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Chapter 10

REGULATING REPRODUCTIVE TECHNOLOGIES IN CANADA

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I. INTRODUCTION

This chapter will identify and examine the major legal issues raised by the development and proliferation of technologies involved in assisted reproduction. It will review the application of existing legal principles, statutes and common law rules to these issues, and will illustrate the uncertainty present in the current legal regime in Canada. The chapter will then evaluate the need for a unified regulatory framework for reproductive technologies ("RTs").¹ While the focus of the chapter is an identification and review of the legal issues, it should be understood that these are shaped in a moral, ethical and social context.

As noted by the Law Reform Commission of Canada ("LRC"), "[m]edically assisted procreation is perhaps one of the best examples of the challenges posed by the development of medical science and the tensions to which they give rise for the law."² Distinct from many other forms of medical intervention or practice,

¹ RTs are often defined as "the full range of biomedical/technical interferences during the process of procreation whether aimed at producing a child or preventing/terminating pregnancy" (R.D. Klein, "What's 'new' about the 'new' reproductive technologies?" in G. Corea *et al.*, *Man-made Women: How New Reproductive Technologies Affect Women* (Indiana: Indiana University Press, 1987) at 64). This definition includes abortion, contraception, sterilization, pre-conception, and pre-natal testing and birth practices and techniques. For purposes of this chapter, RTs will have a narrower meaning and will include only those techniques and procedures that are used to produce a child. Moreover, while much of the literature and many of the commissions which have studied these techniques and practices refer to them as "new" RTs, this chapter will refer to RTs, or forms of assisted conception, as a way of acknowledging that one of the practices, assisted insemination, is indeed an old practice.

² Law Reform Commission of Canada, *Medically Assisted Procreation* (Working Paper 65) (Ottawa: Minister of Supply and Services, 1992) [hereinafter "*Medically Assisted Procreation*"] at 1.

the use of RTs by some can fundamentally affect the lives of all Canadians and their children.³ Actions taken behind the traditionally closed door of the doctor-patient relationship involve broader consequences for all members of society.⁴ Because the application of RTs is often carried out within the context of the physician-patient relationship, many conventional health law issues will arise. Among these are questions of informed consent, standards of care, confidentiality and the legal regulation of the practitioners performing various techniques of medically assisted conception. In these cases, traditional sources of health law — including many of the common law standards and principles and statutory provisions discussed in this book — should provide adequate means for regulating practice and resolving disputes in this area. However, because RTs have the potential to transform social relationships, their introduction into medical practice involves issues beyond the physician-patient relationship and the existing regulation of medical practice.

RTs enable the deliberate manipulation of the processes and materials of human reproduction outside of sexual intercourse. Usually, the intention and effect is to produce a child. However, current innovations in reproductive biology and medicine also produce or isolate other reproductive materials or entities: vials of semen, unfertilized ova, zygotes, embryos⁵ — which have not existed in this way before. How are we to regard and treat these novel entities? Who has control over them? For what can they be used? The use of RTs, moreover, makes possible the creation of novel social arrangements: post-mortem insemination,⁶

³ The Royal Commission on New Reproductive Technologies [hereinafter "Royal Commission"] reported that in 1991 between approximately one and two percent of all births in Canada were the result of either artificial insemination or *in vitro* fertilization; Royal Commission, *Proceed With Care: Final Report of the Royal Commission on New Reproductive Technologies* (Ottawa: Minister of Supply and Services Canada, 1993) [hereinafter "*Proceed With Care*"] at 435.

⁴ This point is made by M. Hudson in "Societal Controls on New Reproductive Technologies: A Canadian Perspective" in L. Weir, ed., *Governing Medically Assisted Human Reproduction: Report of an International Symposium* (Toronto: Centre of Criminology, University of Toronto, 1997) 73 at 73.

⁵ As noted by the Royal Commission, there is a problem with the terminology in this area. Technically, the term "zygote" refers to the fertilized egg prior to implantation. "Embryo" refers to the developing entity after implantation into a woman's uterus until about eight weeks after fertilization, when it becomes known as a fetus. However, since the term "embryo" is often used in public discourse in place of "zygote," we continue to use it in reference to the fertilized egg prior to implantation. For further discussion of this issue see: Royal Commission, *supra*, note 3 at 607. See also Bill C-47, *Human Reproductive and Genetic Technologies Act*, 2nd Sess., 35th Parl., 1996 [hereinafter "Bill C-47"], s. 2. Bill C-47 draws a distinction between zygotes (or pre-embryos) and embryos, where the former means a human organism in its first 15 days of development, and the latter refers to one beginning from the 16th day to the 56th day. The fetus is defined by its development beginning from the 57th day to birth. In contrast, the Federal Government's recent draft legislation, "Proposals for legislation governing assisted human reproduction," [hereinafter the "draft AHRA"] defines "embryo" as a "human organism during the first 56 days of its development following fertilization or creation, excluding any time in which its development has been suspended." See Health Canada, "Proposals for legislation governing assisted human reproduction" (May 3, 2001).

⁶ See *Parpalax v. CECOS T.G.I. Creteil*, August 1, 1984, *Gazette du Palais*, September 15, 1984

virgin births, post-menopausal pregnancy,⁷ multiple "parents," anonymous genetic parents, and embryos conceived at one time being born at different times, or to different people. How are we to understand these new social arrangements and how should they be regulated? These and other questions focus on the ways in which RTs are defined and conceptualized in theory, as well as accessed and controlled in practice. The use of RTs has implications for kinship and thereby alters our understanding of the legal, social, and emotional bonds created by heredity and the consequences presumed to ensue from processes of intercourse, conception and birth.

Typically, health law investigates the principles, statutes, and constitutional and policy framework that shape the allocation and delivery of health care services, and the relationship between the health care provider and patient. The World Health Organization ("WHO") defines health as a state of physical and mental well-being — a definition broader than that of medicine. Health is more than the "absence of disease" and includes the harmonious development of the human person.⁸ Moreover, since human beings socially interact, whether in the medical sciences or the daily routines of life, health is a social construction as well as a biological condition; its norms are constructed in a social environment and include not only medical-scientific determinants but also social determinants. Law can be one such determinant. Since law helps to determine and regulate the social relations that underpin individual well-being and, by implication, individual health status, law itself becomes one of the factors which affect individual health.

The emergence of RTs over the last quarter century has sparked numerous efforts at regulatory reform by panels and commissions established in many jurisdictions throughout the world. These assembled groups considered whether or not to establish a new reproductive order, or to find ways of containing the new possibilities engendered by the RTs within the old reproductive order.⁹ While these forums have led to volumes of recommendations, and sometimes to regulations, they have rarely led to legislation.¹⁰

(France). See *infra*, note 206 (dispositional control over the deceased's sperm deposit); *Hecht v. Superior Court of the State of California for the County of Los Angeles (Kane)*, 20 Cal. Rptr. 2d 275 (1993) (deceased's sperm as part of his estate distributed in light of his intentions to procreate after death); *R. v. Human Fertilisation and Embryology Authority, ex parte Blood*, [1997] 2 All E.R. 687 (C.A.) (use of sperm taken from comatose husband without prior written consent as required by legislation).

⁷ See A. Lippman, "'Never Too Late': Biotechnology, Women and Reproduction" (1995) 40 *McGill L.J.* 875.

⁸ See online: World Health Organization <<http://www.who.int/aboutwho/en/definition.html>>.

⁹ D. Roy, J. Williams & B. Dickens, *Bioethics in Canada* (Scarborough, Ontario: Prentice Hall Canada Inc., 1994) at 132.

¹⁰ B. M. Knoppers & S. LeBris, "Ethical and Legal Concerns: Reproductive Technologies 1990-1993" (1993) 5 *Current Opinion in Obstetrics and Gynaecology* 630 at 631. See, for example, in the United Kingdom, *Human Fertilisation and Embryology Act, 1990*, ch. 37(5) (Eng.); in Victoria, Australia, *Infertility Treatment Act (1995)*; in France, *Loi sante, Loi justice, Loi recherche*.

There are two ways to regulate RTs: one can regulate just the ends, or both the means and the ends. On the one hand, it has been argued that regulation should focus solely on the particular ends ethically unacceptable to society,¹¹ rather than widely constrain and "chill" medical science and technology. Alternatively, a regulatory regime might account for the use of RTs as both a means of assisting biological processes and as an end with social and ethical implications. This chapter will explore the legal ramifications of pursuing either approach to the regulation of RTs.

Currently, there is a legal vacuum regarding the express regulation of reproductive technologies in Canada.¹² Although statutes and case law in America and other jurisdictions provide some guidance, their application as persuasive forces in the Canadian context remains questionable.

There have been efforts to fill this vacuum. In Canada, the dominant tendency has been to regulate reproductive technologies as medical practice and to apply existing legislation and common law principles to their regulation. The increasing use of RTs, however, has heightened calls for comprehensive regulation by interested citizens and practitioners who seek clear guidance from statutory law. Several proposals for legal reform have been put forward by a number of formal commissions, most significantly, the Royal Commission on New Reproductive Technologies ("Royal Commission"). At the time of writing, however, these efforts have yet to result in the enactment of comprehensive legislation. Bill C-47, the first attempt to regulate reproductive technologies in Canada, died on the order paper when Parliament dissolved on April 27, 1997, just prior to a federal election. More recently the federal Minister of Health has asked the Standing Committee on Health to review *draft* legislation regulating assisted reproduction and to report back by the end of January 2002. While this draft legislation has no legal effect (at the time of writing), it illustrates how the federal government has recently approached regulatory concerns regarding RTs. In this chapter, we will draw upon Bill C-47 and the new draft legislation to describe past and present regulatory attempts, and to illustrate possible forms of regulation regarding the use of RTs in Canada.

This chapter begins by canvassing the basic definitions of infertility, taking into account both the biological factors and social norms that colour the stipulation of infertility as a medical condition. We then describe the RTs used in the treatment of infertility. The chapter briefly reviews a range of existing and proposed legal mechanisms with which to regulate RTs and goes on to raise a number of legal issues arising from the introduction of RTs in medical practice. These issues include: access to RTs; informed consent; the legal rules governing

¹¹ B. Dickens, "Do Not Criminalize New Reproductive Technologies" (March 1996) Policy Options 11.

¹² For a discussion of possible regulatory approaches in Canada see: P. Healy, "Statutory Prohibitions and the Regulation of New Reproductive Technologies under Federal Law in Canada" (1995) 40 McGill L.J. 905; Hudson, *supra*, note 4; A. Harvison Young & A. Wasunna, "Wrestling With the Limits of Law: Regulating New Reproductive Technologies" (1998) 6 Health L.J. 239; M.A. McTeer, *Tough Choices: Living and Dying in the 21st Century* (Toronto: Irwin Law, 1999).

the status, control and disposition of sperm, ova and embryos; embryo research; stem cell research; and human cloning. This chapter explores the constitutional, statutory and common law implications of such issues and considers a range of possible legal and regulatory frameworks governing the use of RTs.

A. INFERTILITY

Reproductive technologies are generally considered to be a treatment for the condition of infertility. Infertility, however, can be seen as either a medical problem or as a social condition of childlessness. The Royal Commission states that "[d]efining infertility as a socially generated problem implies that we should look to social solutions."¹³ Discussion of infertility involves particular language and definitions chosen by medical practitioners, legislators, and other interested parties — language that can be medical and/or social.¹⁴

The use of RTs traditionally presupposes the medical model of infertility. In the medical model, physicians and other health care practitioners identify and evaluate the condition of infertility, and then make choices about the appropriate use of RTs. Many critics and commentators have questioned the appropriateness of the medical model. We will now consider alternative models and illustrate the ways in which the definition of infertility shapes the legal regulation of RTs.¹⁵

According to most medical definitions, infertility is the inability to produce a child despite regular unprotected intercourse over a certain period of time during a woman's fertile period. According to Bernard Dickens, in an oft-quoted passage:

¹³ Royal Commission, *supra*, note 3 at 173. The common assumption is that the need and desire to have children is a normal part of our lives.

¹⁴ Several courts have found that employees' decisions to undergo *in vitro* fertilization treatment for infertility are reasonable and that the employees should be compensated for time off due to sickness or disability under the respective collective bargaining regimes. See, for example: *Metropolitan General Hosp. and O.N.A., Re* (1987), 32 L.A.C. (3d) 10 (Ont.); *Canadian Union of Postal Workers and Canada Post Corp. CUPW (744-95-00073)*, [1999] C.L.A.D. No. 81; *O.P.S.E.U. v. Ontario (Ministry of Health)*, [1989] O.J. 2434 (QL) (Gen. Div.); *Hamilton Civic Hospitals and O.N.A., Re* (1988), 32 L.A.C. (3d) 284 (Ont.).

¹⁵ See Royal Commission, *supra*, note 3 at 172-75. See also S. Franklin, "Deconstructing 'Desperateness': The Social Construction of Infertility in Popular Representations on New Reproductive Technologies" in M. McNeil, I. Varcoe & S. Yearley, eds. *The New Reproductive Technologies* (New York: St. Martin's Press, 1990) at 200. See also T. Balakrishnan & R. Fernando, "Infertility Among Canadians: An Analysis of Data from the Canadian Fertility Survey (1984) and General Social Survey (1990)" in Royal Commission, *The Prevalence of Infertility in Canada*, vol. 6 (Ottawa: Ministry of Supply and Services, Canada, 1993). Infertility has also been categorized as perceived or inferred infertility, where the former refers to the woman's "subjective" perception of infertility, and the latter to an "objective" inference of infertility according to basic criteria. "Aggregate infertility" is said to be a combination of perceived and inferred infertility; T.R. Balakrishnan & P. Maxim, "Infertility, Sterilization, and Contraceptive Use in Ontario" in Royal Commission on New Reproductive Technologies, *Research Vol. 6: The Prevalence of Infertility in Canada* (Ottawa: Ministry of Supply and Services, 1993) 163-90 at 165-66.

Infertility includes infecundity, meaning inability to conceive or to impregnate, and pregnancy wastage, meaning failure to carry a pregnancy to term through spontaneous abortion and stillbirth. Infertility includes primary infertility, where a couple has never achieved conception, and secondary infertility, where at least one conception has occurred but the couple is currently unable to achieve pregnancy.¹⁶

In Canada, infertility is typically defined as failure to conceive within one year of regular unprotected sexual intercourse.¹⁷ The WHO, however, stipulates a time period of two years.¹⁸ At least some medical practitioners treat infertility negatively as a "malfunctioning" of the human system over a period of time, and thus as a "disease."¹⁹ In Canada, three formal commissions have enunciated three different definitions of "infertility" which span the spectrum of the medical and the social. The Ontario Law Reform Commission ("OLRC") defined infertility in terms of couples who "have attempted, but failed, to produce a child and do not respond to conventional therapy."²⁰ The OLRC's definition is limited to medical criteria, and does not include "personal choices that bear no relation to the issue of medical need."²¹ Similarly, the LRC defined infertility as "the involuntary, significant reduction of reproductive capacity," as based on the "inability to become pregnant after one year of unprotected intercourse."²² On the other hand, the Royal Commission simply defined the "prevalence of infertility" over one year: "The absence of pregnancy in a couple who have been cohabiting for at least the past year and who have not used contraception during that period."²³ The Royal Commission elaborated an account addressing "the physiological and sociological aspects of infertility."²⁴ The three definitions of infertility above contain a variety of social and medical factors. The recommendations by each formal commission, and thus possible regulatory regimes, seem to vary according to the definitions of infertility. (Note that these medical definitions of infertility typically assume that infertility is something that affects heterosexual couples; we will discuss this further below.)

Infertility is caused by, or at least associated with, several medical (or biological), environmental and social factors. The more common physiological

¹⁶ B. Dickens, "Reproduction Law and Medical Consent" (1985) 35 U.T.L.J. 255 at 281.

¹⁷ Royal Commission, *supra*, note 3 at 183.

¹⁸ *Ibid.*

¹⁹ *Ibid.*, at 172.

²⁰ Ontario Law Reform Commission, *Report on Human Artificial Reproduction and Related Matters*, vol. 1 (Toronto: Ministry of Attorney General, 1985) at 9. Conventional therapy for males and females varies and may include infertility counselling, hormones, and surgery (at 14-15).

²¹ *Ibid.*, at 10.

²² LRC, *supra*, note 2 at 14.

²³ Royal Commission, *supra*, note 3 at 186. The Royal Commission also considered a two-year definition, substituting into the quoted version, "for at least the past two years." The Royal Commission, however, failed to address the definition and issue of contraception, nor did it account for lesbian and single women not cohabiting with a male partner.

²⁴ *Ibid.*, at 173. The Royal Commission assumed that physiological dimensions can be, at times, entirely separated from sociological dimensions.

causes are sexually transmitted diseases, smoking, and age.²⁵ When people wait longer before attempting to reproduce, they face lower chances of success due to biological aging and the increased exposure to risk factors over time.²⁶ Infertile individuals may also wait longer than those who are fertile before seeing a physician. Other possible causes of biological infertility include environmental toxins, workplace hazards, diet, alcohol, caffeine, illicit drugs, disease, medical procedures with unintended effects,²⁷ sterilization, and contraception.²⁸

In addition to being seen as a medical problem, infertility can also be seen as a social condition deviating from a social norm. The social norm involves the model of a nuclear family, consisting of married heterosexual parents and their biologically related children. Under this model, infertility deviates from the "ideal family." This model generates strong social pressure to satisfy the norm for couples to procreate. The basic assumption is that the need and desire to have children is a normal part of our lives.²⁹

The stigma of childlessness is especially difficult for women, who have historically been defined and identified through their roles as mothers.³⁰ The "treatment" of women for the condition or "disease" of infertility must therefore be viewed in this gender-specific context. RTs generate stresses and problems when "infertile" women feel pressured to use them, and continue to do so, cycle

²⁵ Royal Commission, *supra*, note 3 at 172.

²⁶ *Ibid.*, at 190-91, 255, 261-62; OLRC, vol. 1, *supra*, note 20 at 12-13. It is well known that age affects the fertility of females much more than males.

²⁷ There are several reported tort cases that have awarded plaintiffs compensation to pay for IVF treatments in cases of medical negligence causing infertility. See, for example: *Berezowski-Aitken v. McGregor*, [1998] M.J. No. 180 (QL) (Q.B.) (the court awarded \$50,000 for IVF treatments to the female plaintiff as compensation for infertility due to medical negligence); *Lanthier-Rochon v. Sim*, [1996] O.J. No. 4449 (QL) (Gen. Div.) (Chadwick J. awarded \$15,000 for IVF treatments in the case of the negligent performance of a tubal ligation). However, in *Bains v. Green*, [1997] B.C.J. No. 943 (QL) (S.C.), Fisher J. declined to award damages for the cost of IVF and ICSI to a young, single man with a spinal cord injury as a result of a motor vehicle accident, stating "I find the future both as to time and relationship very indefinite regarding fertilization, and as well the likelihood of its non-success amount to speculation that each procedure would occur." In addition, courts have held that plaintiffs are not required to use RTs in order to reasonably mitigate damages for the loss of reproductive capacity or fertility. See, for example: *Adan v. Davis*, [1998] O.J. No. 3030 (QL) (Gen. Div.); *Kelly v. Lundgard*, [2001] A.J. No. 906 (QL) (C.A.). For discussion of IVF and ICSI, see B. Reproductive Technologies in the next section of this chapter.

²⁸ Royal Commission, *supra*, note 3 at 199-338. See LRC, *supra*, note 2 at 15-17. See also OLRC, *supra*, note 20 at 10-14.

²⁹ It has been argued that the "need" and "desire" for children conflate social and biological explanations of infertility; S. Franklin, "Deconstructing 'Desperateness': The Social Construction of Infertility in Popular Representations on New Reproductive Technologies," *supra*, note 15. See also K. Alpern, "Genetic Puzzles and Stork Stories: On the Meaning and Significance of Having Children" in K. Alpern, ed., *The Ethics of Reproductive Technology* (Oxford: Oxford University Press, 1992) at 147.

³⁰ See N. Pfeffer, "Artificial Insemination, In Vitro Fertilization, and the Stigma of Infertility" in M. Stanworth, ed., *Reproductive Technologies: Gender, Motherhood and Medicine* (Minneapolis: University of Minneapolis, 1987) at 81.

after cycle, even when treatment repeatedly fails. This pressure can have significant economic, physiological and psychological costs. Women who choose to pay to reproduce (in surrogacy contracts) may be stigmatized as "deviant" — or even criminal under some proposed legislative models. The commercialization of procreation is viewed as problematic in light of societal norms; the basic assumption is that human reproduction is usually outside the market realm.

But let us return to the medical definitions of infertility to make an important point: many people who are not medically infertile may nonetheless still be candidates for RTs. This category includes people without partners of the opposite sex, such as lesbian couples and single women who wish to procreate without the involvement of a male partner. This category also includes women who wish to have a child without becoming pregnant. Moreover, individuals and couples who carry genetic conditions may wish to avoid natural procreation in order to avoid passing these conditions on to their child. These cases challenge the assumption that RTs are merely treatments for the medical condition of infertility.

Under many medical definitions, infertility is regarded as affecting couples, thus reinforcing the idea that RTs should be available only to socially recognized unions. This obscures the fact that single individuals may be concerned about their reproductive health status and may seek to use RTs even before wishing to reproduce. Where infertility is reported only as a percentage of the adult population of childbearing age, teens and post-menopausal women (who have now gained access to RTs in some countries)³¹ who are infertile will be excluded. Furthermore, as noted earlier, single women may wish to procreate without a partner. These and numerous other considerations illustrate how social values and policy preferences have circumscribed the biological definitions of infertility and, implicitly, the pool of candidates for RTs. The medically infertile couple has maintained dominance as a privileged form of social relationship.

Infertility is not purely a medical (or biological) phenomenon; it is also social and gendered. Most reproductive technologies focus on women as the problematic part of the couple. Women can be the subjects of treatment even when the male partner is medically (or biologically) infertile. Sometimes, fertile women undergo invasive procedures, such as *in vitro* fertilization, for the treatment of their infertile husbands.³² Yet empirical evidence indicates that the incidence of

³¹ For example, see "Baby Sparks Dispute" *The Globe and Mail* (12 January 1995). See also A. Lippman, "'Never Too Late': Biotechnology, Women and Reproduction" (1995) 40 McGill L.J. 875.

