[49]

These two articles were collapsed as article 7.2.2 in the *2002 Guidelines*[50] and reprinted (with minor modification) as article 8.3.2 in the *2005* and *2006 Guidelines*.

> 8.3.2 At the time when the embryos are to be used for research to derive and study ES cells (and other human cells or cell lines of a pluripotent nature), consent of the embryo providers must be reiterated. This requirement affirms the right to withdraw and is necessary because of the possible lengthy delay between the time at which the original consent is given and the time at which the embryos are utilized for research purposes....[51]

The principled and pragmatic reason for requiring a reiteration of the initial consent to the research use of embryos is to allow women to change their mind. Evidence suggests that decision-making regarding the future disposition of embryos is complicated and influenced by one's experiences during fertility treatment.[52] Indeed, in 2001, Klock et al. reported that only 29% of couples stuck with their initial disposition decision, and more specifically, that 88% of couples who initially decided to donate their frozen embryos to research changed their mind.[53] More recently, in a 2006 survey of one Canadian IVF clinic, Nisker et al. reported that only 55% of couples who had specifically designated their frozen embryos for donation to research consented to embryonic stem cell research when contacted to reiterate their consent to this research use of their frozen embryos.[54] Thus, it appears that many IVF patients who initially consent to the future donation of excess frozen embryos to research (consent provided prior to the creation of *in vitro* embryos) change their mind once they are no longer in active treatment and no longer potentially influenced by what their physicians want.[55]

The fourth consent issue concerns the right to withdraw. The *Governing Council Report* explicitly addressed the right to withdraw consent for both the embryo providers and the gamete providers.

> 5.7 Consent to the research use of embryos is always revocable by the embryo providers who may change their mind regarding the future research use of embryos no longer wanted for reproductive purposes. Gamete providers who consent to the possible future research use of embryos created using their gametes cannot later withdraw their consent. They should be so advised during the informed choice process.[56]

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48 Françoise Baylis and Natalie Ram, "Eligibility of Cryopreserved Human Embryos for Stem Cell Research in Canada" (2005) 27:10 Journal of Obstetrics and Gynaecology Canada 949.

49 *Supra* note 11 at arts. 5.2, 5.6.

50 *Supra* note 18 at art. 7.2.2.

51 *Supra* note 25 at art. 8.3.2.

52 Robert D. Nachtigall *et al.*, "Parents' Conceptualization of Their Frozen Embryos Complicates the Disposition Decision" (2005) 84:2 Fertility and Sterility 431. See also, C.A. McMahon *et al.*, "Mothers Conceiving through in Vitro Fertilization: Siblings, Setbacks, and Embryo Dilemmas after Five Years" (2000) 10:3 Reproductive Technologies 131.

53 S.C. Klock, S. Sheinin & R.R. Kazer, "The Disposition of Unused Frozen Embryos" Letter (2001) 345 New Eng. J. Med. 69.

54 Jeffrey Nisker *et al.*, "Development and Investigation of a Free and Informed Choice Process for Embryo Donation to Stem Cell Research in Canada," (2006) 28:10 Journal of Obstetrics and Gynaecology Canada 903.

55 Carolyn McLeod & Françoise Baylis "Women Donating Fresh Embryos to Stem Cell Research: In Whose Interests?" (in review); and Carolyn McLeod & Françoise Baylis "The Ethics of Asking IVF Patients to Donate Fresh Embryos to Stem Cell Research" (Poster presented to the Canadian Fertility and Andrology Meeting, Ottawa, November 2006) [unpublished].

56 *Supra* note 11 at art. 5.7.

There is no comparable article in either the *2002, 2005* or *2006 Guidelines* that both affirms the embryo providers' right to withdraw and limits the gamete providers' right to do so. There is an indirect reference to the embryo providers' right to withdraw in article 7.2.2 of the *2002 Guidelines* and article 8.3.2 of the *2005 and 2006 Guidelines* with the statement about how the "requirement [for a reiterated consent] affirms the right to withdraw".[57] There is no statement in either the *2002, 2005* and *2006 Guidelines*, however, limiting the gamete providers' right to withdraw, as per the *Governing Council Report*. Indeed, article 7.2.3 of the *2002 Guidelines* and article 8.3.3 of the *2005* and *2006 Guidelines* stipulate that "prospective research participants are free not to participate and have the right to withdraw at any time before an anonymized cell line is created."[58] As gamete providers are clearly prospective research participants, then contrary to the *Governing Council Report*, it would appear that they have the right to withdraw "at any time before an anonymized cell line is created".[59]

In sum, for those committed to free and informed consent, it is distressing that many of the ethically sound consent requirements carefully outlined in the *Governing Council Report* were amended in the *2002 Guidelines* (and that many of these amendments were retained in subsequent updates to the *Guidelines*). This is of particular concern because the *2002 Guidelines* (not the more comprehensive and ethically sound *Governing Council Report*) have been formally incorporated into the *AHR Act*.[60] This *Act* defines consent as follows:

> "consent" means fully informed and freely given consent that is given in accordance with the applicable law governing consent and that conforms to the provisions of the *Human Pluripotent Stem Cell Research Guidelines* released by the Canadian Institutes of Health Research in March, 2002, as detailed in the Regulations.[61]

Furthermore, in its administrative section, the *AHR Act* requires that

> (3.1) The Agency shall not issue a licence under subsection (1) for embryonic stem cell research unless it has received the written consent of the original gamete providers and the embryo provider in accordance with the *Human Pluripotent Stem Cell Research Guidelines* released by the Canadian Institutes of Health Research in March, 2002, as specified in the regulations.[62]

One can only dream of how much better consent law on embryo research could have been if the original *Governing Council Report* had not been amended with the release of the *2002 Guidelines*. Imagine, for example, if the original disclosure requirements had been included in the *2002 Guidelines* instead of the general statement about the "usual information" with no clear instruction as to the authoritative source for the content of the "usual information". Unfortunately, even if CIHR were persuaded to revise its *Guidelines* (yet again) to better correspond with the *Governing Council Report*, it cannot amend this aspect of the law. The legislation is clear; given the specificity of the reference to the guidelines in the *AHR Act*, that the consent requirements of the *2002 Guidelines*, not any subsequent revisions, have legal force.[63]

B. Consent to embryo research not a condition of access to treatment

The *Governing Council Report* required "that consent to the use of unwanted embryos or aborted fetal tissue never be a condition of access to treatment."[64] Several articles in the *Report* specifically addressed this issue.

> 4.1 Research to derive and study human embryonic stem cell lines or other cell lines of a pluripotent nature from human embryos is eligible for funding provided that:

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57 *Supra* note 18 at art 7.2.2 and *supra* note 25 at art 8.3.2.

58 *Supra* note 18 at art 7.2.3 and *supra* note 25 at art 8.3.3.

59 *Ibid*.

60 *Supra* note 10.

61 *Supra* note 10 at s. 3.

62 *Supra* note 10 at s. 40(3.1).

63 Applying principles of statutory interpretation, the definition of "consent" in section 3 of the Act is exhaustive: see Pierre-André Côté, The Interpretation of Legislation in Canada, 3d ed. (Scarborough: Thomson Canada Limited, 2000) 62: "A first reading is usually sufficient to indicate whether a definition is exhaustive or not: if introduced by the word 'means' it is deemed to be exhaustive." In this case, the definition of consent in section 3 starts with the deeming word "means". At 61, Côté says, "An exhaustive definition purports to encompass all possible meanings of a term." In this case, only the March *2002 Guidelines* are encompassed in the definition as a possible meaning in relation to consent.

64 *Supra* note 11 at App. iii.

> ...
>
> 3. Neither the ova nor the sperm from which the embryos were created, nor the embryos themselves, were obtained through commercial transactions, including exchange for service.
>
> 4.2 Research to derive and study human embryonic germ cell lines, or other cell lines of a pluripotent nature from human fetal tissue or amniotic fluid is eligible for funding provided that:
>
> The proposed research does not compromise the pregnant woman's decision on whether to continue her pregnancy....
>
> 5.3 For research to derive and study EG cells and other human cells or cell lines of a pluripotent nature from human fetal tissue, the option of using fetal tissue for research must only be discussed with the pregnant woman after a free and informed choice has been made to have a therapeutic abortion. A woman's decision about whether to continue her pregnancy must not in any way be influenced by the possible research use of the fetal material.
>
> 5.4 For the purpose of obtaining free and informed consent to human stem cell research, at a minimum, researchers shall provide prospective research participants or authorized third parties with the following information.
>
> ...
>
> An explanation that consent to, or refusal of, research participation will not affect access to treatment....
>
> 5.10 Consent to the research use of unwanted embryos, aborted fetal tissue, umbilical cord or adult tissues should never be a condition, explicit or implicit, of access to treatment.[65]

In the *2002 Guidelines*, article 4.1(3) appeared verbatim as article 7.1.1(3). In the *2005* and *2006 Guidelines*, this article appeared as 8.1.1(3) with the text amended to redefine commercial transactions as "payment of money in excess of costs actually incurred or in exchange for healthcare services."[66] In the *2002 Guidelines*, article 4.2(1) became article 7.1.2(1) and in the *2005* and *2006 Guidelines* this was included as part of article 8.1.2(1) with the following additional text: "To ensure that such compromise does not occur, the stem cell researcher shall provide SCOC with satisfactory evidence that the pregnant woman's decision to discontinue the pregnancy was made prior to any request made to her to participate in the research." In this way a version of article 5.3 was reintroduced as part of article 8.1.2 in the *2005* and *2006 Guidelines*. The other two articles (5.4.4 and 5.10) were eliminated from the *Guidelines*, though there is a statement to the effect that embryos (no mention of fetal or other tissues) cannot be used for research if they were obtained through commercial transactions (defined differently in the *2002* and the *2005* and *2006 Guidelines*).[67]

The importance of the original articles in the *Governing Council Report* in shielding women from potential forms of coercion must not be overlooked. Coercion is often unintentional and is not always obvious; this makes it imperative that the rules governing stem cell research remove all foreseeable potential sources of coercion. Article 5.3 of the *Governing Council Report*,[68] for example, circumvented several possible sources of coercion by insisting that the research use of fetal tissue "must only be discussed with the pregnant woman after a free and informed choice has been made to have a therapeutic abortion".[69] This constraint recognized that the decision to have a therapeutic abortion might be influenced by discussion about the potential use of fetal material for stem cell research.[70] For example, a woman might feel obliged to donate her fetal material for research, fearing that her physician will be angry or upset with her if she did not want to donate, or worse, would not assist her with access to treatment. From another perspective, knowledge of the option of fetal tissue donation for research use might persuade an ambivalent person to forge ahead whereas under other circumstances she might have reconsidered her decision.

The importance of article 5.3[71] in the original *Governing Council Report* protecting pregnant women against possible forms of coercion is affirmed by its reintroduction in the *2005* and *2006 Guidelines* in article 8.1.2.[72] It is of concern, however, that only this missing article was reintroduced.

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65 *Supra* note 11 at arts. 4.1, 4.2, 5.3, 5.4.4, 5.10.

66 *Supra* note 25 at art 8.1.1.

67 *Supra* note 18 at art. 7.1.1; *supra* note 25 at art. 8.1.1.

68 *Supra* note 11 at art. 5.3.

69 *Supra* note 11 at art. 5.3

70 National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research: Volume 1 Report and Recommendations of the National Bioethics Advisory Commission* (Rockville: National Bioethics Advisory Commission, 1999) at 69, online: National Bioethics Advisory Commission <http://www.georgetown.edu/research/nrcbl/nbac/stemcell.pdf>.

71 *Supra* note 11 at art. 5.3.

72 *Supra* note 25 at art. 8.1.2.

C. No research team role for members of the health care team

In an effort to minimize the potential problem of conflict of interest, the *Governing Council Report* specified that persons in a clinical relationship with the women considered prospective research participants should not be members of the research team. The *Governing Council Report* required that "the physician responsible for the fertility treatment, the person seeking a consent to the disposition of embryos or the physician responsible for the therapeutic abortion, not be part of the stem cell research team."[73]

Several articles in the *Governing Council Report* addressed this concern:

> 5.5 To help ensure voluntariness and to minimize the risk that women and couples will be pressured to create more embryos than needed for reproductive purposes, the physician responsible for the fertility treatment and the person seeking a consent to the disposition of embryos no longer wanted for reproductive purposes (including the option of embryo research) may not be part of the stem cell research team.
>
> 5.9 To help ensure voluntariness and to minimize the risk that pregnant women will be pressured to terminate their pregnancy to provide fetal tissue for research purposes, the physician responsible for the therapeutic abortion may not be part of the stem cell research team.[74]

These two articles were collapsed into one in the *2002 Guidelines* as article 7.2.7 and in the *2005* and *2006 Guidelines* as article 8.3.7: "Physicians responsible for fertility treatment and physicians responsible for termination of pregnancy will not be part of a stem cell research team."[75] Significantly, persons "seeking consent to the disposition of embryos" were not listed among those excluded from membership on the hESC research team. If the persons "seeking consent to the disposition of embryos" are not also the "physicians responsible for fertility treatment", then the problem of conflict of interest arises. To explain, there are several legitimate options for the disposition of embryos no longer wanted for infertility treatment including destruction, donation to another couple, use for instructional purposes, and research use. If the persons seeking consent to the disposition of these embryos are members of an hESC research team, they have a particular interest in promoting the research option in preference to other options.

Equally problematic for the *2005 Guidelines*, but not the *2006 Guidelines*, is article 8.3.2. This article is identical to article 7.2.2 of the *2002 Guidelines* but for the addition of the following statement: "Members of the health team treating and/or counseling the client should not be the persons to obtain consent from the embryo provider at *the time of re-consent*."[76] A first problem with this article is the requirement for a re-consent when there is no longer a requirement for an initial consent in the *2005 Guidelines* (article 8.3.1 eliminated the requirement for decision-making and only required the disclosure of disposition options). A second problem with this article for the *2005 Guidelines* is that it potentially introduces ambiguity regarding who is responsible for any possible, but not required, "initial consent". With the original *Governing Council Report*[77] and the *2002 Guidelines*,[78] members of the fertility treating team were responsible for the initial consent to IVF, embryo freezing, and the future disposition of unwanted embryos, and if the woman chose to donate unwanted embryos to research, then, at the time of anticipated research use, members of the research team were responsible for the re-consent. The *Governing Council Report*[79] and the *2002 Guidelines*,[80] further stipulated that members of the treating team were precluded from being members of the research team. With the *2005 Guidelines*, there is an explicit statement to the effect that members of the treating team should not be involved in the re-consent, but it is not clear what role they do or do not have with any possible initial consent and whether this consent process does or does not include a general consent to research use, that is then to be followed up by others seeking a re-consent to specific research use. These problems are eliminated with the *2006 Guidelines* because the text for article 8.3.1 has reverted to the text in article 7.2.1 of the *2002 Guidelines*.

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73 *Supra* note 11 at App. iii.

74 *Supra* note 11 at arts. 5.5, 5.9.

75 *Supra* note 18 at art. 7.2.7; *supra* note 25 at art. 8.3.7.

76 *Supra* note 25 at art. 8.3.2. [emphasis added].

77 *Supra* note 11.

78 *Supra* note 18.

79 *Supra* note 11.

80 *Supra* note 18.

D. Fresh embryos for hESC research

In the *Governing Council Report* and the *2002 Guidelines*, it was understood that, for ethical reasons, embryos used for stem cell research usually would be frozen embryos. Generally, it is not in the medical or other-regarding interests of infertile women using assisted reproductive technologies to donate their fresh embryos for research when these could be frozen for later infertility treatment.[81] In a subsequent treatment cycle, frozen embryos not transferred in the initial treatment cycle may be thawed and transferred, thereby: (i) increasing the chance of pregnancy and childbearing; (ii) decreasing the number of risky or painful procedures; (iii) decreasing the psychological stress experienced as a result of IVF; (iv) decreasing the social disruption that IVF causes; and (v) decreasing the financial burden of infertility treatment. Indeed, studies have shown that there is an "emphatic benefit" associated with the use of frozen embryos in subsequent cycles, as such transfers are not only low risk, "avoid[ing] the hazards of oocyte retrieval and ovarian hyperstimulation syndrome",[82] but they are also highly cost-effective.[83] Neither infertility patients nor their physicians can know whether non-transferred embryos will be wanted for future reproductive use unless these embryos are being discarded for morphological, biological, or genetic reasons.[84] It follows that if embryos are truly being created for therapeutic purposes, as required by the *Governing Council Report*, the *2002*, *2005* and *2006 Guidelines*, and the *AHR Act*, then usually they would be frozen for such future use.[85]

The *Governing Council Report* and the *2002 Guidelines* were silent on the issue of frozen versus fresh embryos. In both of these documents, however, there was a clear requirement for a dual consent because of possible lengthy delays between the time at which the initial consent was given (prior to the creation of embryos) and the time at which the embryos might be used for research (when the consent was to be reiterated). This original consent requirement clearly presumed that frozen (not fresh) embryos were to be used for research, as with fresh embryos the maximum delay between the time of fertilization and the research use of these embryos to derive stem cells would only be three to five days—hardly a lengthy delay. On this point—as to when consent should be obtained—the Ethics Committee of the American Society for Reproductive Medicine holds that:

> Using only frozen embryos for research ensures that time passes between the creation of embryos for conception and their donation for research. Still, it is reasonable to expect questions eventually to arise about the donation of fresh but supernumerary embryos. Donation of fresh embryos raises the possibility that a physician might induce a patient to allow insemination of extra eggs so that they may be donated for research. Moreover, this increases the chance that decisions will be made quickly and later regretted by couples. Without evidence that fresh embryos are significantly preferable to frozen embryos for ES cell use, it is appropriate to use only spare embryos that have been frozen. The number of embryos created and frozen should be determined by the clinical needs of the infertile couple.[86]

The *2005 Guidelines* changed the presumption that non-transferred healthy embryos typically would be frozen for later therapeutic use and explicitly endorsed the research use of fresh embryos. Unfortunately this change remains in the *2006 Guidelines* despite the lack of evidence to support the claim that there is any scientific benefit to the research use of fresh versus frozen embryos, and the abundance of evidence showing that this is potentially harmful to women. Significantly, the little evidence that is available comparing the efficacy of fresh versus frozen embryos suggests that it is easier to derive human embryonic stem cells from frozen-thawed embryos than fresh embryos.[87] Further, the *2005* and *2006 Guidelines* do not limit the research use of fresh embryos to embryos that could not otherwise be frozen for future therapeutic use (e.g., embryos with a morphological, biological, or genetic disorder). This policy change potentially undermines the commitment to prohibit the purposeful creation of embryos for research use any time more embryos are created than are intended for transfer (usually between three and

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81 *Supra* note 55.

82 Ian S. Tummon, Mark A. Wentworth & Alan R. Thornhill, "Frozen-thawed embryo transfer and live birth: Long-term follow-up after one oocyte retrieval" (2006) 86:1 Fertility and Sterility 239.

83 Bradley J. Van Voorhis *et al.*, "The efficacy and cost effectiveness of embryo cryopreservation compared with other assisted reproductive techniques" (1995) 64:3 Fertility and Sterility 647.

84 Jeffrey Nisker & Angela White, "The CMA Code of Ethics and the Donation of Fresh Embryos from Stem Cell Research" (2005) 173:6 Canadian Medical Association Journal 621.

85 *Supra* note 11 at art. 4.1; *supra* note 18 at art. 7.1.1; *supra* note 25 at art. 8.1.1.

86 ASRMEC "Donating", *supra* note 9 at 959.

87 A. Sjogren *et al.*, 'Human blastocysts for the development of embryonic stem cells', online: (2004) 9:3 Reproductive Biomedecine Online 326 <http://www.rbmonline.com>.

five embryos, depending upon clinic practice). Article 8.1.1 identifies the types of research that conform to the *2005* and *2006 Guidelines*:

> 8.1.1 Research to derive and study human embryonic stem (ES) cell lines or other cell lines of a pluripotent nature from human embryos, provided that:
>
> 1. The embryos used, *whether fresh or frozen*, were originally created for reproductive purposes and are no longer required for such purposes....[88]

This amendment to explicitly authorize the research use of fresh embryos for hESC research (under review in the *2005 Guidelines* and fully endorsed in the *2006 Guidelines*) marks an important and troubling shift in CIHR stem cell research policy.

III
THREATS TO THE INTEGRITY OF THE CIHR POLICY-MAKING PROCESS

As explained in detail above, the *2002*, *2005* and *2006 Guidelines* substantially amended the *Governing Council Report* in relation to (i) several aspects of free and informed consent, (ii) the prohibition on consent to stem cell research as a condition of access to treatment, (iii) the prohibition on members of the health care team also being members of the stem cell research team, and (iv) the presumption that frozen (not fresh) embryos generally would be used for hESC research. And, while there is a public record of the changes made to the *2002 Guidelines* as well as the *2005 Guidelines*, there is no public accounting of the substantive changes made to the *Governing Council Report*. How did these changes occur? Who made them and on what authority?

Governing Council authorized very specific content for its stem cell research guidelines through its unanimous and verbatim adoption of the *ad hoc* Working Group final report, but this content is not completely and accurately reflected in the *2002 Guidelines*. Given (i) the explicit reference to the *Governing Council Report* in the release of the *2002 Guidelines*, (ii) the failure to publicly identify and explain any changes made to the *Governing Council Report*, (iii) the fact that Governing Council was unaware of any changes,[89] and (iv) the fact that such changes were made without the authority of Governing Council, this raises the uncomfortable possibility that those who drafted and/or released the *2002 Guidelines* did not wish the readers of the guidelines (including members of Governing Council) to realize that changes had been made—changes that removed certain constraints on stem cell research and in so doing introduced certain risks of harm to women. This possibility raises profound questions about CIHR's valuation of the public consultation process and the deliberations of the *ad hoc* Working Group. As well, it raises important questions regarding the perceptions within CIHR about the authority of the Governing Council. These questions, in turn, potentially undermine public trust and confidence in the integrity of CIHR's policy-making process.

With the *2005* and *2006 Guidelines*, unlike the *2002 Guidelines*, the public record indicates that some of these changes were proposed by the Governing Council while others were proposed by the Stem Cell Oversight Committee. All of the proposed changes were approved by the Governing Council. As such, there are no unanswered questions about who made what changes and on what authority. Questions remain, however, as regards why some of the changes, especially with the *2005 Guidelines*, were made. The official rationale for the *2005 Guidelines* is summarized in the Governing Council March 2005 minutes as follows:

- minor editorial changes for better clarity and interpretation;
- changes to clarify alignment with the Tri-Council Policy Statement;
- changes to inform researchers that stem cell research applications falling within the scope of the Guidelines must be reviewed by both a local Research ethics Board and SCOC; and ...
- deletion of a section which references a suggestion by the Ad Hoc Working Group on Stem Cell Research for a national research ethics board, which is not relevant to the current Guidelines;
- *changes to recognize that fresh embryos (and not just frozen embryos) and stem cells derived from embryos created by parthenogenesis are also being used for stem cell research* [;]

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88 *Supra* note 25 at art. 8.1.1 [emphasis added].

89 One of the authors (Françoise Baylis) was a member of Governing Council and can report that the Governing Council was never informed of the changes. Françoise Baylis first became aware of some of the changes to the *2002 Guidelines* on the eve of the press release, March 3, 2002. A few corrections were made at that time, reducing (but clearly not eliminating) the number of inconsistencies between the *Governing Council Report* and the *2002 Guidelines*.

- *to recognize that fresh embryos (and not just frozen embryos) are also being used for stem cell research; and …*
- updates to clarify how human stem cells that are created outside Canada will be evaluated for compliance with CIHR's guidelines.[90]

While this list raises many questions, the most important one concerns the Governing Council decision to amend the *2002 Guidelines* to explicitly allow the research use of fresh embryos in order to align the guidelines with current research practice (see text in emphasis). This change was recommended to the Governing Council by the Stem Cell Oversight Committee as recorded in the minutes of the January–February 2005 meeting—the same meeting at which the Committee approved Canada's first two hESC lines (CA1 and CA2), both of which were derived from fresh embryos. With surprising frankness the Stem Cell Oversight Committee recommended the change in policy "to recognize that stem cells derived from fresh embryos (and not just frozen embryos) are also being used for stem cell research".[91] The Governing Council accepted this recommendation at its March 2005 meeting and determined that changes were needed "to recognize that fresh embryos (and not just frozen embryos) are also being used for stem cell research".[92]

The stated rationale for the change is perplexing, to say the least. The fact that a specific research practice is potentially inconsistent with the *2002 Guidelines* hardly counts as an ethically sound or sufficient reason to amend the *2002 Guidelines*. Indeed, a more reasonable response would be to investigate any apparent inconsistency between the stem cell guidelines and current research practice in terms of possible non-compliance and to determine whether, (i) contrary to appearances, the practice is indeed consistent with the existing *Guidelines*, highlighting the need for "editorial changes for better clarity and interpretation"; (ii) the practice is inconsistent with the *Guidelines*, thus requiring sanctions as per the rules governing non-compliance; or (iii) the practice is inconsistent with the *Guidelines*, but that upon careful reflection the original *Guidelines* are ethically unsound and in need of revision, in which case a sound ethical reason could be articulated for proposed revisions to the *Guidelines*.

It is also troubling to note that the practice with which the Stem Cell Oversight Committee and the Governing Council sought to align the guidelines—namely the ongoing research use of fresh embryos to derive stem cells—was only publicized after the *2005 Guidelines* were released. To explain, the *2005 Guidelines* were approved by Governing Council in March of 2005. They then had to be reviewed and accepted by Natural Sciences and Research Council of Canada (NSERC) and the Social Sciences and Humanities Research Council of Canada (SSHRC) which delayed the public release of the *2005 Guidelines* until June 7, 2005. Two days later, on June 9, 2005, the successful derivation of Canada's first two hESC lines was announced and the research use of fresh embryos was disclosed.[93] As these hESC lines appear to have been approved by the Stem Cell Oversight Committee at its January–February 2005 meeting, questions arise about the delay in reporting this scientific accomplishment to the public. For example, could it be that the announcement of the successful derivation of these hESC lines—based on research involving the use of fresh embryos and dating back to 2003[94]—was delayed until the *2005 Guidelines* (explicitly allowing the research use of fresh embryos) were in the public domain? *Res ipsa loquitur*?

CONCLUSION

The federal government, the Canadian public, and the CIHR have each independently expressed explicit concern about the potential threats to the well-being of women with the rise of assisted human reproductive technologies and hESC research. For example, subsection (c) in the Principles section of Canada's *AHR Act* states that "while all persons are affected by these technologies, women more than men are directly and significantly affected by their application and the health and well-being of women must be protected in the application of these technologies."[95] Similarly, during the CIHR *ad hoc* Working Group's

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90 *Supra* note 23 [emphasis added].

91 Canadian Institutes of Health Research. 4th Meeting of the Stem Cell Oversight Committee, January 31–February 2, 2005, online: Canadian Institutes of Health Research <http://www.cihr-irsc.gc.ca/e/28853.html>.

92 *Supra* note 23.

93 Katie Rook, "Canadian Stem-Cell Research Wins Approval" *The Globe and Mail* (9 June 2005) A13.

94 Helen Branswell, "Toronto Institute Develops Canada's First Two Embryonic Stem Cell Lines" *Canadian Press* (8 June 2005).