³² See, for example, *Cameron v. Nova Scotia (Attorney General)* (1999), 177 D.L.R. (4th) 611 (N.S.C.A.), affg (1999), 172 N.S.R. (2d) 227 (S.C.), leave to appeal dismissed (without reasons), [1999] S.C.C.A. No. 531 (June 29, 2000), reconsideration of leave to appeal dismissed (November 15, 2001). In this case the female partner requested IVF treatment together with her husband's use of ICSI as a treatment for his "severe male factor infertility." Both parties claimed discrimination under *Charter* s. 15 on the grounds that infertility constituted a "disability." The majority of the Court of Appeal recognized that the exclusion of ICSI and IVF from the public health insurance plan amounted to discrimination on the basis of disability or on analogous grounds. They found, however, that the exclusion from coverage under the public health insurance plan was saved under s. 1 of the *Charter*.

infertility among men is 50-100 per cent of the incidence among women.³³ Nonetheless, men's infertility is much less researched and understood than women's.³⁴ Another example of how infertility is a social and gendered phenomenon: although infertility is generally thought to be on the rise, this may, in part, stem from the large number of women who delay having children to establish their careers. It is therefore appropriate to consider infertility a condition that is due to a combination of social and medical (or biological) factors.

The infertile are said to have three options: treatment by RTs, adoption, or "live with it." These options must be viewed in their social context, particularly in light of the prevailing perceptions and attitudes towards "family" relations.³⁵ The adoption and "live with it" options have not yet alleviated public concerns. Public adoption, as reported in 1993, involves an average six-year wait due to a shortage of babies to be adopted.³⁶ The process is long and complex, and remains difficult for single women and men. Widespread acceptance of the "live with it" option would require a notable shift in Canadian norms. The lack of adoption opportunities and the basic social unacceptability of the "live with it" option have contributed to the increasing demand for RTs and their regulation. The demand for RTs is high partly because the alternatives are difficult and/or undesirable.

In addition to treatment, another policy response to infertility is prevention. The Royal Commission recommended that priority be given to prevention of infertility rather than focussing solely on its treatment.³⁷ The federal government's 1996 White Paper proposed to address the condition of infertility by stressing "infertility prevention, social solutions and, lastly, infertility interventions that are appropriate, safe, and effective."³⁸ Such proposals, if implemented, would require the re-allocation of resources among lines of prevention and treatment within the health care system.

³³ A report conducted for the Royal Commission found that male infertility occurred in one-quarter of couples who sought treatment at a fertility clinic; *supra*, note 3 at 167. The OLRC reports that "[t]here appears to be general agreement that the causes of infertility are distributed evenly among male factors, female factors, and a combination of both male and female factors"; OLRC, *supra*, note 20 at 11. See also another study reported by the OLRC indicating marked differences similar to those found by the Royal Commission; *supra*, note 3, at note 6. It should be noted, however, that empirical studies on infertility, in light of the social stigmatization attached to their reporting, fall under a shroud of mystery. The lack of data, moreover, seems to benefit the *status quo*, focusing on women's infertility rather than men's. Furthermore, such studies may exclude those who deliberately choose, for genetic or other reasons, not to attempt conception.

³⁴ Royal Commission, *supra*, note 3 at 167.

³⁵ The Royal Commission contended that, at times, the biological and sociological aspects of reproduction are intertwined; *ibid.*, at 169. See also J. Dolgin, "Choice, Tradition, and the New Genetics: The Fragmentation of the Ideology of Family" (Winter 2000) 32 Conn. L. Rev. 523.

³⁶ Royal Commission, *supra*, note 3 at 370. See also the OLRC, *supra*, note 20 at 15-17.

³⁷ Royal Commission, *supra*, note 3 at 177.

³⁸ Health Canada *New Reproductive Technologies: Setting Boundaries, Enhancing Health* (Ottawa: Supply and Services Canada, 1996) at 19.

We will now consider the challenges of RTs and their regulation as a primary treatment for infertility, providing new opportunities for reproduction by infertile individuals and couples.

B. REPRODUCTIVE TECHNOLOGIES

Several reproductive technologies exist for treatment of infertility, namely, donor or non-donor artificial insemination, *in vitro* fertilization ("IVF") and related technologies, and embryo manipulation and research.³⁹ Artificial insemination is the oldest and most basic reproductive technique, and may occur by husband/partner ("AIH") or by donor ("AID").⁴⁰ It involves the artificial (or therapeutic) placement of sperm into the vagina, cervix, uterus, or fallopian tube at the appropriate time. The placement coincides with ovulation so as to increase the chances of conception. As a relatively inexpensive and non-invasive procedure, artificial insemination has been a popular first choice for the treatment of biological and social infertility. However, where infertility is due to the absence or blockage of a woman's fallopian tubes (*i.e.*, if the egg cannot pass through the fallopian tubes to be fertilized and implanted in the uterus), or in cases of male factor infertility, another reproductive technique is required.

In vitro fertilization has rapidly developed since its introduction in the late 1970s, and has brought with it many new possibilities for assisted reproduction.⁴¹ *In vitro* fertilization basically involves the retrieval of a woman's eggs from her ovaries and the fertilization of those eggs (in a glass petri dish, or *in vitro*) outside her body and their re-implantation either into her womb or that of another woman.⁴² The *in vitro* process usually involves the creation of many embryos and the selection of a few for implantation; the remaining embryos may be destroyed, frozen for later use, donated to other women or couples, or used for research. *In vitro* fertilization is much more onerous than artificial insemination. The monitoring of ovulation, the inducement of superovulation, and the retrieval of a woman's eggs are invasive with attendant medical risks and side effects.⁴³

Assisted reproduction may also involve related technologies such as gamete intra-fallopian transfer ("GIFT") and intracytoplasmic sperm injection ("ICSI"). In treatment of male factor infertility, *in vitro* fertilization may be combined

³⁹ For a more detailed discussion, see LRC, *supra*, note 2 at 22-76; Royal Commission, *supra*, note 3 at 425-659.

⁴⁰ Artificial insemination is also called therapeutic insemination by husband/partner ("AIH") or by donor ("AID"). In practice, the semen by the husband/partner may be mixed with that of the donor to increase the likelihood of conception. The Royal Commission concludes that this practice is not considered good practice as it generates ambiguity over parentage (*supra*, note 3 at 439).

⁴¹ C.L. Meyer, *The Wandering Uterus: Politics and the Reproductive Rights of Women* (New York: New York University Press, 1997).

⁴² For a more detailed description, see LRC, *supra*, note 2 at 22-50.

⁴³ The side effects of superovulation, for example, can include hot flushes, abdominal discomfort, blurred vision, and ovarian cysts. See D.L. Steinberg, *Bodies in Glass: Genetics, Eugenics, Embryo Ethics* (Manchester: Manchester University Press, 1997) at 34-35.

with the micromanipulation techniques of sperm injection and egg manipulation (*i.e.*, zona cutting or drilling for easier sperm penetration). ICSI, which involves the careful selection and injection of a single sperm into an egg, is now a widely accepted procedure for the treatment of severe male factor infertility.⁴⁴ GIFT is a procedure which places sperm and eggs directly into the fallopian tube.⁴⁵ It is combined with superovulation, a preliminary process that produces additional eggs for placement back into the fallopian tube to increase the possibility of conception. The fertilization itself is said to occur naturally. The GIFT process, however, does not assist women with fallopian tube blockage.

Embryos may also be genetically screened or even manipulated prior to implantation. For example, it may be possible to manipulate an embryo to produce one containing the same genetic information as a living or deceased human being; to alter its genetic structure so that such alteration may be transmitted to a subsequent generation to clone human embryos; or to create animal-human hybrids.⁴⁶ These modified embryos may be implanted into a woman and even brought to term. Moreover, *in vitro* fertilization and genetic testing may be used to screen and genetically alter embryos for particular genetic conditions and traits. This practice of pre-implantation genetic diagnosis is likely to become more common with the increased development of genetic testing if coupled with societal acceptance of genetic selection of offspring.

So far, we have described the RTs commonly used in Canada. These have been developed in line with medically accepted definitions of infertility and are evolving continually. As illustrated above, however, any effective regulatory framework will have to contend with the controversy surrounding the establishment of a generally agreed-upon definition of infertility, and by implication, who may be eligible for what forms of medical treatment. In the absence of such social consensus, any suggested regulatory framework would need to be flexible to account for differing outlooks on the definition, prevention and treatment of infertility.

C. REGULATING REPRODUCTIVE TECHNOLOGIES IN CANADA

The regulation of RTs in Canada currently involves statutes, case law, the *Constitution Act, 1982*,⁴⁷ and professional ethical guidelines. In this section we will canvass existing legislation concerning the transfer and storage of human tissues, as well as the constitutional constraints imposed on the regulation of RTs by the division of powers and the *Canadian Charter of Rights and Freedoms*⁴⁸ ("Charter"). In addition, we will review two recent Canadian proposals to regulate RTs in Canada: Bill C-47 and the draft AHRA.

⁴⁴ ICSI, when combined with epididymal sperm aspiration — making it possible to retrieve sperm from the epididymis or the testicles — creates new reproductive opportunities for men with low sperm counts (Toronto Centre for Advanced Reproductive Technology, *Newsletter*, 1996).

⁴⁵ See LRC, *supra*, note 2 at 50-53.

⁴⁶ See Bill C-47 (2nd Sess., 35th Parl.), s. 4; draft AHRA, s. 3.

⁴⁷ Being Schedule B to the *Canada Act 1982* (U.K.), 1982, c. 11 [hereinafter "*Constitution Act*"].

⁴⁸ Part I of the *Constitution Act, ibid.*

The legal regulation of RTs may be broadly classified under the categories of public and private law. The former involves statutory regulation by governments while the latter involves judicial resolution of disputes among private parties at common law. Private ordering may be challenged under human rights legislation, whereas public regulation may, in addition, face review under the *Constitution Act*. Some would argue that human reproduction and associated medical research properly belong to the private sphere and should not be restricted by public regulation unless there are exceptionally compelling reasons. These voices effectively propose a free market for RTs, using liberal arguments against government intrusion. In this argument, medical laboratories are analogous to bedrooms as sites of human reproduction. It is further argued that government regulation would produce a "chilling" effect on medical research and development of RTs. Others, however, reply that private ordering shelters actual or potential unethical medical research and practice from public scrutiny.

In Canada, comprehensive legislation has yet to be enacted addressing the legal issues raised by RTs.⁴⁹ Moreover, there has been limited case law and common law guidance in this area. In the absence of express law, RTs may be implicated in a number of ways, for example, under the heads of human tissue legislation, property law, contracts, torts, criminal law, the regulation of professions, and constitutional law. In the absence of existing legislation and case law directly applicable to RTs, these areas of law become relevant to the regulation of RTs.

II. LEGISLATION AND CASE LAW

A. EXISTING LEGISLATION

Although the federal and provincial governments have not yet committed themselves to a comprehensive response to the Royal Commission's recommendations, some relevant legislation has been enacted. Under regulations of the *Food and Drugs Act*,⁵⁰ which became enforceable June 1, 1996, the federal govern-

⁴⁹ For discussion of RTs in other jurisdictions see, E. Bernat, "Towards a New Legal Regulation of Medically Assisted Reproduction: The Austrian Approach" (1992) 11 *Medicine and Law* 547; B. Knoppers & E. Sloss, "Recent Developments: Legislative Reforms in Reproductive Technology" (1986) 18 *Ottawa L. Rev.* 663; Royal Commission, *supra*, note 3; LRC, *supra*, note 2; L. Jonsson, "Regulation of Reproductive Technologies in Sweden" in L. Weir, ed., *Governing Medically Assisted Human Reproduction: Report of an International Symposium* (Toronto: Centre of Criminology, University of Toronto, 1997) at 87; L. Waller, "Australian Legislation on Infertility Treatments" in L. Weir, ed., *Governing Medically Assisted Human Reproduction: Report of an International Symposium* (Toronto: Centre of Criminology, University of Toronto, 1997) at 91; J. Woodside, "The Role and Function of the Human Fertilisation and Embryology Authority: Legislation, Regulation and Consultation" in L. Weir, ed., *Governing Medically Assisted Human Reproduction: Report of an International Symposium* (Toronto: Centre of Criminology, University of Toronto, 1997) at 97.

⁵⁰ *Food and Drugs Act*, R.S.C. 1985, c. F-27.

ment controls the processing, testing and distribution of semen for donor insemination under the definition of "drug."⁵¹ In the absence of compulsory professional guidelines across Canada, the *Processing and Distribution of Semen Regulations* were intended to establish uniform national standards to decrease the risk of infectious disease transmission, and therefore reduce the costs to provincial health care systems.⁵² These regulations require that a "processor or importer" quarantine semen for at least six months to test for HIV and various other sexually transmitted diseases.⁵³ Where a physician who had performed assisted conception has reasonable grounds to believe that an infectious agent was transmitted through the semen, then he or she must quarantine the semen, inform the persons to whom the semen was distributed, destroy or quarantine the remaining semen, inform the donors about the results of investigation, and submit a final report.⁵⁴ The *Excise Tax Act*⁵⁵ also contains provisions relating to the importation of human sperm.⁵⁶

In Quebec, the *Public Health Protection Act*⁵⁷ regulates "gametes or embryo conservation centres," which is defined as "premises outside a facility maintained by an institution operating a hospital centre, designed for the collection, conservation or distribution of human gametes or embryos with a view to using the gametes or embryos for medical or scientific purposes." This Act gives the Director the authority to "coordinate the measures for the protection of public health and the distribution and supervision of the services relating to such pro-

⁵¹ *Processing and Distribution of Semen for Assisted Conception Regulations*, SOR/96-254 ("Processing and Distribution of Semen Regulations"), as amended, under the *Food and Drugs Act*, *ibid.* See also Regulatory Impact Analysis Statement, C. Gaz. 1996.II.1718. The Regulations also follow the Guidelines for *Therapeutic Donor Insemination*, published by the Department of Health, Ottawa (July 2000); see s. 1. Sections 5 to 8 allow for the importation of tested semen, if additional processing criteria are met, including written notice to the Director. In addition, the Regulations require specific procedures for the distribution of semen for assisted conception be undertaken pertaining to screening, laboratory controls, labelling, records, and tracing of semen; ss. 9-18. Recent amendments to the Regulations now provide physicians with an alternative to obtaining semen under the usual processing guidelines, *supra*. Physicians may obtain "special access" authorization by fulfilling specific criteria, including a written rationale for the request, assurances that no reasonable grounds exist to believe there is a serious risk of transmitting an infectious agent, and that the patient has been informed of the risks to the patient and to the child to be conceived; see s. 19.

⁵² Regulatory Impact Analysis Statement, *supra*, note 51 at 1719, 1721.

⁵³ *Ibid.*, s. 4. (1)(b).

⁵⁴ *Ibid.*, ss. 14-15.

⁵⁵ R.S.C. 1985, c. E-15.

⁵⁶ Various acts to amend the *Excise Tax Act*, *ibid.*, have described human sperm using the language of property: *Goods and Services Tax Act*, S.C. 1990, c. 45, s. 180(1) and *Excise Tax Act*, S.C. 1993, c. 27, s. 180(2), address the importation of human sperm; R.S.C. 1985, E-15, Sch. VI, "Zero-Rated Supplies," Part I, s. 5 considers "a supply of human sperm" under the heading of prescription drugs and biologicals deemed "zero-rated supplies" for purposes of G.S.T. application.

⁵⁷ *Public Health Protection Act*, R.S.Q., c. P-35, s. 1 (the cited definition is not yet in force).

tection," including the assurance of public access to services, the collection of medical information, and the issuance of permits for medical services.⁵⁸

In addition, Quebec, Newfoundland, and the Yukon, under family law have regulated the use of donor sperm.⁵⁹ These provinces have legislated the presumption that the male partner of a woman inseminated with donor sperm is deemed the father of the child if he consented to the donor insemination. Quebec is the only province to have regulated procreation and gestation agreements.⁶⁰ It deems procreation or gestation agreements made on behalf of another person as "absolutely null."⁶¹ In Quebec, the gestational mother is deemed to be the mother for legal purposes.⁶² The province also provides that a child born from medically-assisted procreation may apply to a court to have health-related information about his or her genetic parents transferred to the medical authorities, where the deprivation of this information would cause serious injury to the child's health or the health of close relatives.⁶³

All provinces have legislation regulating the exchange of human tissues, ostensibly for the purpose of organ transplantation. The legislation in most provinces involves the same definition for human tissue: "includes an organ, but does not include any skin, bone, blood, blood constituent or other tissue that is replaceable by natural processes of repair."⁶⁴ A few provinces and territories have not explicitly defined "tissue."⁶⁵ The question of whether or not human tissue includes gametes and embryos is left to the courts in these jurisdictions. One might argue that gametes are genetically unique and "replaceable by natural processes of repair," like blood. On the other hand, while embryos are genetically unique, they are not exactly replaceable.

In response to this legislative uncertainty, the provinces of Ontario, Manitoba and Prince Edward Island amended the human tissue legislation to expressly exclude gametes and embryos. Ontario, for example, now defines human tissue

⁵⁸ *Ibid.*, s. 2.

⁵⁹ See *Children's Act*, R.S.Y.T. 1986, c. 22, s. 13; arts. 538-542 *Civil Code of Quebec*, S.Q. 1991, c. 64 [hereinafter C.C.Q.]; *Children's Law Act*, R.S.N. 1990, c. C-13, s. 12.

⁶⁰ An analysis of the legal implications of gestational agreements is beyond the scope of this chapter.

⁶¹ Art. 541 C.C.Q.

⁶² See art. 53 C.C.Q.

⁶³ Art. 542 C.C.Q.

⁶⁴ For example, see *Human Tissue Gift Act*, R.S.A. 2000, c. H-15, s. 1(e); *Human Tissue Gift Act*, R.S.B.C. 1996, c. 211, s. 1; *Human Tissue Gift Act*, R.S.Y. 1986, c. 89, s. 1; *Human Tissue Gift Act*, R.S.N.S. 1989, c. 215, s. 2(c); *Human Tissue Act*, R.S.S. 1978, c. H-15, s. 2(c); *Human Tissue Act*, R.S.N.B. 1973, c. H-12, s. 8(1), as am.; *Human Tissue Act*, R.S.N. 1990, c. H-15, s. 2. But see also art. 19 C.C.Q., which states that a person may "... alienate a part of his [sic] body only if that part is capable of regeneration and provided that no serious risk to his [sic] health results." Article 25 of the *Civil Code of Quebec* requires that "[t]he alienation by a person of a part or product of his body shall be gratuitous; it may not be repeated if it involves a risk to his [sic] health."

⁶⁵ See *Human Tissue Act*, R.S.N.W.T. 1988, c. H-6. Nunavut has adopted the Northwest Territories legislation. Similarly, the *Civil Code of Quebec* does not define "body parts"; see arts. 11-25 C.C.Q.

as: "a part of a living or dead human body and includes an organ but, unless otherwise prescribed by the Lieutenant Governor in Council, does not include bone marrow, spermatozoa, an ovum, an embryo, a foetus, blood or blood constituents."⁶⁶ The legislative amendments by Ontario, Manitoba and Prince Edward Island arguably increase the likelihood that courts in provinces without clear definitions of "human tissue" will include gametes and embryos. We will further discuss human tissue legislation later in this chapter.

B. PROPOSED LEGISLATION

In response to growing public concerns, the Government of Canada appointed the Royal Commission on New Reproductive Technologies in October 1989.⁶⁷ The mandate empowered the Royal Commission to examine: "[the] implications of new reproductive technologies for women's reproductive health and well-being," "the causes, treatment and prevention of male and female infertility," various reproductive and related technologies, "social and legal arrangements, the status and rights of people using or contributing to reproductive services," and "the economic ramifications of these technologies."⁶⁸ The Royal Commission set forth an "ethic of care" framework and a guiding set of eight ethical principles for decision-making: "individual autonomy, equality, respect for human life and dignity, protection of the vulnerable, non-commercialization of reproduction, appropriate use of resources, accountability, and balancing of individual and collective interests."⁶⁹ In doing so, the Royal Commission promoted "mutual care and connectedness" between individuals, families and communities.⁷⁰ The Royal Commission further elaborated, "[t]he ethic of care means that a large part of ethical deliberation is concerned with how to build relationships and prevent conflict, rather than being concerned only with resolving conflicts that have already occurred." The interests of individuals and communities thus may be considered interdependent.⁷¹

Under an "ethic of care" framework, the Royal Commission analyzed much empirical evidence and formalized its position on the regulation of new reproductive and genetic technologies in Canada. In November 1993, the Royal Commission made public 293 recommendations, concluding: "decisive, timely, and comprehensive national action is required with respect to the regulation of new reproductive technologies."⁷² In particular, the Royal Commission called

⁶⁶ *Trillium Gift of Life Network Act*, R.S.O. 1990, c. H. 20, s. 1, as am. Manitoba and P.E.I. have also explicitly excluded spermatozoa, ova, embryos, blood, and blood constituents: *Human Tissue Gift Act*, S.M. 1987-88, c. 39, s. 1; *Human Tissue Donation Act*, R.S.P.E.I. 1988, c. H-12.1, s. 1. The Manitoba provision also excludes placenta from the definition of "tissue."

⁶⁷ The Royal Commission was established under Part I of the *Inquiries Act*, R.S.C. 1985, c. I-11, with a mandate by Order in Council Nos. P.C. 1989-2150 (October 1989) and P.C. 1991-524 (March 1991).

⁶⁸ Royal Commission, *supra*, note 3 at 3.

⁶⁹ *Ibid.*, at 53.

⁷⁰ *Ibid.*, at 50.

⁷¹ *Ibid.*, at 52.