95 *Supra* note 10 at s. 2(c).

consultation process, members of the public expressed concern for the well-being of women involved in stem cell research, collectively stating their worry that "an increasing demand for human embryos or fetal material could result in coercion of couples involved in fertility treatment or women considering therapeutic abortion."[96] Further, CIHR's *ad hoc* Working Group shared this concern and developed its recommendations with this concern as a principal guide. What is more, CIHR's Governing Council unanimously voted to adopt the recommendations set out by the *ad hoc* Working Group, with its focus on the protection of women from potential sources of coercion and exploitation in stem cell research at the forefront. It follows that the *Governing Council Report*, unlike the *2002*, *2005* and *2006 Guidelines*, sought to effectively insulate women from various potential sources of coercion and exploitation as actual or prospective participants in stem cell research.

It should be the grave worry of those concerned with the welfare of Canadian women, then, that articles directly related to the protection and promotion of women's interests, as outlined in the *Governing Council Report*, were not accurately reflected in the CIHR stem cell guidelines. This is a problem for both the women whose interests are not adequately protected and for the integrity of CIHR's policy-making process.

We hope this comparative analysis of the *Governing Council Report* and the *2002*, *2005* and *2006 Guidelines* will spur action on the part of CIHR Governing Council to direct the reinstatement of those articles in the *Governing Council Report* that were either omitted or significantly amended. Such a move would not only foster trust in the legitimacy and accountability of CIHR's policy-making process, but would also give women a fair chance of escaping the many potential sources of coercion and exploitation surrounding stem cell research involving the use of eggs, embryos, or fetal tissue. Properly revised stem cell research guidelines might also usefully inform future parliamentary deliberations on the regulations pursuant to the *AHR Act* as well as future possible revisions to the *Act*.

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96 *Supra* note 11 at App. iii [emphasis omitted].

DEFINING THE STANDARD OF PRENATAL CARE: AN ANALYSIS OF JUDICIAL AND LEGISLATIVE RESPONSES

Kristin Ali[*]

By revisiting the Supreme Court's reasoning in Dobson v. Dobson, *the author questions whether Alberta's* Maternal Tort Liability Act *(*MTLA*), enacted in 2005, is consonant with the Court's decision six years prior. The* MTLA *creates an exception to maternal tort immunity by imposing liability on insured pregnant women for the negligent use or operation of a motor vehicle. While the Court refused to create such an exception to maternal tort immunity in* Dobson v. Dobson, *it acknowledged that this question of social policy falls squarely within the purview of the legislature, and so Alberta respected the Court's ruling in enacting the* MTLA.

The author considers whether the MTLA *would pass constitutional muster if it were challenged as a violation of section 7 of the* Canadian Charter of Human Rights and Freedoms *(*Charter*). She concludes that it is sufficiently narrow and exceptional that it would likely not infringe the pregnant woman's right to "life, liberty and security of the person", nor would it constitute a violation of the principles of fundamental justice for being vague, overbroad, or arbitrary.*

Concerned that the MTLA *may be seen as a signal to further promote fetal rights, the author considers whether legislation that lifted maternal tort immunity altogether would be deemed unconstitutional under section 7. She concludes that the all-encompassing nature of a general standard of prenatal care could violate both a pregnant woman's personal autonomy, and the principle of fundamental justice that laws must not be vague. These violations may constitute a breach of section 7 incapable of being saved by section 1 of the* Charter, *since the legislation would have more negative consequences than benefits.*

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The author wishes to thank the anonymous reviewers for their helpful comments. She is also grateful to Professor Angela Campbell, Rachel St-John, and Alexander Wall for their insight on earlier drafts of this paper. Finally, she would like to thank the editors of the McGill Health Law Publication for their valuable editorial assistance.

INTRODUCTION

Brooklynn Hannah George Rewega was born with brain damage, blindness, and cerebral palsy, and suffers up to ten seizures a day.[1] These conditions are the result of injuries she sustained in a car accident when she was in her mother's womb. When her mother Lisa Rewega was driving to church on New Year's Eve of 2000, she lost control on the highway and was thrown through the windshield. Four months later, Brooklynn was born prematurely with severe health problems. Hoping their insurance company would pay for Brooklynn's special health care needs, Doug Rewega sued his wife for negligence, as well as the owners of the vehicle, George and Tina Rewega. Justice Moreau of the Alberta Court of Queen's Bench and Justice Ritter of the Alberta Court of Appeal, confirmed the Supreme Court's ruling in *Dobson (Litigation Guardian of) v. Dobson*,[2] holding that a child cannot sue his or her mother for prenatal injuries.[3] However, had Brooklynn's father been the one driving the car, Brooklynn would have been permitted to sue him since the *Dobson* decision draws a distinction between pregnant women and third parties.

Faced with the Rewega family's tragic circumstances, the Alberta legislature moved to collapse the distinction between mothers and third parties in the context of negligent driving. In the Spring of 2005, the Alberta legislature introduced Bill Pr. 4, a private bill explicitly allowing Brooklynn Rewega to commence an action against her mother for prenatal injuries sustained in the car accident.[4] The Standing Committee on Private Bills deferred consideration of Bill Pr. 4 until the fall to give the Alberta government the opportunity to consider whether it would introduce similar legislation. In the Fall Sitting, the government presented Bill 45, the *Maternal Tort Liability Act*,[5] which provides a strict exception to the common law by granting a civil right of action to a child who sustains prenatal injuries as a result of the negligent use or operation of a motor vehicle by the child's mother during her pregnancy. The bill protects mothers by prohibiting claims against them beyond the limits of their insurance policies. Because Bill 45 would not have a retroactive effect and could not help the Rewega family, the Committee recommended Bill Pr. 4 to proceed with amendments that reflected the restrictions in Bill 45. Both the *Rewega Right of Civil Action Act* and the *Maternal Tort Liability Act* were passed into law in December of 2005.[6]

This article will first consider whether Alberta's *Maternal Tort Liability Act* is consonant with the Supreme Court's ruling in *Dobson*, second, it will address the possibility of a *Charter* challenge under section 7, and third, it will examine whether an expanded form of the legislation that permits children to sue their mother for *any* kind of prenatal negligence would be constitutional under section 7.[7]

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[1] Katherine Harding, "Alberta bill would 'protect' fetuses hurt in crashes" *The Globe and Mail* (4 November 2005), online: The Globe and Mail <www.globeandmail.com>.

[2] [1999] 2 S.C.R. 753 [*Dobson*].

[3] *B.R. v. L.R.*, [2004] A.J. No. 259 (QL) at para. 2 [*B.R.*]; *Rewega (next friend of) v. Rewega*, [2005] A.J. No. 1443 (QL) at para. 10 [*Rewega*]. While the Court of Queen's Bench and the Court of Appeal agreed that the *Dobson* ruling prohibits a child from suing his or her mother for negligent driving causing him or her prenatal injuries, it does not address whether the owners of the vehicle could be vicariously liable for the acts of the driver, deemed to be their agent, when there is no cause of action against the driver. This question of vicarious liability was the focus of the *Rewega* litigation, not the question of exceptions to maternal tort immunity.

[4] Bill Pr. 4, *Brooklynn Hannah George Rewega Right of Civil Action Act*, 1st Sess., 26th Leg., Alberta, 2005.

[5] Bill 45, *Maternal Tort Liability Act*, 1st Sess., 26th Leg., Alberta, 2005.

[6] *Brooklynn Hannah George Rewega Right of Civil Action Act*, S.A. 2005, c. 51; *Maternal Tort Liability Act*, S.A. 2005, c. M-7.5 [*MTLA*].

[7] A discussion of whether the *MTLA* violates section 15 of the *Charter* is beyond the scope of this paper but it is an important legal question to consider in the overall assessment of the maternal-fetal conflict. Mr. Agnihotri raised this question when the *Act* was in Second Reading as Bill 45:

> It is logical to assume that this bill could easily be challenged under section 15, Equality Rights, of the Canadian Charter of Rights and Freedoms. Even with the specific exceptions to allow this type of duty of care to apply only to motor vehicle accidents, it is still subject to the provisions of the Charter, and the argument can then be made that placing this burden of care upon pregnant women that is not applied to women who are not pregnant or to men infringes upon the equality rights of women.

Legislative Assembly, *Alberta Hansard*, No. 47 (21 November 2005) at 1774 (Bharat Agnihotri).

I
CONTRADICTING *DOBSON*?

The *Maternal Tort Liability Act* (*MTLA*) imposes a legal duty upon a pregnant woman towards her fetus and subsequently-born child, a duty which the Supreme Court decided it would not impose upon pregnant women in *Dobson*. Thus, at first glance, the Alberta legislature appears to be contradicting the Court's ruling in *Dobson*.

The facts in *Dobson* are similar to the *Rewega* case. When Cynthia Dobson was twenty-seven weeks pregnant, she was involved in a serious car accident that caused prenatal injuries to her fetus. Ryan Dobson was born the next day with permanent mental and physical impairment. He brought an action for damages against his mother alleging that his prenatal injuries were caused by her negligent driving.

Justice Cory, speaking for the majority, held that the Supreme Court would not allow for this kind of tort recovery. Justice Cory arrived at this conclusion by analyzing the duty of care a pregnant woman may have to her fetus and subsequently-born child through the criteria articulated in *Kamloops*.[8] This decision requires a court to consider the legitimacy of a duty of care in light of the proximity between the two parties and policy considerations that may militate against the establishment of such a duty of care. Justice Cory found that the relationship between a mother and a fetus was sufficiently proximate to warrant a *prima facie* duty of care; however, he also found that judicially imposing such a duty would be an unjustifiable intrusion into the lives of pregnant women as individuals, and into their family lives overall.[9]

For these public policy reasons, the majority of the Supreme Court held that it should not impose a legal duty of care upon the pregnant woman. This ruling, however, did not bar the provincial legislatures from enacting legislation in this field, subject to certain limits.[10] The majority explained that:

> Although the law of torts has traditionally been the province of the courts, to impose tort liability on mothers for prenatal negligence would have consequences which are impossible for the courts to assess adequately. This development would involve extensive intrusions and frequently unpredictable effects on the rights of bodily integrity, privacy and autonomous decision-making of pregnant women. The resolution of such fundamental policy issues is a matter best left to the legislature.[11]

By way of example, the Court cited legislation from the United Kingdom that carves out an exception to maternal tort immunity in the motor vehicle context, subject to the limits of the mother's insurance policy.[12] Borrowing from this legislation, the Court went so far as to articulate what an appropriate legislative measure would involve in Canada:

> [A] rule based on a strictly defined motor vehicle exception to delineate the scope of maternal tort liability should not be created by the judiciary. To do so would be to sanction a legal solution based solely on access to insurance. If this approach were to be adopted, the provincial legislatures would be required to amend their legislative compensation regimes for motor vehicle accidents. Any such amendment might well be required to specify that it constituted an exception to the general rule of maternal tort immunity for prenatal negligence, and that the injured child could not recover damages above the limit established by the insurance scheme. A carefully tailored solution could benefit both the injured child and his or her family, without unduly restricting the privacy and autonomy rights of Canadian women.[13]

The Alberta legislature followed the Court's recommendations. Indeed, the *Dobson* decision was referred to and quoted from several times in the legislative debates surrounding Bill 45 to show how the bill satisfied the Court's requirements. Mr. Oberle, the member who introduced Bill 45, pointed out that "[t]he Supreme Court has invited, in fact encouraged the Legislatures to venture into this area provided that it's restricted to car accidents and to the level of the mother's insurance, and that's what this legislation does."[14] Thus, a close reading of *Dobson* reveals that the *MTLA* does not undermine the Court's decision in *Dobson* but rather affirms it insofar as the legislature, according to the Court, is the proper forum for deciding this question of social policy.

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8 *Kamloops (City of) v. Nielsen*, [1984] 2 S.C.R. 2.

9 *Dobson*, *supra* note 2 at para. 79.

10 *Ibid*. at para. 70.

11 *Ibid*. at para. 36.

12 *Congenital Disabilities (Civil Liability) Act 1976* (U.K.), s. 1(1), cited in *ibid*. at para. 35.

13 *Dobson*, *ibid*. at para. 81.

14 Legislative Assembly, *Alberta Hansard*, No. 44 (16 November 2005) at 1682 (Frank Oberle).

II
THE CONSTITUTIONALITY OF THE *MATERNAL TORT LIABILITY ACT*

As a matter of social policy, it is the legislature's prerogative to pass laws that affect the bodily integrity, privacy, and autonomous decision-making of pregnant women. However, legislation like the *MTLA* is subject to *Charter* scrutiny, and may be deemed invalid by the courts if it is found to be unconstitutional.[15] To determine whether this *Act* is consistent with the *Charter*, I will discuss whether it violates the liberty rights of the pregnant woman, which are guaranteed under section 7.

A. Life, Liberty and Security of the Person

Section 7 of the *Charter* provides that "everyone has the right to life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice."[16] The case that initially interpreted section 7, the *Motor Vehicle Reference*, held that a violation of section 7 could be either procedural or substantive.[17] In so doing, the decision left open the possibility of expanding the scope of section 7, but at the same time failed to offer a clear direction for its development. Since the *Motor Vehicle Reference*, the Court has commented more specifically on the content protected under section 7 by addressing the scope of "life, liberty and security of the person" on the one hand, and the meaning of fundamental justice on the other.

The Supreme Court of Canada first addressed the *Charter* rights of the pregnant woman in the *Morgentaler* decision, where the concurring judges in the majority offered different ways of interpreting "life, liberty and security of the person".[18] In this landmark case on abortion, the Court, by a majority of five to two, held that the restriction in the *Criminal Code* requiring abortions to be approved by a therapeutic abortion committee of an accredited hospital was unconstitutional. The five judges in the majority agreed that the legislation caused a health risk to pregnant women, depriving them of security of the person. They disagreed, however, on whether "life, liberty and security of the person" extends beyond health and safety. Chief Justice Dickson, writing for the majority, argued that state interference with bodily integrity and serious state-imposed psychological stress, at least in the criminal law context, constitutes a breach of security of the person.[19] Justice Wilson, in a concurring opinion, argued that section 7 encompasses more than physical and psychological security; the right to liberty contained in section 7 guarantees to every individual a degree of personal autonomy over important decisions intimately affecting their private lives.[20]

The latter, more generous interpretation of section 7 was followed in *Rodriguez*, a more recent Supreme Court decision.[21] In *Rodriguez*, a terminally ill plaintiff challenged the constitutionality of the *Criminal Code* prohibition on assisted suicide. While her claim was not successful, eight of the nine judges of the Court held that this prohibition, preventing the plaintiff from controlling her body, deprived her of security of the person insofar as it failed to respect her personal autonomy.[22]

Assuming therefore that Justice Wilson's wider view of "life, liberty and security of the person" reflects the Court's current approach to section 7, would such an interpretation support the constitutionality of the *MTLA*?

To answer this question, it is first necessary to determine whether the legislation as a matter of tort law is sufficient to trigger scrutiny under section 7 of the *Charter*. Both *Morgentaler* and *Rodriguez* address the constitutionality of criminal law matters, as does most section 7 jurisprudence.[23] However, section 7 should not be seen as a check upon the criminal law alone. While imprisonment—a consequence of breaching criminal legislation—is one way in which liberty and security of the person can be infringed,

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15 *RWDSU v. Dolphin Delivery Ltd.*, [1986] 2 SCR 573.

16 *Canadian Charter of Rights and Freedoms*, Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982 (U.K.)*, 1982, c. 11. s. 7.

17 *Reference re Motor Vehicle Act (British Columbia) s. 94(2)*, [1985] 2 S.C.R. 486 [*Motor Vehicle Reference*].

18 *R. v. Morgentaler*, [1988] 1 S.C.R. 30 [*Morgentaler*].

19 *Ibid.*, Dickson C.J. at 56.

20 *Ibid.*, Wilson J. at 171.

21 Wilson J.'s approach to section 7 in *Morgentaler* was also applied by the Supreme Court in *Godbout v. Longueil (City of)*, [1997] 3 S.C.R. 844 at para.65 [*Godbout*].

22 *Rodriguez v. British Columbia (Attorney General)*, [1993] 3 S.C.R. 519 at 588–89, 617–19, 630–31 [*Rodriguez*], Peter Hogg, *Constitutional Law of Canada* (Scarborough: Carswell, 2003) at 981 [Hogg].

23 Hogg, *ibid.* at 977–78.

it is not the only way; the Court in *Malmo-Levine* reaffirms that "[l]iberty accordingly means more than freedom from physical restraint."[24] This wider reading of section 7 is manifest in *Blencoe v. British Columbia*,[25] and *Chaoulli v. Quebec (Attorney General)*,[26] both of which are recent Supreme Court decisions analyzing section 7 outside of the criminal law context. Given this jurisprudential trend, the *MTLA* is not *prima facie* outside of the scope of section 7; the Court's willingness to invoke section 7 in civil matters suggests that the *Act*, as a matter of tort law, could trigger constitutional scrutiny under section 7.

Whether the legislation actually is constitutional under section 7 depends on a two-pronged analysis. Any legislation that is challenged under this provision must breach two conditions: first, the complainant must prove a violation of life, liberty and security of the person; and second, the complainant must prove a violation of fundamental justice. The first part of the analysis hinges upon whether holding a pregnant woman liable for negligent driving causing prenatal injuries to her subsequently-born child violates a pregnant woman's security of the person in any of three ways discussed by the Court in *Morgentaler*: (i) interfering with her bodily integrity, (ii) imposing state-induced psychological stress, or (iii) depriving her of personal autonomy.

The first two questions are not difficult to answer. First, this legislation does not interfere with the bodily integrity of a pregnant woman; it imposes neither imprisonment nor detainment.[27] Rather, the legislation requires her to compensate the child for the prenatal injuries she caused through negligent driving, limited to the amount of her insurance coverage. Second, the legislation would not cause the pregnant woman psychological stress, as she is already subject to a duty to drive carefully under ordinary negligence law; imposing a duty to act reasonably—the standard for assessing negligence—is not sufficiently restrictive to cause an individual serious psychological stress. Moreover, pregnant women need not fear financial burdens as a result of liability because the child's compensation cannot exceed the mother's insurance coverage. In response, an argument could be made that the *Act* does violate a pregnant woman's bodily integrity insofar as it effectively divides her body into what is her own and what is the child's. This account of violating bodily integrity is more conceptual or metaphysical than the physical standpoint from which the courts have assessed bodily and psychological intervention, and may thus be overly speculative for the purposes of adjudication.

The third question—whether it would violate her right to personal autonomy—is more difficult to answer. Section 7 of the *Charter* protects a sphere of personal autonomy wherein individuals may make inherently private choices free from state interference. This protected sphere does not, however, guarantee unbridled freedom;[28] rather, section 7 protects activities that are central to an individual's human dignity.[29]

In dissent in *Dobson*, Justice Major suggests that the freedom to drive negligently is not a fundamentally personal activity central to the autonomy of a woman. He argues that the pregnant woman's autonomy is not violated because

> [s]he was not legally free to operate a motor vehicle without due care. She did not have the freedom to drive carelessly. Therefore, it cannot be said that the imposition of a duty of care to her born alive child would restrict her freedom to drive.... [T]he values enshrined in the *Canadian Charter of Rights and Freedoms* do not grant pregnant women interests of any kind in negligent driving.[30]

Justice Major articulates this point forcefully and succinctly, but in so doing fails to address possible countervailing viewpoints. One objection to Justice Major's argument is the way in which he characterizes the right or interest at stake. Instead of construing the interest as a right to drive negligently, the right can be alternatively described as the right to choose when and where to drive. In many parts of Canada outside of large urban centres, driving is the only mode of transportation reasonably available. Purchasing groceries, getting to work, and going to the doctor are all necessary tasks requiring the use of an automobile. Characterizing the decision to drive in poor weather conditions, for example, as negligent, may thus restrict a pregnant woman from making "basic choices going to the core of what it means to

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24 *R. v. Malmo-Levine; R. v. Caine*, [2003] 3 S.C.R. 571 at para. 85.

25 [2000] 2 S.C.R. 307.

26 [2005] SCC 35.

27 See e.g. *Winnipeg Child and Family Services (Northwest Area) v. G.(D.F.)*, [1997] 3 S.C.R. 925.

28 See e.g. *Godbout, supra* note 21 at para. 66.

29 See *ibid*.

30 *Dobson*, *supra* note 2 at paras. 113–114.

enjoy individual dignity and independence."[31] Imposing a duty of care upon a pregnant woman towards her fetus and subsequently-born child might impose an unfair choice upon her: she may have to choose to stay at home or risk incurring liability for choosing to drive.[32]

That being said, the Alberta legislature has designed the liability provision of the *Act* to minimize hardship on women. Women who are deemed liable under this legislation for the negligence caused to their child in the womb are not expected to provide compensation out of pocket; rather, the legislation aligns with the *Dobson* ruling by restricting recovery to the mother's insurance coverage. This way, pregnant women need not fear additional financial burdens from this legislation and should not be deterred from driving or performing routine activities during their pregnancy. The effect of the legislation amounts to providing financial assistance to women who have children with special needs. Even if women of child-bearing age were faced with increased insurance premiums, this potential consequence of the legislation does not affect their dignity by limiting their basic choices.

Yet from a strictly legal standpoint, the legislation does impose an additional burden on pregnant women. While this burden is not a financial one—since the *Act* restricts the maximum damages to the amount of the mother's insurance coverage—the *Act* still creates the possibility of deeming a pregnant woman negligent for damages caused to herself as the carrier of the fetus and subsequently-born child. Because of this special biological relationship, only the pregnant woman could be considered legally negligent to herself and face this kind of liability. As Justice Cory states in *Dobson*, the "unique relationship between a pregnant woman and her fetus is so very different from the relationship with third parties. Everything the pregnant woman does or fails to do may have a potentially detrimental impact on her fetus."[33] Justice Cory cites the reasoning of the Supreme Court of Illinois to emphasize that the "relationship between a pregnant woman and her fetus is unlike the relationship between any other plaintiff and defendant".[34] Ultimately, Justice Major wants to treat the pregnant woman like everyone else by imposing the standard duty of care to drive carefully, but then treats her differently by imposing a duty that could not be imposed on anyone else.

In response to this objection, an argument could be made that this additional burden is justified because the pregnant woman has chosen to carry a fetus to term, and should therefore be responsible for performing this activity prudently and diligently. The fact that only women are the targets of this legislation may be more a question of moral luck or biological reality—only women can bear children—rather than a question of undue state intervention into a woman's sphere of personal autonomy. Moreover, the right to drive negligently or, alternatively, the right to choose when and where to drive, is not a right that is so fundamental to personal autonomy that it merits section 7 protection. While driving may be a necessity for most pregnant women, there is no reason why they need to do so negligently.

On the one hand, it seems that creating the possibility for children to sue their mothers for negligent driving threatens the personal autonomy of pregnant women because they are faced with the possibility of self-imposed liability; but on the other hand, this burden is mitigated by the fact that the legislation insulates pregnant women from financial responsibility by shifting the costs of recovery to the insurance company. Given that the legislature explicitly followed the recommendations set out by the majority in *Dobson* for creating a sufficiently narrow exception to maternal tort immunity that not only shields mothers from financial responsibility, but also assists them financially, it seems unlikely that the *Act* would be successfully challenged for violating the personal autonomy of pregnant women under section 7 of the *Charter*.

In the event that the courts did find that the *Act* interferes with the life, liberty and security of pregnant women, they would turn to the second step of section 7 to determine whether the *Act* violates the principles of fundamental justice.

B. The Principles of Fundamental Justice

The principles of fundamental justice are not exhaustive, and are simply defined in the *Motor Vehicles Reference* as being found in the "basic tenets of our legal system".[35] In any given case, it is

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31 *Godbout*, *supra* note 21 at para. 66.

32 Imposing unfair choices upon individuals in the context of liberty is discussed by the Supreme Court in *Godbout* (*ibid.* at para. 68).

33 *Dobson*, *supra* note 2 at para. 27.

34 *Stallman v. Youngquist*, 531 N.E.2d 355 (1988), cited in *Dobson*, *ibid*. at para. 37.

35 *Motor Vehicle Reference*, *supra* note 17 at 503.

important to clearly identify the relevant principles of fundamental justice because, otherwise, the court may dismiss the claim altogether.[36] Laws that satisfy these principles are 1) not vague, 2) not over-inclusive, and 3) not arbitrary.[37]

1. *Vagueness*

Chief Justice McLachlin, in *Canadian Foundation*, stated that a law is unconstitutionally vague if it "does not provide an adequate basis for legal debate" and "analysis"; "does not sufficiently delineate any area of risk"; or "is not intelligible".[38] The *MTLA* mirrors the Supreme Court's recommendation in *Dobson* in setting out specific conditions that make this right of civil action reasonably intelligible. The legislation, as a limited exception to maternal tort immunity, is clearly defined: "[a] mother may be liable to her child for injuries suffered by her child on or after birth that were caused by the mother's use or operation of an automobile during her pregnancy"[39] and such liability is limited to her automobile insurance coverage.

It could be argued, however, that the *MTLA* is vague in its description of the activity that is subject to liability—the "use or operation of an automobile". An automobile could be "used" for driving but it could also be "used" as a "hotbox" (an enclosed space in which to concentrate marijuana smoke). Both activities could result in prenatal injuries to the fetus, and potentially lead to a claim under this *Act*. But if we read the legislation as a whole, the section limiting liability to insurance coverage suggests that the legislature meant to restrict the "use and operation of an automobile" to those activities that are covered by insurance. This interpretation sufficiently informs the meaning of "use of an automobile" so that it is clear enough to avoid a challenge on the grounds of vagueness.

2. *Over-inclusiveness*

Yet even if the *Act* is clear, it might still be too broad. Legislation may be unconstitutional if it is over-inclusive or overbroad, meaning that it uses means that go beyond what is necessary to accomplish the law's objective.[40] From the legislative assembly's debates, the purpose of the *Act* is clear: to provide compensation to children who sustained prenatal injuries as a result of their mother's negligent driving while ensuring that no financial burden is placed on the mothers. The *Act* achieves this purpose by limiting the exception to maternal tort immunity to the negligent use or operation of an automobile by mothers who are insured under a contract of automobile insurance. By contrast, had the *MTLA* not specified that the exception is limited to the "use or operation of an automobile" but granted a general exception for "negligent activity occurring in motor vehicles", an applicant could claim under the *Act* for prenatal injuries caused by his or her mother's abuse of drugs in a motor vehicle, rather than only those caused by the mother's negligent driving, as the law intended. In this case, there would be no question of vagueness—a total exception for all activities in motor vehicles is clear—but such an exception includes far more activities than is necessary to achieve the law's purpose of providing compensation for prenatal injuries suffered as a result of their mother's negligent driving. Likewise, had the *Act* not specified that only mothers with automobile insurance are excluded from maternal tort immunity, both insured and uninsured mothers would be subject to liability, contrary to the intention of the *Act* to impose no financial burden on mothers. As written, however, the *Act* is narrowly defined: there is a clear connection between the purpose and the scope of the exception.

3. *Arbitrariness*

In dissent, Justice McLachlin (as she then was) explained in *Rodriguez* that, "[a] particular limit will be arbitrary if it bears no relation to, or is, inconsistent with the objective that lies behind the legislation."[41] The *Act* achieves the objective of compensating children who sustained prenatal injuries because of their mother's negligent use or operation of an automobile by creating an exception to

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36 *Auton (Guardian ad litem of) v. British Columbia (Attorney General)*, [2004] 3 S.C.R. 657 at para. 66.

37 For a discussion of arbitrariness, vagueness, and overbreadth as examples of principles of fundamental justice, see generally *Canadian Foundation for Children, Youth and the Law v. Canada (Attorney General)*, [2004] 1 S.C.R. 76 [*Canadian Foundation*]; *Morgentaler*, *supra* note 18; *Rodriguez*, *supra* note 22.

38 *Canadian Foundation*, *ibid*. at para. 15.