⁷² *Ibid.*, at 107.

for legislation to set clear boundaries around acceptable and non-acceptable uses of new reproductive and genetic technologies and to regulate and monitor the use of acceptable practices and developments in this field. To achieve this goal, the Royal Commission stated that the federal government should use its power under the *Criminal Code*⁷³ to prohibit practices that "because of their unsafe or unethical character [are] considered unacceptable under any circumstances."⁷⁴ In addition, the Royal Commission recommended the establishment of a national regulatory commission charged with the responsibility of setting and enforcing standards for those practices deemed acceptable. The major functions of this proposed national commission were to be: "licensing and monitoring; guideline and standard setting; information collection, evaluation, and dissemination; records storage; consultation, coordination, and intergovernmental cooperation; and monitoring of future technologies and practices."⁷⁵

In July 1995, the federal Minister of Health, the Honourable Diane Marleau, called for an interim moratorium on specific applications of new reproductive and genetic technologies, and announced the appointment of an advisory committee to monitor compliance with the moratorium.⁷⁶ In June 1996, the federal government introduced Bill C-47, *An Act Respecting Human Reproductive Technologies and Commercial Transactions Relating to Human Reproduction* (in short, *The Human Reproductive and Genetic Technologies Act*), providing for criminal sanctions for the most serious acts including those named in the moratorium. The Bill would have prohibited "practices that commercialize reproduction or are inconsistent with the principles of human dignity, including the buying and selling of eggs and sperm, sex selection for non-medical reasons, and commercial surrogacy."⁷⁷ In addition, Bill C-47 included in the list of prohibited activities: implanting animal embryos into humans or *vice versa*; fusing human and animal zygotes or embryos; maintaining human embryos outside the human body (beyond the 14-day limit); germ-line alterations; manipulating ova or embryos; fertilizing animals with human sperm, or *vice versa*; retrieving the ovum or sperm from a fetus or cadaver with the intention of maturing, fertilizing or implanting the ovum in a woman or outside the human body; or causing the fertilization of an ovum outside the human body for purposes of research. Sanctions for engaging in prohibited activities ranged from significant fines to imprisonment for a term not exceeding 10 years.

⁷³ R.S.C. 1985, c. C-46.

⁷⁴ Royal Commission, *supra*, note 3 at 108.

⁷⁵ *Ibid.*, at 115-16.

⁷⁶ Health Canada, News Release 1996-44 (Ottawa, 14 June 1996). See J. Woodard "Policy Experimentation in a Petri Dish" (14 August, 1995) 10:30 Western Report 36. See also Health Canada, *New Reproductive Technologies: Setting Boundaries, Enhancing Health* (Ottawa: Supply and Services Canada, 1996) at 24-26. Marleau's narrow response may have been directly related to the Royal Commission's position against a general moratorium; see Royal Commission, *ibid.*, at 15.

⁷⁷ Health Canada, News Release 1996-44, *supra*, note 76; Bill C-47, *Human Reproductive and Genetic Technologies Act*, 2nd Sess., 35th Parl., 1996, ss. 3-7.

Bill C-47 received a range of responses, including much criticism of the government's use of criminal prohibitions.⁷⁸ The Canadian Bar Association ("CBA") strongly criticized the use of absolute criminal prohibitions for failing to balance "individual autonomy" and "the dangers inherent in the use of the technology."⁷⁹ They also discussed concerns about the possible "chilling effect" on research and clinical practice. The CBA supported policy guidelines that would allocate a determinative role to the professions in self-regulation and to patient autonomy. While supporting scientific freedom, the CBA criticized several provisions of Bill C-47 for their "highly scientific" and "inaccessible" language and expressed a general concern over the "complexity, over-breadth and lack of precision" of the legislation, particularly given the absolute criminal prohibitions. Bill C-47 was also criticized for its lack of focus and unenforceability.⁸⁰ According to another commentator, a regulatory framework seems preferable to the use of criminal law sanctions, which may create an underground market for human reproduction.⁸¹ A regulatory framework might better support women's reproductive autonomy, while avoiding problems in reaching a public consensus, the unavailability of donors, and the potential exploitation of women within an underground market.⁸²

At the same time as the introduction of Bill C-47, the federal government published a White Paper, entitled *New Reproductive Technologies: Setting Boundaries, Enhancing Health*⁸³ promising to establish a regulatory body and framework within which the regulation of acceptable practices would take place. A two-step enactment process was proposed for legislation that would eventually combine prohibitions (under Bill C-47) and regulatory controls to provide for "a comprehensive management regime for new reproductive and genetic technologies."⁸⁴ Any such regime would promote a multidisciplinary approach, and would be established under an agency removed from central government.⁸⁵ The proposed regime would centre on the issuance of licences for various new reproductive and genetic technologies and related practices, and the establishment of appropriate standards by a range of enforcement mechanisms, as well as information registries and health surveillance procedures. Due to the various pressures of an upcoming federal election, the proposed regime failed to materialize, and Bill C-47 died on the order paper.

⁷⁸ See the Canadian Bar Association, "Submission on Bill C-47" [on file with authors]; A. Harvison Young, "Brief Prepared for the Standing Committee on Health on Bill C-47"; P. Healy, "Statutory Prohibitions and the Regulation of New Reproductive Technologies Under Federal Law" (1995) 40 McGill L.J. 905.

⁷⁹ Canadian Bar Association, *supra*, note 78.

⁸⁰ *Ibid.*

⁸¹ Healy, *supra*, note 78.

⁸² Harvison Young, *supra*, note 78. The Supreme Court of Canada decision of *R. v. Morgentaler*, [1988] 1 S.C.R. 30, has often been cited for constitutional support of a woman's reproductive autonomy in the context of abortion.

⁸³ See *New Reproductive Technologies: Setting Boundaries, Enhancing Health*, *supra*, note 76.

⁸⁴ *Ibid.*, at 27.

⁸⁵ *Ibid.*

In May 2001, Allan Rock, the federal Minister of Health, took the unusual step of presenting new draft legislation entitled "Proposals for Legislation Governing Assisted Human Reproduction" before the Parliamentary Standing Committee on Health. He instructed the Committee to review the draft legislation and report on it by the end of January 2002.⁸⁶ The draft legislation combines the criminal prohibitions in Bill C-47 with the regulatory framework outlined in the 1996 White Paper. Therefore, the draft legislation includes both *prohibited activities*, which carry criminal sanctions, and *controlled activities*, which are regulated through the issuance of licences.

The draft AHRA, like Bill C-47, contains a preamble that sets out a number of guiding principles and considerations that inform the Act, and guides lawmakers in interpreting and implementing the legislation. Included in this list are: recognition of the need to "protect and promote the best interests of children"; recognition that "women more than men are directly and significantly affected by" the application of RTs; a commitment to the principle of "free and informed consent" in the use of RTs; a recognition of the "health and ethical concerns inherent in the trade in the reproductive capacities of women and men," and in their exploitation and that of children for commercial ends; and a recognition of the "importance of preserving and protecting human individuality and the integrity of the human genome." A number of these principles were stated in Bill C-47 as well. However, there is a significant shift in the attitude towards reproductive and genetic technologies expressed in the two pieces of draft legislation. Whereas the preamble of Bill C-47 began with an expression of grave concern "about the significant threat to human dignity, the risks to human health and safety, both known and unknown, and other serious social and ethical issues posed by certain reproductive and genetic technologies," the preamble of the draft AHRA begins with an acknowledgment of "the benefits to individuals and to society in general of assisted human reproductive technologies" and "believes that those benefits can be most effectively secured by taking appropriate measures for the protection and promotion of human health, safety, dignity and rights in the use of such technologies." Another difference between Bill C-47 and the draft AHRA is that the former contained a set of legislative objectives.⁸⁷ Although the draft AHRA is silent about the objectives of the legislation, information published by Health Canada at the time the draft legislation was introduced states that it has two primary objectives: first, to "ensure that Canadians using assisted human reproduction techniques do so without compromising their health and safety," and second, to "ensure that promising research involving human reproductive materials takes place within a regulated environment."⁸⁸

⁸⁶ The common procedure would have been to introduce a bill in the House of Commons rather than instructing a Standing Committee to review draft legislation.

⁸⁷ The objectives set out in Bill C-47, s. 3 were: the protection of "health and safety of Canadians in the use of human reproductive materials"; ensuring the appropriate treatment of *ex utero* human reproductive materials "in recognition of their potential to form human life," and protection of the "dignity of all persons, in particular children and women, in relation to uses of human reproductive materials."

⁸⁸ Health Canada, News Release, "Rock launches review of draft legislation on assisted human

This second purpose, while not overtly expressed in the text of the draft legislation, appears to inform many of the activities designated as controlled.

As stated earlier, the draft AHRA identifies both prohibited and controlled activities. Those activities prohibited under the draft legislation are very similar to those prohibited under Bill C-47 and include: human cloning by embryo separation and somatic cell nuclear transfer; germ-line genetic alteration; the development of an embryo outside a woman's body beyond the accepted 14-day limit; the creation of embryos solely for research; creating an embryo from another embryo or fetus; transplanting reproductive material from animals into humans; the use of human reproductive material previously transplanted into an animal; the sale and purchase of human embryos; sex selection (except for reasons relating to the health of the resulting human being); the purchase, barter or exchange of sperm or ova; and commercial surrogacy arrangements. In addition, the draft AHRA contains specific provisions prohibiting the use of gametes obtained from a minor and prohibiting the counseling or inducement of a minor to become a surrogate.⁸⁹ The prohibition against human cloning and provisions related to minors are the only new items to be added to this list. Anyone convicted on indictment of a prohibition may face a fine of up to \$500,000, or a jail term of no more than 10 years, or both. Summary convictions may result in a fine of up to \$250,000, or a jail term of no more than 4 years, or both.

In addition to setting out a range of prohibited practices, the draft AHRA also lists controlled activities permitted only if carried out under license and in accordance with the regulations of the draft AHRA. The controlled activities set out in the draft AHRA include: altering, manipulating or treating human reproductive material for the purpose of creating an embryo or facilitating human reproduction; using an *in vitro* embryo, or part of one for research or the prevention, diagnosis or treatment of a disease, injury or disability; exporting, storing or handling gametes or embryos for reproductive or research purposes; the creation of a chimera; combining any part of the human genome with that of an animal species; and reimbursing the donor of gametes, *in vitro* embryos, human cells or genes for expenses incurred in the course of donating, or reimbursing a surrogate mother for her expenses incurred in relation to her pregnancy. The classes of controlled activities are not fixed, however, as the Governor in Council may make regulations "designating classes of controlled activities that may be authorized by a license issued under subsection 12(1)" of the draft AHRA.⁹⁰

The draft legislation recognizes the significance of health information, both as a privacy issue and as an important societal resource for the promotion of health. To this end, the draft AHRA mandates the maintenance of a personal

reproduction to ban cloning and regulate related research" (3 May 2001), online: <http://www.hc-sc.gc.ca/english/media/releases/2001/2001_44e.htm>. See also: Health Canada "Assisted Human Reproduction — Frequently asked Questions" (May 2001), online: <http://www.hc-sc.gc.ca/english/media/releases/2001/2001_44ebk3.htm>.

⁸⁹ See ss. 4(5) and 7(1) and (2) of the draft AHRA.

⁹⁰ *Ibid.*, s. 40(1)(a). This section also refers to "classes of controlled activities that may not be authorized."

health information registry⁹¹ and a public health registry.⁹² The draft AHRA seeks to restrict personal nominative information and endeavours as far as possible to keep the use of such information at the discretion of donors and persons conceived through RTs.⁹³ It also mandates the collection of health information for purposes of public health and makes that information available for public health purposes and accessible to the descendants of donors.⁹⁴ The draft legislation further mandates access to the information used to evaluate and adjudicate applications for a licence.⁹⁵ The exact nature of the information to be disclosed for the purposes of public health is subject to regulations, the details of which are not specified in the draft legislation.

The draft AHRA empowers the Minister of Health with broad discretion to regulate the proposed controlled activities.⁹⁶ The main regulatory instrument specified in the draft legislation with respect to these activities is the issuing of licences under the discretion of the Minister of Health. This proposed licensing regime does not distinguish between clinical reproductive uses and research uses of reproductive materials but rather includes them in the same regulatory framework. The language of the statutory provisions outlining the Minister's authority to administer the regulatory regime is permissive rather than directive ("the Minister may" rather than "the Minister shall")⁹⁷ and includes the power to: amend or revoke the terms and conditions of a licence at any time,⁹⁸ amend or suspend a licence,⁹⁹ and renew a licence.¹⁰⁰

In general, the draft AHRA proposes control over a broad range of activities pursuant to regulations under the Governor in Council. These regulations are not specified in the legislation, but the promotional literature from Health Canada that accompanied the introduction of the draft AHRA suggests that the regulations will set out: counselling requirements for donors and recipients; safety requirements of laboratories; how human gametes and embryos are to be handled and stored; limitations on the number of embryos that can be transplanted during IVF; and requirements for informed consent.¹⁰¹ However, only one of the subjects listed is specifically mentioned in s. 40(1), the section empowering the Governor in Council to make regulations to implement the Act.

Following the recommendations of the Royal Commission, it was broadly anticipated that a specialized body would be established to oversee and regulate the practice and use of reproductive and genetic technologies. However, the

⁹¹ *Ibid.*, s. 21(2).

⁹² *Ibid.*, s. 22.

⁹³ *Ibid.*, s. 19.

⁹⁴ *Ibid.*, s. 20.

⁹⁵ *Ibid.*, s. 22.

⁹⁶ *Ibid.*, s. 12.

⁹⁷ See, for example, ss. 12, 13, 14, 16, 17, 21 and 23.

⁹⁸ *Ibid.*, s. 13.

⁹⁹ *Ibid.*, s. 14.

¹⁰⁰ *Ibid.*, s. 13.

¹⁰¹ Health Canada, "Proposals for legislation governing assisted human reproduction: Executive summary" (May 2001), online: <http://www.hc-sc.gc.ca/english/media/releases/2001/2001_44ebk1.htm>.

draft legislation says only that the Minister of Health may "take into account information and observations offered by any person and may seek the advice of persons having expertise" when considering an application for a licence. The draft legislation neither mandates nor empowers the establishment of a specialized expert commission to implement and administer the regulatory regime.¹⁰² In the absence of any specialized body mandated by this draft legislation, only the bureaucracy of Health Canada can administer the licensing policy. In a puzzling discrepancy, a document released by Health Canada to accompany the draft AHRA envisages the establishment of a regulatory body, either within Health Canada or at arm's length to it, responsible for the implementation of the proposed legislation.¹⁰³ The document identifies four functions to be carried out by that body: licensing and enforcement, health information, policy development, and communications. It further suggests that the composition of the regulatory body will be "broadly representative of all parties interested in assisted human reproduction."¹⁰⁴ By contrast, the draft legislation itself mandates only the designation of inspectors by the Minister to enforce the regulatory scheme.¹⁰⁵ Furthermore, the draft AHRA recognizes the concurrent nature of federal jurisdiction of the subjects regulated under the draft legislation by empowering the Governor in Council to suspend its regulations by agreement with a province where equivalent regulations and prohibitions exist.¹⁰⁶

C. CONSTITUTIONAL CONSTRAINTS

Prior to legislative drafting, governments must consider constitutional dimensions. RTs must be regulated according to the division of powers of the *Constitution Act, 1867*,¹⁰⁷ and must also meet the guarantees under the *Charter*.

1. Division of Powers

Sections 91 and 92 of the *Constitution Act, 1867* set forth the division of powers between the federal and provincial governments. Section 91 distributes legislative

¹⁰² Section 15(1) of the draft AHRA.

¹⁰³ Health Canada, "Proposals for Legislation Governing Assisted Human Reproduction: An Overview" (May 2001) at 9, online: <http://www.hc-sc.gc.ca/english/pdf/reproduction/repro_over.pdf>.

¹⁰⁴ *Ibid.*, at 10.

¹⁰⁵ Section 23 of the draft AHRA.

¹⁰⁶ *Ibid.*, s. 41(1). See also the final report on the draft AHRA: House of Commons Standing Committee on Health, "Assisted Human Reproduction: Building Families" (December 2001). Among its 36 recommendations, the Standing Committee stated that: the enactment of new legislation should be a priority; embryos should be used for research only if no other biological materials are available; payments to gamete donors and surrogates should be prohibited; donors of gametes and embryos should consent to the release of identifying information; the federal and provincial governments should enter into agreements ensuring uniform standards and enforcement; a regulatory body should be created semi-independent to and outside of the Department of Health; and the *Patent Act* should be amended to prohibit the patenting of human materials.

¹⁰⁷ (U.K.), 30 & 31 Vict., c. 3.

jurisdiction to the federal government as a matter of "national interest and concern" under the criminal law [s. 91(27)], trade and commerce [s. 91(2)], taxation [s. 91(3)], federal spending (as inferred from various sections), and treaty powers (as inferred), as well as the residual category of peace, order and good government.¹⁰⁸ Under s. 92, the provinces have legislative jurisdiction for matters of property and civil rights [s. 92(13)], hospitals [s. 92(7)], and the residual category of matters of a merely local or private nature in the province [s. 92(16)]. The courts have generally recognized that Parliament or the provincial legislatures have jurisdiction over a specific area if it falls in "pith and substance" under an enumerated category. However, the constitutionality of federal or provincial legislation is not undermined where the legislation has an incidental effect on other enumerated categories. As well, the courts have recognized that a matter may have a "double aspect" in that it falls under provincial jurisdiction for one purpose, and federal jurisdiction for another purpose.¹⁰⁹

It has been argued that the very fact the federal government initiated the Royal Commission is evidence enough to pull it under federal jurisdiction as a "national concern."¹¹⁰ Parliament may also find the power to regulate RTs under other areas, including criminal law, trade and commerce, taxing, federal spending, and treaty powers. Parliament could possibly regulate reproductive technologies under the *Canada Health Act*.¹¹¹ However, even if the federal government can regulate RTs under one or more of these categories, the provinces may nonetheless regulate incidental effects under, for example, their powers over hospitals and health plans.

The federal and provincial governments have not yet formally addressed issues of standardization and uniformity for the definition and treatment of infertility, access criteria, and funding of RTs. It remains to be seen in which ways mutual co-operation will be required of federal and provincial governments, in light of the *Constitution Act, 1867*. A regulatory framework at the federal level may best address not only rapidly changing RTs and social norms, but also changing tensions in federal-provincial relations. It seems, nevertheless, that many unfolding issues concerning the regulation and effects of RTs, and particularly the uncertainty in the use and disposition of human "materials," are best a matter for legislatures (as a more representative body) and not the elite institutions of courts.

¹⁰⁸ M. Jackman, "The Constitution and the Regulation of New Reproductive Technologies" in Royal Commission on New Reproductive Technologies, *Overview of Legal Issues in New Reproductive Technologies*, vol. 3 (Ottawa: Ministry of Supply and Services, 1993) [hereinafter, "Regulation of NRTs"] 1; M. Jackman, "Constitutional Jurisdiction Over Health in Canada" (2000) 8 Health L.J. 95; M.A. McTeer, *Tough Choices: Living and Dying in the 21st Century* (Toronto: Irwin Law, 1999).

¹⁰⁹ For an interesting and detailed discussion, see Jackman, "The Constitution and the Regulation of New Reproductive Technologies," *supra*, note 108.

¹¹⁰ *Ibid.*, at 5.

¹¹¹ R.S.C. 1985, c. C-6.

2. The Charter

The *Charter* guarantees rights and freedoms except where the government can show reasonable and demonstrable justification in a free and democratic society. The *Charter* applies only to government conduct and legislation (and inaction); it does not directly concern private activities.¹¹² The governmental regulation of RTs may face *Charter* scrutiny under various sections, particularly s. 7 (the right to life, liberty and security of the person) and s. 15 (equality). There are a number of issues involving the use of RTs which are likely to require *Charter* analysis, including: the "right" to biological parenthood through the use of and access to RTs, and whether or not the rights and interests of surrogate mothers, gamete donors, embryos and fetuses may be recognized under the *Charter*. In the absence of Canadian jurisprudence, some limited guidance may be gathered from American and other foreign jurisprudence on similar constitutional issues. We will address *Charter* issues, specifically the issue of access through a right to biological parenthood, and the issue of the legal status of gametes and embryos, as they arise in subsequent sections in this chapter.

D. HUMAN RIGHTS LEGISLATION

While the *Charter* applies only to government action or inaction, human rights legislation applies to both public and private sector activities, including those of individuals and corporations.¹¹³ Most human rights codes in Canada recognize that individuals shall not be discriminated against on the basis of "race, national or ethnic origin, colour, religion, age, sex, sexual orientation, marital status, family status, disability and conviction for which a pardon has been granted." Section 3(2) of the *Canadian Human Rights Act* further states: "Where the ground of discrimination is pregnancy or child-birth, the discrimination shall be deemed to be on the ground of sex." Although similar in substance, the provincial human rights codes for each Canadian province contain nuances based on varying language that may warrant further analytical attention. The Ontario *Code*, for example, states: "Every person has a right to equal treatment with respect to services, goods and facilities, without discrimination because of race, ancestry, place of origin, colour, ethnic origin, citizenship, creed, sex, sexual orientation, age, marital status, same-sex partnership status, family status or disability."¹¹⁴ The Quebec *Charter*, on the other hand, more broadly states: "Every

¹¹² See *Eldridge v. British Columbia (A.G.)*, [1997] 3 S.C.R. 624 (equality of rights for disabled's access to sign language interpreters as covered under a publicly funded scheme and where the Medical Services Commission has discretion over the expenditure and thus provision of medical care services under such scheme).

¹¹³ See, for example, the *Canadian Human Rights Act*, R.S.C. 1985, c. H-6, s. 3, as am.; *Human Rights Code*, R.S.O. 1990, c. H.19, s. 1; *Charter of Human Rights and Freedoms*, R.S.Q., c. C-12, s. 10; *Human Rights, Citizenship, and Multiculturalism Act*, R.S.A. 2000, c. H-14, s. 7; *Human Rights Code*, R.S.B.C. 1996, c. 210, s. 7(1).

¹¹⁴ Ontario *Human Rights Code*, *supra*, note 113, s. 1. The B.C. *Human Rights Code* includes "race, colour, ancestry, place of origin, religion, marital status, family status, physical or mental disability, sex, sexual orientation or age of that person or that group or class of persons." The

person has a right to full and equal recognition and exercise of his [*sic*] human rights and freedoms, without distinction, exclusion or preference based on race, colour, sex, pregnancy, sexual orientation, civil status, age except as provided by law, religion, political convictions, language, ethnic or national origin, social condition, a handicap or the use of any means to palliate a handicap.¹¹⁵ In the context of RTs, it is likely that human rights legislation will be most commonly invoked by those wishing to use assisted procreation but who are denied access on the basis of one of the prohibited grounds of discrimination. We will discuss the case law concerning human rights legislation as part of the section on access to reproductive technologies later in this chapter.

E. COMMON LAW

In the absence of comprehensive legislation regulating RTs, the courts have resolved disputes by resorting to existing common law rules and principles. While the jurisprudence regarding RTs remains relatively undeveloped in Canada, there are several cases that have considered issues related to RTs in the areas of family, contract, employment and tort law. These cases include issues related to the standards for medical practice concerning RTs, the status and quality of sperm donation, determinations of paternity where AID has been used, access to RTs, and the assessment and measure of damages. We will refer to these cases throughout the remainder of this chapter.