39 *MTLA*, *supra* note 6, s. 4.

40 Hogg, *supra* note 22 at 1016.

41 *Rodriguez*, *supra* note 22 at 619–20, McLachlin J. (as she then was), dissenting.

maternal tort immunity and by turning to automobile insurance to compensate these children. Yet the debates of the Alberta legislature reveal that several members were concerned about whether this solution properly advances the objective. By offloading the costs associated with compensating children who sustain chronic prenatal injuries to insurance companies, plaintiff compensation is restricted to the amount of the tortfeasor's insurance coverage, which differs from family to family. One member of the legislature pointed to the inherent unfairness of the *Act*: "Some people have only a $200,000 liability limit, and others have $2 million or more. Yet in the latter case a claim for 10 times more compensation could be made by a child who has suffered injuries that are similar to the child who can only make a claim up to $200,000."[42]

A solution that would actually advance the objective of providing compensation to families with children who have special needs would be the creation of a fund that would assist all families in this situation, and not just those who have automobile insurance whose children were injured from negligent driving. Such a measure was proposed by another member of the legislature who was concerned about the limited effect of this *Act* and reminded the Assembly that Justice Cory himself suggested the creation of a fund to cover prenatal injuries as one possible policy initiative a legislature might take.[43]

While these concerns are legitimate and pose serious challenges to the desirability of the *Act*'s insurance scheme, they may not be enough to deem the *Act* arbitrary. The *Act* may not provide the best solution to all families with children who sustain prenatal injuries, but it does allow some children to recover some compensation that would not otherwise be available because of the ruling in *Dobson*. To this extent the insurance scheme and the narrow exception to maternal tort immunity do advance the objective of compensation.

On the whole, given the careful design of the *Act*, *viz.* its explicit characterization as a limited exception to maternal tort immunity, its strict application to the motor vehicle context, and its restriction of liability to the mother's automobile insurance coverage, it is unlikely that the courts would find a violation of a pregnant woman's personal autonomy. Even in the event that an interference was found, the *Act* might not constitute a section 7 violation for it does not seem to violate principles of fundamental justice such as vagueness, overbreadth, or arbitrariness.

III
THE CONSTITUTIONALITY OF A GENERAL STANDARD OF PRENATAL CARE

When the Alberta legislature was debating Bill 45, there was concern that it may be expanded in the future. While the *MTLA* is designed as a narrow exception to maternal tort immunity, one member pointed out that it may not necessarily retain its current incarnation: it could be modified or amended by the legislature in the future to provide more robust measures for attaining its objective of compensating children for injuries sustained *in utero*.[44] The current rationale could invite litigation or legislation that might expand liability to all negligent acts of pregnant women, including acts not covered by insurance, such as drug and alcohol abuse, or refusal to undergo certain medical procedures (such as caesarean delivery or anti-retroviral therapies to reduce the risk of perinatal HIV transmission). In the interests of protecting the fetus, the legislature may decide to extend liability beyond the context of negligent driving to allow scrutiny of almost any act or omission of a pregnant woman. If this happened, the child would have a civil right of action to recover for negligence even in situations where there is no insurance to cover the damages award.[45]

A. Life, Liberty and Security of the Person

Legislation lifting the common law ban on claims against mothers for negligent prenatal care would, however, be subject to *Charter* analysis. Given the particularly intimate relationship between the mother and the fetus, all of the mother's actions could potentially harm the fetus, and thus all of her actions could be legally evaluated for their effects on the fetus. Justice McLachlin (as she then was) states in *Dobson*:

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42 Legislative Assembly, *Alberta Hansard*, No. 52 (30 November 2005) at 2023 (Raj Pannu).

43 *Ibid.* (Bruce Miller), citing *Dobson*, *supra* note 2 at para. 48.

44 Legislative Assembly, *Alberta Hansard*, No. 44 (16 November 2005) at 1685–86 (Bill Bonko).

45 Diana Ginn, "A Balancing that is Beyond the Scope of the Common Law: A Discussion of the Issues Raised by *Dobson (Litigation Guardian of)* v. *Dobson*" (2001) 27 Queen's L.J. 51 at 88 [Ginn].

> Virtually every action of a pregnant woman—down to how much sleep she gets, what she eats and drinks, how much she works and where she works—is capable of affecting the health and well-being of her unborn child, and hence carries the potential for legal action against the pregnant woman. Such legal action in turn carries the potential to bring the whole of the pregnant woman's conduct under the scrutiny of the law. This in turn has the potential to jeopardize the pregnant woman's fundamental right to control her body and make decisions in her own interest.[46]

In this passage, Justice McLachlin (as she then was) refers to Justice Wilson's remarks in *Morgentaler* to remind the Court that section 7 of the *Charter* prevents the law from interfering with a pregnant woman's right to control her body.[47]

An expanded form of the *MTLA* could therefore be seen as a breach of "life, liberty and security of the person". But this is not enough to be a violation of the section as a whole. The impugned legislation must also violate the second part of section 7 which requires legislation to be in accordance with the principles of fundamental justice.

B. The Principles of Fundamental Justice

Expanding the legislation does not seem to have an effect on the level of over-inclusiveness or arbitrariness, but it may introduce too much vagueness.

1. *Over-inclusiveness*

Removing the tortious immunity of pregnant women in the context of prenatal care may not be too broad a measure. Since the objective of the expanded legislation would be to provide compensation to all children injured *in utero* through another's negligence, the legislation necessarily requires that all negligent individuals—including pregnant women—be held liable for the injuries they cause. There seems to be no "halfway measure" that could be relied upon to fully achieve the legislation's purpose.[48]

2. *Arbitrariness*

But while removing maternal tort immunity does not seem to be over-inclusive, there is some question as to whether it is arbitrary. One could argue that the legislation is arbitrary because in most cases allowing children to recover for their prenatal injuries by suing their mothers just as they would any other third party would result in merely shuffling money back and forth, taking it away from the mother as tortfeasor only to give it back to her as the child's caregiver. In these cases, it could be argued, the means used by the legislation is not connected to its goal of providing compensation to injured children. But where the mother and child are estranged, this measure need not be arbitrary. For example, in situations of adoption there could be a real difference in financial support for the child; after adoption the biological mother has no more obligation to the child than the general duty of care that all persons have towards one another, so allowing the child's adopted parents to sue on his or her behalf could provide them with additional money for the child's care. Therefore, while such legislation might not be an ideal means of compensation for prenatal injuries, it is not arbitrary since in some cases it could provide children with financial support that they would not otherwise have.

3. *Vagueness*

An expanded form of the Alberta legislation may be found to be vague by the courts because it would be difficult to determine what conduct would count as negligent. Consider the following situations in which a pregnant woman may easily find herself:

> Is she to be liable in tort for failing to regulate her diet to provide the best nutrients for the foetus? Is she to be required to abstain from smoking and all alcoholic beverages? Should she be found liable for failing to abstain from strenuous exercise or unprotected sexual activity to protect her foetus? Must she undertake frequent safety checks of her premises in order to avoid falling and causing injury to the foetus?[49]

By raising these questions in *Dobson*, Justice McLachlin (as she then was) argues that there is no rational limit to the types of claims that may be brought if such a tortious duty of care were imposed upon

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46 *Dobson*, *supra* note 2 at para. 85.

47 *Ibid*.

48 For an analysis of over-inclusive legislation, see *Rodriguez*, *supra* note 22 at 614.

49 *Dobson*, *supra* note 2 at para. 28.

pregnant women. It would be unclear what activities would count under this duty, which indicates it is overly vague. Because the legislation is so vague, Teresa Foley has expressed concern that a judge would have an inappropriate amount of discretion to apply his or her own views of proper maternal behaviour, and may fail to consider the

> great disparities in the financial situations, education, access to health services, and ethnic backgrounds of each pregnant mother.... Maternal prenatal civil liability might have the effect of defining women solely by their reproductive capacities, reducing women to 'baby machines' whose sole purpose is to produce the perfect child.[50]

Like the Chief Justice, Foley is concerned that the vagueness of the standard of prenatal care will lead to an undue restriction on the personal autonomy of pregnant women protected by section 7 of the *Charter*.

Yet these critics might be underestimating the interpretive nature of adjudication. Courts are well equipped to decide what constitutes negligent behaviour, because the duty of care is a principled way of approaching negligence by invoking the reasonable person as the standard for judging negligent conduct. As the Chief Justice states in *Canadian Foundation*,

> the law has long used reasonableness to delineate areas of risk, without incurring the dangers of vagueness. The law of negligence, which has blossomed in recent decades to govern private actions in nearly all spheres of human activity, is founded upon the presumption that individuals are capable of governing their conduct in accordance with the standard of what is "reasonable." ... The reality is that the term "reasonable" gives varying degrees of guidance, depending upon the statutory and factual context. ... In each case, the question is whether the term, considered in light of principles of statutory interpretation and decided cases, delineates an area of risk....[51]

Just because the standard may be subjective—what is reasonable to the private citizen may not be reasonable to a judge—does not necessarily mean it is vague. The common law method allows the court to flesh out the standard through the adjudication of particular cases, and in this way the standard becomes clearer and more defined.

Foley addresses this notion by arguing that even if the court established criteria for circumscribing the duty of care, with a gross negligence standard or an illegal behaviour test, for instance, the duty would remain overly vague. Under a gross negligence standard, where the mother must know or ought to know that her action posed a serious threat to the life or health of the fetus, the court would still have difficulty assessing her conduct because what constitutes a serious threat is unclear; some people may argue that smoking during pregnancy counts as a serious harm to the fetus, while others would regard it as a risk, but not a serious one. She also objects to the illegal behaviour standard that would impose negligence upon a pregnant woman for engaging in illegal activities that cause prenatal harm to her subsequently-born child. While this standard may solve the problem of vagueness, it triggers the problem of arbitrariness because it would regard a woman as negligent for smoking marijuana during her pregnancy, but not for excessive drinking and causing fetal alcohol syndrome in her baby.[52]

Once again, Foley's difficulty with the reasonable person and gross negligence standards is actually a criticism of adjudication. Foley is concerned that judges will invoke their own private standard of morality instead of applying the law. This concern about activist judges pertains to all areas of adjudication, and can be addressed by emphasizing the authority of the common law over personal standards of morality, and asserting the role of the court as an interpreter of the law rather than the creator of social policy.

Similarly, Foley's concern about arbitrary categories—imposing liability for marijuana usage but not drinking alcohol—is also a general critique of the law, but here it is a critique of the criminal law's prohibition of marijuana and not alcohol. Critiquing the arbitrariness of the criminal law does not provide grounds for discrediting a standard of prenatal care; if the law were changed so that both excessive drinking and marijuana usage were criminal offences, Foley would have no basis for impugning the standard for arbitrariness, and it would offer a bright line against which the courts court determine the appropriate standard of prenatal care.

Despite these problems, vagueness offers the strongest critique of a standard of prenatal care out of the three principles of fundamental justice discussed above. While the Supreme Court's expertise in the law of negligence suggests an ability to establish a reasonable standard of prenatal care, the current make-up of the bench and the Chief Justice's objections to the feasibility of a prenatal standard of care make it likely that the Court would strike down a legislatively-imposed standard of prenatal care for violating the two aspects of section 7, on grounds of personal autonomy and vagueness.

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50 Teresa Foley, "*Dobson v. Dobson*: Tort Liability for Expectant Mothers?" (1998) 61 Sask. L. Rev. 177 at 190 [Foley].

51 *Canadian Foundation*, *supra* note 37 at paras. 27–8.

52 Foley, *supra* note 50 at 191–92.

C. The *Oakes* Test

If a court found that an expanded form of the *MTLA* violated section 7, it would then have to examine the legislation under section 1 of the *Charter* in accordance with the two-step test established in *R. v. Oakes*.[53] First, I will consider the validity of the legislative objective, and second, I will determine whether a reasonable balance has been struck between the legislative objective and the means chosen to achieve that objective.

As discussed above, an expanded form of the legislation would aim at providing compensation to children injured in the womb because of their mother's negligence. Underlying this purpose is the general premise of tort law: individuals should be compensated for injuries sustained as a result of another's negligence. Ultimately, the legislation seeks to protect the fetus and subsequently-born child as a vulnerable member of society, which is a pressing and substantial legislative objective.

The second branch of the *Oakes* test considers whether the impugned legislation is rationally connected to the objective, whether it minimally impairs the right in question, and whether the violation of the right is proportional to the importance of the objective sought to be achieved.

1. *Rational Connection*

If an expanded form of the legislation included all kinds of prenatal negligence beyond motor vehicle accidents, it may not be rationally connected to the objective of protecting the fetus and injured child. Insurance companies may have an obligation to compensate their premium holders for injuries sustained in car accidents, but they do not have an obligation to compensate individuals outside of this context. So if a woman were held liable to her subsequently-born child for smoking or drinking during her pregnancy, the woman would have to pay the damages herself. This requirement might not help the family unit as a whole because the compensation to the child would come from the negligent actor who may also be his or her primary caregiver.

Alternatively, it could be argued that holding a pregnant woman liable for prenatal negligence would be in line with the objective of protecting the fetus and subsequently-born child because the spectre of liability may deter her from engaging in negligent behaviour. Holding these women liable for failing to care for the fetus they have chosen to carry to term could promote the health and safety of the fetus. This argument is discredited by Kary Moss in the context of drug addiction:

> [I]t is not true that the majority of these women are insensitive to their children's needs and simply need reminders of the dangers of drug use. Real resource constraints often prevent these women from securing treatment or proper care during their pregnancies. Even when women can secure treatment, they still may be constrained by the nature of the addiction process itself. Addiction typically involves loss of control over use of the drug and continued involvement with the drug *even when* there are serious consequences. Thus, to treat pregnant addicts as indifferent and deliberate participants is to misunderstand the addiction process.[54]

Even in a situation where the mother is negligent for behaviour unrelated to drug abuse, imposing liability may not protect the fetus because the woman may choose to terminate her pregnancy for fear of liability when she would otherwise have carried the fetus to term. Liability may also discourage pregnant women from seeking medical care when they have acted negligently out of fear that their physician or health care provider will discover their wrongful behaviour.[55] The failure to deter negligence, the potential of increasing unwanted abortions, and the possibility of discouraging prenatal care suggest that imposing liability is not in the child's interests, and so may not be rationally connected to protecting or supporting the child.

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[53] [1986] 1 S.C.R. 103. The purpose of the section 1 analysis is to determine whether the infringement of the *Charter* right in question is justifiable in a free democratic society. Theoretically, it is difficult to conceive of how legislation that violates a principle of fundamental justice under section 7 could be justified as a reasonable limit in a free and democratic society under section 1. The section 1 analysis seems redundant when section 7 already considers arbitrariness, overbreadth, and vagueness, which are effectively the same as rational connection, minimal impairment, and proportionality in section 1. McLachlin C.J. recently confirmed the difficulty with using section 1 to justify violations of section 7 rights in *Charkaoui v. Canada (Citizenship and Immigration)*, 2007 SCC 9 [*Charkaoui*]. Quoting Lamer J. (as he then was) in the *Motor Vehicle Reference*, she emphasized that courts may resort to section 1 to justify violations of section 7 "but only in cases arising out of exceptional conditions, such as natural disasters, the outbreak of war, epidemics, and the like" (*Motor Vehicle Reference*, *supra* note 17 at 518, quoted in *Charkaoui*, at para. 66).

[54] Kary Moss, "Substance Abuse During Pregnancy" (1990) 13 Harv. Women's L.J. 278 at 287 [emphasis in original, footnotes omitted].

[55] Alexandre-Philippe Avard & Bartha Maria Knoppers, "L'Immunité légale de la femme enceinte et l'affaire *Dobson*" (2000) 45 McGill L.J. 315 at 330 [Avard].

2. *Minimal Impairment*

Courts tend not to strike down legislation on the rational connection test,[56] so it is important to consider whether lifting the prohibition on suing pregnant women for negligence would minimally impair the pregnant woman's personal autonomy guaranteed under section 7. Increasing state funding for social support services would contribute much more to the well-being of those with special needs than a legislatively-imposed standard of prenatal care would, and the pregnant woman's personal autonomy would not be violated.[57] Awareness campaigns publicizing the risks of smoking or drinking during pregnancy, for instance, are another way of protecting the fetus without infringing the pregnant woman's personal autonomy.[58] Faced with these alternatives, courts may claim that it is not their role to second-guess the wisdom of the policy choices made by the legislature, and that while these options may not infringe the liberty interests of the pregnant woman, they may not be clearly or well designed to protect the fetus and facilitate compensation of children who sustain prenatal injuries because of maternal negligence.

3. *Balancing the Salutary and Deleterious Effects*

Out of the three considerations under the second branch of the *Oakes* test, an expanded form of the legislation would most likely fail at the third step, where it must be determined whether the infringement of the right is sufficiently proportional to the importance of the objective that is sought to be achieved. While imposing liability on pregnant women for prenatal negligence may deter some women from this conduct and provide some compensation to the injured child, there are a number of negative consequences attached to such a legislative intervention.

For example, insurers might raise insurance premiums for women of child-bearing age to offset potential compensation costs, or, if faced with a discrimination complaint, raise insurance premiums for everyone. While increased insurance premiums are a problem, this legislation would create the larger problem of shifting what ought to be state responsibility to the insurance industry, thus undermining the principle of social responsibility for those with special needs.[59]

This legislation also forces families to turn to adversarial litigation rather than the state for support. In so doing, the possibility of tort recovery for prenatal negligence creates a tension in the family unit by setting the mother up against the child, thus subverting the social conception of the mother-fetus relationship.[60] Even though the interests of the mother and child were aligned in both the *Dobson* and *Rewega* cases, this may not necessarily be true for all families. The Dobsons and the Rewegas wanted the courts to find the mother negligent because they wanted compensation from their insurance companies. However, if a mother is found negligent for actions that are not covered by her insurance company, the mother and fetus have a conflict of interest. As Avard and Knoppers note:

> Des tensions inévitables risquent de surgir au sein de la cellule familiale et maritale lors de la grossesse. Obligée par la loi d'adopter un mode de vie irréprochable du point de vue de la santé de l'enfant à naître, la femme enceinte risque d'être constamment sous la surveillance étroite de son conjoint et, plus généralement, de l'ensemble de sa famille.[61]

Such scrutiny of a pregnant woman's behaviour may open the door to other kinds of legislation. Given that the abortion debate is resurfacing in the United States, and that there are problems with accessing therapeutic abortions in Canada,[62] this legislation may be seen as prioritizing the security of the fetus over the personal autonomy of the pregnant woman. Allowing children to recover for their mother's prenatal negligence may be seen by the courts as an indication of a change in political attitudes towards the maternal-fetal conflict. The legislatures and the courts may be more inclined to (i) allow actions on behalf of a fetus, not just a born-alive child; (ii) assess the fiduciary duty between the pregnant woman and the

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56 Hogg, *supra* note 22 at 807.

57 Ginn, *supra* note 45 at 91–92.

58 Avard, *supra* note 55 at 333.

59 For a thorough discussion of policy considerations that militate against lifting maternal tort immunity, see Ginn, *supra* note 45 at 89–91.

60 Avard & Knoppers, *supra* note 55 at 332–33.

61 *Ibid.* at 332.

62 Sanda Rodgers "The Legal Regulation of Women's Reproductive Capacity in Canada" in Jocelyn Downie, Timothy Caulfield & Colleen Flood, eds., *Canadian Health Law and Policy*, 2d ed. (Markham, Ont: Butterworths, 2002) 331 at 342.

fetus; (iii) authorize non-consensual treatment to be imposed on a pregnant woman; and, (iv) reconsider the legality of abortion.

On the whole, allowing a child to recover for prenatal injuries caused by his or her mother's negligent actions may unfairly burden the insurance industry, shield the state from social responsibility, divide families in adversarial litigation, and intrude on the autonomy of pregnant women by subjecting all of their actions to legal scrutiny. These concerns outweigh the benefits of compensation that such tort recovery would provide to injured children. A legislatively-imposed standard of prenatal care would thus be likely to fail at this stage in the section 1 analysis, and render the legislation unconstitutional.

CONCLUSION

By revisiting the Supreme Court's reasoning in *Dobson*, it becomes clear that the decision to allow children to recover for prenatal injuries caused by their mothers' negligence should be made by the legislatures and not the courts. This is not to say that the issue is not justiciable; if a legislature chooses to enact such a duty of care, this legislation would be subject to *Charter* review by the courts. Alberta's *MTLA* is sufficiently narrow and exceptional that it would likely not constitute a violation of section 7 under the *Charter*: it would not infringe the pregnant woman's right to "life, liberty and security of the person" nor would it constitute a violation of the principles of fundamental justice for being vague, overbroad, or arbitrary.

However, such legislation may be seen as a signal to further promote fetal rights, and may encourage litigation beyond the context of motor vehicle accidents and perhaps even outside the application of insurance coverage. Moreover, if the legislature were to propose an expanded version of the *MTLA*—one that eroded maternal tort immunity—such legislation would likely infringe the pregnant woman's liberty interests protected under section 7. A legislatively-imposed standard of prenatal care could subject all of a pregnant woman's actions to legal scrutiny, restricting her freedom in ways in which the freedom of others is not restricted. The all-encompassing nature of a general standard of prenatal care could violate a pregnant woman's personal autonomy and could also violate the principle of fundamental justice that laws must not be vague. These violations may constitute a breach of section 7, on the whole, and would not be saved by section 1 of the *Charter* because the legislation has more negative consequences than benefits. A legislatively-imposed standard of prenatal care would, thus, likely be deemed unconstitutional by the courts. Ultimately, the implicit dialogue between the Supreme Court and the Alberta legislature in the *Dobson* decision and the *Maternal Tort Liability Act* indicates their willingness to work together and protect different stakeholders in regulating this particular incarnation of the maternal-fetal conflict.

LEGAL ASPECTS OF ANIMAL-HUMAN COMBINATIONS IN CANADA

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This article examines the current legal regime applicable to animal-human combinations under the Assisted Human Reproduction Act *(Canada). The* Act *prohibits as criminal offences the use of non-human reproductive material in humans, the use in humans of human reproductive material previously transplanted into a non-human life form, the creation of chimeras made from human embryos, and the creation for reproductive purposes of human/non-human hybrids. Additional animal-human combinations, such as transgenic life forms, may be regulated pursuant to section 11 of the* Act *in the future.*

The underlying concerns of the Act *in establishing this regime appear to be the protection of human health and safety, human dignity and individuality, and the human genome. The* Act *seems calibrated to prohibit the creation of animal-human combinations that are currently unsafe and scientifically and ethically problematic, while leaving open the possibility of regulating other such combinations with more immediate scientific potential, although these also raise ethical questions.*

Currently, certain differences subsist in Canada between what is permissible for researchers and institutions funded by federal agencies and those in privately funded research. The development of the regulatory framework under the Act *will reveal how freedom of research will be balanced against the need for scientifically valid and ethically justifiable research, and whether these differences will continue to apply.*

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INTRODUCTION

Recent press coverage underlines the fact that we are moving towards a world that was science fiction not so long ago: mice and chimpanzees with partly human brains now inhabit our laboratories;[1] pigs with human lymphocytes are being designed as possible sources of organs for transplantation into humans;[2] and rabbit oocytes have been fused with human cells to make hybrid embryos.[3] These developments have raised ethical and legal questions, and have led to calls for regulation, although the question of what constitutes appropriate regulation is not easily resolved. Recently, the British Human Embryology and Fertilisation Authority made news when it decided to postpone a decision to license experiments involving nuclear transfer of a human somatic cell into animal eggs until a public consultation process is completed.[4]

As noted by Henry Greely, there are many possible types of interspecies mixtures.[5] Providing examples of both naturally occurring and artificial combinations, he proposed a taxonomy of these based on several criteria—the type of biological material combined, the relevant species included in the combination, and the developmental stage at which the combination is performed, for example. The mule is an example of a naturally occurring interspecies mixture known to man for millennia.[6] In contrast, the transplantation of animal organs into human beings, such as a baboon heart in a human child, is a recent development that has not been entirely successful.[7]

In 2004, Canada passed the *Assisted Human Reproduction Act* (*AHRA* or the *Act*), which also addresses some types of animal-human combinations at the genetic, cellular, and tissue levels.[8] This paper will briefly review the current legislative framework dealing with animal-human combinations in this statute and consider the ethical themes underpinning it. After some background information concerning the passage and structure of the *Act*, the regulatory scheme it proposes concerning animal-human combinations will be described, as will some of the differences between the legislative scheme contained in the *AHRA* and the currently applicable federal guidelines for research funding. A brief overview of the relevant ethical considerations explicitly referred to in the *Act* will then be undertaken, with reference to some international instruments.

Although man is "*un animal doué de raison*",[9] the reader should be aware that for simplicity the term "animal" is used throughout this paper as meaning "non-human animal".

I
HISTORICAL BACKGROUND AND STRUCTURE OF THE *AHRA*

The process of adopting legislation concerning assisted human reproduction was long and protracted in Canada, and is discussed here with an emphasis on animal-human combinations. A Royal Commission on New Reproductive Technologies was appointed in 1989 and produced its final report in 1993. This final

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1 Irving Weissman at Stanford University is working on mice with brains that contain human neurons; reported in, among others, Sharon Begley, "Science Journal: Chimeras exist, and what if some turn out to be too human?" *The Wall Street Journal* (6 May 2005), online: The Pittsburgh Post-Gazette <http://www.post-gazette.com/pg/05126/500265.stm>. Experiments with African green monkeys receiving human neurons are taking place at the St. Kitts Biomedical Research Foundation: see Tim Bearden, "Chimeras: Animal-Human Hybrids" *Online News Hour PBS* (16 August 2005), online: Public Broadcasting Service Online News Hour <http://www.pbs.org/newshour/bb/science/july-dec05/chimera_8-16.html>.

2 At the Mayo Clinic in Rochester, Minnesota, Christopher McGregor is working on designing such pigs. See Mayo Clinic, News Release, "Mayo Investigator Awarded $4.5 Million from NIH for Transplant Research" (11 July 2005), online: Mayo Clinic <http://www.mayoclinic.org/news2005-rst/2930.html>.

3 See, among others, Maryann Mott, "Animal-Human Hybrids Spark Controversy" *National Geographic News* (25 January 2005), online: National Geographic <http://news.nationalgeographic.com/news/2005/01/0125_050125_chimeras.html>.

4 Human Fertilisation and Embryology Authority, News Release, "Press Statement Regarding Human-Animal Hybrid Research" (11 January 2007), online: Human Fertilisation and Embryology Authority <http://www.hfea.gov.uk/cps/rde/xchg/SID-3F57D79B-C3CE7A8F/hfea/hs.xsl/1478.html> [HFEA Press Statement].

5 Henry T. Greely, "Defining Chimeras... and Chimeric Concerns" (2003) 3:3 American Journal of Bioethics 17.

6 Mules, generically, are the result of a cross between a female horse and a male donkey.

7 Lawrence K. Altman, "Baboon's heart implanted in infant on coast" *The New York Times* (28 October 1984), online: The New York Times <http://query.nytimes.com/gst/fullpage.html?sec=health&res=9C01E1DD1239F93BA15753C1A962948260>.

8 S.C. 2004, c. 2 [*AHRA*].

9 Robert Merle, *Un animal doué de raison* (Paris: Gallimard, 1967).

report recommended that the creation of animal-human hybrids be criminally prohibited.[10] In July of 1995, the federal government called a voluntary moratorium on nine reproductive technologies, including the creation of animal-human hybrids.

In 1996, Bill C-47[11] was tabled; its goal was the criminal prohibition of certain practices, including the fertilization of human ova by animal sperm (or the converse manipulation) for the purpose of producing a zygote capable of differentiation; the fusion of human and animal zygotes or embryos; and the implantation of a human embryo in an animal, or of an animal embryo in a woman. At the same time, a document entitled *New Reproductive Technologies: Setting Boundaries, Enhancing Health*[12] was tabled to propose a framework for the regulation of those reproductive technologies that were not prohibited, and thus achieve an integrated approach to reproductive technologies. The proposed framework did not deal with animal-human combinations specifically.

Bill C-47 was never passed, and in 2001 Health Canada issued the *Proposals for Legislation Governing Assisted Human Reproduction*[13] for review by the House of Commons Standing Committee on Health. The *Proposals* would have prohibited the transplantation of animal reproductive material into a human and the use of human reproductive material previously transplanted into an animal. The creation of both chimeras and transgenic animals was to be regulated under a licensing system.

The Standing Committee on Health's response emphasized the necessity of forbidding the creation and use of all animal-human hybrids for the purpose of reproduction, in addition to the proposed prohibitions.[14] No recommendation was made with respect to the animal-human combinations subject to a licensing regime.

Bill C-56, which reflected the recommendations of the Standing Committee, was tabled in May of 2002;[15] it was not passed during this session and was resubmitted twice, first as Bill C-13[16] in October of 2002 and then as Bill C-6[17] in January of 2004. Finally, more than a decade after the publication of the Royal Commission's final report, the *AHRA* received royal assent on March 29, 2004.[18]

A. Purpose and Overview of the AHRA; Declaration

The purpose of the *AHRA* is to regulate assisted human reproductive technologies and related research, and to secure their benefits for individuals, families, and society.[19] Certain types of animal-human combinations can be created by using reproductive materials and techniques, which explains why they are dealt with in this statute.

The *Act* prohibits certain activities (such as reproductive or research cloning or the knowing creation of transmissible mutations in a person's genome)[20] and regulates others through a licensing scheme (such as the use of human reproductive material to create an embryo).[21] An agency with licensing and enforcement powers, the Assisted Human Reproduction Agency of Canada (the Agency), is created to administer the *Act*.[22] A special regime of privacy and access to personal information collected pursuant to

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10 Canada, *Proceed with Care—Final Report of the Royal Commission on New Reproductive Technologies*, vol. 1 (Ottawa: Canada Communications Group, 1993) at 636–637 [Commission Report].

11 *An Act respecting human reproductive technologies and commercial transactions relating to human reproduction*, 2nd Sess., 35th Parl., 1996.

12 Canada, Health Canada, *New Reproductive and Genetic Technologies: Setting Boundaries, Enhancing Health* (Ottawa: Minister of Supplies and Services, 1996).

13 Health Canada, *Proposals for Legislation Governing Assisted Human Reproduction*, (Draft 2001), online: Health Canada <http://www.hc-sc.gc.ca/ahc-asc/alt_formats/cmcd-dcmc/pdf/media/releases-communiques/2001/legislation.pdf > [*Proposals*].

14 House of Commons, Standing Committee on Health, *Assisted Human Reproduction: Building Families*, December 2001, online: Standing Committee on Health <http://cmte.parl.gc.ca/cmte/CommitteePublication.aspx?COM=218&Lang=1&SourceId=37082>, recommendation 8 [Standing Committee Report].

15 Bill C-56, *An Act respecting human reproduction*, 1st Sess., 37th Parl., 2002.

16 Bill C-13, *An Act respecting human reproduction*, 2nd Sess., 37th Parl., 2002.

17 Bill C-6, *An Act respecting human reproduction*, 3rd Sess., 37th Parl., 2004.

18 The *AHRA* was proclaimed into force on April 22, 2004 except for ss. 8, 12, 14 to 19, 21 to 59, 72 and 74 to 77, S.I./2004-49, C. Gaz. 2004.II.478. Sections 21 to 39, 72, 74, 75 and 77 of the *AHRA* came into force January 12, 2006, except for paragraphs 24(1)(a), (e) and (g), SI/2005-42, C.Gaz. 2005.II.1033.

19 *AHRA*, *supra* note 8, s. 2(b).

20 *Ibid*., ss. 5–9 (all currently in force).

21 *Ibid*., ss. 10–13 (s. 12 is not currently in force).

22 *Ibid*., ss. 21–39.

the *Act* is provided for.[23] Offences are created,[24] and provision is made for the enactment of regulations.[25] The administration of the *AHRA* will be reviewed within three years of the creation of the Agency by a committee of the legislature, which will provide recommendations for changes to the *AHRA* or its administration.[26]

Important portions of the *AHRA* have still not been proclaimed into force.[27] Some that are technically in force have no practical effect; for instance, although the provisions creating the Agency came into force on January 12, 2006, the Agency is not operational at the time of the writing of this article, although in December of 2006, a President, Chairperson, and Board of Directors were named.[28] Those sections that depend on the existence of regulations to have any effect[29] provide another illustration of this, because no regulations have been enacted. As a result, the only currently operative portions of the *AHRA*, in addition to the interpretive provisions, are those setting out prohibited activities and the sanctions attached to contraventions of these prohibitions. Although public consultations have begun on some aspects of regulation under the *AHRA*,[30] to date these consultations have not resulted in any further governmental action.

B. Prohibitions Relating to Animal-Human Combinations

The *AHRA* prohibits the following activities with respect to animal-human combinations:[31]

(i) transplantation of a sperm, ovum, embryo or foetus of a non-human life form into a human being.[32]

The terms "sperm", "ovum", "embryo", and "foetus" are all defined with reference to human beings in the *AHRA*, but the context of this provision clearly requires that the definitions not be referred to for its interpretation.

This prohibition seems to be aimed principally at the possible creation of a being containing mixed genetic or reproductive material from human and non-human species, and at the possibility of a human being acting as surrogate for a non-human life form.

(ii) for the purpose of creating a human being, make use of any human reproductive material or an in vitro embryo that is or was transplanted into a non-human life form.[33]

"Human reproductive material" is defined as "a sperm, ovum or other human cell or a human gene, and includes a part of any of them."[34] It is not limited to germ line cells but includes a somatic cell that

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23 *Ibid*., ss. 14–19 (none is currently in force).

24 *Ibid*., ss. 60–64.

25 *Ibid*., ss. 65–67.

26 *Ibid*., s. 70.

27 These include provisions dealing with the use of reproductive material without consent, reimbursement of surrogate mothers' expenses, the privacy and access to information regime, and sections dealing with the operation of the Agency; the sections creating the Agency came into force on January 12, 2006.

28 Health Canada, News Release, "Canada's New Government announces a President, Chairperson and Board of Directors for Assisted Human Reproduction Canada" (21 December 2006), online: Health Canada <http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/2006/2006_133_e.html>.

29 For instance, most controlled activities require a licence delivered in accordance with the regulations, but no regulations have been adopted concerning the licensing conditions. A similar situation occurs with section 11 of the *AHRA*, apparently aimed at the creation of transgenics, which requires a licence for certain types of interspecies combinations at the genetic level, with the particulars to be provided by regulation (see section I(C) below).

30 Health Canada gave notice in October of 2004 that it intended to develop the components of the regulatory framework under the *AHRA* and announced its intention to undertake public involvement activities for the development of these components (C. Gaz. 2004.I.3003). This process was initiated for section 8 (Consent) of the *AHRA* and draft regulations were published in September of 2005 (C. Gaz.2005.I.3165). Workshops have been held on several topics, such as expense reimbursement for gamete donors and counselling for reproductive services; public comment has been requested on preimplantation genetic diagnosis, for example, and a public consultation is currently ongoing for counselling services. None of these activities has been concerned with animal-human combinations, however.

31 *AHRA*, *supra* note 8, s. 5(1). The introductory language of this provision states that "no person shall knowingly ...", so knowledge of what one is doing is necessary for these prohibitions to apply.

32 *Ibid*., s. 5(1)(g).

33 *Ibid*., s. 5(1)(h).

might be used for cloning by nuclear transfer,[35] for example. Thus, the intention is clearly that the *Act* cover methods of reproduction beyond fertilization. "Sperm" and "ovum" are also defined in the *AHRA* and refer in each case to the human sperm or ovum, whether mature or not. As noted by others, the reference to maturity in these definitions will prevent the use of earlier-stage gametes to circumvent the prohibitions or controls provided for in the *Act*.[36]

"Embryo" is defined as "a human organism during the first 56 days of its development following fertilization or creation, excluding any time during which its development has been suspended, and includes any cell derived from such an organism that is used for the purpose of creating a human being."[37] Here also, the intent to cover methods of reproduction other than fertilization is clear from the use of the word "creation". Presumably, this language was inspired by the desire to avoid a situation like the *Quintavalle*[38] case in the United Kingdom, which dealt with the interpretation of the term "embryo" in the British *Human Fertilisation and Embryology Act 1990*.[39] The House of Lords confirmed the Court of Appeal's decision that the word "embryo", although defined in the British *Act* solely by reference to fertilization, should be interpreted to include the result of nuclear transfer.

Since the prohibition applies only "for the purpose of creating a human being", the use of human reproductive material previously transplanted into an animal for cell or gene therapy is not covered here. Thus, the use of xenotransplants from animals modified to carry human genes, for example, would not be prohibited by this section. However, the use of animal surrogates for human beings is clearly prohibited.

> *(iii) create a chimera, or transplant a chimera into either a human being or a non-human life form*.[40]
>
> A "chimera" is defined as either
>
> (a) an embryo into which a cell of any non-human life form has been introduced; or
>
> (b) an embryo that consists of cells of more than one embryo, foetus or human being.[41]

Two remarks should be made here: firstly, the prohibition applies only at the embryonic stage, so that cell therapy (or the introduction of "foreign" cells for other purposes), and tissue and organ transplants (from human or animal sources) at fetal or later developmental stages are not prohibited. Secondly, because embryos are defined as human embryos in the *Act*, only animal-to-human[42] chimeras or human-to-human chimeras are prohibited. Human-to-animal[43] combinations such as introducing human cells into embryonic animals are not targeted by this provision.

A recent search revealed no reported experiments involving the creation of "chimeras", as defined in the *AHRA*, in the current scientific literature, although experiments involving the introduction of animal brain cells into *adult* humans suffering from Parkinson's disease, for example, have been carried out.[44] However, experiments involving the introduction of human cells into animal embryos (the converse of a chimera, as described in the *AHRA*) are performed in various contexts.[45] These experiments variously attempt to test the capacity and mechanisms of differentiation of human cells during development, to

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34 *AHRA*, *supra* note 8, s. 3.

35 Nuclear transfer, the process used to clone the famous sheep Dolly, involves using an oocyte (egg cell) from which the nucleus has been removed, and introducing the nucleus of a cell from the organism to be cloned into the egg. After appropriate stimulation, the egg with the new nucleus can be induced to divide and develop as an embryo and, sometimes, into an adult animal. For an interesting historical and technical account of the cloning of Dolly the sheep, see Ian Wilmut & Roger Highfield, *After Dolly—The Uses and Misuses of Human Cloning* (New York: W. W. Norton Company Inc., 2006).

36 Glenn Rivard & Judy Hunter, *The Law of Assisted Human Reproduction* (Markham: LexisNexis/Butterworths, 2005) at 44.

37 *AHRA*, *supra* note 8, s. 3.

38 *R (Quintavalle) v. Secretary of State for Health*, 2003 UKHL 13, [2003] 2 A.C. 687 (H.L.) [*Quintavalle*].

39 (U.K.), 1990, c. 37.

40 *AHRA*, *supra* note 8, s. 5(1)(i).

41 *Ibid*., s. 3.

42 Meaning chimeras created by adding animal cells to a human embryo.

43 Meaning chimeras created by adding human cells to an animal embryo.

44 J. Stephen Fink *et al*., "Porcine xenografts in Parkinson's disease and Huntington's disease patients: preliminary results" (2000) 9 Cell Transplant 273.

45 Alysson R. Muotri *et al.*, "Development of functional human embryonic stem cell-derived neurons in mouse brain" (2005) 102:51 Proceedings of the National Academy of Science of the USA 18644.

create models for the study of certain types of disease, and to develop better sources of cells for transplantation into humans.

One author, Baylis, questions whether the prohibition in the *AHRA* is too narrow,[46] and contrasts the *Act* with the stem cell research guidelines adopted by the Canadian Institutes of Health Research (CIHR). These guidelines proscribe a greater range of chimera-making, including the introduction of human pluripotent cells into animal embryos.[47] The differences between the *AHRA* and the *Stem Cell Guidelines* are further discussed in section II below, and arise as a result of the divergent goals of these instruments. Baylis also supposes that those chimeras not prohibited by section 5 of the *Act* might be regulated under section 11,[48] which is discussed in section I(C) below.

Both the creation and the transplantation of a chimera into any life form are prohibited by the *Act*; thus, no pre-transplantation experimentation may take place with chimeras, whereas the situation appears to be different for hybrids.

> *(iv) create a hybrid for the purpose of reproduction, or transplant a hybrid into either a human being or a non-human life form*.[49]

A "hybrid" is defined as

> (a) a human ovum that has been fertilized by a sperm of a non-human life form;
>
> (b) an ovum of a non-human life form that has been fertilized by a human sperm;
>
> (c) a human ovum into which the nucleus of a cell of a non-human life form has been introduced;
>
> (d) an ovum of a non-human life form into which the nucleus of a human cell has been introduced; or
>
> (e) a human ovum or an ovum of a non-human life form that otherwise contains haploid sets of chromosomes from both a human being and a non-human life form.[50]

This prohibition is aimed only at the creation of hybrids for reproductive purposes and at their transplantation into a life form, which would permit further development and, eventually, birth. The possibility remains that hybrids could be created *in vitro* for purposes of research, for example, and that development might take place *in vitro* for some time, as long as the purpose of the experiment is not "reproductive".[51] This does raise the question of how far such development might be allowed to take place, but the *AHRA* does not address this directly; regulations may do so in the future. This question is not academic, as experiments have been carried out in which human nuclei have been transferred into rabbit oocytes[52] to create what would qualify as "hybrid" embryos in an attempt to generate human embryonic stem cells for research. This technique would have the advantage of producing essentially human[53] embryonic stem cells for research purposes without making use of human eggs, a scarce and ethically problematic resource. These hybrid embryos could also prove a useful tool for the study of the reprogramming and differentiation of human nuclei.

Here also, the *Act* attempts to anticipate potential technological developments: the final clause of the definition of hybrids considers their creation by any method that leads to the creation of a human or non-

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46 Françoise Baylis, "Betwixt and Between Human Stem Cell Guidelines and Legislation" (2002) 11:1 Health Law Review 44.

47 Canadian Institutes of Health Research, *Updated Guidelines for Human Pluripotent Stem Cell Research, June 28, 2006*, online: Canadian Institutes of Health Research <http://www.cihr-irsc.gc.ca/e/31488.html> [*Stem Cell Guidelines*].

48 *Supra* note 46.

49 *AHRA*, *supra* note 8, s. 5(1)(j).

50 *Ibid*., s. 3.

51 This also means that certain techniques used to test the suitability of sperm for fertilization, such as the incubation of human sperm with hamster oocytes, will not be prohibited.

52 Chen Ying *et al*., "Embryonic stem cells generated by nuclear transfer of human somatic nuclei into rabbit oocytes" (2003) 13:4 Cell Research 251. For a recent report of interspecies nuclear transfer (mouse nuclei transferred into cow oocytes), see Gretchen Vogel, "Team Claims Success With Cow-Mouse Nuclear Transfer" (2006) 313 Science 155.

53 During nuclear transfer to produce such a hybrid embryo, the nucleus of a human cell would be introduced in an animal egg from which the nucleus has been removed, as described in note 35, *supra*. Most of the genetic material in a cell is located in the nucleus; therefore the resulting embryo would be "mostly" human. Animals' cells also contain small organelles known as mitochondria, which are involved in generating energy; these mitochondria would remain present in the hybrid embryo, and contain some genes coding for proteins involved in energy metabolism. The "hybrid embryo" would therefore also contain a very small number of animal genes (37) in addition to all the human nuclear genes (currently estimated at approximately 23,000 genes). See Human Genome Project Information, *How many genes are in the human genome?*, online: <http://www.ornl.gov/sci/techresources/Human_Genome/faq/genenumber.shtml>.

human ovum with haploid sets of chromosomes from both a human and non-human life form. It does not seem to catch the situation in which a cell other than an ovum is used as starting material for the creation of such an organism, something which is not currently technically possible but which might become so. However, section 11 of the *AHRA*, discussed below, may also be used to address this situation in the future.

As previously mentioned,[54] the regulation of "hybrid" embryos created by nuclear transfer will be the subject of a public consultation in the United Kingdom this year. Recent proposals dealing with potential reform to the current United Kingdom legislation on this topic have reached differing conclusions: the December 2006 white paper published by the Department of Health recommended that this practice be prohibited generally, with a mechanism in place to permit the licensing and regulation of individual experiments;[55] whereas the 2005 report of the House of Commons Science and Technology Committee suggested that this type of experiment should be permitted, with any resulting embryos being destroyed after fourteen days of development.[56]

In addition to the prohibitions discussed thus far,[57] the *AHRA* also regulates several activities, including the creation of other possible animal-human combinations, as "controlled activities".

C. Controlled Activities

> No person shall, except in accordance with the regulations and a licence, combine any part or any proportion of the human genome specified in the regulations with any part of the genome of a species specified in the regulations.[58]

"Human genome" in this case refers to the totality of the deoxyribonucleic acid sequence of the human species, and "species" means any taxonomic classification of non-human life.[59]

The scope of this provision is impossible to determine in the absence of the regulations specifying the portions or subsets of the human genome and the species for which combinations will be restricted. Theoretically, it could cover the creation of organisms containing a haploid set of each of a human being and a non-human being,[60] the creation of transgenic animals using human genes, as well as the use of animal genes for gene therapy in humans[61] (and reciprocal combinations, although these are less likely).

Existing examples of transgenic animals include the Harvard oncomouse,[62] which was engineered with human DNA sequences to be more susceptible to cancer and to serve as a model for the human disease. Another is a "transchromosomic" mouse, whose cells contain not merely a few human genes, but an almost complete copy of human chromosome 21. Such mice are used as a model to study Down syndrome.[63] Many other transgenic animals are currently used in medical and pharmaceutical research as models for other diseases or for toxicity studies, or as potential donors for xenotransplantation. Transgenic animals have also been engineered to produce human proteins as drugs.[64] The creation of

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54 See HFEA Press Statement, *supra* note 4 and accompanying text.

55 United Kingdom, Department of Health, *Review of the Human Embryology and Fertilisation Act* (London: Licensing Division, 2006) at s. 2(85).

56 United Kingdom, House of Commons Science and Technology Committee, *Human Reproductive Technologies and the Law* (London: Stationery Office Limited, 2005) at para. 66.

57 Subsections 5(2) and 5(3) the *AHRA* also make it an offence to offer to do or to advertise the doing of anything prohibited in subsection 5(1), and to pay or offer to pay consideration to any person for doing anything so prohibited.

58 *AHRA*, supra note 8, s. 11.

59 *Ibid*., s. 3.

60 The creation of these hybrids for reproductive purposes is prohibited by paragraph 5(1)(j) of the *AHRA*, but is currently not explicitly prohibited for experimental, non-reproductive purposes. Thus, regulations adopted pursuant to section 11 of the *AHRA* could be used to regulate specific types of hybrids, or methods to produce hybrids that are not currently covered by paragraph 5(1)(j).

61 As previously noted, transmissible alterations of the human genome are prohibited by the *AHRA*, so only somatic cell gene therapy would be a controlled activity.

62 This mouse is famous in Canada, as it was held to be a non-patentable higher life form. See *Harvard College v. Canada (Commissioner of Patents)*, 2002 SCC 76, [2002] 4 S.C.R. 45.

63 Aideen O'Doherty *et al.*, "An Aneuploid Mouse Strain Carrying Human Chromosome 21 with Down Syndrome Phenotypes" (2005) 309 Science 2033.

64 The first transgenically produced drug to be approved for human therapeutic use in the world is ATryn, a recombinant form of human antithrombin produced in the milk of transgenic goats. It obtained marketing approval from the European Commission on August 2, 2006, and will be used for the prevention of embolism in patients with congenital antithrombin deficiency undergoing surgery. Charlie Schmidt, "Belated approval of first recombinant protein from animal" (2006) 24:8 Nature Biotechnology 877. See also GTC Therapeutics, News Release, "European Commission Approves ATryn" (2 August 2006), online: GTC Therapeutics

some of these animals may be subject to section 11 of the *AHRA* in the future. In addition, because "species" as defined in this section refers to non-human life, section 11 could be used to cover other interspecies combinations involving human and plant, bacterial, yeast or viral DNA. These are currently used to produce a wide range of medications, such as insulin or growth hormone, in bioreactors. In most cases, however, regulating these combinations pursuant to a statute expressly intended to regulate human reproductive technologies might be difficult to justify.

The creation of constructs used in human gene therapy could potentially be regulated by this provision, as it often involves the combination of viral DNA and human or other genes that are introduced in human patients.[65] Although in terms of its safety and efficacy as a treatment this type of therapy would currently be regulated under the *Food and Drugs Act*,[66] any regulations adopted pursuant to the *AHRA* could impose limits on the design of these combinations. For gene therapy and most other current uses of transgenic animals, concerns like human and environmental safety are already addressed by other statutes.[67] One might therefore expect regulations aimed at preventing or licensing experiments raising "moral" questions, such as the transfer of genes participating in human cognition or speech into non-human primates, for example.

As previously mentioned, Baylis has argued that section 11 may be used to regulate the creation of "chimeras" that are not covered by paragraph 5(1)(i).[68] This argument is based upon the meaning ascribed to the word "combination". In her opinion, mixing cells with different genomes in one organism (such as introducing animal cells in a human embryo) could be interpreted as creating a "combination" of genomes in that organism. In connection with this, it should be noted that the *Act* states that pursuant to section 11 regulations may be made "designating controlled activities or classes of controlled activities that may be authorized by a licence",[69] and "specifying parts or proportions" of the human and other genomes to which section 11 will apply.[70] Until regulations shed more light on this, the possibility that section 11 might cover certain types of chimeras, such as the introduction of human embryonic stem cells into primate blastocysts, remains open.[71]

Transgenic animals, or recombinant bacteria and plants that contain sequences of non-human species but do not contain human sequences, are not addressed by this provision.

II
CHIMERAS AND HYBRIDS IN THE *AHRA* AND THE CIHR RESEARCH GUIDELINES

As previously discussed, the *AHRA* prohibits (i) the creation of chimeras that combine any cell of a non-human life form with a human embryo, while not addressing combinations involving animal embryos or human fetuses and adults, and (ii) the creation of hybrids for reproductive purposes. The focus of the *AHRA* on human embryos is understandable, given the *Act's* goal of regulating human reproductive technologies. In contrast, guidelines for federally funded research approach the topic of animal-human combinations from different angles—stem cell research and research with human subjects and human biological material. Three of the main federal granting agencies for research, including the CIHR,[72] have jointly adopted certain research guidelines and require that these guidelines be complied with by all researchers and institutions that receive funding from them.[73] These include the *Stem Cell Guidelines*[74]

<http://www.transgenics.com/pressreleases/pr080206.html> (press release issued by the manufacturer).

65 Human Genome Project Information, "Gene Therapy", online: Human Genome Project Information <http://www.ornl.gov/sci/techresources/Human_Genome/medicine/genetherapy.shtml>.

66 R.S., 1985, c. F-27.

67 Examples are the *Food and Drugs Act, ibid*., which regulates constructs used in gene therapy and drugs produced by transgenic animals, and the *Canadian Environmental Protection Act, 1999*, S.C. 1999, c. 33, which applies to the creation or introduction into Canada of new animal species.

68 *Supra* note 46.

69 *AHRA*, *supra* note 8, s. 65(1)(c).

70 *Ibid*., s. 65(1)(d).

71 Jason Scott Robert, "Regulating the Creation of Novel Beings" (2002) 11:1 Health Law Review 14 [Robert, "Regulating"].

72 The other agencies involved are the Social Sciences and Humanities Research Council (SSHRC) and the National Sciences and Engineering Research Council of Canada (NSERC), together with CIHR [Granting Agencies].

73 Subsection 5(2) of the *Memorandum of Understanding* to be entered into between the Granting Agencies and an institution receiving funding requires that all such institutions receiving funding comply with both the *TCPS* and the *Stem Cell Guidelines*. See Natural Sciences and Engineering Research Council of Canada, *Memorandum of Understanding*, online: Natural Sciences and Engineering Research Council of Canada <http://www.nserc.ca/institution/mou_doc_e.htm>.

and the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*,[75] which deal with chimeras and hybrids, respectively. The *Stem Cell Guidelines* are intended to serve as an interpretation and extension of the *TCPS*, and are eventually to be integrated in the *TCPS*.

Under the *Stem Cell Guidelines*, research involving the creation of certain chimeras is not permitted: (i) research in which human or non-human embryonic stem cells, embryonic germ cells or other cells that are likely to be pluripotent are combined with a human embryo[76] or a human fetus,[77] and (ii) research in which human embryonic stem cells, embryonic germ cells, or other cells that are likely to be pluripotent are combined with a non-human embryo[78] or a non-human fetus.[79] Thus, the *Stem Cell Guidelines* not only forbid the creation of chimeras using any cells likely to be pluripotent in a human embryo, but extend the prohibition to the creation of a "chimera" at a later developmental stage (fetal) than the *AHRA*, and also to the creation of a "chimera" using non-human embryos and fetuses as a substrate for the addition of pluripotent cells of human origin. However, they do not target the use of non-pluripotent cells to create chimeras, whereas the *AHRA* prohibits the introduction of any type of animal cell into a human embryo.

As a result, in Canada, privately funded research on chimeras, being subject only to the *AHRA*, is currently less restricted than federally funded research using pluripotent cells. At the present time, experiments to create mice with human neurons by injecting pluripotent cells in mouse embryos[80] could only be carried out in Canada if neither the researcher carrying it out nor the institution of which he is a member receive funds from one of the Granting Agencies. In contrast, the National Academies of Science (United States) suggest the outright prohibition of only two types of chimeras—those in which embryonic stem cells of any origin are introduced into human blastocysts, and those created by the introduction of human pluripotent stem cells in non-human primate blastocysts.[81]

The narrower scope of the prohibition in the *AHRA* may reflect a concern with the constitutional validity of a wider prohibition in legislation explicitly aimed at dealing with human reproductive technologies. It is also possible that by the time the *AHRA* was enacted, research was moving in directions that seemed to make the prohibition of human-to-animal chimeras an overly restrictive measure, and regulation a preferable alternative. It bears noting that, since 1964, the *Helsinki Declaration* has explicitly required that research be carried out on animal models, where possible, prior to human experimentation.[82]

It remains to be seen whether the federal government will adopt regulations under section 11 that aim to regulate the creation of chimeras, and what type of controls will be exerted if this occurs. As noted by Robert,[83] the *Proposals* initially suggested that the creation of chimeras be a regulated activity, and

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74 *Supra* note 47.

75 Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council, and Social Sciences and Humanities Research Council, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (1998, with 2000, 2002, and 2005 amendments), online: Interagency Advisory Panel on Research Ethics <http://www.pre.ethics.gc.ca/english/pdf/TCPS%20October%202005_E.pdf> [*TCPS*].

76 *Stem Cell Guidelines*, *supra* note 47, s. 8(2)(4).

77 *Ibid*., s. 8(2)(5).

78 *Ibid*., s. 8(2)(6).

79 *Ibid*., s. 8(2)(7).