F. PROFESSIONAL GUIDELINES AND POLICIES

Medical professionals whose practice involves the use of RTs must satisfy the formal requirements of professional regulation in their area of practice, and follow the practice guidelines established by their respective regulatory bodies.¹¹⁶ Several societies and associations have created ethical guidelines for medical professionals concerned with assisted reproduction. The Society of Obstetricians and Gynaecologists of Canada ("SOGC") and the Canadian Fertility and Andrology Society ("CFAS") have produced a joint policy statement on ethical issues to guide the conduct of medical professionals practising in the area of assisted reproduction.¹¹⁷ This document includes policy statements on access to RTs, informed consent, commercial preconception agreements, embryo research, and the use and transfer of gametes and embryos.

Alberta Human Rights Citizenship and Multiculturalism Act [Alberta Human Rights Code], in contrast, encompasses "race, religious beliefs, colour, gender, physical disability, mental disability, age, ancestry, place of origin, marital status, source of income or family status of that person or class of persons." See also *Vriend v. Alberta*, [1998] 1 S.C.R. 493, which read into the *Alberta Human Rights Code* protection against discrimination based on sexual orientation.

¹¹⁵ Quebec Charter of Human Rights and Freedoms, *supra*, note 113, s. 10.

¹¹⁶ For more information about this issue and the regulation of health care professionals in general, see chapter 2 of this book.

¹¹⁷ Society of Obstetricians and Gynaecologists of Canada, "Policy Statement: Ethical Issues in Assisted Reproduction" (January 1999) 21(1) J. Soc. Obstet. Gynaecol. Can. 1 [hereinafter the *Joint Policy Statement of Medical Professionals*].

Because RTs are used in both clinical and research contexts, guidelines and policies exist regarding their use in both of these contexts. A statement of professional guidelines for embryo research can be found in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* ("Tri-Council Policy Statement"), which was drafted on behalf of the three federal funding agencies in 1998.¹¹⁸ This document sets out ethical guidelines that must be satisfied before research is eligible for government funding.¹¹⁹ In addition to case law and legislation, professional guidelines play an important role in the regulation of the use of RTs in the clinical and research contexts. We will discuss the *Tri-Council Policy Statement* and the *Joint Policy Statement of Medical Professionals* in more detail throughout the remainder of this chapter.

III. SPECIFIC LEGAL ISSUES AND CHALLENGES

A. ACCESS TO REPRODUCTIVE TECHNOLOGIES

Most individuals seek access to RTs because they wish to have a child and are either unable or unwilling to do so through sexual intercourse. Not all individuals who want to use RTs will be able to do so. Access to reproductive technologies may be limited by a number of considerations, such as formal or informal medical criteria and the high cost of treatment. In some circumstances, decisions about access to RTs will be made by physicians who screen applicants according to criteria established by private infertility clinics or set out in professional guidelines. Provincial health insurance legislation may also restrict access by not insuring certain forms of RTs under provincial health care insurance plans.¹²⁰ Furthermore, legislatures may also specify who may have access to RTs and in what circumstances. Where individuals encounter such barriers that limit their access to RTs, the barriers may be challenged under the *Charter* and/or provincial human rights codes. We will now focus on a few of the more likely *Charter* challenges under ss. 7 and 15 and their relevance to the regulation of RTs.

To access RTs, individuals or couples usually approach a physician in a private fertility clinic or public hospital. Clinics and hospitals use a variety of criteria to determine access to RTs. First, the clinic or hospital determines whether the individual or couple would benefit overall from such assistance. The criteria typically centre on the potential benefits and risks to the health and safety of participants based on various medical factors, including the condition of infer-

¹¹⁸ *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (Ottawa: Public Works and Government Services Canada, August 1998).

¹¹⁹ *The Tri-Council Policy Statement* was created by the Medical Research Council of Canada, the Social Sciences and Humanities Research Council of Canada, and the Natural Sciences and Engineering Research Council of Canada. See also the Canadian Institutes of Health Research, *Human Pluripotent Stem Cell Research: Guidelines for CIHR-Funded Research* (4 March 2002), online: <http://www.cihr.ca/about_cihr/ethics/stem_cell/stem_cell_guidelines_e.shtml> (date accessed: 23 April 2002).

¹²⁰ See, for example, the Ontario *Health Insurance Act*, R.S.O. 1990, c. H.6.

tility and the participants' age. Some physicians have also adopted other, non-medical criteria to limit access to *in vitro* fertilization, including a woman's or couple's ability to parent. Factors some practitioners consider relevant to successful parenting include: psychological immaturity; below-average intelligence; physical disability; other children living with the prospective parents; low income; and place of residence. Other criteria relate to the couple's or individual's marital status, the presence of a partner, and sexual orientation.¹²¹ Individuals and couples may also face discriminatory barriers based on race and ethnicity.

Cost is another barrier to RTs. Access criteria vary among clinics and across provinces, raising concerns not only about the uniformity of standards, but also about mobility barriers based on class.¹²² Many individuals and couples who seek access to RTs depend upon health care insurance to pay for RTs, but few RTs are paid for under provincial health insurance schemes. In Ontario, for example, the *Ontario Health Insurance Plan* ("OHIP") guidelines regulate such funding and thus establish access barriers. Women may access public funding for *in vitro* fertilization if they show "complete bilateral anatomical fallopian tube blockage."¹²³ Moreover, OHIP only provides funding for up to three complete cycles of *in vitro* fertilization, and does not fund micro-manipulation techniques for the treatment of male infertility, such as intracytoplasmic sperm injection. This suggests that perhaps access to health care funding is shaped by the view that RTs are treatment of a female medical problem.

Any regulatory framework that limits access to RTs may face challenges under the *Charter*. The *Charter* may be invoked to challenge statutory provisions and regulations that limit access either directly on the basis of medical factors, or indirectly on the basis of listed services under provincial health insurance plans. Three clusters of constitutional arguments could be invoked in order to gain access to RTs. Broadly speaking, an argument for a positive "right to procreate" may be constructed on the basis of s. 7 rights to liberty. Alternatively, access to reproductive technologies could be sought using s. 7 on the grounds that it includes a positive right to health care and that access to RTs is an intrinsic component of that right. A third basis from which to challenge access to RTs is s. 15. Where government legislation or action provides some individuals access to RTs but not others, it may be possible to claim discrimination where such access is denied to individuals who are members of an enumerated or analogous class under s. 15. This line of argument would claim access to RTs as a negative right. The categorization of positive and negative rights is important in light of the Supreme Court of Canada's reluctance to recognize socio-economic rights under the *Charter* generally, and specifically, under s. 7.

A *Charter* challenge places the onus on the parties seeking access to RTs to show that a right or freedom has been infringed in legislative purpose or effect.

¹²¹ Royal Commission, *supra*, note 3 at 552, citing T. Stephens & J. McLean, "Survey of Canadian Fertility Programs," *Royal Commission on New Reproductive Technologies*, vol. 10 (Ottawa: Minister of Supply and Services Canada, 1993), table 16.

¹²² Royal Commission, *supra*, note 3 at 552.

¹²³ *General Regulation* under the *Health Insurance Act*, R.R.O. 1990, Reg. 552, s. 24.

(A person seeking access under s. 7 of the *Charter* has the onus to demonstrate that the deprivation of life, liberty or security of the person is not in accordance with the principles of fundamental justice.) Once an infringement has been established, the focus turns to s. 1 of the *Charter* where the onus shifts to the government to show that the legislation is reasonable and demonstrably justified in a free and democratic society.

Section 7 of the *Charter* states 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." The first analytical step is to determine whether life, liberty or security of the person has been deprived by legislation or government conduct. In light of recent trends in Canadian courts, the regulation of access to RTs is unlikely to fall within the right not to be deprived of life.¹²⁴ In other words, Canadian courts have not yet shown any interest in supporting a right to biological parenthood as essential to one's life.

A more fruitful line of argument might be to establish a positive right to procreate under Canadian constitutional law. A 1993 Report by the LRC discusses a positive right to procreate and concludes: "it seems likely that either liberty or security of the person, or both, will be found in a future case to include the right to procreate."¹²⁵ The *Charter* does not expressly include a right to procreate. However, if such a right exists, it is most likely to be within the s. 7 right to liberty or security of the person.

Section 7 has been raised in a reproductive context in two cases before the Supreme Court of Canada: *R. v. Morgentaler*¹²⁶ and *E. (Mrs.) v. Eve*.¹²⁷ However, it is only in the former that the Court addressed substantive interests involving reproductive claims. Relying on an expansive interpretation of the right to liberty, Wilson J. stated that the right to liberty in s. 7 of the *Charter* "guarantees to every individual a degree of personal autonomy over important decisions intimately affecting their private lives."¹²⁸ With respect to the decision of whether to terminate a pregnancy, Wilson J. stated:

This decision is one that will have profound psychological, economic and social consequences for the pregnant woman ... It is a decision that deeply reflects the way the woman thinks about herself and her relationship to others and to society

¹²⁴ LRC, *supra*, note 2 at 152.

¹²⁵ *Ibid.*, at 164.

¹²⁶ [1988] 1 S.C.R. 30.

¹²⁷ [1986] 2 S.C.R. 388.

¹²⁸ *R. v. Morgentaler*, [1988] 1 S.C.R. 30 at 171. In *R. v. Jones*, [1986] 2 S.C.R. 284 at 318, Justice Wilson affirmed that this broad conception of liberty ought to be protected by s. 7. In *Jones*, the plaintiff argued that an Alberta legislative regime regarding educational instruction violated his parental rights to educate his own children as he saw fit contrary to the s. 7 right to liberty. In her dissent, Wilson J. stated at 318 that:

I believe that the framers of the Constitution in guaranteeing 'liberty' as a fundamental value in a free and democratic society had in mind the freedom of the individual to develop and realize his [*sic*] potential to the full, to plan his [*sic*] own life to suit his [*sic*] own character, to make his [*sic*] own choices for good or ill ... to be ... 'his [*sic*] own person' and accountable as such.

at large. It is not just a medical decision; it is a profound social and ethical one as well. Her response to it will be the response of the whole person.¹²⁹

In protecting a sphere of reproductive liberty in relation to a woman's abortion decision, Wilson J. acknowledged that such a choice falls within the realm of decisions that are protected from state interference by the right to liberty. In articulating the conception of liberty protected by the *Charter*, Wilson J. relied upon a series of American cases that have held that the right to privacy, while not expressly enumerated in the American Constitution and its Amendments, is an aspect of the right to liberty and includes the right to procreate.¹³⁰ One could argue that Wilson J.'s conception of liberty in *Morgentaler* supports the view that a general prohibition on the use of RTs would constitute an infringement of s. 7, as such a prohibition could infringe personal autonomy over important decisions that fundamentally affect the way a woman thinks about herself and her relationship to others.

In *E. (Mrs.) v. Eve*, the Supreme Court of Canada considered whether a court had the power, pursuant to its *parens patriae* jurisdiction, to authorize the contraceptive sterilization of a mentally disabled woman and whether such a sterilization would be in the woman's best interests. In concluding that courts do not have jurisdiction to authorize a non-consensual sterilization for non-therapeutic purposes, La Forest J. writing for the Court stated:

The grave intrusion on a person's rights and the certain physical damage that ensues from non-therapeutic sterilization without consent, when compared to the highly questionable advantages that can result from it, have persuaded me that it can never safely be determined that such a procedure is for the benefit of that person. Accordingly, the procedure should never be authorized for non-therapeutic purposes under the *parens patriae* jurisdiction.¹³¹

In coming to this conclusion, La Forest J. did not find it necessary to rely on the *Charter*. Therefore, whether there is a constitutionally protected right to procreate has yet to be determined. However, throughout his decision, La Forest J. did suggest that there was a "growing legal recognition of the fundamental character

¹²⁹ *Morgentaler*, *supra*, note 28 at 171.

¹³⁰ *Skinner v. Oklahoma*, 316 U.S. 535 (1942) at 541, holding that the forced sterilization of habitual criminals violated the equal protection clause. In his opinion, Douglas J. characterized the right to reproduce as "one of the basic civil rights of man." *Eisenstadt v. Baird*, 405 U.S. 438 (1972) at 453, in which Brennan J. for the majority recognized that the right to privacy includes "the right of the individual, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child"; *Griswold v. Connecticut*, 381 U.S. 479 (1965) recognizing that the right to personal privacy includes the choice to use contraceptives to avoid procreation; *Roe v. Wade*, 410 U.S. 113 (1973), recognizing the right to abortion as an aspect of the right to privacy.

¹³¹ *Supra*, note 127 at 431.

of the right to procreate"¹³² and that a non-consensual sterilization would constitute a deprivation of this right. As noted by the LRC:

Justice La Forest pointed out the "growing legal recognition of the fundamental character of the right to procreate," "the great privilege of giving birth," and "[t]he importance of maintaining the physical integrity of a human being ... particularly as it affects the privilege of giving life." He characterized the proposed sterilization as a "grave intrusion on a person's rights" and an "irreversible and serious intrusion on the basic rights of the individual."¹³³

It remains to be seen whether Canadian courts will accept an interpretation of s. 7 that supports individual autonomy in procreation. Moreover, even if the courts were to find a right to procreate protected by s. 7 of the *Charter*, this right may be viewed as a negative right — the right to be able to procreate without state interference — rather than a positive right to medically assisted procreation.

The second *Charter* argument is that s. 7 should be interpreted as creating a positive right to basic social services, including the right to health care.¹³⁴ The claim is that such services are fundamental to protecting the values of life, liberty and security of the person. However, even if s. 7 of the *Charter* is found to guarantee the right to health care, it is unlikely that access to RTs would be included under the framework of protected services. Rather, it is likely that a distinction will be drawn between basic health care services which are necessary to sustain life and basic well-being, and those services such as RTs, whose absence, while impoverishing one's quality of life, do not threaten life itself. Therefore, it is not likely that the courts will interpret the *Charter* in a manner that requires legislatures to provide access to RTs. However, where governments do undertake to legislate with respect to the delivery of RTs, the *Charter* may be invoked to ensure that this is carried out in a manner consistent with s. 15.

Section 15 of the *Charter* provides a basis upon which to argue for non-discriminatory access to reproductive technologies. Section 15(1) states that "[e]very individual is equal before and under the law and has the right to the equal protection and equal benefit of the law without discrimination and, in particular without discrimination based on race, national or ethnic origin, colour, religion, sex, age or mental or physical disability."¹³⁵ A law must not discrimi-

¹³² *Ibid.*, at 419-20.

¹³³ LRC, *supra*, note 2 at 163.

¹³⁴ See generally, M. Jackman, "The Protection of Welfare Rights Under the Charter" (1988) 20 *Ottawa L. Rev.* 257; I. Morrison, "Security of the Person and the Person in Need: Section 7 and the Right to Welfare" (1988) 4 *J. L. & Soc. Pol'y* 33; I. Johnstone, "Section 7 of the Charter and the Right to Welfare" (1988) 46 *U.T. Fac. L. Rev.* 1; M. Jackman, "Poor Rights: Using the Charter to Support Social Welfare Claims" (1993) 19 *Queen's L.J.* 65; B.F. Windwick, "Health Care and Section 7 of the Canadian Charter of Rights and Freedoms" (1994) 3:1 *Health L. Rev.* 20; Canadian Bar Association, Task Force on Health Care, *What's Law Got To Do With It?: Health Care Reform in Canada* (Ottawa: Canadian Bar Association, 1994).

¹³⁵ See *Andrews v. Law Society of British Columbia*, [1989] 1 S.C.R. 143.

nate on enumerated or analogous grounds by design or by impact against particular individuals or groups. One could argue that the infertile as a group are discriminated against based on "physical disability." Grounds for access would entail arguing that this group is prevented by the state from having children despite the existence of a remedy in the form of medical treatment using RTs. However, even if the court finds infertility to be a physical disability and that the infertile are discriminated against as a class, this need not result in mandatory access to RTs. The court may hold that alternative remedies (such as adoption, for example) are available to mitigate this form of discrimination. Where access to RTs is available only as an uninsured medical service, there may be grounds to challenge the lack of publicly-insured access on the grounds of socio-economic discrimination. However, since s. 15 properly applies only to areas of positive state action, it would be difficult to employ unless it could be found that the decision not to fund access to RTs was deliberately discriminatory.

A more promising line of argument, therefore, would be to apply s. 15 to those individuals and groups who are currently denied access to RTs under provincial eligibility criteria, where, for example, provinces provide and insure access to some but not to other couples or individuals. Access criteria that rely upon a particular definition of infertility may be more susceptible to challenge under s. 15. Where these definitions appear to rule out or exclude certain groups, for example, single lesbians, or lesbians in a conjugal relationship, but allow access to married heterosexual couples, there may be grounds for a finding of discrimination.¹³⁶ The infertile may claim analogous grounds under s. 15(1), particularly on the basis of social, political and legal disadvantage.¹³⁷ To the extent that infertility, by whatever cause, constitutes a disability, the state may be construed to have favoured the reproductive opportunities of some groups over others through either action or non-action. Economic arguments of budget constraint may not be used to systematically favour particular groups over others.

Provincial authorities (and indeed hospitals) may not be protected against charges of discrimination under the argument that access criteria are based on strictly medical-scientific factors. Some argue that where access criteria for *in vitro* fertilization, for example, are based strictly on medical infertility, then discrimination is unlikely to occur.¹³⁸ However, such arguments ignore the possibility that bias in these criteria may mask the subjective preferences and social prejudices of both those who devise such criteria as well as those medical practitioners who apply them. For example, under many definitions, lesbian couples

¹³⁶ See Royal Commission, *supra*, note 3 at 426-38. Another issue not yet considered by the courts is whether or not gay men can legally access RTs, for example, by way of surrogacy arrangements, in hopes of creating a new form of family.

¹³⁷ See Jackman, "The Constitution and the Regulation of New Reproductive Technologies" in Royal Commission on New Reproductive Technologies, *Overview of Legal Issues in New Reproductive Technologies*, vol. 3 (Ottawa: Ministry of Supply and Services, 1993) at 24-25.

¹³⁸ LRC, *supra*, note 2 at 196. The Royal Commission supports the separation of medical and social factors; *supra*, note 3 at 174.

can never be "medically infertile." In *Korn v. Potter*¹³⁹ the British Columbia Supreme Court affirmed a human rights tribunal decision that a physician's refusal to provide artificial insemination to a lesbian couple was discriminatory on the basis of sexual orientation. This is consistent with the Royal Commission's recommendation that "[a]ccess to *in vitro* fertilization treatment be determined on the basis of legitimate medical criteria, without discrimination on the basis of factors such as marital status, sexual orientation, or economic status."¹⁴⁰

Recently, a case brought before the Nova Scotia Court of Appeal involved a s. 15 challenge to the funding criteria applied under the Nova Scotia *Health Services and Insurance Act*¹⁴¹ in relation to the provision of IVF and ICSI. In *Cameron v. Nova Scotia (Attorney General)*,¹⁴² the appellants argued that the failure to fund ICSI and IVF constituted discrimination on the grounds of disability under the *Charter*. The majority of the Court of Appeal, Chipman and Pugsley J.J.A., found that the policy of not insuring IVF and ICSI draws a distinction between the fertile and infertile. Only the infertile need, but do not obtain, full coverage for the use of RTs. The majority recognized the social, cultural, and political context of infertility and concluded that "infertile people can be classified as physically disabled."¹⁴³ Such a distinction based on personal characteristics was either an enumerated or analogous grounds under *Charter* s. 15(1).¹⁴⁴ This distinction amounts to adverse effect discrimination:

The government has failed to ameliorate the position of the infertile compared with fertile people. They are unequally treated because they are denied a medically recommended treatment appropriate for them. The fertile on the other hand have no restrictions on access to Medicare for pre-natal treatments and treatments relating to childbirth. "Every aspect is covered."¹⁴⁵

The Court of Appeal, however, found that the exclusion of IVF and ICSI from public health insurance coverage was justifiable under *Charter* s. 1. The government's policy tries to establish the best possible health care coverage given limited financial resources, which means controlling health care costs by excluding some services. The objective of this policy was determined pressing and substantial. The exclusion of IVF and ICSI was rationally connected to the aim of the legislation. The Majority also held that the Camerons' *Charter* rights to equality were minimally impaired by the exclusion, and that the effect of the exclusion on these rights was proportional to achieving the legislative objectives.

¹³⁹ (1996), 134 D.L.R. (4th) 437 (B.C.S.C.).

¹⁴⁰ Royal Commission, *supra*, note 3 at 554.

¹⁴¹ R.S.N.S. 1989, c. 197.

¹⁴² (1999), 177 D.L.R. (4th) 611 (N.S.C.A.), affg (1999), 172 N.S.R. (2d) 227 (S.C.), leave to appeal dismissed (without reasons), [1999] S.C.C.A. No. 531.

¹⁴³ *Ibid.*, at 655 (D.L.R.).

¹⁴⁴ In separate reasons, Bateman J.A. rejected the distinction drawn between the infertile and the fertile as a grounds for discrimination under *Charter* s. 15, instead taking a more restrained approach to interfering with governmental decisions.

¹⁴⁵ *Supra*, note 142 at 654-55 (D.L.R.).

While the *Cameron* decision for the first time recognizes that unequal access to RTs as a treatment for infertility amounts to a *Charter* infringement, the infringement was deemed less serious — and justifiable given the government's objective to control health care costs. Rather than take a proactive approach, the Court deferred to the government and its chosen administration for determining which services would be "medically necessary" as part of a comprehensive and cost-effective health care system. The Court of Appeal followed the Supreme Court of Canada decision in *Eldridge*, holding that the exclusion of RTs from the coverage of public health insurance falls within the government's "wide latitude" to make decisions about the distribution of limited resources, especially if the government must choose between disadvantaged groups when distributing social benefits.¹⁴⁶

B. INFORMED CONSENT

Access to RTs by infertile individuals requires adequate information and counselling upon which to base a decision and consent to treatment. Inadequate information concerning the potential benefits, costs, and risks of RTs, as well as prejudiced forms of communication, might influence an individual's choice to use RTs. It is important, therefore, that communication between physicians and prospective patients remains mutually open and accessible. Moreover, it is through such communication, necessary for informed consent, that non-visible discriminatory factors may become influential. In current practice, physicians may, under the facade of "legitimate medical criteria," inquire about the person's lifestyle, including sexual history and orientation. Keeping in mind that two chapters of this book are devoted to consent, we will now explore specific issues in the context of RTs.