80 See e.g. Muotri *et al.*, *supra* note 45.

81 National Research Council, National Academy of Sciences, Committee on Guidelines for Human Embryonic Stem Cell Research, *Guidelines for Human Embryonic Stem Cell Research* (Washington, D.C.: National Academies Press, 2005) recommendation 3(c) [American Guidelines]. However, research involving the introduction of human embryonic stem cells into non-human animals at any stage of development is singled out for review by an ESCRO committee in addition to the usual animal use committees and institutional review board reviews. See also recommendation 3(b).

82 World Medical Assocation, *World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*, adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the 29th WMA General Assembly, Tokyo, Japan, October 1975, 35th WMA General Assembly, Venice, Italy, October 1983, 41st WMA General Assembly, Hong Kong, September 1989, 48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996 and the 52nd WMA General Assembly, Edinburgh, Scotland, October 2000, note of clarification on Paragraph 29 added by the WMA General Assembly, Washington 2002, and note of clarification on Paragraph 30 added by the WMA General Assembly, Tokyo 2004 [*Helsinki Declaration*], online: World Medical Association <http://www.wma.net/e/policy/pdf/17c.pdf>.
See article 11, which states:

> Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and on adequate laboratory and, where appropriate, animal experimentation.

83 Robert, "Regulating", *supra* note 71.

contained a much broader definition of "chimera" than does the *Act*;[84] this definition included animal-to-human chimeras created at the fetal stage, as well as human-to-animal chimeras created at both the embryonic and fetal stages. Thus, the previously expressed intention to regulate some types of chimeras not currently prohibited may resurface.

In the case of hybrids, a difference between the statutory provisions of the *AHRA* and the federal guidelines also exists. The *TCPS* deems it unacceptable to create or intend to create hybrid individuals,[85] or to undertake research that involves the *formation* of animal-human hybrids.[86] These prohibitions seem to target the creation of hybrids for both research and reproductive purposes, in contrast to the *Act*. The *TCPS* would appear to prohibit the transfer of human nuclei into, for example, the rabbit oocytes previously described, although it does not define "hybrid", so it is difficult to ascertain whether it intended to cover hybrids resulting from nuclear transfer experiments. Thus, hybrids present another case in which experiments in privately funded institutions currently seem to be less restricted than federally funded research. As with chimera regulation, it may be that the creation of hybrids for research will be further regulated pursuant to section 11 of the *AHRA*.

III
ENFORCEMENT: OFFENCES AND GRANDFATHERING CLAUSE

The consent of the Attorney General of Canada must be obtained before prosecution for an offence under the *AHRA*.[87] Breaches of the regulatory schemes set up by the *Act* have serious consequences. The prohibitions against animal-human combinations are given "teeth" by section 60 of the *AHRA*, which makes it an offence to contravene any of them. Conviction on indictment can entail a fine not exceeding $500,000, imprisonment for a term not exceeding ten years, or both, while a summary conviction means liability for a fine up to $250,000, imprisonment for a period not exceeding four years, or both.

For controlled activities like those eventually targeted by section 11, the picture is different. Section 71 reads as follows:

> Notwithstanding sections 10 to 13, a person who undertakes a controlled activity at least once during the period of one year preceding the coming into force of those sections may subsequently, without a licence, undertake the controlled activity and use any premises required for that purpose until a day fixed by the regulations.[88]

Thus, technically, since section 11 came into force on April 22, 2004, anyone who was performing the type of experiment referred to in section 11 may continue to do so until regulations fix a date when the licence will become necessary. The difficulty is that, while section 11 is technically in force, the absence of the regulations referred to in this provision renders it impossible to determine which activities require a licence, and therefore which activities may only be carried out by persons who were carrying them out before April 22, 2004. This seems to rob the transitory measure of section 71 of any effect in connection with section 11. Thus, effectively, experiments that involve combining the human genome with portions of the genome of other species may currently be undertaken by anyone (to the extent they are not prohibited by other legislative provisions). Once the regulations are adopted, and unless they provide otherwise, a literal interpretation of section 71 would be to "grandfather" those whose activities before April 22, 2004 were covered by section 11 but not those who have begun similar activities after that date.

A person convicted of a breach of the regulations, or of the sections requiring a licence for "controlled activities", such as section 11 of the *AHRA*, is liable, on conviction or indictment, to a fine of up to $250,000 or imprisonment for a term not exceeding five years, or both. On summary conviction this

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84 See *Proposals*, *supra* note 13, s. 9(3).

85 See *TCPS*, *supra* note 75, art. 9(3), which reads as follows:
It is not ethically acceptable to create, or intend to create, hybrid individuals by such means as mixing human and animal gametes, or transferring somatic or germ cell nuclei between cells of humans and other species.

86 *Ibid*., art. 9.5, which reads as follows:
It is not ethically acceptable to undertake research that involves ectogenesis, cloning human beings by any means including somatic cell nuclear transfer, formation of animal/human hybrids, or the transfer of embryos between humans and other species.

87 *AHRA*, *supra* note 8, s. 63.

88 This provision seems to have a "freezing" effect. Persons who manipulate human reproductive material for the purpose of creating an embryo, for example, an activity regulated pursuant to section 10 of the *AHRA*, may continue to do so if they were performing these activities prior to April 22, 2004, the date section 10 came into force, until the regulations fix a date when a licence will be required. Until the Agency becomes operational and the regulations concerning licences are adopted, therefore, no one who was not carrying out these activities before may begin to do so.

person would be liable to a fine not exceeding $100,000, imprisonment for a term not exceeding two years, or both.[89]

In addition, a court imposing a fine or term of imprisonment in respect of an offence under the *AHRA* may order the forfeiture and disposition of any material or information by means of which, or in relation to which, the offence was committed. If such an order is applied for by the attorney general, moreover, a court may order the convicted person not to engage in any activity that in its opinion may lead to the commission of an offence under the *AHRA*.[90]

The Agency may also notify professional licensing or disciplinary bodies of the identity of persons charged with an offence under the *AHRA*, or for whom there are reasonable grounds to believe that they acted in breach of a professional code of conduct.[91]

IV
CONSTITUTIONAL NOTE

The constitutionality of the *AHRA* has been the subject of some comment,[92] with several authors arguing that the recourse to regulatory schemes creating criminal offences was necessary to anchor the legislation within federal jurisdiction. Although any detailed analysis of this topic is beyond the scope of this article, some remarks are necessary because the constitutionality of the *Act* bears on the regulation of animal-human combinations in Canada. Most authors agree that the constitutional basis for the federal government's passage of the *AHRA* is its exclusive authority to legislate for criminal law.[93] However, general jurisdiction over health matters, such as the provision of health care, is usually understood to be with the provincial domain.[94] Assisted human reproduction services, such as *in vitro* fertilization, are generally characterized as health services, which presents the possibility that provinces may claim that they properly fall within their jurisdiction. For this reason, certain provisions of the *AHRA* dealing with controlled activities are open to constitutional challenge.[95]

Perhaps in recognition of this, the *AHRA* itself provides that certain of its provisions—describing controlled activities, aspects of privacy of personal information, and enforcement,[96] and corresponding regulations—may not apply in a province if the federal minister of health and the government of that province agree in writing that there are laws in force in the province that are equivalent to the *AHRA* provisions.[97] This could be understood as a mechanism to foster cooperation between the different levels of government in order to achieve uniform regulation without triggering a jurisdictional debate.

The Government of Quebec is of the opinion that the *AHRA* exceeds the federal government's jurisdiction by legislating in the area of health and civil rights. As a result, the Attorney General of Quebec has been mandated by order in council to proceed with a reference case before the Quebec Court of Appeal, questioning whether the federal government has overstepped its jurisdiction by adopting sections

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89 *AHRA*, *supra* note 8, s. 61.

90 *Ibid*., s. 63.

91 *Ibid*., s. 64.

92 See Rivard & Hunter, *supra* note 36, at 28–30. See also, *inter alia*, the following articles: Alison Harvison-Young & Angela Wasunna, "Wrestling with the Limits of Law: Regulating New Reproductive Technologies" (1998) 6 Health L.J. 239 at 255 (concerning a previous draft bill on assisted reproductive technologies); National Health Law and Family Law Sections, Canadian Bar Association, "Submission on Draft Legislation on Assisted Human Reproduction" (2002) 10:2 Health Law Review 25; Angela Campbell, "A Place for Criminal Law in the Regulation of Reproductive Technologies" (2002) 10 Health L.J. 77 at 95; Alison Harvison-Young, "Let's Try Again... This Time with Feeling: Bill C-6 and New Reproductive Technologies" (2005) 38 U.B.C. L. Rev. 123 [Harvison-Young, "Let's Try Again"].

93 *Constitution Act, 1867* (U.K.), 30 & 31 Vict., c. 3, s. 91(27), reprinted in R.S.C. 1985, App. II, No. 5 [*Constitution Act, 1867*]. The federal government also has authority to legislate for the peace, order and good government of the country, but this power has seen variation in its interpretation in recent years and is not seen as secure a basis for legislation dealing with services, such as *in vitro* fertilization, that are perceived as health services. See Harvison-Young, "Let's Try Again", *ibid*., for a discussion of this.

94 This is based on those provisions of the *Constitution Act, 1867*, *ibid.*, granting jurisdiction to the provinces for the "Establishment, Maintenance, and Management of Hospitals, Asylums, Charities, and Eleemosynary Institutions in and for the Province, other than Marine Hospitals" (s. 92(7)), "Property and Civil Rights in the Province" (s. 92(13)), and "Generally all Matters of a merely local or private Nature in the Province" (s. 92(16)).

95 Besides the provisions explored in this paper concerning animal-human combinations, the *AHRA* aims to prohibit or regulate the use of reproductive material without consent, use of human reproductive material, including for the provision of infertility services, protection of minors, and expense reimbursement for surrogate mothers.

96 *AHRA*, *supra* note 8, ss. 10–16, 46–53, 61.

97 *Ibid*., s. 68.

8–12 of the *AHRA*.[98] This challenge is not concerned with the criminal prohibitions against animal-human combinations contained in section 5 of the *AHRA*, but it does target section 11, which purports to regulate the combination of the human genome with that of other species. As previously mentioned, this section is, in practice, currently inoperative because the regulations that would give it effect have not been adopted. As a result, Quebec's constitutional challenge of the *AHRA*, even if successful, would not have any immediate effect on the regulation of animal-human combinations as it now exists. However, if section 11 is found to lie outside the competence of the federal government, Quebec's challenge may succeed in preventing federal regulation of animal-human combinations at the genome or genetic level pursuant to section 11 the *AHRA* in the whole of Canada. This would not be conducive to the "one standard" approach that is often perceived as desirable in these matters, but would respect the autonomy of the provinces on matters within their jurisdiction. Eventually, if the provinces adopted different regimes for these animal-human combinations, and in the absence of professional self-regulation, researchers might resort to "forum-shopping" within the country for such experiments. It should be kept in mind, however, that research conducted under the auspices of federal granting agencies would still be subject to the *Stem Cell Guidelines*, the *TCPS*, or other such government policies.

On December 16, 2004, the Government of Quebec tabled Bill 89, *An Act respecting clinical and research activities as regards assisted human reproduction and amending other legislative provisions*, which deals with assisted human reproduction activities but does not address the question of animal-human combinations.[99] At the time of the writing of this article this bill has not been passed. If enacted and judged equivalent to the *AHRA* by the federal and provincial governments through a reciprocity agreement, the Quebec *Act* would apply in Quebec. Bill 89 does not contain a provision equivalent to section 11 of the *AHRA* or one dealing explicitly with animal-human combinations at the genome level. It is therefore unlikely that section 11 would be included in such a reciprocity agreement unless the current text of the bill is amended.

V
ETHICAL CONSIDERATIONS UNDERLYING THE REGULATION OF ANIMAL-HUMAN COMBINATIONS IN THE *AHRA*

The *AHRA* opens with a declaration of the interpretive principles that apply to it.[100] In the context of animal-human combinations, the most relevant principles cited are "the protection and promotion of human health, safety, dignity and rights" in the use of assisted human reproductive technologies and related research,[101] as well as the protection of "human individuality and diversity" and of "the integrity of the human genome".[102] Before a conclusion is reached as to the scope of the *AHRA* and its likely effect in the field of animal-human combinations, these interpretive principles will be very briefly reviewed[103] in order to determine the extent to which they might underlie the prohibitions[104] set forth in the *AHRA*.

A. Health and Safety

The protection and promotion of human health and safety are explicitly identified in the *AHRA* as key concerns. The Standing Committee on Health, when reporting on a draft version of the *AHRA*, was concerned with the safety of both the transplantation of animal reproductive material into a human, and

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98 D. 1177-2004, G.O.Q. 2005.II.62 (Order in council 1177-2004, December 15, 2004). The reference to the Quebec Court of Appeal has been scheduled for hearing on September 19, 2007. A constitutional challenge was also initiated by the Quebec government in respect of the federal privacy and information statute, the *Personal Information Protection and Electronic Documents Act*, S.C. 2000, c. 5, which provides that the Canadian privacy commissioner may declare that a province has equivalent privacy legislation in place, in which case the federal act will not apply in that province except to federal undertakings. See D. 1368-2003, G.O.Q. 2004.II.184. The reference to the Quebec Court of Appeal on this is not yet scheduled for a hearing.

99 1st Sess., 37th Leg., 2004.

100 *AHRA*, *supra* note 8, s. 2.

101 *Ibid*., s. 2(b). Section 22 of the *AHRA* also states that the objectives of the Agency (when functioning) will be to protect and promote the health and safety, and the human dignity and human rights, of Canadians, as well as to foster the application of ethical principles in relation to assisted human reproduction and other matters to which the *AHRA* applies, including research.

102 *Ibid*., s. 2(g).

103 An in-depth consideration of these topics is beyond the scope of this paper.

104 Because no regulations have been passed to permit us to ascertain the scope of section 11, meaningful discussion of this section is not possible at this time.

the reverse. As a matter of consistency, it also recommended that the creation of animal-hybrids for reproductive purposes be banned.[105]

In the context of animal-human combinations, safety concerns include the possibility that new human diseases might arise from the close proximity of animal and human tissue through "humanization" of animal pathogens.[106] Recent examples of the "humanization" of an animal pathogen causing new human diseases are SARS[107] and mutations of an avian flu virus that have been shown to be transmissible among humans, with serious consequences.[108] This would be a concern in all cases of the transfer of biological material between humans and animals, or of animal-human combinations prohibited by the *AHRA*. It is also a serious concern in xenotransplantation[109] and other types of animal-human combinations that the *AHRA* does not cover. As a serious risk that is not well understood, the possibility of zoonoses requires careful consideration of safety measures for all situations in which biological materials of animal origin are put in close contact with human beings.

The prevention of zoonoses alone, however, does not explain the prohibitions found in the *AHRA*. Whereas the creation of chimeras by adding material of human origin to a human embryo is prohibited, the creation of similar chimeras at the fetal stage is not. Similarly, the converse experiment of adding material of human origin to an animal embryo or fetus is not prohibited, despite the fact that it raises questions with respect to pathogens.[110] Thus, the possible humanization of animal pathogens does not by itself explain the structure of the regulatory scheme.

Another health and safety concern is the possibility of creating beings suffering from serious malformations and disorders. To a certain extent, the prohibitions of the *AHRA* seem to take this danger into account. For example, no hybrid being may be created for reproductive purposes, because the results of the interaction between two different haploid genomes are unknown. Similarly, animal-to-human chimeras constructed at the embryonic level, where the introduction of foreign material might have the greatest effect on development of the organism, are prohibited. However, this possibility does not fully account for the chosen regime: although from a developmental point of view an organism at the embryonic stage is most vulnerable to the introduction of "foreign" biological material, a fetus is probably also quite vulnerable to such a manipulation, which might cause malformation or disease. Furthermore, the introduction of human material in a non-human embryo is not prohibited under the *AHRA*. A suffering, malformed being could certainly arise from this type of experiment. It must be concluded that these concerns, although real, lie outside the appropriate scope of the *AHRA*, and should therefore be left to other statutes or regimes dealing with the protection of human beings in medicine and research, or the protection of animals used in research.

The regulations eventually adopted under section 11 may alter this analysis, because they could effectively create additional prohibitions. It remains that decisions based on safety are not sufficient to explain the *a priori* choice of prohibitions made in the *AHRA*. The focus of the *AHRA* on human reproduction may explain it in part, but documents prepared in connection with the legislative process suggest that other factors are also involved.

B. Human Dignity

The protection and promotion of human dignity and human rights are explicitly referred to in section 2 of the *AHRA* as principles that must guide its application, but the *Act* itself does not provide any further interpretive insight. The *AHRA* was based on the work carried out by the Royal Commission, which recommended that human zygote/embryo research related to animal-human hybrids and the transfer of zygotes to another species be prohibited under threat of criminal sanction.[111] The Commission grounded its recommendations on an exploration of the attitudes of Canadians and on its own ethical reasoning. Its

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105 Standing Committee Report, *supra* note 14.

106 Such diseases are referred to as "zoonoses".

107 Wendong Li *et al.*, "Bats Are Natural Reservoirs of SARS-Like Coronaviruses" (2005) 310 Science 676; Dennis Normile, "Researchers Tie Deadly SARS Virus to Bats" (2005) 309 Science 2154.

108 Declan Butler, "Family Tragedy Spotlights Flu Mutations" (2006) 442 Nature 114.

109 See Health Canada, *Proposed Canadian Standard for Xenotransplantation, Draft 14*, available upon request from Health Canada.

110 These animals are generally isolated from the outside world in a way that human beings cannot be, so the potential risk in this case may be smaller.

111 Commission Report, *supra* note 10 at 637.

report notes that certain manipulations, such as interspecies crosses, are unethical in themselves when applied to human beings, and contrary to the Commission's ethical principles and the values of Canadians.[112] The creation of an animal-human hybrid would deny the embryo's connection to the human community, and thus violates human dignity.[113]

The House of Commons Standing Committee on Health commented that both the transplantation of animal reproductive material into a human[114] and the use of human reproductive material or an *in vitro* embryo that was transplanted into a non-human life form for reproductive purposes[115] contravene human dignity, without providing further explanation.

The perception that animal-human combinations offend human dignity seems central to the legislative choices made in the *AHRA*, but very little is in fact offered to support this viewpoint. In the bioethics literature the concept of human dignity remains an elusive one, readily invoked (especially in the field of biotechnology) but without a common meaning and often without adequate explanation concerning how and why it is infringed.[116] A common justification for attributing dignity to human beings is that, because they share certain characteristics, they should be treated as ends in themselves.[117] Basing dignity on the possession of these characteristics, of course, begs the question of what to do with human beings that do not possess them, or beings other than humans who do. These questions are far from resolved.

In international instruments, all born members of the human species have human dignity, which grounds their enjoyment of human rights.[118] According to article 1 of the *Universal Declaration on the Human Genome and Human Rights*,[119] the human genome at the level of the species is what grounds the recognition of humanity and of an individual being's dignity. Thus, some international instruments display a "species-centric" approach to human dignity.

The prohibitions in the *AHRA* appear to cluster around the exchange or combination of reproductive material or very early developmental material between species. They focus on cases in which the animal-human combination may affect the apparent "human" character of the resulting being, making it no longer wholly human. This tends to support a "species-centric" view of dignity.

If that is the underlying logic of the *AHRA*, the prohibition against creating chimeras at the embryonic, but not the fetal or later, stage may seem like an omission. It may be that a fetus—defined in the *AHRA* as the human being from the fifty-seventh day of development—is already sufficiently developed that its "human" character would not be affected by the combination. However, manipulation at this stage could still have profound effects on the developing organism. It may also be that a fetus affected with a disease could benefit from cell therapy, and that this possibility would make chimeras at the fetal stage a matter for regulation rather than prohibition. That this avenue is left open (although it may be regulated at a later date) suggests that the possibility of therapy may be a better example of

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112 *Ibid*. According to the Commission, there is widespread agreement among Canadians that the formation of animal-human hybrids and the gestation of human zygotes in the uterus of another species are unacceptable.

113 See *ibid*. at 55 for a brief discussion of the Commission's view on human dignity.

114 Standing Committee Report, *supra* note 14.

115 *Ibid.*

116 Timothy Caulfield & Roger Brownsword, "Human dignity: a guide to policy making in the biotechnology era?" (2006) 7:1 Nature Reviews Genetics 72. See also Jason Scott Robert, "The science and ethics of making part-human animals in stem cell biology" (2006) 20:7 Federation of American Societies for Experimental Biology Journal 838 [Robert, "Science and Ethics"].

117 The question of which characteristics confer dignity on human beings (and whether any number of them is necessary or sufficient for this) is a controversial one and will not be dealt with here in any detail. It has been argued, in the context of discussions on chimeras, that the capacities required for human dignity include not only the ability to reason, choose freely, and act for moral reasons, but also the ability to use a sophisticated language, function in a complex social network, develop a worldview, and display empathy and sympathy, for example. Philip Karpowicz, Cynthia B. Cohen & Derek van der Kooy, "Developing Human-Nonhuman Chimeras in Human Stem Cell Research: Ethical Issues and Boundaries" (2005) 15:2 Kennedy Institute of Ethics Journal 107 [Karpowicz, Cohen & van der Kooy].

118 See *Universal Declaration of Human Rights*, GA Res. 217(III), UN GAOR, 3d Sess., Supp. No. 13, UN Doc. A/810 (1948) 71, [*UDHR*] art. 1 , which states: "All human beings are born free and equal in dignity and rights." It is interesting in connection with this to note that the *Canadian Charter of Rights and Freedoms*, Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (U.K.), 1982, c. 11, and the *Canadian Human Rights Act*, R.S.C. 2985, c. H-6, do not mention dignity at all, while the *Canadian Bill of Rights*, S.C. 1960, c. 44 mentions it in its preamble. In contrast, all the provincial and territorial human rights legislation refers to human dignity, some referring to the *UDHR*.

119 GC Res. 29 C/16, UNESCO(OR), 29 Sess., (1997), GA Res. 152, U.N. GAOR, 53d Sess., U.N. Doc. A/RES/53/152 (1999) [1997 Declaration].

respect for human dignity than the preservation of the "pure" human character of the developing human being.

It is interesting in this respect to note that although chimeras (in the *AHRA*, the combination of cells of animal or human origin with a human embryo) may not be produced at all, hybrids may not be produced for *reproductive purposes*. The human embryo is granted a status that does not permit it to be mixed with "other" biological material at all. On the other hand, the human "embryo" that would result from cross-species fertilization can apparently be created and then destroyed for research purposes. This also supports the idea that a "species-centric" view of human dignity underlies some of the prohibitions included in the *Act*, and raises anew the question of the status of an "embryo" created by introducing a human nucleus in a non-human egg. As a "hybrid" under the *AHRA*, this embryo may not be created for reproductive purposes, but could be created for experimental purposes (unless regulations provide otherwise in the future). As previously discussed, this embryo would be genetically mostly human,[120] yet it seems to be treated differently.[121]

The regulations adopted pursuant to the *AHRA*, when known, may allow us to draw better conclusions about the conception of human dignity underlying the current regulatory scheme for animal-human combinations.[122] How the creation of a chimera using an animal embryo and human cells will be treated, for example, could be revealing. Concerns have been expressed that this type of manipulation could result in a being with "almost-human" attributes,[123] such as increased cognitive ability.[124] From the perspective that bases human dignity on the possession of a cluster of capacities, this creates concern: some feel that creating a chimera using an animal embryo and human cells violates human dignity, because the human capacities tied to dignity would be transferred to an organism unable to fully exercise them due to physical limitations.[125] Others are afraid of our probable failure to treat such a creature appropriately.[126] Interestingly, both viewpoints approve of the prohibition of experiments involving the transfer of human pluripotent cells into non-human primate blastocysts found in the American Guidelines.[127] The Canadian *Stem Cell Guidelines* currently take a more restrictive stance, prohibiting this type of experiment for all animal embryos and fetuses.[128]

This brief exploration of human dignity as a basis for the regulation of animal-human combinations confirms a recent observation: in a pluralistic society "human dignity", although an ill-defined concept, can justify prohibitions on biotechnology because of its "constructive ambiguity".[129] Despite this, a better articulation of the reasons why certain animal-human combinations are seen as violations of human dignity is clearly required.[130]

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120 See *supra* note 53.

121 This difference in treatment may be due to an assumption that this "embryo" cannot develop and is not therefore a potential human life; however, that assumption cannot be fully tested without contravening the *Act*, since hybrids cannot be created for "reproductive purposes". Some insight may be gained into this question by allowing *in vitro* development of these embryos for a length of time. No legislative or regulatory provisions currently govern the time periods during which such embryos might be kept *in vitro*.

122 Although at first blush experiments involving animals and human cells, or animal and human genes, may seem to lie outside the scope of the *AHRA*, the definition of "human reproductive material" includes human cells and genes, which would allow these types of experiments to be classified as research-related to assisted human reproduction. It is by no means certain, however, that regulations concerning additional chimeras will in fact be adopted under the *AHRA*.

123 This possibility is taken seriously by some legal scholars, who have discussed the granting of personhood to certain kinds of chimeric or transgenic animals: D. Scott Bennett, "Comment: Chimera and the Continuum of Humanity: Erasing the Line of Constitutional Personhood" (2006) 55 Emory L.J. 347; Michael D. Rivard, "Comment: Toward a General Theory of Constitutional Personhood: A Theory of Constitutional Personhood for Transgenic Humanoid Species" (1992) 39 UCLA L. Rev. 1425.

124 A similar concern may apply to transgenic animals—assuming that genes involved in human cognition were identified and transferred to close relatives of human beings such as chimpanzee, for example. These types of experiments may be what will be targeted by regulation under section 11.

125 Karpowicz, Cohen & van der Kooy, *supra* note 117.

126 From this perspective, the creation of such "enhanced" animals is not an infringement of human or animal dignity, so long as the resulting being is treated appropriately, given its moral status. Robert Steiffer, "At the Edge of Humanity: Human Stem Cells, Chimeras, and Moral Status" (2005) 15:4 Kennedy Institute of Ethics Journal 347 [Steiffer].

127 *Supra* note 81.

128 *Supra* note 47, ss. 8(2)(4)–8(2)(7).

129 Caulfied & Brownsword, *supra* note 116.

130 *Ibid*.; Robert, "Science and Ethics", *supra* note 116; Steiffer, *supra* note 126.

C. Individuality

Intertwined with human dignity is the notion of individuality, which also seems to play a role in explaining the prohibitions on chimeras found in the *AHRA*. In the creation of a "chimera"[131] cells from a different organism are added to an existing embryo. This embryo already contains all of the genetic instructions necessary to make a human being, if the appropriate environment is provided. The introduction of foreign material from an animal may markedly affect its development and characteristics. The *AHRA* prohibitions can therefore be understood as expressing a concern for preserving the individuality of the future person.

Although the manipulation of a human embryo in this manner most likely involves considerations of human dignity, the prohibition on human-human and animal-human chimeras implies that some notion in addition to that of human dignity is involved. The objection must be not only to the introduction of animal material, but of material that, even if from a human being, will seriously affect the development of the existing embryo and compromise its identity and individuality.

Human individuality and identity are also concerns identified in international instruments, although they are ordinarily mentioned to underline the contribution of factors other than genetics to individuality[132] and to prohibit discrimination against persons on the basis of their genetic identity.[133] They are not discussed in the context of animal-human combinations.[134]

D. Protection of the Human Genome

In addition to more general issues of human dignity and individuality, a concern for the integrity of the human genome underlies the prohibition of certain animal-human combinations. Each individual human being is the embodiment of its expressed genome, giving the genome a personal dimension that places it within the scope of individual autonomy. However, an individual's genome also has a connection with that of others, because it is transmitted to a person's descendants. Therefore, any changes made by the individual to the personal genome will affect others.

The *AHRA* explicitly prohibits the intentional alteration of the human genome, whether in a human being or an embryo, such that the alteration is capable of being transmitted to descendants.[135] The combination of the human genome with portions of the genome of another species, whether directly (as in making a hybrid or transgenic being) or indirectly (as a result of cell fusion in a chimeric creature[136]) also raises the question of possibly transmissible alterations in the human genome.

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131 As defined in the *AHRA*, *supra* note 8, s. 3.

132 See article 3 of the *International Declaration on Human Genetic Data*, GC Res. 22 UNESCO(OR), 31st Sess., (2003), which reads as follows:

> Each individual has a characteristic genetic make-up. Nevertheless, a person's identity should not be reduced to genetic characteristics, since it involves complex educational, environmental and personal factors and emotional, social, spiritual and cultural bonds with others and implies a dimension of freedom.

See also the preamble to the *Universal Declaration on Bioethics and Human Rights*, GC Res. 36 UNESCO(OR) 33d Sess., (2005) [2005 Declaration], which states that "a person's identity includes biological, psychological, social, cultural and spiritual dimensions".

133 See article 2 of the 1997 Declaration, *supra* note 119, which reads as follows:

> (a) Everyone has a right to respect for their dignity and for their rights regardless of their genetic characteristics.
> (b) That dignity makes it imperative not to reduce individuals to their genetic characteristics and to respect their uniqueness and diversity.

See also article 1 of the Council of Europe, P.A., *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine* (4 April 1997, Eur. T.S. 164, entry in force December 1, 1999) [Oviedo Convention], which states in its relevant part:

> Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine.

134 The *Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings* (12 January 1998, Eur. T. S. 168, entry in force March 1, 2001) seems to consider that cloning, being the process of creating a human being with the same nuclear gene set as another human being, is a threat to the identity of human beings.

135 For a discussion of the dignity debate in the context of transmissible mutations of the human genome, see Law Reform Commission of Canada, *Human Dignity and Genetic Heritage: a study paper* by Bartha Maria Knoppers (Ottawa: Law Reform Commission of Canada, 1991) [Knoppers]; see also Caulfield & Brownsword, *supra* note 116.

136 It could also be queried whether, even if there is no cell fusion and therefore no contact between the two genomes involved in a chimera *in the same cell*, the co-expression of two genomes in the same organism could be seen as threatening the integrity of each of them individually.

One strong argument for avoiding transmissible changes in the human genome is that we currently lack scientific knowledge of the effect of such changes on the gene pool and on the general fitness of the species. Complex gene-environment interactions make this kind of prediction extremely difficult, even in the case of attempting to "correct" apparently deleterious mutations.[137] This uncertainty may apply all the more to modifications that mix animal and human sequences.

Other reasons for specifically protecting the human genome have been expanded upon in international instruments. Unfortunately, these instruments do not deal explicitly with animal-human combinations. As previously mentioned, according to article 1 of the 1997 Declaration, the human genome is what grounds the recognition of humanity and of an individual being's dignity. In addition, as the "heritage of humanity", the human genome (at the level of the species) must be protected as a common resource for future generations.[138] Thus, the modification of one's genome in a transmissible manner seems to exceed the scope of purely individual autonomy and may even threaten the dignity of future humans.

Taken together, these considerations would point towards restricting experiments that might generate beings with a modified, but recognizably human, genome,[139] or at least require that their reproduction be prohibited, a recommendation found in the American Guidelines.[140]

CONCLUSION

This paper has reviewed certain aspects of animal-human combinations in Canada, as regulated by the *Assisted Human Reproduction Act*. Although not entirely in force, the *Act* prohibits the use of non-human reproductive material in humans, the use in humans of human reproductive material previously transplanted into a non-human life form, the creation of chimeras by adding material of non-human origin to human embryos, and the creation for reproductive purposes of human/non-human hybrids. In the future, the creation of some transgenic life forms may also be regulated pursuant to section 11 of the *Act*.

The creation of certain types of animal-human chimeras, such as those obtained by introducing cells of animal origin into a human fetus, and introducing material of non-human or human origin into a non-human embryo, are not currently prohibited activities under the *Act*. The creation of hybrids (including by nuclear transfer) for non-reproductive purposes also appears to be permitted. These activities may eventually be regulated, although no draft regulations concerning animal-human combinations have yet been published. In the meantime, certain differences subsist in Canada between what is permissible for researchers and institutions funded by federal agencies, currently restricted from carrying out certain experiments, and in privately funded research.

Overall, the *Act* seems calibrated to prohibit the creation of animal-human combinations that are currently unsafe, as well as scientifically and ethically problematic, while leaving open the possibility of regulating other such combinations with more immediate scientific potential, although these also raise ethical questions. Despite not being mentioned in the *Act*, freedom of research seems to have been an important consideration underlying this scheme. A recognition that benefits flow from research is found in subsection 2(b), which states that the protection and promotion of human health, safety, dignity, and rights is the best way to secure the benefits of research related to assisted human reproductive technologies for individuals and society. Thus, freedom of research must be exercised in a way that takes ethical considerations into account, and experiments must be scientifically valid and ethically justifiable.[141] The development of the regulatory framework under the *Act* will reveal how these various concerns will be balanced against each other.

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137 One example of this is the selective advantage apparently conferred on carriers of the sickle cell disease trait against malaria mortality, despite the high mortality rate among homozygotes. See Michael Aidoo *et al.*, "Protective effects of the sickle cell gene against malaria morbidity and mortality" (2002) 359 Lancet 1311.

138 This concern is also present in the 2005 Declaration, *supra* note 132, which states at article 16 that "the impact of life sciences on future generations, including on their genetic constitution, should be given due regard", and in the *Oviedo Convention*, *supra* note 133, article 13 of which permits only preventive, diagnostic, or therapeutic interventions on the genome, that do not aim to introduce changes in the genome of descendants. For a critique of this "naturalist" or static approach, see Knoppers, *supra* note 135.

139 The question of what is a "human genome" is of course raised here; much like the question of what is a "human being", it is a difficult question that reaches well beyond the scope of this paper.

140 American Guidelines, *supra* note 81, recommendation 3(c)(iii).

141 This is discussed in the context of chimeras in Robert, "Science and Ethics", *supra* note 116.

INTERFACE OF LAW & ETHICS IN CANADIAN RESEARCH ETHICS STANDARDS: AN ADVISORY OPINION ON CONFIDENTIALITY, ITS LIMITS, & DUTIES TO OTHERS

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In special relationships clothed with duties of professional secrecy, what instances—if any—justify an infringement of confidentiality? The question is an old one. But new contexts and considerations keep the issues alive. Thirty years after the California Supreme Court recognized a limited duty-to-warn exception to strict confidentiality standards in mental health treatment, the principles of the Tarasoff *case continue to exert influence beyond the U.S. health law milieu from which they arose. For instance, to help secure participation in research involving humans, researchers will typically assure human subject/participants, as part of the informed consent process, of the general confidentiality of participants' information. Sometimes, however, those conducting research on prostitution, drug use, illegal behaviour, family abuse, infectious diseases, etc., will discover legally or socially sensitive information from participants that implicates risks to third parties. In such circumstances, do Canadian human research ethics standards impose a "*Tarasoff*-like duty" on researchers to infringe confidentiality when necessary to warn identified at-risk individuals? To answer the question as part of its mandate to provide independent, multidisciplinary advice on the interpretation, use, and evolution of the federal* Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans *(TCPS), the Interagency Advisory Panel on Research Ethics has developed an advisory opinion, "Researchers and the Duty to Warn: Limits on the Continuum of Confidentiality?" The opinion elaborates the TCPS approach for balancing respect of confidentiality with other public interests, like human safety, in this conflict of societal values and sometimes competing duties.*

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[**] The views expressed in the following advisory opinion are those of the Interagency Advisory Panel on Research Ethics; they do not necessarily reflect those of the federal granting agencies or the Government of Canada. PRE members who participated in this opinion are: Marlene Brant-Castellano, Trent University, Aboriginal Studies; Norman Frohlich, University of Manitoba School of Business; Anne Dooley, Community Member, Saskatchewan; Pierre Deschamps, McGill University Faculty of Law & Canadian Human Rights Tribunal; Paul Johnson, PreCarn Incorporated; Derek J. Jones (*ex officio*), Interagency Secretariat on Research Ethics; Ian Mitchell, University of Calgary, Bioethics & Faculty of Medicine; Sam Ludwin, Queen's University Faculty of Health Sciences; Florence Piron, University of Laval Department of Information and Communications; and Susan Sykes, University of Waterloo Office of Research Ethics, and Department of Psychology. In cases of real, perceived, or potential conflict of interest regarding a TCPS interpretation question and a PRE member, the concerned member is recused from participating in developing PRE's response.

I
PROLOGUE

And the seasons they go round and round...
We're captive on the carousel of time.
We can't return, we can only look
Behind from where we came...[1]

A. A Duty to Warn: From *Tarasoff* to Research Ethics?

As with the retro-trends in pop culture, some legal themes from the 1970s continue to offer their insights, and those insights sometimes infuse ethics. In this sense, a recent advisory opinion on confidentiality from the Government of Canada's Interagency Advisory Panel on Research Ethics (PRE) should be of interest to scholars, lawyers, researchers, ethicists, universities, policy analysts, and committees that conduct ethical review of research involving human participants. As background to PRE's advisory opinion, below, this prologue (i) summarizes the 1970s court decision that has prompted research ethics issues, and (ii) outlines PRE's role in developing advisory opinions on such issues.

Thirty years ago, the California Supreme Court decided *Tarasoff v. Regents of University of California*.[2] The landmark case arose at the campus of the University of California at Berkeley in the late 1960s, after a patient confided to his university psychotherapist his intention to kill his girlfriend. Unfortunately, he then proceeded to do so. Neither the girlfriend nor her family was warned of the intention. The family sued the psychotherapist for negligence.

The facts presented a question: does a professional, cloaked with obligations of confidentiality, nevertheless owe a duty to an identified third party at imminent risk of serious harm? In theory, such a duty might flow from various sources—for example, ethico-legal responsibilities for preventing harms, moral conduct becoming the professional, a vision of public responsibilities in civic society. If the court were to respond yes to the question, then the omission or the failure to act on a legal duty may ground liability. Indeed, the court found that affirmative legal duties of care to third parties may arise from special relationships, like that shared by a patient and her or his physician or psychotherapist. The court concluded that when necessary to avert serious and foreseeable danger to third parties, a legal duty to exercise reasonable care to protect them may include a limited duty to warn.

An important dimension of *Tarasoff* was its recourse to professional ethics norms to inform the legal analysis. Professional ethics norms serve many purposes. They provide principled guidance for situational ethics, are thought to further professional integrity, and provide formal accountability to one's peers, clients, and the public. Since the 1950s, the code of ethics of the American Medical Association had provided that physicians keep the confidences entrusted to them "unless ... required to do so by law or unless it becomes necessary in order to protect the welfare of the individual or of the community".[3] The exception recognizes that legal duties or moral necessity may shape the precise contours and paramount obligations in commitments of professional secrecy.

B. Making, Breaking, & Telling Secrets: Amid the Duties

Following the decision, the case was remanded for trial, before which the parties agreed to settle the lawsuit. The *Tarasoff* decision thus entered the annals of law. Over three decades, it has proved to be a touchstone for evolving thought on legal and ethical duties in the making, breaking, and telling of secrets. The issues have arisen in varied contexts of health law, professional practice, public policy, and the ethics[4] of conflicting obligations. *Tarasoff* duties to warn have thus been incorporated into ethical codes and statutory standards of care for mental health professionals in many jurisdictions in the United States.[5]

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1 Joni Mitchell, "The Circle Game," *Ladies of the Canyon LP* (1970).

2 17 Cal. 3d 425, 551 P.2d 334, 131 Cal. Rptr. 14 (Cal. 1976) [*Tarasoff*].

3 *Ibid*., at 347. See American Medical Association, *Code of Medical Ethics: Opinions with Annotations* (Chicago: American Medical Association, 2006-2007) at 136, art. 5.05.

4 See e.g. David B. Resnick & Richard R. Sharp, "Protecting Third Parties in Human Subjects Research" (2006) 28:4 IRB: Ethics & Human Research 1.

5 Paul B. Herbert & Kathryn A. Young, "*Tarasoff* at Twenty-Five" (2002) 30 Journal of the American Academy of Psychiatry and the Law 275.

U.S. courts have also applied *Tarasoff* to questions of whether health professionals have a duty to warn family members about avertable genetic risk from transmissible diseases diagnosed in their patients.[6] Analysts have asked whether health professionals have a duty to warn third parties at risk of infection from sexually transmitted diseases or from public health contagion.[7]

Tarasoff has also influenced international analyses.[8] Indeed, shortly after the California Supreme Court decision, *Tarasoff* was considered in Canadian mental health law jurisprudence.[9] The duty to warn has since been debated in the Canadian literature.[10] More recently, *Tarasoff* has been drawn upon in a case that asked whether in the exercise of reasonable ethical discretion the concerned professional may, in exceptional circumstances, breach confidences. Though the case did not directly concern an affirmative duty to warn, the Supreme Court of Canada positively noted the reasoning of the *Tarasoff* court, and outlined a public safety exception to the high confidentiality requirements of the solicitor-client relationship.[11]

Such developments have prompted questions on whether a duty to warn applies to the responsibilities of researchers who collect confidential, and sometimes legally sensitive, data from research participants. The advisory opinion below addresses such issues from the perspective of Canada's *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*.[12]

C. The Tri-Council Policy Statement

PRE was created by the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council of Canada to provide multidisciplinary and independent advice on the evolution, use, and interpretation of their joint research ethics policy, the TCPS.

Since its release in 1998, the TCPS has been formally adopted by most universities and many colleges in Canada. Institutions do so as a condition for the receipt of funding from the above agencies, meaning that they agree to develop and apply TCPS norms to research conducted under their auspices.[13] This contractual approach contrasts with a federal or central regulatory model of human research statutes in countries like the United States[14] or France.[15] Canada has no equivalent national human research law. Instead, it relies on a mosaic of relevant federal[16] or provincial research,[17] privacy, and consent[18] laws, policy norms, and ethical[19] and professional[20] standards. In this mosaic of Canadian norms, the breadth of

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6 *Safer v. Estate of Pack*, 677 A.2d 1188 (N.J. Super. Ct. App. Div. 1996). See generally Martin Letendre, "Le devoir du médecin de prévenir les membres de la famille d'un patient atteint d'une maladie génétique" (2004) 49 McGill L.J. 555.

7 See William J. Curran & Larry Gostin, "AIDS Screening, Confidentiality, and the Duty to Warn" (1987) 77:3 American Journal of Public Health 361.

8 Danuta Mendelson & George Mendelson, "*Tarasoff* Down Under: The Psychiatrist's Duty to Warn in Australia" (1991) 19:1-2 J. Psychiatry & Law 33.

9 See *Tanner v. Norys*, [1980] 4 W.W.R. 33 (Alta. C.A.).

10 H. E. Emson, "The Duty to Warn in the Canadian Context" (1993) 149 Canadian Medical Association Journal 1781.

11 *Smith v. Jones*, [1999] 1 S.C.R. 455 [*Smith*]. See a description of this case in PRE's opinion, *infra*, at paras. 21 and 28.

12 Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (1998 with 2000, 2002 and 2005 amendments), online: CIHR <http://www.pre.ethics.gc.ca/english/pdf/TCPS%20October%202005_E.pdf> [TCPS].

13 Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, *Memorandum of Understanding on the Roles and Responsibilities in the Management of Federal Grants and Awards* (2002), Sch. 2.

14 Federal Policy (Common Rule) for the Protection of Human Subjects, 56 Fed. Reg. 28003 (1991) (codified in part at 45 C.F.R. § 46).

15 See e.g. *Loi nº 88-1138 du 20 décembre 1988*, J.O., 22 December 1988, as amended.

16 See e.g. Correctional Services Canada, *Commissioner's Directive 009—Research Guidelines 009* (2004); Health Canada, *Regulations Amending the Food and Drug Regulations (1024 – Clinical Trials)*, S.O.R./2001-1042, especially ss. C.05.001, C.05.006, C.05.010(d), C.05.012 (Drugs for Clinical Trials Involving Human Subjects); *Assisted Human Reproduction Act*, S.C. 2004, c. 2, ss. 3, 5, 8–10, 40; Law Reform Commission of Canada, *Biomedical Experimentation Involving Human Subjects* (Ottawa: Law Reform Commission of Canada, 1988).

17 Compare Bill 23, *An Act to Establish a Health Research Ethics Authority for the Province*, 3rd Sess., 45th Leg., Newfoundland, 2006, and *Scientists Act*, R.S.N.W.T. 1988, c. S-4.

18 See e.g. *Civil Code of Québec*, S.Q. 1991, c. 64, arts. 10–11, 20–24 [C.C.Q.].

19 See e.g. *Code of Ethics of Social Workers*, R.R.Q., c. C-26, r. 180, ss. 3.06.01, 4.05.01.

20 Compare *Labrie c. Roy*, [2003] R.J.Q. 18063 (Qc. C.A.) and *Gomez c. Michaud*, [2001] R.J.Q. 2788 (Qc. C.A.) at paras. 84–

the TCPS across diverse research disciplines, its adoption in research institutions throughout the country, and its use by federal and provincial entities as operative guidance, indicate its functions as part of national standards.

A significant innovation of the TCPS flows from one of its founding premises: fundamental research ethics principles transcend disciplinary boundaries to guide and unite health, social and natural sciences, humanities, and engineering research. Some of the transcendent, guiding ethical principles of the TCPS include free and informed consent, minimizing harm and maximizing benefits, respect for privacy and confidentiality, justice, and human dignity.

TCPS principles and standards come into practice at important junctures in the research process. They are intended to help researchers foresee, identify, and address the ethical design and planning of research projects. They should guide prospective review of projects by the interdisciplinary research ethics committees found in most universities. They should also help address ethics issues that arise during research projects. Of course, the principles and standards of the TCPS convey their particular impact in the specifics of a research project. A commitment to the principle of free and informed consent, for instance, may raise conceptual or implementation issues in clinical trials that differ from those raised in participant observation research, or those in research involving communities. For such reasons, the TCPS encourages its users to take a context-centred approach to applying ethical principles.[21] The research discipline and its methods, applicable laws, professional or scholarly norms, and new developments then come into play for the research in question. This interplay is not static. Out of it may arise specific questions about the TCPS.

D. PRE's Role in Interpreting the TCPS: Interdisciplinary Advisory Opinions

As part of its mandate, PRE provides advisory opinions on TCPS issues in response to written queries from researchers, research ethics committees, administrators, etc. The diversity and complexity of the questions vary. But they typically concern issues like textual ambiguities, silences or definitions, research ethics procedure, substantive issues like confidentiality, waivers of consent or children in research, legal issues, and even disputes over the decisions of research ethics committees or institutions. The latter two matters lie beyond the mandate of the PRE. Since it is not designed to be an ethics dispute resolution entity, PRE does not serve as an appeal body for TCPS-related decisions made by institutions or their ethics committees.[22] Nor does it provide legal advice or opinions, though its "analyses may address ethical dimensions of legal issues in research ethics".[23]

PRE's role in interpreting the TCPS thus serves important purposes. It furthers institutional ethical deliberation through the provision of outside interdisciplinary advice on often complex human research ethics questions. External deliberation may help to problem-solve concrete issues, dilemmas, or policy options. Such reflection and problem-solving may, in turn, prompt policy reform. For example, by bringing conceptual, practical, and experiential quandaries of the TCPS to national attention, the interpretation dialogue may identify a need to clarify, address voids in, or otherwise amend the TCPS.

In this context, questions on the applicability of *Tarasoff* in research ethics have been put to PRE. In response, it has developed the following advisory opinion on confidentiality, its limits, and the duty to warn under the TCPS. Because the advisory opinion is based on the existing TCPS, it does not discuss whether the TCPS ought to be amended to address more directly a duty to warn in research ethics. Any such amendments or reforms remain for another day.

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85 (applying physician's professional code of ethics to research).

21 TCPS, *supra* note 12 at i.9.

22 See PRE's mandate, online: PRE <http://www.pre.ethics.gc.ca/english/aboutus/mandate.cfm> [Mandate].

23 PRE, *Interpreting the TCPS* (Ottawa: PRE, 2004) at 6.

II
ADVISORY OPINION: RESEARCHERS & THE DUTY TO WARN: LIMITS ON THE "CONTINUUM OF CONFIDENTIALITY?"[24]

Dear Madam/Sir:

1 Thank you for your query concerning the standards and limits of confidentiality under the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS).[25]

You have raised three questions, namely:

- whether the TCPS bestows on researchers a "*Tarasoff* duty" to infringe research participants confidentiality when necessary to warn identified at-risk third party individuals or communities;
- whether any such "*Tarasoff* duty" is triggered by a standard of preventing "significant harms" or by a higher standard of preventing "serious physical injury or death";[26] and
- whether the TCPS requires researchers immediately to inform participants of a researcher's infringement of confidentiality, when done to protect life and limb.

A. Response Summarized

2 Your inquiry has been referred to the Interagency Advisory Panel on Research Ethics (PRE) for advice.[27] As elaborated below, the TCPS acknowledges a dynamic, intricate interface between ethics and law in human research that implicates informational privacy. The TCPS thus deems respect of research participants' privacy and confidentiality a fundamental principle of modern research ethics. It also recognizes that in collecting sometimes sensitive information for research, however, value conflicts may arise between preserving confidentiality and acting on competing ethical or legal duties that advance other societal values.

3 As also noted below, the TCPS does not impose on researchers a so-called *Tarasoff* duty to warn. The TCPS acknowledges that such disclosure duties may arise from other sources (from the law, for example), and recognizes the potential conflict of duties and values. Accordingly, it accommodates ethical deliberations thereon by specifying criteria for evaluating and balancing competing duties: confidentiality should be respected save in narrow and exceptional circumstances that may justify limited infringements, such as disclosure or reporting to protect human "health, life and safety" or to advance other "compelling and specifically identifiable public interests."[28] Some have reasoned that disclosures to avert a "clear, serious and imminent" risk of bodily harm or death to identifiable persons may be justified as a compelling public interest. The reasoning is congruent with the principles of the TCPS. Any such disclosures should be minimized to what is necessary and proportionate to address the compelling public interest in question. Researchers and research ethics boards (REBs) should anticipate and address foreseeable limits on confidentiality early in the design of the research, to enable informed choices of participants, and to help to minimize unanticipated urgencies about the methods, duties, scope, and timing of any necessary disclosures. Doing so requires concerted multidisciplinary analyses throughout the ethics review process.

B. Introduction: Confidentiality & Value Conflicts

4 As a general matter, we note that an important value conflict underlies your questions. Scholars conducting research on prostitution, drug use, illegal or threatening behaviour, family abuse, infectious diseases, etc., may discover legally or socially sensitive information from participants involved in the

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24 The phrase is adopted from a U.S. case involving confidential research data: *In re Cusamano v. Microsoft Corporation*, 162 F.3d 708 (1st Cir. 1998).

25 Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (1998 with 2000, 2002 and 2005 amendments), online: CIHR <http://www.pre.ethics.gc.ca/english/pdf/TCPS%20October%202005_E.pdf> [TCPS].

26 *Smith v. Jones*, [1999] 1 S.C.R. 455 [*Smith*]. See a description of this case in PRE's opinion, *infra*, at paras. 21 and 28.

27 See PRE's mandate, online: PRE <http://www.pre.ethics.gc.ca/english/aboutus/mandate.cfm> [Mandate].

28 TCPS, *supra* note 25 at 3.1.

research. To help secure participation, researchers will have typically assured participants, as part of the informed consent process, of the general confidentiality of participants' information. When it turns out that the collected information implicates high responsibilities to, or risk regarding, third parties, what are the researcher's obligations? On the one hand, society respects and values privacy and confidentiality. On the other hand, society cherishes and values other interests, like the protection of health, safety, and human life.

5 When these two values conflict in the research ethics context, how is the conflict to be addressed? Do privacy and confidentiality prevail? Or, do other societal interests like the protection of safety or life prevail? If neither clearly nor uniformly prevails, how do researchers strike a reasonable balance? Precise guiding criteria for evaluating and weighing the interests or values thus become important.

6 The value conflict and balancing challenge are embedded in both your inquiry and the privacy and confidentiality norms of the TCPS. Accordingly, we begin our response to your query by summarizing the privacy and confidentiality norms of the TCPS from an historic perspective. Then we apply them to your questions.

C. TCPS Privacy & Confidentiality Norms

7 Privacy and confidentiality had already become valued norms of the modern information society by the turn of the last decade, when the TCPS was adopted. As privacy and confidentiality issues prove important to society, they prove important to the research ethics community. Their importance is reflected in at least two sections of the TCPS—the TCPS Ethics Framework and a chapter devoted to their workings in research ethics review.

1. TCPS Ethics Framework

8 Respect of privacy and confidentiality is one of the foundational principles of the Ethics Framework that informs the entire TCPS. As a foundational principle in the Ethics Framework, respect for confidentiality and privacy is important in at least three respects.

9 First, the Ethics Framework explains the source and importance of respect for privacy and confidentiality:

> Respect for human dignity also implies the principles of respect for privacy and confidentiality. In many cultures, privacy and confidentiality are considered fundamental to human dignity. Thus, standards of privacy and confidentiality protect the access, control and dissemination of personal information.[29]

10 Secondly, the Ethics Framework recognizes that even with fundamental ethical principles like respect for confidentiality, the ethics review process may reveal value conflicts: "If the application of principles yields conflicts, then such conflicts properly demand probing ethical reflection and difficult value choices. Such choices and conflicts are inherent in the ethics review process."[30] In other words, putting ethical principles like respect for privacy and confidentiality into the practice of ethics review requires some deliberative weighing and balancing.

11 Thirdly, the Ethics Framework notes a dynamic relationship between ethics and law. It acknowledges, for instance, that the law "affects and regulates" privacy and confidentiality standards for research involving humans.[31] Reasonable and responsible research should respect the law,[32] meaning that research projects that raise privacy or confidentiality issues generally need to adhere to applicable legal and ethics norms. Research professionals, institutions, participants, and ethics committees play vital roles in respecting, testing, and changing legal norms on research ethics, as part of evolving civil society in a democracy. Testing or questioning a legal norm is not synonymous with violating it,[33] and "it is only in

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29 *Ibid*. at i.5.

30 *Ibid*. at i.9.

31 *Ibid*. at i.8.

32 Interagency Advisory Panel on Research Ethics**,** *Reasonably Designed Inclusion and Exclusion Criteria and Applicable Human Rights Legislation* (2003), online: <http://www.pre.ethics.gc.ca/english/pdf/interpretations/Reasonably%20Designed%20Inclusion%20and%20Exclusion%20Criteria%20and%20Applicable%20Human%20Rights%20Legislation_Jan%202003.pdf>.

33 See Ted Palys & John Lowman, "Anticipating Law: Research Methods, Ethics, and the Law of Privilege" (2002) 32:1 Sociological Methodology 1; Geoffrey R. Stone, "Discussion: Above the Law: Research Methods, Ethics, and the Law of Privilege"

very exceptional cases that it might be ethically acceptable for a researcher to violate a current rule of law", as the Norwegian National Committee for Research Ethics in the Social Science and the Humanities has observed.[34] For such reasons, respect for legal norms is often an important principle of the ethical guidelines of professionals involved in research.[35] At the same time, the Ethics Framework of the TCPS recognizes that "legal and ethical approaches to issues may lead to different conclusions" in research ethics, and that such differences may further ethical and legal reflection and reform.[36]

12 The TCPS does not intend that researchers or participants ponder alone the dynamic and intricate interface of law and ethics. Article 1.3 of the TCPS outlines relevant norms for including in the membership of REBs those with ethical and legal knowledge. The multidisciplinary expertise of a duly composed REB is intended to help identify and address the thicket of professional, ethical, and legal issues and requirements that may arise from the application of confidentiality and privacy laws to research. Sometimes, the identification of legal issues by the REB will necessitate scrutiny or formal legal advice by competent local legal counsel to the institution.