The common law in Canada requires that a physician obtain a patient's informed consent prior to performing a medical procedure on that patient.¹⁴⁷ This means that the patient must be informed about the benefits and risks of treatment, alternative courses of action, and the consequences of not having the treatment. Moreover, the standard for disclosure is not what the reasonable physician would see fit to disclose, but what the reasonable person in the patient's position would want to know.¹⁴⁸ The relevant information for *in vitro* fertilization, for example, would include success rates of the procedure, including a clarification of the meaning of "success rates" (*i.e.*, conception or live birth). Patients should also be informed about the potential for multiple births and the

¹⁴⁶ *Ibid.*, at 663 (D.L.R.). See *Eldridge v. British Columbia (A.G.)*, [1997] 3 S.C.R. 624, *per* La Forest J., at para. 85.

¹⁴⁷ *Reibl v. Hughes* (1980), 114 D.L.R. (3d) 1 (S.C.C.) provides the authoritative statement on the law of informed consent in Canada. See also the Ontario *Health Care Consent Act, 1996*, S.O. 1996, c. 2, Sch. A., which supersedes the common law in its broad application to treatment. Section 2 of the Act defines treatment as "anything that is done for a therapeutic, preventive, palliative, diagnostic, cosmetic or other health-related purpose, and includes a course of treatment [or] plan of treatment"

¹⁴⁸ *Reibl v. Hughes*, *supra*, note 147.

possibility of low birth-weight babies in addition to other social factors and financial costs. The precise nature of the information to be communicated by the physician to the patient under informed consent in the context of reproductive technologies has not been established by case law.

The physician may inform the patients directly, or refer them to counsellors. Independent counselling might avoid some concerns over a physician's potential bias in providing treatment services. Moreover, independent counselling may support the timely provision of needed information on new and changing reproductive technologies. The Royal Commission recognized the importance of patients having "time to discuss and fully comprehend the meaning and implications of consent," and that consent should be revocable "at any stage of treatment without jeopardizing future care or treatment."¹⁴⁹ The Royal Commission recommended a standardization of informative materials, including alternatives to treatment, such as adoption and living without children.

The importance of informed consent to the use of RTs is reinforced in the draft AHRA. As noted earlier, the preamble to the draft legislation includes respect for autonomy and the promotion of free and informed consent as a core principle. In addition, s. 6 of the draft AHRA specifies the requirement of written informed consent in relation to a number of practices under the draft legislation. Pursuant to s. 6(1), in order to use donated human reproductive material to create an embryo or to assist in human reproduction, the donor must have consented in writing. Section 6(2) makes it an offence to remove human reproductive material from a donor's body after the donor's death to facilitate human reproduction unless the donor provided his or her prior written consent. Use of an *in vitro* embryo (or any part of one) for the purpose of research or the prevention, diagnosis or treatment of disease, injury or disability would constitute an offence under s. 6(3) unless the donor gave written consent. The specific disclosure requirements with respect to providing consent for purposes of these sections, however, have not been set out in the draft legislation but may be specified in regulations.¹⁵⁰

C. STATUS OF GAMETES AND EMBRYOS

A couple that decides to reproduce using RTs may part company, or one or both of them may die, at some stage of reproduction. They might have placed their gametes (sperm and ova) separately in storage banks, or have already generated an embryo also frozen and stored in a bank. In difficult cases, courts may be called upon to determine the status of gametes and embryos, and who should have an interest in, and dispositional control over them — that is, who should have the power to control human reproductive materials and ultimately, human reproduction along specific genetic lines. The law may protect the rights and interests of: the producers (the genetic contributors) of reproductive "materials";

¹⁴⁹ Royal Commission, *supra*, note 3 at 550.

¹⁵⁰ Section 40(1)(c) of the draft AHRA.

the non-genetic "parents"; the biomedical researchers and clinical physicians who transfer the materials and help generate the products of conception; the hospitals and the owners of storage and handling facilities; the interests of these "products" as potential life forms; and the interests of society-at-large. The law might be called upon to address such issues in the staging and evaluation of life-forming processes, from pre-conception arrangements to the definition of death. The framing of the legal issues that arise will depend, in part, upon whether gametes and embryos are considered as property, persons, or something in-between. The following section explores law's responses to the status of reproductive "materials" (sperm and ova) and the "products" of conception (zygotes, embryos, and fetuses).¹⁵¹ The primary issue of the status of gametes and embryos implicates a range of existing law including property, contracts, wills and trusts, torts, criminal law, and constitutional law.

1. The Property Approach

One approach to the characterization of gametes and embryos focuses on the concept of property.¹⁵² Property refers not to physical objects, but to "rights of control or domination" over objects or activities. A traditional property approach treats sperm, ova, and embryos as objects to be controlled like any other. The reason for this treatment as objects centres on their generation as a product of one's body and the fact that they are alienable from it. According to some proponents of a property model, each individual is said to have dominion and control over her or his body, including its derivatives such as blood, sperm, ova and embryos.¹⁵³ It has also been argued that each individual should have the right to exclusively control the uniquely identifying information contained in her or his genes. The argument in favour of viewing the body and its parts as property is supported by the understanding that property is considered uniquely

¹⁵¹ The following section focuses on gametes, zygotes (pre-embryos), and embryos. For a more detailed discussion on fetuses, see chapter 9, "The Legal Regulation of Women's Reproductive Capacity in Canada."

¹⁵² See M. Litman & G. Robertson, "Reproductive Technology: Is a Property Law Regime Appropriate?" in Royal Commission on New Reproductive Technologies, *Overview of Legal Issues in New Reproductive Technologies*, vol. 3 (Ottawa: Minister of Supply and Services Canada, 1993) at 233; M. Litman & G. Robertson, "The Common Law Status of Genetic Material" in B. Knoppers, T. Caulfield & T.D. Kinsella, eds., *Legal Rights and Human Genetic Material* (Toronto: Emond Montgomery, 1996) at 51; M. Hirtle, "Civil Law and the Status of Human Genetic Material, in *Legal Rights and Human Genetic Material*" in B. Knoppers, T. Caulfield & T.D. Kinsella, eds., *Legal Rights and Human Genetic Material* (Toronto: Emond Montgomery, 1996) at 85; I. Kennedy, "The Moral Status of the Embryo" in I. Kennedy, *Treat Me Right: Essays in Medical Law and Ethics* (Oxford: Clarendon Press, 1991) at 119; B. Steinbock, "Sperm as Property" (1995) 6 *Stan. L. & Pol'y Rev.* 57; B. Brown, "Reconciling Property Law With Advances in Reproductive Science" (1995) 6 *Stan. L. & Pol'y Rev.* 73; D. Walther, "'Ownership' of the Fertilized Ovum In Vitro" (1992) 26 *Fam. L.Q.* 235.

¹⁵³ See Litman & Robertson, "The Common Law Status of Genetic Material," *supra*, note 152 at 60; Litman & Robertson, "Reproductive Technology: Is a Property Law Regime Appropriate?" *supra*, note 152 at 250.

personal and therefore private.¹⁵⁴ If my body and its parts do not belong to me, then to whom do they belong? The primary motivation in favour of regarding gametes and embryos as property, therefore, is to ensure that the individuals who generated them have the full power to control their ultimate use.

Alternatively, some academics argue in favour of quasi-property approaches where, for example, gametes would have special status as property.¹⁵⁵ A quasi-property approach might affirm personal control and rights over disposition of gametes and/or embryos, but deny the right to alienate these materials for commercial purposes or for remuneration. This approach would argue that an object may be property (in its weakest form, without all traditional incidents) for some purposes but not others.¹⁵⁶ The potential suspension of reproductive stages, and the recognition of a form of potential life, generates obvious concerns of de-humanization. By removing embryos and ova from the body, the only place where they had existed prior to the advent of RTs, a *de facto* condition of objectification is created. While the legal characterization of human reproductive materials has not been determined in Canada, it has been indirectly considered.

In *ter Neuzen v. Korn*¹⁵⁷ the Supreme Court of Canada considered the case of a woman who underwent artificial insemination and contracted HIV through the donated semen. One argument raised by the plaintiff in her law suit against the physician who performed AID was the existence of an implied condition or warranty that the semen he used be of merchantable quality and fit for its purposes under contract law and the *Sale of Goods Act*.¹⁵⁸ The Court first rejected the argument under the *Sale of Goods Act*, which only applies if a contract existed for the sale of "primarily" goods rather than medical services.¹⁵⁹ The Court then considered the specific nature of the contract and the relationship between the parties in order to determine whether the parties intended to imply such a warranty at common law. The Court noted the medical context and vulnerability of physicians, stating that "it must be recognized that biological products such as blood and semen, unlike manufactured products, carry certain inherent risks."¹⁶⁰ The Court held that no implied warranty of fitness and merchantability could exist in the circumstances, and if such a warranty did exist, it would be met by the physician's reasonable care.¹⁶¹ While the Court did not directly

¹⁵⁴ For example, see *Moore v. Regents of the University of California*, 249 Cal. Rptr. 494 (Ct. App. 1988), in Litman & Robertson, "Reproductive Technology: Is a Property Law Regime Appropriate?" *supra*, note 152 at 251-53.

¹⁵⁵ See Litman & Robertson, "Reproductive Technology: Is a Property Law Regime Appropriate?" *supra*, note 152 at 232, 247 (the authors support a *sui generis* approach, using examples such as law's dealing with human corpses).

¹⁵⁶ Litman & Robertson, "The Common Law Status of Genetic Material," *supra*, note 152 at 67.

¹⁵⁷ [1995] 3 S.C.R. 674.

¹⁵⁸ R.S.B.C. 1996, c. 410.

¹⁵⁹ The Court, however, did not consider the issue of whether the sperm was donated rather than sold.

¹⁶⁰ *Supra*, note 157 at 717.

¹⁶¹ It has been previously argued that the transfer of sperm should be legally characterized as a "sale" in order to resort to the protection of commercial law; A.M. Hodgson, "The Warranty of Sperm: A Modest Proposal to Increase the Accountability of Sperm Banks and Physicians in

confront the issue of the characterization of semen in *ter Neuzen v. Korn*, its refusal to extend the application of the *Sale of Goods Act* and the implied warranty at common law, suggests that the court recognizes that semen has a character distinct from "merchantable goods." We will now turn to an examination of how the legal characterization of human reproductive materials has been considered in other jurisdictions.

In *Hecht v. Superior Court of the State of California for the County of Los Angeles (Kane)*,¹⁶² the California Court of Appeal held that cryopreserved sperm was a "unique category of property" as part of the estate of the deceased donor.¹⁶³ The value of the donor's sperm arose from its potential to generate life upon fertilization, thus providing the donor an interest "in the nature of ownership." In *Davis v. Davis*,¹⁶⁴ the court directly confronted the issue of whether cryopreserved pre-embryos are property. The Davis couple underwent *in vitro* fertilization, storing their pre-embryos for later use. They eventually divorced, leading to a custody battle over the frozen pre-embryos. Ms. Davis sought to implant the embryos. She argued the "best interests of the child" test, and that the pre-embryos were in fact "living persons." In opposition, Mr. Davis contended that the pre-embryos were under joint control. Justice Young of the Tennessee Circuit Court ruled in favour of *parens patriae* jurisdiction and the family law approach emphasizing the best interests of the child, and thus rejecting a traditional property approach.¹⁶⁵ In rejecting the "bailment" approach of *York v. Jones*,¹⁶⁶ Young J. focussed on a "minority" scientific opinion, suggesting that the differentiation of cells in such embryos means that they are fully constituted, "living persons." When faced with legal classification, Young J.

the Performance of Artificial Insemination Procedures" (1993) 175 Specialty Law Digest: Health Care Law 9. Hodgson claims that such characterization would hold sperm banks and physicians liable for breach of implied warranties. This argument, however, does not address the inadequacies of commercial law in dealing with sensitive reproductive "materials" of a unique nature.

¹⁶² 20 Cal. Rptr. 2d 275 (1993).

¹⁶³ The court in *Hecht, ibid.*, cited for persuasive support, among others, the decision of *Parpalaix v. CECOS T.G.I. Creteil*, August 1, 1984, Gazette du Palais, September 15, 1984 (France) (widow sought disposition of decedent's sperm stored in a sperm bank). The court in *Hecht v. Superior Court, ibid.*, at 288-89 cited *Parpalaix* as an example where a court rejected traditional property and contract analyses, focussing instead on the husband's unequivocal intentions to have a child after his death.

¹⁶⁴ 842 S.W.2d 588 (Tenn. 1992). See also K. Luongo, "The Big Chill: *Davis v. Davis* and the Protection of 'Potential Life'?" (1995) 29 New Eng. L. Rev. 1011; T. Feliciano, "Note: *Davis v. Davis*: What About Future Disputes?" (1993) 26 Conn. L. Rev. 305; R. Muller, "Note: *Davis v. Davis*: The Applicability of Privacy and Property Rights to the Disposition of Frozen Preembryos in Intrafamilial Disputes" (1993) 24 U. Tol. L. Rev. 763; M. Simon, "Note: 'Honey, I Froze the Kids': *Davis v. Davis* and the Legal Status of Early Embryos" (1991) 23 Loy. U. Chi. L.J. 131.

¹⁶⁵ *Davis v. Davis*, W.L. 140495 (Tenn. Cir. Ct. 1989), revd 59 U.S.L.W. 2205 (Tenn. Ct. App. 1990), affd 842 S.W. 2d 588 (Tenn. 1992), partial rehearing granted, W.L. 341632 (Tenn. 1992), cert. denied, 61 U.S.L.W. 3437 (U.S. 1993).

¹⁶⁶ 717 F. Supp. 421 (E.D. Va. 1989) (a property-based approach where the court upheld the transfer of pre-embryos between fertilization institutes).

relied upon medical science, without much discussion about the problems of deference to medical science and the lack of critical inquiry and challenge.¹⁶⁷

By the time the case reached the Court of Appeal, both parties had remarried. Ms. Davis no longer wished to implant the pre-embryos, but instead wanted to donate them to other women. Thus, the facts and perhaps the support of public policy had changed direction. The Court of Appeal reversed the previous ruling, awarding instead joint control over the pre-embryos. In the *Davis* case, the *ex utero* pre-embryos were frozen at an early stage of development. The American Court recognized that Mr. Davis had a "constitutionally protected right not to beget a child where no pregnancy has taken place."¹⁶⁸ Some academics have argued that the *Davis* analysis sounds "suspiciously property-like."¹⁶⁹ And yet, the court's reference to the fact that the embryos had been created but not yet implanted supports Ms. Davis' reproductive contribution in relation to the father. At the same time, the court recognized the father's contribution and his wish not to proceed. In the end, the husband received a complete "veto" over the disposition of the frozen *ex utero* pre-embryos. The Tennessee Supreme Court affirmed the Court of Appeal decision.¹⁷⁰ The Supreme Court, however, noted that "pre-embryos are not, strictly speaking, either 'persons' or 'property,' but occupy an interim category that entitles them to special respect because of their potential for human life."¹⁷¹ It focussed on the Davis' interest "in the nature of ownership, to the extent that they have decisional authority,"¹⁷² in light of a balance of opposing interests by the two genetic contributors. The Supreme Court in *Davis* also suggested two exceptions to the right of one progenitor to veto parenthood: (1) where one parent cannot otherwise become a parent; (2) where a prior agreement between the parties indicates their clear intentions for the disposition of embryos.

In *Kass v. Kass*,¹⁷³ the New York Court of Appeal considered a pre-existing written agreement between the parties, specifying disposition of the cryopreserved pre-embryos in the event that the parties subsequently disagreed. Ms. Kass unsuccessfully underwent numerous IVF cycles before the last cycle in which cryopreservation was used for the first time to store pre-embryos. Prior to this last cycle, Maureen and Steven Kass had entered into a written agreement

¹⁶⁷ See Litman & Robertson, "Reproductive Technology: Is a Property Law Regime Appropriate?" *supra*, note 152 at 259. The authors note that scientific arguments are not determinative of this particular legal issue. See *Tremblay v. Daigle*, [1989] 2 S.C.R. 530 at 553. See generally, *RJR-MacDonald Inc. v. Canada (A.G.)*, [1995] 3 S.C.R. 199.

¹⁶⁸ 59 U.S.L.W. 2205 (Tenn. Ct. App., 1990) at 2206.

¹⁶⁹ Litman & Robertson, "Reproductive Technology: Is a Property Law Regime Appropriate?" *supra*, note 152 at 260.

¹⁷⁰ *Davis v. Davis, supra*, note 165.

¹⁷¹ *Ibid.*, at 597.

¹⁷² *Ibid.* See M. Litman & G. Robertson, "Reproductive Technology: Is a Property Law Regime Appropriate?" in Royal Commission on New Reproductive Technologies, *Overview of Legal Issues in New Reproductive Technologies*, vol. 3 (Ottawa: Minister of Supply and Services Canada, 1993) at 79.

¹⁷³ 696 N.E.2d 174 (N.Y. 1998), affg 663 N.Y.S.2d 581 (N.Y. Sup. Ct. 1997), revg WL 110368 (N.Y. Sup. Ct. Jan 18, 1995).

concerning the storage and disposition of frozen pre-embryos. After unsuccessful treatment, they divorced. Maureen Kass then sought sole custody of the pre-embryos for implantation into herself. A unanimous seven member panel of the New York Court of Appeal upheld the written agreement between the parties, providing the IVF programme with dispositional control over the pre-embryos for purposes of "biological studies" and "research investigation." The Court of Appeal affirmed the 3-2 decision of the Supreme Court, Appellate Division, which had in turn reversed the trial court decision. The Court of Appeal held that the disposition of frozen pre-embryos was governed by a mutual consent agreement and the common law principles for contractual interpretation. Although the Court of Appeal cited, with approval, the *Davis* decision and the "special type of property" approach, it remained steadfast to the traditional common law categories of contract law and informed consent. The Court of Appeal emphasized the "seriousness and integrity of the consent process" and the certainty obtained from contract, discounting Maureen Kass' previous efforts and loss of reproductive capacity.

In Canada, the courts have yet to decide on the issue of whether or not reproductive materials should be considered as "property."¹⁷⁴ A recent lower court decision in Alberta, however, has commented on some of the American jurisprudence in this area in the context of determining whether separate damages could be awarded for loss of a fetus. In *Martin v. Mineral Springs Hospital*,¹⁷⁵ Rowbotham J. considered a negligence suit brought against a doctor concerning a stillbirth. According to Rowbotham J., the current law in Canada does not provide separate damages for the loss of a fetus due to negligent conduct, and therefore runs counter to a line of American cases that have awarded damages for the loss of *in vitro* embryos.¹⁷⁶ In Rowbotham J.'s view, the cited American decisions:

treat the embryo as property, and provide compensation for the loss of a chattel. Notwithstanding the embryo's classification as property, the damages granted include awards for pain and suffering. See: *Del Zio v. Presbyterian Hospital* (1978) 74 Civ. L.D. 3588 (memorandum decision) (U.S. Dist. Ct., S.D.N.Y.) and *Davis v. Davis* (1990), 16 F.L.R. 1535 (U.S. Tenn. Ct. App., 1990). However repugnant the 'property' classification may be, it presents the quandary that the loss of an embryo at an early cellular stage of development may be compensable, while a fully developed unborn child is not.¹⁷⁷

It is our view that the above reading of the American jurisprudence is incorrect. As discussed previously, the Tennessee Supreme Court in *Davis v. Davis* found that pre-embryos are neither persons nor property, but "occupy an interim

¹⁷⁴ Litman & Robertson, "Reproductive Technology: Is a Property Law Regime Appropriate?" *supra*, note 172 at 51. Litman and Robertson warn of the symbolic and psychological effects on persons whose genetic materials and information are characterized as property.

¹⁷⁵ (2001), 90 Alta. L.R. (3d) 299, [2001] A.J. No. 78 (QL) (Q.B.).

¹⁷⁶ *Ibid.*, at paras. 25-26.

¹⁷⁷ *Ibid.*, at para. 26.

category that entitles them to special respect because of their potential for human life."¹⁷⁸ The *Davis* Court, moreover, decided the issue of dispositional authority over the embryos, and did not consider the issue of damages for the loss of embryos. In *Del Zio*,¹⁷⁹ the Court awarded damages of \$50,000 for the plaintiff's emotional distress when a physician deliberately destroyed her *in vitro* eggs (not embryos). The eggs had been placed in a petri dish with the aim of fertilization by her husband's sperm. *Del Zio* raises again the distinction between gametes and embryos, with the latter often recognized as deserving more respect for its potential for human life.

Gametes and embryos might be considered more like property than persons, or *vice versa*, depending upon the stage of development and the context of the owner's assertion of control.¹⁸⁰ Some commentators argue that the property approach "may well be able to accommodate competing interests in a more responsive and responsible manner than the law pertaining to persons."¹⁸¹ Yet, the property and quasi-property approaches seem inadequate since they objectify human reproductive "materials" and disregard important social and moral dimensions such as the sanctity of human life and the power relationships in human reproduction. Moreover, the concerns over commodification and commercialization would appear to outweigh any arguments in favour of treating gametes and embryos as a form of property — to be controlled and dominated as objects. The use of a property approach, even in the absence of the language of "property" and "ownership," does not provide a convincing solution,¹⁸² but merely hides the substantive problems discussed above. Moreover, the category of property has been much criticized as disregarding such feminist concerns as: "the objectification of women; the economic exploitation of women; the denigration of human reproduction and the treatment of women as 'baby-making machines'; women's alienation from their bodies; the commodification and destruction of human values."¹⁸³ It would, therefore, seem odd to consider gametes and embryos strictly as traditional property. On the other hand, courts in Canada and other common law jurisdictions have so far shown no indication that gametes and embryos have full status as legal persons.¹⁸⁴ To do otherwise, the courts would oppose the reproductive freedom of the parents. It remains to be seen how Canadian courts might work beyond traditional property conceptions of gametes and embryos.

¹⁷⁸ *Supra*, note 165.

¹⁷⁹ *Del Zio v. Columbia Presbyterian Medical Center*, 1978 U.S. Dist. LEXIS 18443 (US Dist. Ct., SD NY, Apr. 12, 1978, No. 74-3558). See also *Kass v. Kass*, *supra*, note 173.

¹⁸⁰ See Litman & Robertson, "Reproductive Technology: Is a Property Law Regime Appropriate?" *supra*, note 172.

¹⁸¹ *Ibid.*, at 244.

¹⁸² *Ibid.*, at 267-68.

¹⁸³ J. Nedelsky, "Property in Potential Life? A Relational Approach to Choosing Legal Categories" (1993) 6:2 Can. J. L. & Jur. 343. See also N. Wikler, "Society's Response to the New Reproductive Technologies: The Feminist Perspectives" (1986) 59 S. Cal. L. Rev. 1043.

¹⁸⁴ See Litman & Robertson, "Reproductive Technology: Is a Property Law Regime Appropriate?" *supra*, note 172 at 235-42.

2. The Personhood Approach

The personhood approach basically treats gametes and embryos as full legal persons, with all rights and interests that other living persons might enjoy. This approach emphasizes one's personal control over unique genetic information as essential to one's personality and liberty; human beings are considered inviolable and inalienable. This approach differs from a property approach in two major respects: (1) it does not support commercialization, and (2) information is considered to be common to all persons, rather than a "thing" to be appropriated.¹⁸⁵ The personhood approach, however, must contend with the problem that gametes and embryos can be separated from the person(s) who generated them and be implanted in third persons. Can these still be viewed as extensions of the person who generated them, or should these be seen as autonomous persons imbued with the full range of the rights of persons? Under a personhood approach, destruction of gametes and embryos could be tantamount to murder, while their commercial exploitation may be the equivalent of slavery.

Quebec civil law considers the control over one's body in light of "rights to personality" and individual liberty.¹⁸⁶ In civil law, a personality rights approach seems more accepted for personal control over one's body and its contained information. The *Civil Code of Quebec* holds that every human being has, among other rights, the right to life, personal security, inviolability, and the integrity of the person.¹⁸⁷ Marie Hirtle notes that the "multiple personality rights found under Quebec civil law would ... confer the right to follow, to examine, and to control information concerning and originating from a person."¹⁸⁸ The basic presupposition is that "the human body is dissolubly both person and thing."¹⁸⁹ This bespeaks the in-between approach, where gametes and embryos are treated as somewhere between property and persons, depending on the specific context. This is the *sui generis* approach discussed below.

3. *Sui Generis* and Other Approaches

Rather than treat gametes and embryos as one of the two extremes — as objects (property) or as subjects (persons) — the courts may consider some type of *sui generis* or relational approach on a case-by-case basis.¹⁹⁰ It has been said that "the emerging trend is to characterize the legal status of the embryos *ex utero*

¹⁸⁵ M. Hirtle, "Civil Law and the Status of Human Genetic Material in Legal Rights and Human Genetic Material" in B. Knoppers, T. Caulfield & T.D. Kinsella, eds., *Legal Rights and Human Genetic Material* (Toronto: Emond Montgomery, 1996) at 104.

¹⁸⁶ *Ibid.*, at 85.

¹⁸⁷ See also *R. v. Morgentaler*, [1988] 1 S.C.R. 30.

¹⁸⁸ *Supra*, note 185 at 108.

¹⁸⁹ *Ibid.*, at 116.

¹⁹⁰ The *sui generis* approach, however, cannot be "policy neutral"; the policy choices merely embody the subjective views of one judge, participant or another. However, for an opposite opinion, see Litman & Robertson, "Reproductive Technology: Is a Property Law Regime Appropriate?" *supra*, note 172.

and gametes as *sui generis*."¹⁹¹ *Sui generis* means "its own type" or "class by itself." In other words, such an approach denies any analogy between this class of objects and any other type of relationship or entity. In using this approach, the focus remains on the factual setting and "particularly, on the relationship between the parties, and not the genetic material itself."¹⁹² A *sui generis* approach, whether considered under the concept of property or personhood, supports a more flexible consideration of relations among persons and things. It also emphasizes the application of policy interests on a case-by-case basis. On the other hand, while a *sui generis* approach might escape the traditional constraints of a property approach, it does so only to rely upon the discretion of courts.

This approach may be criticized as simply begging the question, "To what class do gametes and embryos belong?" In order to fill the legal void and arrive at a reasoned outcome, the courts may determine that these materials or relationships are "like" persons or property, thereby falling back on familiar statuses or relationships in an effort to arrive at a more certain legal outcome. The *sui generis* approach may ultimately become self-defeating and result in a body of inconsistent analogies applied in different cases.

A possible way out of this dilemma may be offered by the relational approach, which acknowledges that these materials differ from existing categories but recognizes the intrinsic interests which are generated by the manner in which these materials emerge and the purposes to which they are applied. The relational (or relationship) approach provides an alternative to that of traditional property, personhood, and *sui generis*. The relational approach focuses on relationships and the conditions that foster capacity to form relationships.¹⁹³ Rather than focussing on individualistic conceptions, such as rights, the relational approach acknowledges relationships among individuals and communities, for example, those of power, responsibility, trust, obligation, respect, and caretaking.¹⁹⁴ In doing so, the law might sensitively adapt to changing societal values and advances in RTs, and perhaps better address issues of "control, decision-making authority, and responsibility" for potential human life.

Although the relational approach provides a critical alternative to the traditional property and personhood approaches, choices and decisions must yet be made about the status and disposition of gametes and embryos, and the relationships among the women and men who contribute genetically or non-genetically to human reproduction. The choices and decisions resulting from the resolution of legal disputes in practice create hierarchies of relationships deemed worthy of legal recognition and status. A relational approach, however, may appear useful in allowing courts to better recognize relationships of power and control over

¹⁹¹ M. Litman & G. Robertson, "The Common Law Status of Genetic Material" in B. Knoppers, T. Caulfield & T.D. Kinsella, eds., *Legal Rights and Human Genetic Material* (Toronto: Emond Montgomery, 1996) at 55.

¹⁹² *Ibid.*, at 55.

¹⁹³ Nedelsky, *supra*, note 183. See also R. Rao, "Reconceiving Privacy: Relationships and Reproductive Technology" (1998) 45 U.C.L.A. L. Rev. 1077.

¹⁹⁴ Nedelsky, *supra*, note 183.

the lives of genetic contributors and gestational providers, especially those women who bear additional responsibilities,¹⁹⁵ as well as in recognizing gametes and embryos as potential human life. As the Royal Commission states, it is "essential to ensure that zygotes (and presumably, gametes) are treated with respect because of their connections to the human community."¹⁹⁶ Having discussed various conceptual frameworks for the status and control of gametes and embryos, we now analyze specific legal issues related to the control and use of gametes and embryos.

D. CONTROL AND USE OF GAMETES AND EMBRYOS

1. Gamete and Embryo Donation

A woman may wish to reproduce using the sperm or ova of known or anonymous donors in a number of circumstances including: the absence of a male partner, the existence of male factor infertility in her partner, or the desire to avoid the transferring of infectious diseases or genetic conditions to offspring. Ovum and embryo donation can be used in cases of female factor infertility, or for example, where two women choose to share the genetic and gestational aspects of pregnancy. In some cases sperm and ovum may be treated or otherwise manipulated to facilitate fertilization. We now consider the regulation of gamete and embryo donation in Canada, highlighting differences encountered in their regulation. The analysis will illustrate a range of solutions depending upon the choice of conceptual framework to be applied to gametes and embryos: whether they are treated as property, persons, or something in between (*sui generis*).

(a) Gametes

The special nature of gametes (sperm and ova) has led to attempts to regulate their use and transfer in Canada and elsewhere. In Canada, the federal government now regulates the processing and distribution of semen for assisted conception.¹⁹⁷ This legislation addresses the screening of semen for health and safety purposes in assisted human reproduction. While the law regulates the processing and distribution of donor semen and thus sperm, it does not regulate donor ova. Since the draft AHRA has not yet been enacted, and where express legislation concerning gametes is absent, one could interpret human tissue legislation as applying to gametes. Whereas all provinces have legislation to control the transfer of human tissues for organ transplantation, several provinces have broadly defined "tissue" and do not expressly exclude gametes and embryos. It may be argued that gametes and embryos are unique in their potential to create life and that they are not necessarily "replaceable by natural processes of repair."¹⁹⁸ Although human tissue legislation may or may not apply to gam-

¹⁹⁵ *Ibid.*

¹⁹⁶ Royal Commission, *supra*, note 3 at 17.

¹⁹⁷ *Processing and Distribution of Semen for Assisted Conception Regulations*, SOR/96-254.

¹⁹⁸ For example, see *Human Tissue Gift Act*, R.S.A. 2000, c. H-15, s. 1(e); *Human Tissue Gift Act*,

etes and embryos, Canadian courts may find it useful to draw parallels to the statutory provisions of such legislation.

Gamete donation may occur during the donor's lifetime, or after her or his death. The common law has distinguished between the various forms of a gift *inter vivos* and a gift *causa mortis* (or postmortem gifts). These two scenarios have traditionally led to different responses under the law of property. The transfer of reproductive "materials" and the use of RTs, however, require a more complex approach to legal analysis than traditionally applied under the law of property. We will now consider the regulation of donor gametes as an *inter vivos* gift and as a postmortem gift.

The preliminary issue is whether or not an individual can legally transfer his or her gametes for implantation into others. Several provincial statutes regulate who may donate human tissues generally and genetic material specifically. Section 3(1) of the British Columbia *Human Tissue Gift Act*, for example, states that a person may consent to an *inter vivos* gift for transplant if he or she is at least 19 years old, mentally competent, and able to make a free and informed decision. Under s. 4, the gift can be made "for therapeutic purposes, medical education or scientific research." Article 538 of the *Civil Code of Quebec* provides that a person may donate gametes for "[p]articipation in the parental project of another person by way of a contribution of genetic material." The draft AHRA would allow for the donation of gametes under a regime that combines prohibitions and licensed conditions to control their transfer and the requirements for consent. In relation to sperm and ova, the draft Act defines "donor" as "the individual from whose body they are obtained, whether for consideration or not."¹⁹⁹ It also prohibits the use of sperm or ovum from a person under 18 years of age, except as provided for in the regulations.²⁰⁰

Gametes from a donor who has since died may be used for reproduction. Persons can now store their gametes in sperm or ova banks for subsequent donation after death. It seems that courts will recognize the special nature of gametes, and requirements and conditions for the exchange of human tissue, especially in the case where contributors have since died.²⁰¹ As a matter of public policy, however, some argue that the gametes of deceased donors should not be used for

R.S.B.C. 1996, c. 211, s. 1. But see also art. 19 C.C.Q., which states that a person may "... alienate a part of his body only if that part is capable of regeneration and provided that no serious risk to his health results." Article 25 of the *Civil Code of Quebec* requires that "[t]he alienation by a person of a part or product of his body shall be gratuitous; it may not be repeated if it involves a risk to his health." In Ontario, Manitoba, and P.E.I., human tissue legislation specifically excludes gametes and embryos; see *supra*, note 66.

¹⁹⁹ Section 2 of the draft AHRA. Since the draft AHRA has not yet been enacted, medical professionals may refer to the *Joint Policy Statement of Medical Professionals*, which recognizes that the transfer of sperm and eggs are morally acceptable only for non-commercial cases of donation and where the donors provide informed consent; *supra*, note 117 at 18.

²⁰⁰ Section 7(2) of the draft AHRA.

²⁰¹ M. Martin *et al.*, "The Limits of Freedom of Contract: The Commercialization of Reproductive Materials and Services" in Royal Commission on New Reproductive Technologies, *Overview of Legal Issues in New Reproductive Technologies*, vol. 3 (Ottawa: Minister of Supply and Services Canada, 1993) at 401.

reproduction because of the possible effects on children born without live genetic parents. Ethical issues also arise when gametes are retrieved from donors who are deceased persons or fetuses. For example, a woman might wish to use sperm from a dead male partner,²⁰² or a man might wish to use ova from a dead female partner to be fertilized by *in vitro* fertilization and implanted in a gestational mother.²⁰³ The transfer of gametes, however, may be considered morally unacceptable where retrieval of sperm and ova requires an invasive procedure on a "brain dead" person, in contrast to retrieval from existing supplies in storage banks, or where the gamete donor would likely not have consented. Further issues arise as to whether or not the deceased should be considered the legal father or mother for purposes of birth registration or inheritance.

There are no Canadian cases that deal with the issue of a postmortem transfer of gametes. In the absence of specific legislation, Canadian courts may draw analogies to organ transplantation under human tissue gift legislation and perhaps the law of adoption. If ova and sperm fall under human tissue gift legislation, postmortem reproduction may be considered legal. The British Columbia *Human Tissue Gift Act*, for example, provides that a person, if she or he is at least 19 years old, may consent to a postmortem gift, "... in writing signed by the person at any time ... or orally in the presence of at least 2 witnesses during the person's last illness"²⁰⁴ Where the deceased person has not given consent and dies, or cannot give consent by reason of injury or disease, and the person's death is imminent, s. 5(1) provides a lengthy hierarchical list of persons, beginning with spouses, and followed by: children at the age of majority, parents, brothers or sisters, or any other next of kin, who may, on behalf of that person, consent to transplantation. The consent provided for under s. 5(1) must occur in writing, or orally, in the presence of at least two witnesses. Section 5(1)(f) provides that where no relative can be found, transplantation may be authorized by "the person lawfully in possession of the body other than, if the person died in hospital, the administrative head of the hospital." Under s. 5(2), consent cannot be given if there is reason to believe that the deceased person would have objected. The draft AHRA, if enacted, would prohibit the posthumous use of "human reproductive material" from a donor's body after her or his death, unless the donor consented in writing for that specific purpose.²⁰⁵

In dealing with the novel issue of postmortem reproduction, and in the absence of express legislation, Canadian courts may consider the jurisprudence in other countries. For postmortem reproduction, one of the main issues is whether the deceased intended to have children after death. In *Parpalax v. CECOS*,²⁰⁶

²⁰² *R. v. Human Fertilisation and Embryology Authority ex parte Blood*, [1996] 3 W.L.R. 1177 (Q.B.), rev'd [1997] 2 All E.R. 687 (C.A.). See S. Gilbert, "Note: Fatherhood from the Grave: An Analysis of Postmortem Insemination" (1993) 22 Hofstra L. Rev. 521; J. Robertson, "Posthumous Reproduction" (1994) 69 Indiana L.J. 1027.

²⁰³ These scenarios are not so unusual given medical advances in physically maintaining "legally dead" (or "brain dead") persons.

²⁰⁴ B.C. *Human Tissue Gift Act*, *supra*, note 198, s. 4(1).

²⁰⁵ Section 6(2) of the draft AHRA.

²⁰⁶ T.G.I. Creteil, August 1, 1984, Gazette du Palais, September 15, 1984 (France), as discussed in

the French *Tribunaux de grande instance* discussed the dispositional control over the donor's sperm deposit, and the issue of whether the donor intended to have children during his lifetime or after death. The *Tribunaux* held in favour of the deceased donor's wishes to have children after death. In *Hecht v. Superior Court of the State of California for the County of Los Angeles (Kane)*,²⁰⁷ the California Court of Appeal recognized the deceased donor's expressed intentions. In *Hecht*, the court held that the donor had an ownership interest under at least an "interim category," if not personal property law. In the case of *R. v. Human Fertilisation and Embryology Authority, ex parte Blood*,²⁰⁸ the English Court of Appeal considered a woman's attempts to use the sperm samples she obtained from her husband while he lay in a comatose state. The husband died shortly afterwards. The *Human Fertilisation and Embryology Act, 1990*,²⁰⁹ clearly required expressed written consent of a donor for the taking and use of his sperm, including for posthumous reproduction. No written consent existed in this case.²¹⁰

The sale and commercialization of sperm and ova have raised obvious ethical issues, despite the law's insistence that the transfer of gametes be treated as gifts only. There is no express legislation that deals with the sale of gametes, although the regulations under the *Food and Drugs Act*,²¹¹ as discussed previously, uses the language of "donation" when dealing with the processing and use of semen for assisted conception. The control of gametes and embryos, if deemed human tissue, may be subject to legislative provisions that limit their transfer for non-commercial purposes. In most provinces, human tissue legislation prohibits any dealings of human tissue for valuable consideration or for commercial purposes; the transfer of human tissue is considered a gift, not a sale.²¹² The British Columbia *Human Tissue Gift Act*, for example, states: "a person must not buy, sell or otherwise deal in, directly or indirectly, for a valuable consideration, any tissue for a transplant, or any body or parts other than blood or a blood constituent, for therapeutic purposes, medical education or scientific research."²¹³ The law generally recognizes that commercial exchanges of human tissues are invalid as being contrary to public policy.²¹⁴ Similarly, art. 25 of the *Civil Code of Quebec* states, "[t]he alienation by a person of a part or product of his [*sic*] body shall be gratuitous; it may not be repeated if it involves

E.D. Shapiro & B. Sonnenblick, "The Widow and the Sperm: The Law of Post-mortem Insemination" (1986/87) 1 J.L. & Health 229, as cited in *Hecht v. Superior Court*, 20 Cal. Rptr. 2d 275, 288 (Ct. App. 1993). See also D.J. Jones, "Artificial Procreation, Societal Reconceptions: Legal Insight From France" (1988) 36 Am. J. Comp. L. 525.

²⁰⁷ *Hecht, supra*, note 205.

²⁰⁸ [1997] 2 All E.R. 687 (C.A.).

²⁰⁹ *Human Fertilisation and Embryology Act, 1990*, ch. 37(5) (Eng.).

²¹⁰ Ms. Blood did, however, succeed in receiving the right to use her husband's sperm for artificial insemination. Pursuant to another section of the *Human Fertilisation and Embryology Act, 1990, ibid.*, the sperm could be exported abroad and Ms. Blood inseminated in a European Community state.

²¹¹ *Supra*, note 51.

²¹² See, for example: Alberta *Human Tissue Gift Act*, R.S.A. 2000, c. H-15, s. 10.

²¹³ B.C. *Human Tissue Gift Act, supra*, note 198, s. 10.

²¹⁴ See legislation cited at note 64.

a risk to his [sic] health." The draft AHRA, if enacted, would expressly prohibit "the purchase or offer to purchase sperm or ova from a donor or a person acting on behalf of a donor or advertise for the purchase of sperm or ova from a donor," where "purchase" includes "to acquire or dispose of in exchange for property or services."²¹⁵ Individuals and facilities with a licence under the draft Act, however, may offer donors reimbursement of expenses "incurred in the course of donating any sperm or ovum."²¹⁶ Although reimbursement for gamete donation is usually limited to reasonable expenses, the definition of "expenses" is a matter for interpretation.

Moreover, there has been much concern over the exploitation of women who exchange "spare" eggs (or ova) to be implanted in other women in return for compensation or reduced fees for *in vitro* fertilization or other medical services.²¹⁷ In some medical practices, women patients are asked for the "designated donation" of ova in exchange for services or reduced rates. The Royal Commission would prohibit physicians from revoking services when a woman chooses not to donate spare ova. According to the *Tri-Council Policy Statement*, a set of guidelines for federal research funding, the use of gametes obtained from commercial transactions, including exchange for services, for purposes of research is unethical.²¹⁸ Rather than suggesting an absolute ban on such exchanges, several commentators have emphasized the importance of women's informed consent to gamete donation in these circumstances. It has been suggested that informed consent might ameliorate the power imbalances and exploitation that women may face due to socio-economic disparities. Others contend that truly informed consent is not possible in light of an already existing state of gender inequities. We have previously discussed the issue of informed consent. However, it is noteworthy to mention that Canadian courts have not yet faced the issue of revocation of consent by a gamete donor. One might argue that the option to revoke consent prior to actual implantation of gametes into recipients would empower women by making available choices in some circumstances.

Gamete use and transfer also raises health and safety issues about the quality of gametes used for assisted reproduction. As discussed earlier in this chapter, pursuant to regulations of the *Food and Drugs Act*²¹⁹ the federal government regulates the processing and distribution of semen for assisted conception in order to avoid serious risk to the health of the patient and the child to be conceived. This issue of sperm safety has also arisen at common law. In *ter Neuzen v. Korn*²²⁰ the Supreme Court of Canada considered the case of a woman who

²¹⁵ Section 5(1) and (4) of the draft AHRA.

²¹⁶ *Ibid.*, s. 10.

²¹⁷ P. Cheney, "Human egg trade lures elite students" *The Globe and Mail* (9 July 1998) A1.

²¹⁸ Article 9.2.

²¹⁹ R.S.C. 1985, c. F-27.

²²⁰ [1995] 3 S.C.R. 674. At trial the jury found the respondent negligent. However, it is unknown on what basis the jurors reached their decision. The damages awarded by the jury totaled \$883,800, including \$460,000 for non-pecuniary damages. On appeal, the jury's verdict was set aside and the Court of Appeal ordered a new trial on the issue of liability as well as damages: (1993), 81 B.C.L.R. (2d) 39, 103 D.L.R. (4th) 473 (CA).

underwent artificial insemination and contracted HIV through the donated semen. At trial before a jury, *ter Neuzen* claimed negligence against her physician, and that the prevailing medical standards were inappropriate. She also argued the existence of an implied condition or warranty under contract law and the *Sale of Goods Act*.²²¹ The Court affirmed the presence of two fundamental aspects of a claim of professional negligence: (1) breach of duty arising from the failure to be aware of the risk of HIV infection through the use of artificial insemination; and (2) breach of duty with respect to the screening and follow-up of donors. The Court noted the medical context and vulnerability of physicians, stating: "it must be recognized that biological products such as blood and semen, unlike manufactured products, carry certain inherent risks."²²² In the end, the Supreme Court of Canada confirmed that the appropriate legal basis upon which this case should be considered was that of negligence and sent the case back to trial for a determination of the negligence issue and an assessment of damages.

(b) Embryos

Embryo donation for purposes of reproduction raises different issues than those for gametes *per se*. Given their potential for human life, embryos, like fetuses, deserve special attention under existing law or a future regulatory regime. In addition, embryos involve two genetic contributors, each with a potential interest in the embryo. As well, embryos may be implanted in a gestational mother. The common law may therefore distinguish between *in utero* and *ex utero* embryos, where the latter are located in a storage bank while the former are located in the womb of a gestational mother. The legal issues of control and parenthood become more complicated where the gestational mother differs from the genetic mother. Canadian courts have yet to face the difficult issue of revocation of consent for the donation of an embryo by genetic parents to a gestational mother. Another possible scenario is the mistaken implantation of *in vitro* embryos into a gestational mother.²²³ Canadian courts, especially in the context of abortion, have acknowledged that women have full autonomy to make decisions over their bodies and to abort embryos or fetuses they may be carrying.²²⁴ The courts would likely favour the gestational mother in the control and disposition of an embryo that has already been implanted, at least to the point of birth.

²²¹ R.S.B.C. 1996, c. 410.

²²² *ter Neuzen v. Korn*, note 220 at 717.