2. TCPS Section 3—Privacy & Confidentiality

13 The privacy and confidentiality chapter of the TCPS, section 3, builds on the principles of the TCPS Ethics Framework to outline the standards for the access, control, and dissemination of participants' identifiable personal information in human research. The section indicates that privacy and confidentiality must generally be preserved, unless particular exceptions apply.[37]

3. Privacy & Confidentiality—General Principles

14 Privacy is "a fundamental value, perceived by many as essential for the protection and promotion of human dignity."[38] Privacy standards protect individuals' reasonable expectation of privacy, which may range from spatial privacy to informational privacy interests. Themselves a dimension of privacy, confidentiality standards govern information secrecy norms in professional relationships. When a research participant thus confides personal information to a researcher, the researcher has a general duty not to share the information with others: "Information that is disclosed in the context of a professional or research relationship must be held confidential."[39] The duty is grounded on respect for the person and her or his expectations, autonomy, and privacy rights. The unauthorized use or breach of confidential information may cause harms ranging from reputational to psychological, socio-economic, legal, or dignatory harms.[40] Participants, understandably, have a reasonable expectation that personal information and confidences disclosed for research generally will be kept confidential. Participants are more likely to share such confidences with research professionals who have formal duties of confidentiality. The duty helps further the "trust relationship"[41] between researchers and participants, thus enabling the relationship to benefit society through a methodical processing of information.

4. Privacy & Confidentiality—Exceptions

15 Mindful of the ethical conflicts that may arise over access to, or the use of, personal information, section 3 of the TCPS also outlines exceptions to general confidentiality duties. The use of publicly available or anonymized information, consent of the participant, disclosures required or authorized by

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(2002) 32:1 Sociological Methodology 19; James Lindgren, "Discussion: Anticipating Problems: Doing Social Science Research in the Shadow of the Law" (2002) 32:1 Sociological Methodology 29.

34 Norway, National Committee for Research Ethics in the Social Sciences and the Humanities, *Guidelines for Research Ethics in the Social Sciences, Law and the Humanities* (2001) at Introduction [Norway Guidelines].

35 See e.g. Australian & New Zealand Society of Criminology, *Code of Ethics* (2000) at art. 5 [ANZOC Code]; RESPECT Project, *RESPECT Code of Practice for Socio-Economic Research in the EU* (2004), online: <http://www.respectproject.org/code/respect_code.pdf>.

36 TCPS, *supra* note 25 at i.8.

37 *Ibid*. at 3.1ff.

38 *Ibid*. at 3.1.

39 *Ibid*.

40 See *Ibid*. at 3.1–3.2; National Research Council of the National Academies, *Protecting Participants and Facilitating Social and Behavioral Sciences Research* (Washington, DC: National Academies Press, 2003) at 26–30.

41 *Ibid*. at 3.1.

law, or overriding duties to others, are amongst the recognized exceptions. For instance, the reporting of anonymized information for statistical or disease tracking purposes, under mandatory reporting laws, might pose minor infringements of confidentiality or privacy for important public policy purposes. As well, it is respectful of the autonomy and privacy rights of participants to share identifiable personal information, when a participant consents to the disclosure. Participants may thus waive confidentiality protections, and such waiver of rights and consent to disclosure may limit the researcher's duty of secrecy.

16 The TCPS also recognizes that confidentiality duties may sometimes be limited by responsibilities to third parties:

> The values underlying the respect and protection of privacy and confidentiality are not absolute, however. Compelling and specifically identified public interests—for example, the protection of health, life and safety, may justify infringement of privacy and confidentiality. Laws compelling mandatory reporting of child abuse, sexually transmitted diseases or intent to murder are grounded on such reasoning.[42]

17 Hence, while the TCPS defines respect for privacy and confidentiality as a fundamental ethical principle and societal value, it also indicates that confidentiality duties are neither absolute nor unlimited. This view may distinguish the TCPS from some in the academic literature and from language in some professional codes of conduct.[43] Still, as will be seen, it harmonizes it with many academic analyses, professional codes, recent ethical norms, and leading trends in the law. Under the TCPS, research ethics review helps to put confidentiality and privacy principles and their exceptions into research practice.

D. Post-1998 Developments

18 Since the TCPS functions in an evolving research ethics context, researchers, REBs, research participants, and institutional practices and policy are constantly being shaped by laws, ethics, policy, and professional developments. We note that many relevant professional, policy, and legal developments implicating privacy that have unfolded since the adoption of the TCPS, in 1998, have tended to parallel major elements of the TCPS privacy and confidentiality norms.

1. Flourishing Privacy & Confidentiality Norms

19 For instance, amid evolving debates in the scholarly literature, professional groups and government entities in and beyond Canada have, over the last few years, developed and refined ethical guidelines, policy, and laws pertinent to privacy and confidentiality principles in human research ethics. Some of the newer professional standards offer specific ethical guidance to social science researchers. The British and Australian societies of criminology, for example, have adopted revised or new codes of ethics that outline privacy as a fundamental ethical obligation, subject to limited exceptions.[44] So do revised ethical principles for American psychologists, social workers, and epidemiologists, Norwegian researchers in the social sciences and humanities, and social anthropologists in the United Kingdom.[45] The approach of affording high protections to privacy and confidentiality subject to narrow, limited exceptions has also been integrated into privacy legislation adopted since 1998 in Canada,[46] the United States,[47] and the

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42 Ibid. at 3.1.

43 Compare e.g. American Sociological Association, *Code of Ethics* (1997) at art. 11.02, online: <http://www.asanet.org/galleries/default-file/Code%20of%20Ethics.pdf> [ASA Code] (referring to absolute confidentiality); Rik Scarce, "(No) Trial (But) Tribulations: When Courts and Ethnography Conflict" (1994) 23 Journal of Contemporary Ethnography 123 (absolute confidentiality); Michael Traynor, "Countering the Excessive Subpoena for Scholarly Research" (1996) 9:3 Law & Contemp. Probs. 119 at 119: "To date, neither legislatures nor courts have granted researchers an absolute privilege to protect the confidentiality of their research data."; Sissela Bok, *Secrets: On the Ethics of Concealment and Revelation* (New York: Vintage Books, 1989) at 116–125 (limits of confidentiality).

44 ANZOC Code, *supra* note 35; British Society of Criminology, *Code of Ethics for Researchers in the Field of Criminology* (2003) [BSC Code].

45 American Psychological Association, *Ethical Principles of Psychologists and Code of Conduct* (2002) at art. 4, online: <http://www.apa.org/ethics/code2002.pdf> [APA Code]; U.S., National Association of Social Workers, *Code of Ethics* (1999) (ethical standards are set out at s. 5.02(l)); American College of Epidemiology, *Ethics Guidelines* (2000) at s. 3.5, online: <http://www.acepidemiology2.org/policystmts/EthicsGuide.pdf> [ACE Guidelines]; Quebec, *Code of Ethics of Physicians*, O.C. 1213–2002, 23 October 2002, G.O.Q. 2002.II.5574, arts. 20(5), 28, 30; Norway Guidelines, *supra* note 34; Association of Social Anthropologists of the United Kingdom and the Commonwealth, *Ethical Guidelines for Good Research Practice* (1999) at paras. 5(c), 5(d), online: <http://www.theasa.org/downloads/Ethical_guidelines.pdf> [ASAUKC Guidelines]; BSC Code, *ibid.*, at art. 4.

46 See e.g. *Personal Information Protection and Electronic Documents Act*, S.C. 2000, c. 5, s. 7(4) [*PIPEDA*] (privacy principles and exceptions).

European Union.[48] The developments provide a resource base for understanding and applying the TCPS in an evolving national and international policy context, consistent with the PRE's mandate[49] to do so.

2. Ethical & Legal Parallels

20 These trends and developments further underscore the evolving and dynamic relationship between ethics and law envisaged by the TCPS. In this regard, it is instructive to note that since the initial publication of the TCPS, the Supreme Court of Canada has further developed its analysis of privacy and confidentiality principles, and has done so in a manner consistent with the standards of the TCPS. Under the approach, privacy is treasured as a fundamental democratic value that is integral to human dignity and "essential to maintaining relationships of trust".[50] The view is consistent with the TCPS approach to privacy as integral to the trust relationship between participants and researchers.[51]

21 The view also helps explain why a duty to maintain confidences functions critically between health care workers and patients, solicitors and clients, researchers and participants, and like professional relations grounded on trust. The confidential information that individuals entrust to such professionals enables the relationship to serve an important public good—like the provision of health care, legal advice in the justice system, or research data that advances the frontiers of knowledge and public policy. However, even with such highly valued relationships, the interests and values protected by privacy and confidentiality may sometimes be reasonably limited or infringed by other competing democratic values.[52] In short, as within the TCPS, the Supreme Court has indicated that "even the fundamentally important right to confidentiality is not absolute" and sometimes must be "balanced against other compelling public needs."[53] As elaborated below, this standard is substantively identical to the TCPS standard for justifying limited infringements of confidentiality and privacy.

22 Against the background of the TCPS privacy norms and some of the leading post-1998 developments that parallel them, we turn to your questions.

E. Researchers' Duties: Participants & At-Risk Third Parties

1. The Dilemma: A TCPS Duty to Warn?

> [T]he therapist's obligations to his patient require that he not disclose a confidence unless such disclosure is necessary to avert danger to others, and even then that he do so discreetly, and in a fashion that would preserve the privacy of his patient to the fullest extent compatible with the prevention of the threatened danger.... We conclude that the public policy favoring protection of the confidential character of patient-psychotherapist communications must yield to the extent to which disclosure is essential to avert danger to others. The protective privilege ends where the public peril begins.[54]

23 You ask whether the TCPS bestows a "*Tarasoff* duty" on researchers, and if so what are the contours of the duty? By a "*Tarasoff* duty" we understand the phrase to refer generally to a professional's overriding duty of care to share information that an individual has confided to the professional; the professional's disclosure of confidential information aims to avert serious and imminent harm to identified third parties. As the excerpt above suggests, such a duty to third parties was outlined decades ago in a famous U.S. legal case. It involved a health professional who was alleged to have a duty to warn or alert third parties about an imminent risk of serious harm, revealed in confidential information, that one of his dangerous patients shared with him.[55] The court resolved the value conflict between respecting confidentiality of the patient and protecting the safety of another by finding that a health professional so situated may owe an at-risk third party a duty of reasonable care, which may include a limited duty to

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47 See e.g. *Standards for Privacy of Individually Identifiable Health Information*, 45 C.F.R. § 164.510 (2002).

48 European Community, *Commission Directive 95/46/EC of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data*, [1995] O.J. L 281/31 at arts. 8, 13 [*Privacy Directive*].

49 See Mandate, *supra* note 27.

50 *R. v. Mills*, [1999] 3 S.C.R. 668 at paras. 82, 89 (right of privacy of crime victim's counselling records).

51 TCPS, *supra* note 25 at 3.1.

52 See *Smith*, *supra* note 26 at para. 51.

53 *Ibid*. at 74 (public safety exception to the solicitor-client confidentiality). See also *A.M. v. Ryan*, [1997] 1 S.C.R. 157 at para. 24 [*Ryan*] (confidential psychiatrist-patient communications).

54 17 Cal. 3d 425, 551 P.2d 334, 131 Cal. Rptr. 14 (Cal. 1976) at 347 [*Tarasoff*].

55 *Ibid*.

warn. Such limited duties to warn have since been recognized in Canadian professional codes of practice,[56] and discussed in the literature on research ethics.[57]

24 In this context, the TCPS recognizes and accommodates ethical and legal duties to warn, rather than imposing them. Section 3 recognizes that duties to third parties may arise from legal or professional obligations. The TCPS thus acknowledges that other high societal values and duties may sometimes intersect with privacy and confidentiality principles to require limited infringements of privacy or confidentiality, so as to advance "compelling and specifically identifiable public interests"—like the protection of health or safety.[58]

25 In other words, the TCPS foresees that research professionals may sometimes face difficult ethical choices: strictly respect a participant's confidentiality or share some confidential information with appropriate individuals or entities, to avoid a serious and imminent risk of harm to others. By implication, the TCPS leaves to the researcher and the REB—guided by professional guidelines, the particular facts, and relevant ethical and legal[59] duties—the important ethical deliberations that will define any precise duties of disclosure under the circumstances.

2. A Threshold of Harm to Infringe Confidentiality?

26 With respect to the kind of harm that triggers a duty to warn, you ask whether the TCPS permits infringements of confidentiality either to prevent "significant harms" to others or to prevent "serious threats of serious physical injury or death" to identifiable individuals, communities, and the like. The TCPS does not use or rely on such language to specify a threshold for justifying infringements of confidentiality or privacy.

27 Rather, in explaining why "the values underlying the respect of privacy and confidentiality are not absolute," the commentary to section 3 of the TCPS indicates that "[c]ompelling and specifically identifiable public interests, for example the protection of health, life, and safety, may justify infringement of privacy and confidentiality."[60] This suggests that in value contests or conflicts the cherished principle of privacy will often win, but not always because it may not in all circumstances be considered paramount or predominant in the hierarchy of public values. The TCPS observes that laws "compelling mandatory reporting of child abuse, sexually transmitted diseases or intent to murder are grounded on such reasoning."[61] The TCPS language in this context is consistent with the broader TCPS approach to exceptions to fundamental ethical principles—that is, to "preserve the values, purpose and protection that they attempt to advance",[62] exceptions to the principles should be narrow, specific, and limited. Here, the language used to indicate that infringements of privacy should be narrow and limited is that they must be justified for "compelling and specifically identified public interests".[63] The examples of "identified public

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56 See Canadian Psychological Association, *Canadian Code of Ethics for Psychologists* (2000) at arts. I.45, IV.17, IV.18, online: <http://www.pre.ethics.gc.ca/english/pdf/links/Canadian%20Code%20of%20Ethics%20for%20Psychologists%20_2000.pdf> [CPA Code].

57 See e.g. Paul S. Appelbaum & Alan Rosenbaum, "*Tarasoff* and the Researcher: Does the Duty to Protect Apply in the Research Setting?" (1989) 44 American Psychologist 885; Daryl Pullman & Kathy Hodgkinson, "Genetic Knowledge and Moral Responsibility: Ambiguity at the Interface of Genetic Research and Clinical Practice" (2006) 69:3 Clinical Genetics 199.

58 TCPS, *supra* note 25 at 3.1.

59 Such legal duties may arise from diverse sources, including relevant national, international, or provincial legal obligations. On the one hand, for instance, article 2 of the Quebec *Charter of human rights and freedoms* imposes on citizens a duty to aid those whose life is in peril, unless doing so places one in danger or unless there is another legitimate reason for not doing so. On the other hand, researchers bound by the federal *Statistics Act* or relevant provincial data collection laws that generally exclude secondary use of information collected for research purposes need to understand and respect the precise privacy standards, including any applicable exceptions. See *Charter of human rights and freedoms*, R.S.Q. c. C-12; *Statistics Act*, R.S.C. 1985, c. S-19, ss. 17–18 [*Statistics Act*]. See also *Personal Health Information Protection Act*, S.O. 2004, c. 3, Sch. A, ss. 6, 12, 18.

60 TCPS, *supra* note 25 at 3.1.

61 *Ibid*. On the research ethics challenges involving child neglect or abuse reporting laws, compare Camil Bouchard, "Recherche épidémiologique sur la violence envers les enfants: enjeux éthiques" (1998) 17:2 Canadian Journal of Community Mental Health 79; Joan E. Seiber, "Issues Presented by Mandatory Reporting Requirements to Researchers of Child Abuse and Neglect" (1994) 4:1 Ethics and Behavior 1; and *Child and Family Services Act*, R.S.O 1990, c. C-11, s. 72(1)ff.

62 *Ibid*. at i.9.

63 *Ibid*. at 3.1. Other national and international privacy and ethics standards have identified similar "public interests" that may justify limited infringements of privacy protections, such as national security, public safety, prevention of crime, protection of public health, etc. See e.g. *PIPEDA*, *supra* note 46, s. 7(4) and *Privacy Directive*, *supra* note 48 at art. 8.

interests" given in the TCPS indicate that they are illustrative, not exhaustive. The scope of any disclosure should be guided by a proportionality principle recognized in the TCPS: it should be limited in scope to what is reasonably proportionate to respond to the "compelling" interest at hand, thus "minimizing any necessary invasions"[64] of privacy.

28 The word "compelling" thus limits the range of "public interests" to beyond those which may be regarded as minimal; to be "compelling" they should be objectively serious or significant and not remote. For instance, a serious or significant physical or safety risk, or public peril is more likely to be considered compelling the more it is impending, imminent, or proximate, as opposed to remote and distant. As such, identified public interests need to be evaluated in the context of the particular circumstances and facts to determine whether they objectively qualify as "compelling." As noted above, it is instructive that important decisions in privacy law since the adoption of the TCPS have similarly interpreted the word "compelling" to justify limited infringements of confidentiality. Such decisions have reasoned that a "clear, serious and imminent risk" of bodily harm or death to an identifiable group or person constitutes a "compelling public interest" that may justify a limited public safety exception to the normal duty of confidentiality.[65] The reasoning is congruent with the logic, principles, and standards in the balancing approach outlined under the TCPS for infringements of privacy or confidentiality. Moreover, the principle of respect of law logically gives substantial weight to such standards for research ethics, and facilitates the growth and harmonization of ethical and legal norms.

3. Informing Participants About the Limits of Confidentiality

29 You also ask whether the TCPS requires researchers "immediately to inform participants" when a researcher breaches or infringes confidentiality "to protect life and limb". While the TCPS does not require such conduct, it does oblige researchers to respect reasonable privacy pledges, consistent with the process and principle of free and informed consent, unless there are important reasons for not doing so. Indeed, the TCPS outlines specific informed consent duties regarding the limits of confidentiality.

30 ***Free & Informed Consent:*** Article 2.4 of the TCPS indicates that researchers should provide to prospective participants "full and frank disclosure of all information relevant to free and informed consent".[66] Amongst other things, this includes the purpose of the research, research procedures, reasonably foreseeable benefits, harms, and risks of the proposed research. Informed consent is a continuing "process that begins with the initial contact and carries through the end of the involvement of research subjects in the project".[67] The scope and elements of informed consent should be regarded from the perspective of the precise information that a reasonable research participant would likely find relevant and helpful to making an informed decision to participate.[68] For projects in which participants are likely to find confidentiality issues relevant, researchers need to explain such matters as who will have access to identifiable data, how the data will be used, and "how confidentiality will be protected".[69]

31 From a participant's perspective, the possibility that the researcher may be obligated by legal, professional, or ethical duties to disclose normally confidential information is a foreseeable risk directly relevant to participation. Potential participants need to be able to weigh how high the risk is and to evaluate how likely are the associated harms. They may begin to do so with meaningful conversation on the relevant issues, such as the sensitivity of the information, the precise reporting or disclosure duties, the researcher's practice and procedures under such circumstances, the consequences of such disclosure, etc. On grounds of transparency, honesty, respect for informed consent and privacy, and confidentiality rights, it is reasonable to conclude that a prospective participant would wish to know the limits on confidentiality protections.

32 ***Foreseeing Limits:*** Accordingly, the TCPS specifies that researchers should indicate to participants "the extent of the confidentiality that can be promised, and hence should be aware of the relevant law".[70]

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64 *Ibid*. at 3.2.

65 *Smith*, *supra* note 26. See the discussion of the Supreme Court of Canada's analysis in this advisory opinion, *supra*, at para. 21.

66 TCPS, *supra* note 25 at 2.5.

67 *Ibid*. at 2.1.

68 *Ibid*. at 3.1, 2.1ff.

69 *Ibid*. at 2.7, 3.3, A.6.

70 *Ibid*. at 3.2. See also *ibid*. at 2.5, A.6. Article 3.2 indicates that appropriate protections of privacy and anticipated secondary

As some have urged, participants "should be informed about the nature of the law and the researchers' position regarding it".[71] Responding in part to leading Canadian legal decisions[72] that confidentiality seldom is unlimited or protected absolutely, many researchers and REBs customarily indicate in the informed consent process with participants that confidentiality will be protected "within the limits of the law". The approach is standard and is noted in professional codes beyond Canada.[73] Some researchers go further to specify the particular lengths to which researchers intend to go to protect confidentiality in particular circumstances.[74] Both approaches are inspired by a research professional's ethical duty to anticipate the limits of confidentiality,[75] as an integral part of the design of, and informed consent process for, a research project that may involve ethical and/or legal duties to share legally or socially sensitive information with third parties.[76] For example, beyond its 1997 *Code of Ethics*, the American Sociological Association has more recently addressed informed consent and some limits on confidentiality:

> In some instances, confidentiality cannot be maintained (e.g., mandatory reporting of child abuse), and IRBs [Institutional Review Boards] and investigators need to take this into consideration when evaluating confidentiality protections. It is important to understand and resolve existing conflicts between any confidentiality protections and promises and the reporting statute *before* the research progresses. In such situations, it is also important that all consent forms and processes, and research protocols be designed and administered to describe clearly the limits on confidentiality so that the subjects fully comprehend these limits in determining their participation.[77]

33 ***Research Design:*** Research design and appropriate confidentiality protections and data management procedures—based on scrutiny of confidentiality and its limits in the particular project—should thus shape the methods of research, a researcher's confidentiality pledges,[78] and details of the informed consent process. These issues are key, because under the TCPS a researcher generally "is honour-bound to protect the confidentiality ... undertaken in the free and informed consent process, to the extent possible within the law."[79] Such research design methods should reduce the instances when researchers, REBs, or participants find themselves in an unanticipated conundrum or urgency about the duties, contours, and timing of disclosure of identifying sensitive information to third parties.

34 As a further part of the design of research and continuing consent process, the TCPS suggests that participants should be provided with information that may affect their continuing participation in "a timely manner".[80] Timeliness does not necessarily mean immediately. The timing should be objectively reasonable under the circumstances, taking into account relevant ethical, legal, and professional standards applied to the specific facts. For instance, if informing participants about any necessary disclosure were to defeat the purpose of warning a third party or would be prohibited by law, such disclosure would generally seem unreasonable. If reasonably foreseeable, the timing of potential disclosures should also be anticipated and included in the design of the project and the informed consent process.

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uses of data should be considered as part of the REB review process of research involving identifiable information.

71 John Lowman & Ted Palys, "Subject to the Law: Civil Disobedience, Research Ethics, and the Law of Privilege" (2003) 33 Sociological Methodology 391 at 387 [Lowman & Palys].

72 See e.g. *Smith*, *supra* note 26; *Ryan*, *supra* note 53.

73 See e.g. American Educational Research Association, *Ethical Standards of the American Educational Research Association* (2000) at para. II.B.2; APA Code, *supra* note 45 at art. 4; ACE Guidelines, *supra* note 45 at s. 3.2.

74 Lowman & Palys, *supra* note 71.

75 The duty is outlined in such codes as the ASA Code, *supra* note 43 at arts. 11.03, 11.04; American Academy of Criminal Justice, *Code of Ethics* (2000) at para. III.B.18; ASAUKC Guidelines, *supra* note 45 at paras. 5(b), 5(c); India, National Committee for Ethics in Social Science Research in Health, *Ethical Guidelines for Social Science Research in Health*, (2002) at s. IV.3.2; Norway Guidelines, *supra* note 34 at para. 19.

76 See e.g. ASA Code, *ibid*. at art. 11; CPA Code, *supra* note 56 at art. I.45.

77 American Sociological Association, *Issues in Confidentiality and Research Data Protections: A Report and Draft Recommendations to NHRPAC Social and Behavioral Sciences Working Group*, in National Human Research Protections Advisory Committee, *Recommendations on Confidentiality and Research Data Protections* (Rockville, Maryland: National Human Research Protections Advisory Committee, 2002) at 4 [emphasis added].

78 The TCPS specification that researchers need to be aware of "relevant law" may raise ethical quandaries: if legal standards in the relevant jurisdiction provide no absolute or unlimited confidentiality, then what should a reasonable pledge of privacy say of absolute confidentiality? TCPS principles indicate that, as a minimum, the limits on confidentiality should be discussed as part of the informed consent process. See TCPS, *supra* note 25 at 1.3.

79 *Ibid*. at 3.2.

80 *Ibid*. at 2.6.

F. Conclusion

35 We close by noting that the questions and issues raised above are among the more challenging value conflicts and vexing dilemmas in human research ethics. As such, they merit continued study, interdisciplinary reflection and analysis, and policy development for participants, researchers, legislatures,[81] professional or learned societies, and institutions. In the meantime, we hope the foregoing proves helpful to your TCPS research ethics deliberations.

G. Appendix: Selected Readings

(* = available via the PRE's website: www.pre.ethics.gc.ca/*)*

*American College of Epidemiology, *Ethics Guidelines* (2000), sec. 3.5.
*American Educational Research Association, *Ethical Standards of the American Educational Research Association* (2000) at para. II.B.2.
*American Psychological Association, *Ethical Principles of Psychologists and Code of Conduct* (2002) at sec. 4.
*American Sociological Association, *Code of Ethics* (1997) at sec. 35.
American Sociological Association, *Issues in Confidentiality and Research Data Protections: A Report and Draft Recommendations to NHRPAC Social and Behavioral Sciences Working Group* (2002).
Paul S. Appelbaum & Alan Rosenbaum, "*Tarasoff* and the Researcher: Does the Duty to Protect Apply in the Research Setting?" (1989) 44 American Psychologist 885.
*Association of Canadian Universities for Northern Studies, *Ethical Principles for the Conduct of Research in the North* (2003) at principle 4.
*Association of Social Anthropologists of the United Kingdom and the Commonwealth, *Ethical Guidelines for Good Research Practice* (1999).
*Australian & New Zealand Society of Criminology, *Code of Ethics* (2000).
Bok, Sissela, "The Limits of Confidentiality" in *Secrets: On the Ethics of Concealment and Revelation* (Vintage: New York, 1989) at 116-135.
Bouchard, Camil, "Recherche épidémiologique sur la violence envers les enfants: enjeux éthiques" (1998) 17:2 *Canadian Journal of Community Mental Health* 79.
*British Society of Criminology, *Code of Ethics for Researchers in the Field of Criminology* (2003) at art. 4.
*Canada, Interagency Advisory Panel on Research Ethics, *Interpreting the TCPS* (2004).
*Canada, Interagency Advisory Panel on Research Ethics, Social Science and Humanities Special Research Ethics Working Committee, *Giving Voice to the Spectrum* (2004) at 29-32.
Canada, Parliament of Canada, *Personal Information Protection and Electronic Documents Act (PIPEDA)* (2002) at art. 7(4).
Canadian Institutes of Health Research, *Selected International Legal Norms on the Protection of Personal Information in Health Research* (2001).
Canadian Institutes of Health Research, *A Compendium of Canadian Legislation Respecting the Protection of Personal Information in Health Research* (2000, 2005 update).
*Canadian Institutes of Health, Social Science & Humanities Research Council of Canada, Natural Sciences & Engineering Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct on Research Involving Humans* (1998, with 2000, 2002, 2005 amendments).