²²³ Where the embryo matures to the point of birth, however, the courts may favour either the genetic or gestational parents, depending on the circumstances and jurisdiction. See *Perry-Rogers v. Fasano*, [2000] NY - QL 8531 (N.Y.App.Div. 10/26/2000), where the New York Supreme Court, Appellate Division, considered a tragic mix-up at a fertility clinic involving the mistaken implantation of another couple's embryo into the gestational mother. The Court resolved a dispute over custody of the resulting child between the genetic and gestational parents, who were of a different race. The Court held in favour of the genetic parents, suggesting that gestational parents had delayed their actions in correcting the mistake. Visitation rights for the gestational parents were denied.

²²⁴ *R. v. Morgentaler*, [1988] 1 S.C.R. 30.

Embryo donation requires the informed consent of both genetic donors, if known.²²⁵ Consent should be clearly expressed, specific, and in writing. For embryo donation particularly, an agreement might cover disposition for such contingencies as the death of one or both donors. As well, an agreement could expressly address dispositional issues upon the revocation of consent by one or both donors.

A woman who separates from a male partner²²⁶ may seek custody of cryopreserved embryos in which she and her partner genetically contributed. The woman may wish to keep the embryos for herself for subsequent implantation. Or, she may wish to transfer the embryos (or dispositional authority) to a third party, for example, another woman or couple, or to simply destroy the embryos. If the male contributor is opposed to such a transfer or destruction, and if Canadian courts support joint control, then the woman would have no legal recourse. In the United States, the common law has so far supported joint control over embryo disposition where neither contributor is an anonymous donor. In the case of cryopreserved (or frozen) embryos, if the parties cannot mutually agree, then by court order or pre-conception contract, the embryo bank (where the embryos are stored in cryopreservation) may allow the embryo to perish.²²⁷ In *Davis v. Davis*,²²⁸ as we previously discussed, the court directly confronted the issue of whether one genetic contributor, Ms. Davis, could transfer the cryopreserved pre-embryos to another woman, despite Mr. Davis' wishes not to proceed. In the end, the court in *Davis* recognized that each contributor has an equal say in the disposition of the frozen *ex utero* pre-embryos. Mr. Davis' right not to reproduce trumped Ms. Davis' right to transfer the embryos to another woman. In *Kass v. Kass*²²⁹ the New York Court of Appeal upheld a mutual consent agreement providing dispositional control of the pre-embryos to a third party, the IVF programme. In effect, the court sided with Steven Kass' argument to uphold the initial agreement based upon the clear expression of the parties' original intentions. The Court of Appeal emphasized the "quintessentially personal and private" nature of the genetic parents' decision over the disposition of pre-embryos.²³⁰

The emphasis on joint control (based on an agreement or otherwise) does not seem to adequately address gender-based imbalances in power and control over

²²⁵ See the *Joint Policy Statement of Medical Professionals*, *supra*, note 117 at 23. According to the *Joint Policy Statement*, informed consent must be obtained from the woman, if single, or from members of the couple whose embryos are being frozen. It also recommends that informed consent be revisable at any time by the woman, if single, or the couple. If the couple is unable to agree on changes to informed consent, then the original consent form stands, or the embryos will be discarded.

²²⁶ The novelty of reproductive technologies has not yet provided much opportunity for the law to consider same sex couples. See *Korn v. Potter*, *supra*, note 220.

²²⁷ See A. Eser, "The Legal Status of the Embryo in Comparative Perspective" (1992) 11 *Medicine and Law* 579.

²²⁸ 842 S.W.2d 588 (Tenn. 1992).

²²⁹ *Kass v. Kass*, 696 N.E.2d 174 (N.Y. 1998), affg 663 N.Y.S.2d 581 (N.Y. Sup. Ct. 1997), revg WL 110368 (N.Y. Sup. Ct. Jan. 18, 1995).

²³⁰ *Ibid.*, at para. 39.

human reproduction. Genetic parents, like those in *Davis* and *Kass*, may attempt to vary or revoke their consent for embryo donation.²³¹ One or both genetic contributors might revoke consent for embryo donation, despite prior agreement to the contrary. In making decisions over control and disposition, the courts should consider the fact that women undergo an invasive procedure to remove some of their limited supply of ova for donation. In the case of one anonymous contributor, embryo donation may follow the same rules and principles applicable to gamete donation. Moreover, the intended gestational mother might revoke her consent to be the recipient. In the above cases, the courts should proceed cautiously and with careful review of power imbalances and policy interests, in the absence of clear legislation.

The disposition of embryos could also become problematic when one or both of the genetic contributors die. The Royal Commission recommends that embryos not be stored beyond the death of one or both of the genetic contributors.²³² The draft AHRA prohibits the use of "reproductive materials" without written consent for that specific purpose, which presumably will include the use of *in vitro* embryos after the death of one or both of the parties.²³³ Again, it remains to be seen how Canadian courts might decide these latter issues. As we discussed previously, human tissue gift legislation, if applicable to human embryos, provides for the postmortem transfer of dispositional authority to non-family members, provided that there is no "reason to believe that the person who died or whose death is imminent would have objected to it."²³⁴

²³¹ See *A.Z. v. B.Z.*, [2000] No. SJC-08098 (Mass. 03/31/2000), where the husband signed a consent form after the couple's separation, permitting release of the frozen pre-embryos to the wife. The Supreme Court of Massachusetts found the subsequent consent form unenforceable since it would require the father to become a parent over his objections. The permanent injunction against the wife awarded at the lower court was affirmed. In *J.B. v. M.B.*, [2001] NJ-QL 416 (N.J. Supr. Ct. 08/14/2000), the couple separated and the husband wanted to donate the frozen embryos, whereas the wife wanted to discard them. The Supreme Court of New Jersey affirmed the lower court decision by relying upon contract law, not constitutional law. The Court found that the wife's right not to procreate outweighs the impairment to the husband's reproductive rights. While the Court recognized that the party who chooses not to become a biological parent usually prevails, in this case the father, M.B., is capable of fathering additional children. In a concurring opinion, Justice Verniero endorsed the principle that infertile persons should have the right to use pre-embryos, over the objections of others, if this use is the only means to procreate (at para. 92). See also *Litowitz v. Litowitz*, No. 24223-I-II (Wash. App. Div. 2 10/17/2000), where each of the married couple sought control over frozen embryos, which were created from the husband's sperm and donated ova. The wife sought control of the embryos for implantation into a surrogate mother. Whereas the wife intended to raise the resulting child, the father did not wish to become subject to parental obligations. The Court affirmed the lower court ruling, relying upon different reasons, to provide the father control over the embryos. The egg donor contract signed by the parties did not address the couple's dissolution. The only genetic parent before the court, the husband has the constitutional right not to procreate.

²³² Royal Commission, *supra*, note 3 at 599.

²³³ Section 6(1).

²³⁴ See, for example, the British Columbia *Human Tissue Gift Act*, R.S.B.C. 1996, c. 211, s. 5(2). The first publicized case to raise issues about the status and disposition of frozen embryos

A different scenario arises where both the woman and man had initially abandoned the cryopreserved embryos but later found that the embryo bank sought to donate them for implantation into other women. This situation, given the embryo's development and potential for human life, may warrant a higher standard of consent by both genetic contributors for the specific purposes of the embryo implantation, as well as a specific threshold for abandonment.

Recognizing the controversy surrounding the donation of embryos, the draft AHRA, if enacted, would leave the definition of "donor" a subject matter of the regulations, in contrast to "gamete donor," which is directly defined in the draft legislation.²³⁵ It is uncertain whether the federal government did not wish to face such a controversial moral issue, or whether they believed that the regulations would provide a more flexible framework for the law's adaptation of changing societal values. The draft AHRA would prohibit the purchase, sale, or the offering or advertising to purchase or sell, *in vitro* embryos.²³⁶ While the draft Act prohibits only the purchase of gametes, it prohibits both purchase and sale of embryos. Any collection, storage, transfer, destruction, importation, or exportation of *in vitro* embryos would require a license.²³⁷

2. Donor Anonymity and Identification

The use of donor gametes raises issues of identification and anonymity. Some women may choose to bear a child using the sperm or ova of anonymous donors. An infertile couple may wish to combine anonymous donations of sperm and ova, with hopes of implanting the embryo into the woman partner as gestational mother. The availability of sperm and ova will depend upon the supply of and access to anonymous donor contributions, usually through sperm and ova banks. Donor embryos, however, may be even more difficult to locate.

The requirement of informed consent also applies to anonymous donors. The donor must be informed of the specific purpose of the donation and the potential benefits and risks. Anonymous donors, if they provide informed consent, generally waive their beneficial interests and right to control gametes and embryos, as well as future child support obligations and custody rights. Thus, donors receive anonymity in exchange for their own relinquishment of dispositional control and the guarantee that no legal claims will be found against them. Canadian courts, moreover, tend not to hold anonymous donors liable for the quality and fitness

created through *in vitro* fertilization involved Mr. and Mrs. Rios, a wealthy California couple who received *in vitro* fertilization in Australia. Two embryos were frozen when Mr. and Mrs. Rios died in an airplane crash. Apparently the Rioses left no written instructions regarding the fate of the "orphan embryos" and a lengthy and heated debate arose about whether the embryos should be destroyed, made available for anonymous donation, or deliberately gestated in order to permit them to inherit an intestate share of the Rioses' estate. For further discussion of this case and the issues it raises see: George P. Smith II, "Australia's Frozen 'Orphan' Embryos: A Medical, Legal and Ethical Dilemma" (1985-86) 24 J. F. L. 27.

²³⁵ Section 2 of the draft AHRA.

²³⁶ *Ibid.*, s. 5(2).

²³⁷ *Ibid.*, s. 8(3). This section refers to the use of gametes and embryos for the treatment of a disease, injury, or disability.

of the "product."²³⁸ This position supports the policy interest of making available a large pool of sperm and ova for donation. Physicians or facilities as "processors" must maintain information about donors, including personal identification and the results of screening tests.²³⁹ Under the draft AHRA, if enacted, the physician or facility licensee must provide "health reporting information" from a donor of human reproductive material.²⁴⁰ Privacy concerns are raised by the broad definition of "health reporting information" under s. 2 of the draft Act:

- (a) the identity, personal characteristics, genetic information and medical history of donors of human reproductive material, persons who have undergone assisted reproduction procedures and persons who were conceived by means of such procedures; and (b) the custody of donated human reproductive materials and any uses that are made of them.

The donor must be informed in writing of the disclosure requirements. Further disclosure of the information to third parties is prohibited, except with the written consent of the donor, and except as otherwise required by law.²⁴¹

A more controversial issue arises if the donor wishes to remain anonymous, whereas the child seeks access to information that identifies her or his genetic parents. At some point the child's interest in obtaining social, cultural and medical information for her or his psychological or social well-being could override the policy interest to ensure a large supply of donor sperms and eggs. One possible resolution would centre on the child's access to non-identifying genetic information. This would, however, still lead to issues about the nature and extent of such information and its restricted availability. In serious medical cases where the child's health or life is at risk, key genetic information should be made available. In response to this issue, the draft AHRA provides that the Minister of Health may disclose non-identifying information about a donor to a person undergoing assisted reproduction with the donor's gametes or to the person conceived with donor gametes, or to his or her descendants.²⁴² Identifying information about the donor would be released only with the written consent of the donor.²⁴³

A registry is one possible solution to ensure limits to the number of offspring by donors and to guarantee that genetically-related children do not unknowingly reproduce with each other. It might also be helpful for children to receive counselling prior to receiving registry information about their genetic parents. The existence of a donation registry, however, may lead to misuses or abuses of information by governments and private parties. In order to resolve these issues, Canadian courts will likely draw parallels to the statutory and common law respecting adoption.

²³⁸ *ter Neuzen v. Korn*, *supra*, note 220.

²³⁹ *Processing and Distribution of Semen for Assisted Conception Regulations*, SOR/96-254, s. 12.

²⁴⁰ Section 18(1) of the draft AHRA.

²⁴¹ *Ibid.*, s. 19(1) and (2).

²⁴² *Ibid.*, s. 21(4).

²⁴³ *Ibid.*

Genetic and gestational parents, if they differ, may also have a legal obligation to tell children about their genetic heritage. There seems to be a strong societal interest in children knowing the "genetic truth." If such obligations exist, and in the absence of relevant legislation, the courts will likely consider an appropriate age for the disclosure of the fact of donation and for the provision of specific information about the donor. In the absence of such disclosure, children might suffer from "genetic bewilderment" and social stigmatization.²⁴⁴

Children may also attempt to claim support payments or inheritance from an identified donor. The issue remains whether common law courts will refuse to provide children with legal interests against donors or their estates. In deciding such legal issues, Canadian courts would likely consider the "best interests of the child" principle, and the policy interest in the availability of anonymous donation. Where the child wishes, however, the donor might revoke his or her anonymity arrangement.

3. Freezing and Disposal of Gametes and Embryos

The freezing (or cryopreservation) and storing (or "banking") of tissues provide new opportunities for the timing and location of assisted reproduction, as well as the testing and screening of *ex utero* sperm, ova, and embryos for donation. Donated sperm, ova, and embryos may now be screened for HIV and other sexually transmitted diseases, as well as various genetic factors. As we have previously discussed, a physician's duty of care as a medical professional now requires reasonable efforts to test and screen donation, whether known or anonymous.²⁴⁵ This duty has now been specifically detailed and embodied in the regulations of the *Food and Drugs Act* dealing with the processing and distribution of semen.²⁴⁶ The storage of gametes also raises a number of ethical issues, including those of confidentiality, privacy, duration and criteria for storage, use of data, consent and withdrawal of the subject, and maintaining future contact with the subject and her or his family.²⁴⁷

In light of the sensitivity of the subject matter — potential forms of human life and uniquely identifying information — governments may impose limits on the condition and quantity of gametes and embryos stored and transferred between individuals and institutions. In Canada, the federal government now regulates the processing and distribution of semen for assisted conception.²⁴⁸ As we previously discussed in the section "Existing Legislation," these regulations require the processors and importers to quarantine, screen, and test donor se-

²⁴⁴ R. Achilles, "The Social Meanings of Donor Insemination" in *The Royal Commission on New Reproductive Technologies*, vol. 9 (Ottawa: Minister of Supply and Services Canada, 1993); see also J. Robertson, "Embryos, Families, and Procreative Liberty: The Legal Structure of the New Reproduction" (1986) 59 S. Cal. L. Rev. 939.

²⁴⁵ See *ter Neuzen v. Korn*, [1995] 3 S.C.R. 674.

²⁴⁶ *Supra*, notes 50 and 51.

²⁴⁷ See the *Tri-Council Policy Statement*, *supra*, note 118, art. 8.6.

²⁴⁸ *Supra*, notes 50 and 51.

men. Moreover, at common law, storage facilities may have a duty of care to screen and test frozen gametes and embryos for illnesses and genetic conditions.²⁴⁹ However, governmental regulation of the storage and handling facilities for gametes and embryos could also lead to increased use of unlicensed artificial insemination and higher risks due to the absence of donor screening for illnesses and genetic disease.²⁵⁰ In other words, a regulatory regime that too strictly controls the storage and transfer of gametes and embryos could lead to an underground market for reproductive services and "materials."

The few common law cases so far decided indicate the importance of the donor parties' intentions prior to the freezing and storage of gametes and embryos.²⁵¹ The parties should also express their intentions with respect to such dispositional contingencies as the donors' death or abandonment of donation. As previously discussed, human tissue gift legislation, if generally applicable, might also apply to frozen gametes and embryos in storage. If so, this would suggest that storage banks might have a dispositional authority (over "transplantation") based on possession, if no other family member or relative can be found, and there is no reason to believe that the deceased person would have objected.

The abandonment of sperm, ova or embryo donations creates new issues of control and disposition. Storage facilities may assert control over abandoned gametes and embryos on the sole basis of possession. Also, those parties who assisted in the extraction of such reproductive materials and products might attempt to gain dispositional control over them. The situation may also be similar where the donors of gametes and embryos die, without any expressed intentions or specific instructions for donation. The freezing of sperm and ova can therefore lead to complex issues of dispositional authority. Moreover, the disposal of gametes and embryos should occur by means that account for their status as potential (or early) forms of human life.

The commercialization of freezing processes and storage facilities for gametes and embryos raises serious concerns. The Final Report of the Royal Commission recommended: "No profit should be made from the selling of any reproductive material, including sperm, because of ultimately de-humanizing effects. Current commercial practices in storage and distribution of donor sperm contravene these values, and we recommend a licensed, non-profit system."²⁵² The Royal Commission warns against the commercialization of human reproduction and the commodification of gametes and embryos.

The maximum storage period for frozen embryos has been variously debated. The Royal Commission suggested that it would be unethical to store beyond five years or after the death of either partner.²⁵³ One might also argue that time limits

²⁴⁹ See *ter Neuzen v. Korn*, *supra*, note 245.

²⁵⁰ However, see the regulations of the *Food and Drugs Act*, *supra*, note 239, which became enforceable June 1, 1996 (federal government controls the processing, testing and distribution of semen for donor insemination).

²⁵¹ See *Davis v. Davis*, 842 S.W.2d (Tenn. 1992).

²⁵² Royal Commission, *supra*, note 3 at 15.

²⁵³ *Ibid.*, at 599.

be applied to the storage of sperm and ova. Moreover, the personnel for such storage banks should be qualified in the handling, processing and distributing of such sensitive "materials."

In response to the above concerns, the draft AHRA, if enacted, would regulate the transfer and storage of gametes and embryos. Section 8(3) of the draft Act states: "No person shall, except under the authority of a licence issued under subsection 12(1), collect, store, transfer, destroy, import into Canada or export from Canada any sperm, ovum or *in vitro* embryo" for purposes of human reproduction, research or the prevention, diagnosis, or treatment of disease, injury, or disability. Individuals and facilities may be issued a licence to conduct such controlled activities.²⁵⁴ This licensing regime may also ensure that qualified personnel are employed and that facilities are properly maintained and managed. A licensee must also disclose any health reporting information, except information that would identify the participants, "to any individual or organization for scientific research or statistical purposes."²⁵⁵ Moreover, where inspectors believe on reasonable grounds that a controlled activity has occurred in a premise, other than a dwelling house, they may enter the premises for purposes of enforcement of the Act.²⁵⁶

E. EMBRYO RESEARCH

Ovarian stimulation and ovum retrieval usually lead to the generation of a number of embryos, one or some of which are selected and implanted into a woman. It has been generally recognized that the treatment of "spare" embryos is an important matter of human dignity and integrity.²⁵⁷ As previously discussed, embryos, as potential human life, have moral status somewhere in between property and full personhood, and should be treated with respect. Some argue that ova should not be fertilized for the sole purposes of embryo research, except in unusual circumstances as determined by a regulatory body where knowledge cannot be attained by other means, and where such research would benefit society as well as future children.²⁵⁸ Others argue that the fertilization of ova for research should be permitted since it may advance scientific knowledge and benefit society.²⁵⁹ The draft AHRA would prohibit the creation of *in vitro* embryos solely for research purposes.²⁶⁰

A primary issue of public concern is the age limit of embryos subject to research, in light of the initial development of nervous systems and possible hu-

²⁵⁴ Sections 11 and 12 of the draft AHRA.

²⁵⁵ *Ibid.*, s. 19(4).

²⁵⁶ *Ibid.*, ss. 24-25.

²⁵⁷ See I. Kennedy, "The Moral Status of the Embryo" in I. Kennedy, *Treat Me Right: Essays in Medical Law and Ethics* (Oxford: Clarendon Press, 1991) at 119.

²⁵⁸ *Final Report of the Discussion Group on Embryo Research*: "Research on Human Embryos in Canada" (submitted to Health Canada, 15 November 1995) recommendation 10 [hereinafter "*Final Report of the Discussion Group on Embryo Research*"].

²⁵⁹ Royal Commission, *supra*, note 3 at 608-09.

²⁶⁰ Section 3(1)(d). See also the *Joint Policy Statement of Medical Professionals*, *supra*, note 117 at 276; *Tri-Council Policy Statement*, *supra*, note 118 at art. 9.4.

man suffering. It has been recommended that any research be limited to embryos not older than 14 days from conception — which is also the stage at which implantation no longer becomes medically viable.²⁶¹ In light of the moral status of embryos and the potential risks to society, research on embryos may require careful regulation and monitoring. The draft AHRA would recognize the 14th day threshold (from the point of "fertilization or creation") by prohibiting the maintenance of an embryo beyond this point "outside the body of a woman."²⁶²

Most provincial statutes expressly regulate the use of human tissue for research. One could argue that embryos should be included in definitions of human tissue and are therefore subject to statutory protections regarding consent to remove for purposes of research.²⁶³ However, since most of these regulatory frameworks do not explicitly mention "embryos" in the definition of human tissue, embryo research is not necessarily excluded.²⁶⁴ Section 1 of the *Trillium Gift of Life Network Act* of Ontario, on the other hand, expressly excludes embryos from the definition of human tissue, removing any opportunity for a broad interpretation by the courts.²⁶⁵ In Ontario, the statutory protection of consent by an authorized person, according to a hierarchical list of family members, does not apply to embryos for purposes of medical education and research.

The commercialization of embryo research has also been generally recognized as immoral. Article 25 of the *Civil Code of Quebec* states that "[a]n experiment may not give rise to any financial reward other than the payment of an indemnity as compensation for the loss and inconvenience suffered." Some commentators support the allowance of "out-of-pocket" expenses and non-profit costs for storage, handling, transportation and transfer.²⁶⁶ The selling and buying of sperm, ova, and embryos has been widely condemned in Canada and abroad. The draft AHRA would impose criminal sanctions for the sale, purchase, barter or exchange of gametes and embryos, whether for research or other purposes.²⁶⁷ Section 10 of the draft Act, however, would also allow a regulatory system where licensees could request reimbursement for expenses to donors, thus ensuring minimum supplies for embryo research. Existing and proposed statutory law for gamete and embryo donation vaguely define important terms such as "expenses," "compensation" and "losses."

²⁶¹ *Final Report of the Discussion Group on Embryo Research*, *supra*, note 258, recommendation 3. See also the *Joint Policy Statement of Medical Professionals*, *supra*, note 117 at 27; *Tri-Council Policy Statement*, *supra*, note 118 at art. 9.4(d).

²⁶² Section 3(c) of the draft AHRA.

²⁶³ See, for example, art. 22 of the *Civil Code of Quebec*, which stipulates that "a part of the body, whether an organ, tissue or other substance, removed from a person as part of the care he receives may, with his consent or that of the person qualified to give consent for him, be used for purposes of research."

²⁶⁴ See *supra*, note 64.