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[81] Compare Australian, Canadian and the U.S. legislation protecting identifiable research data from compelled third-party access: Australia, *Commonwealth Epidemiological Studies (Confidentiality) Act 1981* (Cth.); Canada, *Statistics Act*, *supra* note 59 at arts. 17–18; United States, 28 C.F.R. § 22.1ff. (confidentiality of statistical or identifiable information in government-funded or conducted criminological research). U.S., *Education Sciences Reform Act of 2002*; *Public Health Service Act*, 42 C.F.R. § 2a (statutory certificates of confidentiality against involuntary disclosure of sensitive research data).

*Canadian Psychological Association, *Canadian Code of Ethics for Psychologists* (2000) at paras. I.44-I.45.

Cecil, Joe S. & Wetherington, G.T., eds., "Court-Ordered Disclosure of Academic Research: A Clash of Values of Science and Law (Symposium)" (1996) 59:1 Law & Contemp. Probs. 191(articles discussing the issues, needs and cases from diverse perspectives, including the researcher, judge, litigator, scientist, expert witness), online: <http://www.law.duke.edu/journals/lcp/>.

Curran, William J., "Protecting Confidentiality in Epidemiological Investigations by the Centers for Disease Control" (1986) 314 N. Eng. J. Med. 1027, discussing *Farnsworth v. Proctor & Gamble Co.*, 758 F.2d 1545 (11th Cir. 1985) (upholding governmental epidemiology research institute's refusal to disclose participants identities in toxic shock syndrome studies).

Feenan, Dermot, "Legal Issues in Acquiring Information About Illegal Behavior Through Criminological Research" (2002) 42 Brit. J. Criminol. 762.

Herbert, Paul B., Young, Kathryn A., "Tarasoff at Twenty-Five" (2002) 30(2) J. Am. Acad. Psychiatry & Law 275.

*India, National Committee for Ethics in Social Science Research in Health, *Ethical Guidelines for Social Science Research in Health* (2002).

In Re Cusamano & Yoffie v. Microsoft Corporation, 162 F3d 708 (1st Cir. 1998).

Israel, Mark, "Strictly Confidential? Integrity and the Disclosure of Criminological and Socio-Legal Research" (2004) 44 Brit. J. Criminol. 715.

Lingren, James, "Discussion: Anticipating Problems—Doing Social Research in the Shadow of the Law" (2002) 32:1 J. Sociological Methodology 29.

Lowman, John & Palys, Ted, "Subject to the Law: Civil Disobedience, Research Ethics, and the Law of Privilege" (2003) 33:1 J. Sociological Methodology 381.

*Norway, National Committee for Research Ethics in the Social Science and the Humanities. *Guidelines for Research Ethics in the Social Sciences, Law, and the Humanities* (2001).

Palys, Ted & Lowman, John. "Social Research With Eyes Wide Shut: The Limited Confidentiality Dilemma" (2001) 43:2 Cdn. J. Criminology 255.

Palys, Ted & Lowman, John. "Anticipating Law: Research Methods, Ethics and the Law of Privilege" (2002) 32:1 J. Sociological Methodology 17.

Scarce, Rik, "(No) Trial (But) Tribulations: When Courts and Ethnography Conflict" (1994) 23 J. Contemporary Ethnography 123 (discussing *In Re Grand Jury Subpoena*, 750 F.2d 223 [2d Cir. 1984] [graduate student's qualified scholar's privilege in criminal hearing]).

Sieber, Joan E., "Issues Presented by Mandatory Reporting Requirements to Researchers of Child Abuse and Neglect" (1994) 4:1 *Ethics and Behavior* 1.

Smith v. Jones, [1999] 1 S.C.R. 455.

Stone, Geoffrey R., "Above the Law: Research Methods, Ethics, and the Law of Privilege" (2002) 32:1 J. Sociological Methodology 19.

Tarasoff v. Regents of University of California, 551 P.2d 334 (Cal. 1976).

United States, National Academies of Sciences, National Research Council, *Protecting Participants and Facilitating Social and Behaviorial Sciences Research* (Washington, D.C.: National Academies Press, 2001) at 113-141.

United States, National Human Research Protections Advisory Committee (NHRPAC): *Recommendations on Confidentiality and Research Data Protections* (July 2002).

Zinger, I., Wichmann C. & Gendreau, P., "Legal and Ethical Obligations in Social Research: The Limited Confidentiality Requirement" (2001) 43 Cdn. J. Criminology 269.

PRE'S "INTERFACE OF LAW & ETHICS IN CANADIAN RESEARCH ETHICS STANDARDS: AN ADVISORY OPINION ON CONFIDENTIALITY, ITS LIMITS & DUTIES TO OTHERS": THE "LAW OF THE LAND" DOCTRINE IN ALL BUT NAME

John Lowman
& Ted Palys[*]

In 2007 the Interagency Advisory Panel on Research Ethics published its "Advisory Opinion on Confidentiality, Its Limits and Duties to Others". We argue that PRE's "limited confidentiality" perspective effectively promotes a "law of the land" doctrine of research confidentiality because it ignores the alternative "ethics-first" approach which suggests that a priori *limitations on confidentiality rarely make sense.*

PRE's limited confidentiality doctrine emphasizes hypothetical risks that have never materialized as actual harms, and ignores the outcome of cases in which research confidentiality has been challenged in various kinds of legal proceedings. By misreading the jurisprudence on the "public safety exception" to therapist-patient confidentiality in the process of applying it to research confidentiality, by encouraging role conflicts in a way that threatens to turn researchers into informers for police and other authorities, and by failing to acknowledge that there is an alternative to its limited confidentiality approach, PRE's advisory opinion could represent a significant threat to the integrity of the research enterprise and academic freedom in Canada. In the process of emphasizing putative limits to confidentiality, PRE says nothing about the important common law methods that can be used in court to defend a promise of strict research confidentiality. Indeed, it is ironic that North American courts have consistently attached a higher value to research-participant confidentiality than does PRE, which appears prepared to surrender confidentiality to hypothetical threats that have never materialized.

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We thank PRE and the editors of the McGill Health Law Publication for this opportunity to comment on PRE's advisory opinion.

INTRODUCTION

After four and a half years of deliberation the Interagency Advisory Panel on Research Ethics (PRE)[1] has released its advisory opinion on confidentiality.[2] In the following commentary we argue that PRE effectively promotes a "law of the land" doctrine of research confidentiality[3] and ignores an alternative "ethics-first" perspective[4] that adheres to a code of strict confidentiality.

PRE's rationale for limited confidentiality is based on an abstract analysis of law. In this sense it appears to fly in the face of the *Tri-Council Policy Statement* (TCPS) injunction that

> [f]or meaningful and effective application ... ethical principles must operate neither in the abstract, nor in isolation from one another. Ethical principles are sometimes criticized as being applied in formulaic ways. To avoid this, they should be applied in the context of the nature of the research and of the ethical norms and practices of the relevant research discipline.[5]

We assert that the same is true of the analysis of the interface of ethics and law. In contrast to PRE's abstract analysis of law, the ethics-first approach is based on an analysis of the law in action. As we attempt to show in the ensuing discussion, from this perspective, *a priori* limitations on confidentiality rarely make sense.

I
PRE MISINTERPRETS THE LEGAL IMPLICATIONS OF THE *TARASOFF*[6] DECISION

As the *Tarasoff* decision makes clear, "under the common law, as a general rule, one person owe[s] no duty to control the conduct of another"[7] or to warn any person endangered by another person's proposed conduct. It is only when there is a "special relationship" that exceptions are made to this rule in common law. Consistent with this principle, there are only a handful of "mandatory reporting laws" such as those requiring reporting of child abuse and sexually transmitted diseases.[8]

Derek Jones's[9] prologue and PRE's advisory opinion take the phrase "special relationship" to mean "professional", but it was not the psychiatrist's role as a *professional* that led to the court's determination that the psychiatrist was liable; it was the particular *kind of knowledge* that psychiatrists possess and their training and putative *ability to predict propensity for violence* that bestows the duty. The psychiatrist's job includes assessing a patient's dangerousness, which is why psychiatrists have the power under civil commitment laws to lock up a patient if they are diagnosed as posing a threat to themselves or others.

Because it is the psychiatrist's role in the prediction and prevention of violence that the court appeared to find determinative in the *Tarasoff* case, Applebaum and Rosenbaum,[10] in an article that PRE

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1 The Interagency Advisory Panel on Research Ethics is a body of external experts established in November of 2001 by three Canadian Research Agencies—the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council, and the Social Sciences and Humanities Research Council.

2 Interagency Advisory Panel on Research Ethics, "Interface of Law & Ethics in Canadian Research Ethics Standards: An Advisory Opinion on Confidentiality, its Limits & Duties to Others" (2007) 1 *McGill Health Law Publication* 106.

3 See Bruce Clayman, "The Law of the Land" *Simon Fraser News* 10:5 (30 October 1997), online: Simon Fraser University <http://www.sfu.ca/mediapr/sfnews/1997/Oct30/opinion2.html>; James Lindgren, "Discussion: Anticipating Problems—Doing Social Science Research in the Shadow of the Law" (2002) 32 Sociological Methodology 29; Florence Piron, "Réponse à Palys et Lowman" (2006) 21:1 C.J.L.S. 187; Geoffrey R. Stone, "Discussion: Above the Law—Research Methods, Ethics, and the Law of Privilege" (2002) 32 Sociological Methodology 19.

4 See e.g. Social Sciences and Humanities Research Ethics Special Working Committee (SSHWC), "Reconsidering Privacy and Confidentiality in the TCPS: A Discussion Paper" (February 2006), online: Interagency Advisory Panel on Research Ethics <http://pre.ethics.gc.ca/english/pdf/sshwc_consultation_eng.pdf>.

5 Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (2005 with 1998, 2000, 2002 and 2005 amendments), online: Interagency Advisory Panel on Research Ethics <http://www.pre.ethics.gc.ca/english/pdf/TCPS%20October%202005_E.pdf> at i.2 [TCPS].

6 *Tarasoff v. Regents of University of California*, 17 Cal. 3d 425, 551 P.2d 334, 131 Cal. Rptr. 14 (Cal. 1976) [cited to Cal. 3d].

7 *Ibid.* at 435.

8 TCPS, *supra* note 5 at 3.1. The TCPS also mentions "intent to murder" but we know of no such law in Canada. We asked Derek Jones, PRE's Executive Director, what the TCPS is referring to, but he did not know either.

9 Derek Jones is an ex officio member of PRE and Executive Director of its supporting Secretariat.

10 Paul S. Appelbaum & Alan Rosenbaum, "*Tarasoff* and the Researcher: Does the Duty to Protect Apply in the Research Setting?" (1989) 44 American Psychologist 885 at 893.

cites, argue that the *Tarasoff* duty to protect (*not* the "duty to warn" that Jones's prologue and PRE's advisory opinion refer to) would apply *only* in a clinical research setting; it would not apply to researchers in general because most researchers do not have the training to assess adequately the validity of any threat. To impose a duty to protect, courts would have to look at more than just the discipline of the researcher (for example, sociologist versus psychologist); they would have to also consider what form of psychology the researcher practised:

> Social and experimental psychologists without clinical training should fall outside the requirements of the duty to protect, as should relatively untrained research assistants who collect data. Thus one can envisage a variety of research situations to which the duty to protect should not apply.[11]

If Applebaum and Rosenbaum's analysis is correct, any extrapolation of *Tarasoff* to non-clinical research settings is just one more example of the insidious nature of biomedical ethical imperialism that is contaminating research ethics in Canada.

In addition to these problems, PRE's imposition of what it sees as a ubiquitous acceptance of a "duty to warn" distorts the situation even within the psychiatric and psychotherapeutic communities themselves, in which critics outline how *Tarasoff* has changed psychiatrists from caregivers to "the new informants"[12] and agents of law enforcement.[13] In this light, the wholesale importation of the psychiatrist's duty to protect into the research setting encourages and exacerbates the conflict of roles that the TCPS specifically warns researchers to avoid.

II
LIMITING CONFIDENTIALITY MAY ENCOURAGE ROLE CONFLICTS

The TCPS says that researchers

> should separate their role as researcher from their roles as therapists, caregivers, teachers, advisors, consultants, supervisors, students or employers and the like.... Researchers should disassociate their role as researcher from other roles, in the recruitment process and throughout the project.[14]

Further, the TCPS says that "[r]esearchers should avoid being put in a position of becoming informants for authorities."[15]

PRE's strategy of limiting confidentiality so that researchers can protect third parties implies that researchers should assume a police function. For example, if a researcher studying the effects of solitary confinement in prisons informs prospective prisoner research participants that any revelation of a plan to escape will be reported to the prison authorities, the researcher not only effectively rules out receiving information that could throw important light on the effects of solitary confinement, but also actively embraces a police function.

III
PRE'S BOTTOM LINE: CONFIDENTIALITY IS NOT ABSOLUTE

Because it recognizes the potential for duties and values to conflict, PRE says that "confidentiality should be respected save in narrow and exceptional circumstances that may justify limited infringements, such as disclosure or reporting to protect human 'health, life and safety' or to advance other 'compelling and specifically identifiable public interests.'"[16]

Because confidentiality in law is not absolute, PRE argues that "[r]esearchers and research ethics boards (REBs) should anticipate and address foreseeable limits on confidentiality early in the design of the research, to enable informed choices of participants...."[17]

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11 *Ibid*.

12 Christopher Bollas & David Sundelson, *The New Informants: The Betrayal of Confidentiality in Psychoanalysis and Psychotherapy* (Northvale, N.J.: J. Aronson, 1995).

13 Paul B. Herbert, "Psychotherapy as law enforcement" (2004) 32 Journal of the American Academy of Psychiatry Law 91.

14 *Supra* note 5 at 2.8.

15 *Ibid*. at 2.4.

16 *Supra* note 2 at para. 3.

17 *Ibid*.

IV
FALSE DICHOTOMIES MAKE FOR FALSE CHOICES

The TCPS holds that exceptional reasons such as the need to protect health, life, and safety *may* justify limited infringements of confidentiality. In these circumstances, what are the researcher's obligations? "On the one hand, society respects and values privacy and confidentiality. On the other hand, society cherishes and values other interests, like the protection of health, safety, and human life."[18]

But what if the purpose of research confidentiality is to gain reliable information for the purpose of protecting health, safety, and human life? The irony of imposing *a priori* limitations on confidentiality is that they may deprive society of the very information that might help the protection of health, safety, or human life.

In opposition to "limited confidentiality", the "ethics-first" perspective holds that because the public interest in the collection of accurate information about certain social phenomena is sufficiently great, and because confidentiality is often indispensable to the gathering of accurate information, the need to maintain confidentiality may outweigh other foreseeable public interests—even the duty to obey a court order to divulge information.

V
CONFIDENTIALITY AND INFORMED CONSENT

PRE argues that:

> Responding in part to leading Canadian legal decisions that confidentiality is seldom unlimited or protected absolutely, many researchers and REBs indicate in the informed consent process with participants that confidentiality will be protected 'within the limits of the law'.[19]

There are at least two problems with this approach beyond the fact that it fails to recognize those researchers who indicate in the informed consent process that confidentiality will not be violated, even under legal pressure.

First, by saying that "confidentiality is seldom unlimited or protected absolutely" PRE distorts the cases it cites. Another way of characterizing these cases is to say that confidentiality is "rarely challenged" and "almost always maintained". Moreover, in articulating the test for a public safety exception to lawyer-client privilege, *Smith v. Jones*[20] clarifies that a violation of lawyer-client privilege is *permissible*, but *not* a duty. The word "must" is only used in the decision to describe what a court "must" do to protect public safety in the event that confidentiality is challenged. However, the decision does *not* bestow a tort duty on therapists or lawyers to violate confidentiality to protect third parties.

Second, because there are disagreements about what it means to protect confidential information "within the limits of law", the promise to protect confidentiality to the "extent possible within the law"[21] does not give research participants the information they need for informed consent. Are the "limits of the law" restricted to statutes, or should the common law be included? For researchers to fulfill their ethical obligation to protect confidentiality within the limits of the law, surely it *must* include the common law. Why does PRE ignore common law protections for confidential communications?

According to the Supreme Court of Canada the Wigmore test[22] is the appropriate mechanism to adjudicate claims of evidentiary privilege on a case-by-case basis,[23] and yet neither the TCPS nor PRE talks about how researchers could—or, in our opinion, *should*—design their research to anticipate the Wigmore test.[24]

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18 *Ibid*. at para. 4.

19 *Supra* note 2 at para. 32.

20 *Smith v. Jones*, [1999] 1 S.C.R. 455.

21 TCPS, *supra* note 5 at 3.2.

22 See John Henry Wigmore, *A Treatise on the System of Evidence in Trials at Common Law: Including the Statutes and Judicial Decisions of All Jurisdictions of the United States, England, and Canada* (Toronto: Canada Law Book, 1905) at para. 3185.

23 *Slavutych v. Baker*, [1976] 1 S.C.R. 254 [*Slavutych*]. See also John Sopinka, Sidney N.Lederman & Alan W. Bryant, *The Law of Evidence in Canada* (Toronto: Butterworths, 1992).

24 Ted S. Palys & John Lowman, "Ethical and Legal Strategies for Protecting Confidential Research Information" (2000) 15 C.J.L.S. 39.

More problematically, PRE paves the way for a *caveat emptor* approach[25] that surrenders research-participant rights without even fighting the battle in court because it absolves researchers and universities from the responsibility of resisting subpoenas.

VI
Informed Consent and Limits on Confidentiality: From Mantra to Fetish

If researchers prepare their defence of confidentiality in anticipation of the Wigmore criteria, the only interest that is likely to override research confidentiality is a defendant's innocence.[26] We cannot find a single case, however, where a researcher was subpoenaed on the ground that a defendant's innocence was at stake, although it is theoretically possible. In light of this, PRE's implied argument that the threat of court-ordered disclosure is a "reasonably foreseeable risk" defies the empirical record. How does one assess the likelihood of a risk that has not materialized as an actual harm in hundreds of thousands of research projects?

With its focus on specifying limits rather than trying to defend confidentiality, PRE turns the mantra of informed consent into a fetish.

VII
When Ethics and Law Conflict: Court-Ordered Disclosure

PRE cites the TCPS statement that "ethics and law may lead to different conclusions",[27] but offers no advice to researchers about how they should proceed if they truly believe that acting ethically would mean refusing to comply with a law or judicial order. At least two researchers, both in the United States, spent periods in jail rather than violate research confidentiality.[28] In this regard many researchers believe they have much the same responsibility as journalists to protect their sources—the most recent of many examples being that of American journalist Judith Miller,[29] who spent 85 days in jail in 2005 for refusing to name a White House source who leaked the identity of a CIA agent.

In contrast to PRE's abstract analysis of limitations to confidentiality, the "ethics-first" perspective is based on an analysis of research confidentiality and law in practice. Consequently, as advocates of that approach, we are able to specify exactly what the "very exceptional cases" would be in which we would place ethical considerations above law. After 25 years conducting criminological research, and after considering the legal cases on record, we have yet to find a situation in which a third party's desire for confidential research information is more compelling than the ethical obligation to protect research participants.

Further, on the basis of the actual court record, we do not anticipate a court ordering the disclosure of confidential research information.[30] No Canadian court has ever ordered a researcher to divulge confidential research information. In the United States, where dozens of researchers have been subpoenaed, courts ordered researchers to disclose confidential information in only three cases.[31] Two of these cases involved grand juries—we do not have grand juries in Canada—and in the third case the court ordered disclosure of information *precisely because the researchers limited confidentiality*.[32]

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25 See Ted S. Palys & John Lowman, "Protecting Research Confidentiality: Towards a Research-Participant Shield Law" (2006) 21 C.J.L.S. 163.

26 Michael Jackson & Marilyn MacCrimmon, "Research Confidentiality and Academic Privilege: A Legal Opinion" (1999), online: Simon Fraser University <http://www.sfu.ca/~palys/JackMacOpinion.pdf>.

27 *Supra* note 5 at i.8.

28 See Samuel Popkin in Bud Schultz & Ruth Schultz, eds., *The Price of Dissent: Testimonies to Political Repression in America* (Berkeley: University of California Press, 2001) at 339. See also Rik Scarce, "(No) Trial (But) Tribulations: When Courts and Ethnography Conflict" (1994) 23 Journal of Contemporary Ethnography 123.

29 Steven Edwards, "Freed Reporter Talks to CIA Leak Inquiry" *Vancouver Sun* (1 October 2005) A15.

30 *Slavutych*, *supra* note 23.

31 John Lowman & Ted S. Palys, "The Ethics and Law of Confidentiality in Criminal Justice Research: A Comparison of Canada and the United States" (2001) 11 International Criminal Justice Review 1.

32 *Atlantic Sugar, Ltd. v. U.S.*, 85 Cust. Ct. 128 (1980).

VIII
IF ETHICS AND LAW CONFLICT, THE RESEARCHER MUST DECIDE

In defence of limited confidentiality, PRE cherry-picks evidence that supports its doctrine and ignores other evidence that, instead of imposing one ethical point of view, recognizes ethical diversity. For example, PRE says that "limited duties to warn have since [*Tarasoff*] been recognized in Canadian professional codes of practice."[33] It cites a part of the Canadian Psychological Association's code of ethics that supports its position, but ignores the section affirming that when ethics and law part company, researchers must follow their ethical conscience:

> IV.17 [Psychologists should] [f]amiliarize themselves with the laws and regulations of the societies in which they work ... and abide by them. If those laws or regulations seriously conflict with the ethical principles contained herein, psychologists would do whatever they could to uphold the ethical principles. If upholding the ethical principles could result in serious personal consequences (e.g., jail or physical harm), decision for final action would be considered a matter of personal conscience.[34]

This section of the Canadian Psychological Association's code provides clear support for the "ethics-first" perspective. Indeed, the three granting councils have already endorsed this position:

> [T]he Councils, as agents of the Canadian government, expect all Council-funded research to conform both to the ethical principles set out in the Tri-Council Policy Statement (TCPS) and the relevant laws. At the same time we also recognise that, in rare instances, ethical and legal approaches can conflict.... If there is a conflict, the researcher must decide on the most acceptable course of action.[35]

In other words, according to the three granting councils that authored it—the Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council of Canada, to whom PRE reports—the TCPS does recognize the right of researchers to refuse to obey a court order to disclose confidential research information should their conscience so dictate. Curiously, PRE did not cite this letter.

CONCLUSION

PRE's mandate is to "promote high ethical standards of conduct in research involving humans" and to "recognize the diversity of approaches used in research involving humans".[36] Why, then, would it promote *a priori* limitations to confidentiality? Its limited confidentiality doctrine emphasizes hypothetical risks that have never materialized as actual harms and ignores the actual outcome of cases in which research confidentiality has been challenged. Indeed, by failing to acknowledge that there is an alternative to its limited confidentiality approach the PRE advisory opinion represents a significant threat to academic freedom in Canada. It is ironic that the courts consistently attach a higher value to research-participant confidentiality and the fate of the research enterprise than does PRE, which appears prepared to surrender to a hypothetical threat that has never materialized.

In light of the granting councils' 2000 ruling, we urge PRE to acknowledge that researchers have the academic freedom to follow an ethics-first approach to research confidentiality.

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33 *Supra* note 2 at para. 23.

34 Canadian Psychological Association, *Canadian Code of Ethics for Psychologists* (2000), online: Interagency Advisory Panel on Research Ethics <http://www.pre.ethics.gc.ca/english/pdf/links/Canadian%20Code%20of%20Ethics%20for%20Psychologists%20_2000.pdf>.

35 Letter from Anne-Marie Monteith, NSERC Research Ethics Officer, to Drs. John Lowman and Ted Palys (27 April 2000), online: Simon Fraser University <http://www.sfu.ca/~palys/TCPSFAQ.pdf>.

36 PRE Terms of Reference, online: Interagency Advisory Panel on Research Ethics <http://pre.ethics.gc.ca/english/aboutus/termsofreference.cfm>.

AFTERWORD / POSTFACE

Jean-Louis Baudouin[*]

Au terme de ce périple qui a promené le lecteur dans un champ particulièrement varié de la bioéthique et de la science, quelques modestes commentaires peuvent être faits.

Le premier est que, comme on peut le constater à la lecture de ces huit textes, les difficultés soulevées par la technoscience sont désormais devenues d'une très grande variété et d'une intense complexité. Pour n'en prendre que quelques exemples, elles touchent aussi bien les risques attachés à la recherche sur les cellules souches (sujet d'actualité s'il en est un !) que les nouveaux rôles des médecins dans le cadre de la santé publique ou encore les problèmes résultant de l'interaction entre l'homme et l'animal, pour ne citer que celles-là.

Le second est qu'à travers l'analyse de ces problèmes particuliers auxquels les textes de cette publication font référence, on retrouve en filigrane une interrogation et préoccupation constantes, de façon explicite ou implicite : comment réglementer ces phénomènes ?

C'est principalement, à mon avis, sur ce point que savants, juristes, éthiciens et philosophes doivent s'interroger. Comment, dans nos sociétés modernes, individualistes, hédonistes et à la constante recherche du progrès scientifique considéré comme un bien en soi, s'assurer que la science travaille dans l'intérêt de la collectivité toute entière et ne succombe pas à des dérapages mettant en danger nos valeurs fondamentales et le bien commun ? Comment, en d'autres termes, concilier et adapter les conséquences des extraordinaires progrès scientifiques avec les impératifs de la vie en société ? Certains pays (notamment ceux de l'Europe) ont cru voir la solution dans la voie législative traçant les grands paramètres de ce qui est jugé acceptable ou non acceptable à un moment de l'évolution de la Cité. D'autres ont préféré faire confiance à la sagesse des chercheurs et cliniciens, laissant les questions se résoudre au sein même de cette communauté par une normativité scientifique. Il s'agit donc alors d'un système d'auto régulation qui d'ailleurs, dans certaines circonstances et dans certains pays, a quand même donné de bons résultats. D'autres enfin, craignant d'une part une stérilisation du développement scientifique par la loi et les effets d'une obsolescence rapide des textes législatifs ou réglementaires et, d'autre part, l'éparpillement et le manque d'universalisme des règles de bioéthique, ont cru trouver la réponse dans l'exercice constant du contrôle judiciaire. Il appartiendrait donc aux juges de décider pour la société de ce qui est acceptable.

Ces trois modèles pourraient, peut-être, être complémentaires et non antagonistes comme on l'a souvent prétendu, à condition de donner à chacun le rôle précis qui lui revient. On peut, en effet, imaginer que la régulation de la techno science se fasse d'abord à travers un encadrement législatif général ayant pour effet de déclarer ce qui, dans une société donnée et à un moment précis de son évolution, est ou reste humainement inacceptable. La loi identifie alors le noyau dur des pratiques défendues ; en d'autres termes, ce qui n'est tout simplement pas négociable.

La régulation peut se faire aussi à un second niveau et en complémentarité, par des règles de bioéthique, normes plus souples, émanant de la communauté scientifique et permettant, sous l'égide de la loi, d'offrir directement des solutions à des problèmes concrets en éthique clinique ou de recherche.

Enfin, et en dernier ressort, le pouvoir judiciaire, gardien des libertés publiques et des droits individuels, peut agir d'abord en cas de conflit et ensuite, lorsque soit par timidité, soit par opportunisme (comme c'est malheureusement le cas souvent), le pouvoir politique refuse d'intervenir ou de prendre partie sur des questions qui lui paraissent trop controversées et donc à haut risque pour le politicien.

Notre réflexion collective m'apparaît donc devoir passer par une meilleure identification des rôles respectifs de la loi, de la bioéthique et du jugement dans l'appréhension et la réglementation de la science.

Le lecteur trouvera sûrement dans les huit textes regroupés ici de quoi nourrir sa réflexion.

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