²⁶⁵ R.S.O. 1990, c. H.20. See also the Manitoba and P.E.I. legislation: *Human Tissue Gift Act*, S.M. 1987-88, c. 39, and *Human Tissue Donation Act*, R.S.P.E.I. 1988, c. H-12.1.

²⁶⁶ *Final Report of the Discussion Group on Embryo Research*, *supra*, note 258, recommendation 16.

²⁶⁷ Section 6(1) of the draft AHRA. See also s. 5(1) and (4).

Various concerns have also been raised over women and men being unknowing experimental subjects. As discussed previously in the section on informed consent in this chapter, donors must provide informed consent specific to the purposes of research on gametes and embryos. Consent for embryo donation for research purposes should be clearly expressed and in written form.²⁶⁸ Informed consent may require that donors be aware of specific research uses, as well as a range of options, including gestational use, donation to other women, or disposal.²⁶⁹ It has been recommended that "a very high level of disclosure" be required, including success rates and the range of possible negative outcomes where known.²⁷⁰ In cases of pre-implantation of an embryo in a woman's body, for example, informed consent requires her awareness of the "experimental, innovative or unproven" nature of techniques, such as pre-implantation genetic diagnosis.²⁷¹ The draft AHRA would emphasize the requirement of informed consent for specific purposes as an important pillar for the use of reproductive technologies, and for the donation of gametes and embryos for research. Section 6(3) would prohibit any use of *in vitro* embryos for purposes of research, unless written consent from the donor is obtained. Any research or medical use of embryos must be licensed under the draft Act.²⁷² Medical scientists, on the other hand, often argue that strict standards for consent, combined with a regime of prohibitions, may "chill" research that could otherwise benefit society. It seems that Canadian society, through dialogue and debate, may consider the effects on embryo research specifically, and biotechnology generally, in light of their social implications.

F. STEM CELL RESEARCH

The advent of stem cell research and its possible regulation has brought widespread media attention.²⁷³ Researchers value stem cells highly, especially those from embryos, since stem cells are much more adaptive and potent than other cells: they are capable of reproducing themselves through self-renewal. Embryonic stem cells at the earliest stages of union between a sperm and egg can multiply and develop (or differentiate) into all other types of cells and tissues.²⁷⁴ The

²⁶⁸ See generally, B. Dickens, "Reproduction Law and Medical Consent" (1985) U.T.L.J. 255; see also *Kass v. Kass*, 696 N.E.2d 174 (N.Y. 1998), affg 663 N.Y.S.2d 581 (N.Y. Sup. Ct. 1997), revg WL 110368 (N.Y. Sup. Ct. Jan. 18, 1995).

²⁶⁹ *Final Report of the Discussion Group on Embryo Research*, *supra*, note 258, recommendations 6 and 7.

²⁷⁰ *Ibid.*, at 17-18.

²⁷¹ *Ibid.* Pre-implantation genetic diagnosis involves the use of *in vitro* fertilization and the testing of embryos for genetic abnormality prior to implantation in a woman's body. See also generally the *Tri-Council Policy Statement*, *supra*, note 118, art. 10.

²⁷² Section 8(2) of the draft AHRA.

²⁷³ For example, see the four-part editorial series in *The Globe and Mail* (5-8 February 2001); and B. Laghi, "Ottawa plans to go slow on stem-cell legislation" *The Globe and Mail* (3 September 2001).

²⁷⁴ These embryonic stem cells are called pluripotent (if they are capable of forming multiple tissues but not an entire organism) or totipotent (capable of forming an entire organism): see L. Knowles, *infra*, note 276 at 4.

process of differentiation provides researchers with information about the effectiveness of cell replacement therapies to treat genetic and other diseases. An abundant supply of stem cells would provide researchers with a foundation for research on stem cell therapy as a potential treatment for serious conditions, such as Alzheimer's and Parkinson's disease, diabetes, heart disease, and spinal cord injuries.²⁷⁵ Stem cell research may lead to the repair of damaged tissues and organs, and perhaps someday even to the creation of replacement organs.

Embryonic stem cells may be obtained from aborted fetuses, or embryos created from: gametes combined specifically for research purposes; *in vitro* fertilization and no longer required for infertility treatment; or somatic cell nuclear transfer. Somatic cell nuclear transfer involves extracting the nucleus of an egg and replacing it with the nucleus from a somatic cell (cells not from a sperm or egg) in order to create an embryo.²⁷⁶

The decision to use a particular source of embryonic stem cells depends on the moral status accorded to embryos. Some argue in favour of using "spare" embryos only (*i.e.*, those created but not required for infertility treatment). Arguably, this approach accords a special status to embryos as potential human life. At the other end of the spectrum, some argue in favour of the creation of embryos for purposes of research, so long as the embryo is not allowed to develop beyond 14 days. According to this view, the embryo is considered more like the property of gamete donors and researchers. Other commentators would prohibit only somatic cell nuclear transfer. In addition to the issue of the source of stem cells, stem cell research raises other issues: informed consent, privacy and confidentiality, and the commercialization of research.²⁷⁷

Until recently, harvesting stem cells has required either the destruction of early human embryos or cell extraction from aborted fetuses, thus research on embryonic stem cells raises several ethical issues.²⁷⁸ However, it may now be possible to use umbilical cords, at least for purposes of organ transplant and future insurance against disease.²⁷⁹ Furthermore, adult stem cells appear to show

²⁷⁵ Canadian Institutes of Health Research, "Human Stem Cell Research: Opportunities for Health and Ethical Perspectives" online: <http://www.cihr.ca/governing_council/ad_hoc_working_groups/stem_cell_e.pdf> (posted: 29 March 2001) [hereinafter "CIHR Discussion Paper"].

²⁷⁶ *Ibid.*, at 5-6. See also L. Knowles, "Comparative Primordial Stem Cell Regulation: Canadian Policy Options" (Ottawa: Canadian Biotechnology Advisory Committee, January 11, 2001), online: <http://www.cbac.gc.ca/documents/Lori_English2.pdf>; A. Mitchell, "Scientists clone human embryo" *The Globe and Mail* (16 November 2001) A1: Researchers at a private laboratory in the United States have reportedly cloned a human embryo for purposes of producing stem cells — so-called "therapeutic cloning." They claim that the objective of their cloning technique is to provide a source of life-saving stem cells for research towards a better understanding of human illness and disease, and not to clone entire human beings.

²⁷⁷ CIHR Discussion Paper, *supra*, note 275.

²⁷⁸ S. Lee, "Human Stem Cell Research: NIH Releases Draft Guidelines" (2000) 28 J.L. Med. & Ethics 81.

²⁷⁹ See "Don't bank on umbilical cord blood: British Report" *CBC News* (22 November 2001). See also S. Kirschenbaum, "Banking on Discord: Property Conflicts in the Transplantation of Umbilical Cord Stem Cells" (1997) 39 Ariz. L. Rev. 1391. In Canada, see the Alberta Cord Blood Bank, which stores umbilical cord blood stem cells, online: <<http://www.acbb.ca/>>.

some promise, especially the multipotent stem cells found in nerves, skin, and muscle.²⁸⁰ At this point, however, adult stem cells have not shown as much promise as those from early embryos.

The 1998 *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* establishes professional guidelines for the federal funding of experimental research on human embryos. Research using aborted fetuses and embryos not required for infertility treatment may be ethically acceptable if specific conditions are met. The *Tri-Council Policy Statement*, however, prohibits the creation of embryos for research purposes, the development of embryos *in vitro* beyond 14 days, the cloning of embryos by somatic cell nuclear transfer, the creation of animal-human hybrids, and the transfer of embryos between humans and animals.²⁸¹

The Canadian Institutes of Health Research ("CIHR") recommends prohibiting the creation of human embryos by *in vitro* fertilization for purposes of deriving stem cell lines, as well as the use of animal-human combinations of stem cells. Furthermore, the CIHR supports a moratorium on funding for the creation of embryos by somatic cell nuclear transfer for purposes of deriving stem cell lines, as well as research that uses stem cells to create human embryos. However, because of the importance of stem cells to medical research, the CIHR recommends that research on stem cells from "spare" embryos that remain after infertility treatments should be allowed and open to funding. The CIHR supports funding research on existing human embryonic cells and on aborted fetuses, for therapeutic purposes. The CIHR also recommends the establishment of a national body to periodically review public and private funding of research on stem cells.²⁸² Mechanisms of accountability to the public in a particular region, an appropriate range of expertise, and the impact of the framework on privately funded research, have been identified as problematic areas for this national body.

Stem cell research is not expressly regulated in Canada. Instead, stem cell research falls under professional guidelines and may fall directly or indirectly under several legislative frameworks. As previously discussed, human tissue legislation in some provinces may apply to the use of gametes and embryos for research purposes. Moreover, patent law might also limit researchers' access to specific human embryonic cell lines, assuming that patents for human cell lines

²⁸⁰ CIHR Discussion Paper, *supra*, note 275 at 4; McGill News Alumni Quarterly, "Stem Cell Breakthrough at McGill" (Fall 2001), online: <<http://www.mcgill.ca/news/archives/fall2001/newsbites/>>.

²⁸¹ See the *Tri-Council Policy Statement*, *supra*, note 118; arts. 9.1-9.5.

²⁸² CIHR Discussion Paper, *supra*, note 275 at 1-3. On March 4, 2002, the Canadian Institutes of Health Research introduced new guidelines for the eligibility for federal funding of stem cell research: *Human Pluripotent Stem Cell Research: Guidelines for CIHR-Funded Research* (4 March 2002), online: <http://www.cihr.ca/about_cihr/ethics/stem_cell/stem_cell_guidelines_e.shtml>. Section 7.1.1 of the Guidelines requires that: embryos be created only for reproductive purposes; gamete donors provide free and informed consent for the purpose of research when embryos are no longer required for reproduction; and gametes and embryos not be obtained through commercial transactions (including "exchange for service").

are legally valid.²⁸³ Other nations have not provided much guidance, since stem cell research is relatively new worldwide and proposals for legislative frameworks are only now appearing.²⁸⁴ Great Britain currently allows the creation of embryos by fertilization or cloning for purposes of stem cell research, so long as the embryos are not developed beyond 14 days from their fertilization or creation.²⁸⁵ The United States Government, on the other hand, is now trying to limit federal funding only to stem cell research on embryos that already exist for purposes of infertility treatment.²⁸⁶

In 1995, the federal government requested a voluntary moratorium on various embryo-related research activities, including the cloning of human embryos, the buying and selling of embryos, germ line genetic alterations, the creation of animal-human hybrids, and research involving the maturation of sperm, eggs, and embryos outside the human body. This voluntary moratorium apparently continues until legislation is put in place. Although we have previously discussed Bill C-47 and the latest draft AHRA, a few provisions are especially relevant to stem cell research. Under the draft AHRA, "embryo" is defined broadly to include a "human during the first 56 days of its development following fertilization or creation." The draft Act prohibits the creation of embryos for the purpose of research. It also expressly prohibits human clones, defined as embryos with exactly the same DNA sequence as other human beings, fetuses, or embryos. Embryos also cannot be genetically altered in a way that transmits across generations, nor can they be maintained outside the human body for more than 14 days.

The effective regulation of stem cell research will draw on social and cultural values pertaining to the moral status of the embryo, the requirements of informed consent, respect for privacy and confidentiality, and concern about the health and safety of women and children, who are disproportionately impacted by such research.

G. HUMAN CLONING

This section will briefly address the ethical, social, and legal concerns about human cloning, particularly the reproductive cloning of embryos.

The term "cloning" means different things to different people. At the most basic level, cloning involves the making of identical copies of molecules, cells, tissues, or even entire organisms.²⁸⁷ The two basic types of cloning are reproductive and

²⁸³ See, for example, "Suit Seeks to Preserve Stem Cell Access" in Bureau of National Affairs, Washington, D.C., *Patent, Trademark & Copyright Law Daily* (16 August 2001), online (to subscribers): <<http://pubs.bna.com/ip/BNA/btb.nsf/>>; I. MacLeod, "Firms seek stem cell patents" *National Post* (20 July 2000).

²⁸⁴ See, for example, CIHR Discussion Paper, *supra*, note 275 at 10-16.

²⁸⁵ See *Human Fertilisation and Embryology Act, 1990*, ch. 37(5) (Eng.), s. 3(4).

²⁸⁶ See, for example, Biotech Watch, "HHS Official Tells House Subcommittee White House Favours Human Cloning Ban" (21 June 2001); CIHR Discussion Paper, *supra*, note 275 at 10-11.

²⁸⁷ Hearing Before the Committee on Science Subcommittee on Technology, "Review of the President's Commission's Recommendations on Cloning," U.S. House of Representatives,

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therapeutic. Somatic cell nuclear transfer is one kind of reproductive cloning in which the DNA of an egg cell is removed and replaced with the DNA from a somatic cell. This method of cloning has been identified as a possible treatment option for infertile individuals who wish to become parents. Embryonic splitting (also called blastomere separation) is another kind of reproductive cloning. In this technique, cells from a blastocyst (a clump of early cells that usually develops into an embryo) are artificially separated so that two or more embryos result from the same source. IVF is required for embryonic splitting, followed by implantation into a surrogate mother. Therapeutic cloning, on the other hand, involves the replication of DNA (using stem cells, for example) for therapeutic purposes that do not affect subsequent attempts at reproduction. The effort to grow human organs for purposes of transplantation is an example of therapeutic cloning.

Because cloning is about replication, not necessarily reproduction, cloning includes several widely accepted practices. Cloning encompasses the replication of fragments of DNA, and in this sense scientists have been cloning DNA for years in order to advance the treatment and understanding of human diseases, such as haemophilia, cystic fibrosis, sickle cell anemia, and emphysema.²⁸⁸

More controversially, researchers have had recent successes in cloning non-human mammals by somatic cell nuclear transfer: for example, Dolly the sheep, and the genetically identical rhesus monkeys used for AIDS testing. Even more recently, there have been reports of the cloning of human embryos.²⁸⁹ Despite these developments, cloning technology remains experimental and unproven in application to entire mammals, especially human beings. The ability to replicate humans would bring at least three novel and controversial developments: replacement of sexual reproduction with asexual replication of an existing set of genes; the ability to predetermine the genes of a child; and the ability to create genetically identical offspring.²⁹⁰

The very possibility of replicating humans has generated widespread concern.²⁹¹ According to at least one poll conducted in 2001, most Canadians

105th Congress, 1st sess. (June 12, 1997) at 33. See also C. Klugman & T. Murray, "Cloning, Historical Ethics, and NBAC" in J. Humber & R. Almeder, eds., *Human Cloning* (Totowa, New Jersey: Humana Press, 1998) 3 at 6-8.

²⁸⁸ Hearing Before the Committee on Science Subcommittee on Technology, "Biotechnology and the Ethics of Cloning: How Far Should We Go?," U.S. House of Representatives, 105th Congress, 1st sess. (March 5, 1997) at 2.

²⁸⁹ See L. Andrews, *The Clone Age: Adventures in the New World of Reproductive Technology* (New York: Henry Holt & Co., 1999) at 248-60; "Review of the President's Commission's Recommendations on Cloning," *supra*, note 287 at 13-24. There have been several media reports about attempts at human reproductive cloning; for example, see Associated Press, "Italian fertility expert to attempt human cloning" *The Globe and Mail* (27 January 2001) A19; P. Koring, "Human cloning dangerous, unethical, experts say" *The Globe and Mail* (29 March 2001) A10; J. Wong, "Clone artist" *The Globe and Mail* (7 April 2001) F1.

²⁹⁰ "Review of the President's Commission's Recommendations on Cloning," *supra*, note 287 at 23.

²⁹¹ "Review of the President's Commission's Recommendations on Cloning," *supra*, note 287. See A. Greene, "The World after Dolly: International Regulation of Human Cloning" (2001) 33

strongly oppose human cloning.²⁹² In response to the outcries, many people and governments have called for an immediate ban on human cloning worldwide.²⁹³ These reactions and calls for outright prohibition raise issues about the lack of public access to information, confusion in the definition of "cloning," and the fact that law and ethics tend to lag far behind the science of cloning.

In order to effectively prohibit or regulate cloning, the law requires, at least, a working definition. In drafting legislation, the definition of "cloning" must be neither so broad that it encompasses many useful activities, nor so narrow that it does not effectively capture the cloning practices to be prohibited. A further issue emerges from the prohibition of cloning: should the government prohibit just the act of cloning, or should the government go further and prohibit cloned materials themselves? Currently, cloned materials may be imported into Canada from nations that allow cloning. Thus, "forum shopping" for cloning services in the United States or elsewhere could undermine Canada's attempts at prohibition. The patent systems in Canada and other nations may also affect access to (and use of) cloning techniques and cloned materials.²⁹⁴ Because cloning involves a variety of procedures and purposes, a variety of positions can be taken with respect to it. Arguably, replicating humans could have significant benefits. Medical science might benefit greatly from the comparison of treatments on genetically identical embryos in their development (even if research were stopped after 14 days). Some claim that the cloning of entire human beings should be allowed as an aspect of scientific freedom and reproductive autonomy. Others argue that, while the cloning of entire humans should not be allowed, the cloning of DNA, genes, cells, and body parts is vital for the advancement of medical research in the search for new treatments and testing for disease. The federal government has suggested that it may allow the cloning

Geo. Wash. Int'l L. Rev. 341; J. Robertson, "Why Human Reproductive Cloning Should Not in All Cases be Prohibited" (2000-01) 4 N.Y.U. J. Legis. & Pub. Pol'y 35; K. Rothenberg, "'Being Human': Cloning and the Challenges for Public Policy" (1999) 27 Hofstra L. Rev. 639.

²⁹² C. Cobb, "Most Canadians want cloning ban, research controls" *The National Post* (20 July 2001). In this large poll conducted for Health Canada, three quarters of the 1,700 adults polled in Canada concluded in favour of the outlawing of human cloning and alterations to the genetic makeup of sperm and eggs. Approximately half of the respondents said that they lacked knowledge about reproductive technologies. This poll's results should be interpreted with the usual caveats about accuracy and representativeness. See also the Royal Commission, *supra*, note 3.

²⁹³ For example, the World Health Assembly, 50th Sess. (14 May 1997), adopted the resolution: "The use of cloning for the replication of human individuals is ethically unacceptable and contrary to human integrity and morality."

²⁹⁴ See, for example, R. Skarstad, "The European Union's Self-Defeating Policy: Patent Harmonization and the Ban on Human Cloning" (1999) 20 U. Pa. J. Int'l Econ. L. 353; T. Magnani, "The Patentability of Human-Animal Chimeras" (1999) 14 Berkeley Tech. L.J. 443. The Supreme Court of Canada will soon hear arguments for the first time concerning the patentability of a genetically-altered mammal (an oncomouse): see *President and Fellows of Harvard College v. Canada (Commissioner of Patents)* (1999), 7 C.P.R. (4th) 1 (F.C.A.), revg (1998), 79 C.P.R. (3d) 98 (F.C.T.D.), leave to appeal to S.C.C. granted, [2000] S.C.C.A. No. 474.

of human embryos for the therapeutic purposes of medical research and organ reproduction only, as is permitted in Great Britain.²⁹⁵

There are no reported cases in Canada on the issue of cloning, and only limited legislation enacted worldwide. The Government of Canada, moreover, has limited guidance from international law. Article 11 of the *Universal Declaration on the Human Genome and Human Rights, 1997* states: "Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted."²⁹⁶ Until new legislation in Canada is put into place, the laws governing family relationships (paternity, egg donation, surrogacy) would apply to embryos produced by cloning procedures.²⁹⁷ Researchers who receive federal funding must also adhere to the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, which prohibits human cloning by any means, including somatic cell nuclear transfer.²⁹⁸

The draft AHRA, if enacted, would explicitly prohibit all forms of reproductive cloning: s. 3 prohibits a person from knowingly creating a human clone or transplant, or participating in the transplantation of a human clone into a human being. Section 2 the draft Act defines "human clone" as an "embryo that as a result of the manipulation of human reproductive material contains the same nuclear deoxyribonucleic acid sequence as is found in the cell of a living or deceased human being, foetus, or embryo." "Human reproductive material" is defined broadly in s. 2 to include: "a sperm, ovum, other human cell, human gene or *in vitro* embryo, and includes a part of any of them." Furthermore, the draft Act defines "embryo" in terms of "fertilization or creation." The language of "creation" also suggests prohibition of cloned embryos created using somatic cell nuclear transfer.²⁹⁹ The draft AHRA also would prohibit the alteration of the "genome of a cell of a human being or *in vitro* embryo such that the alteration is capable of being transmitted to its descendants."³⁰⁰ Embryonic splitting for reproductive purposes is also prohibited under s. 3(1)(e). Moreover, an embryo cannot be sustained *in vitro* beyond 14 days from fertilization or creation.³⁰¹ The

²⁹⁵ See C. Clark, "Cloning of embryos considered" *The Globe and Mail* (24 January 2001) A5. An English court, however, recently ruled that the provisions under the *Human Fertilisation and Embryology Act, 1990* do not prohibit cloning since the language of "fertilisation of embryos" was used instead of "fertilisation or creation," a term used in the draft AHRA. See "Laws don't cover cloning of humans, court says" *The Globe and Mail* (16 November 2001). Some types of cloning involve creation rather than fertilization: for example, somatic cell nuclear transfer and embryonic splitting.

²⁹⁶ UNESCO, 29th session (11 November 1997).

²⁹⁷ See Marcy Darnovsky, "The Case Against Designer Babies: The Politics of Genetic Enhancement" in Brian Tokar, ed., *Redesigning Life? The Worldwide Challenge to Genetic Engineering* (Montreal: McGill-Queen's University Press, 2001) 133-49.

²⁹⁸ *Supra*, note 118, art. 9.5.

²⁹⁹ The draft AHRA basically follows the recommendations of the Final Report by the Royal Commission on New Reproductive Technologies, *supra*, notes 3 and 5. This provision is similar to the now defunct Bill C-47, s. 4(1).

³⁰⁰ Section 3(1)(b) of the draft AHRA.

³⁰¹ *Ibid.*, s. 3(1)(c).

prohibitions above apply broadly to anyone who participates in the creation of human clones.

Cloning is defended by appeal to the intrinsic and instrumental value of free scientific inquiry, and by appeal to personal reproductive autonomy. Many defenders of cloning argue that people are more than just the "sum of their genes": social, cultural and environmental factors combine with our genetic inheritance to make us who we are.³⁰² Cloning would enhance (and not determine) us as human beings.

Opponents of cloning argue that it is inherently wrong as it desensitizes us to human life, potentially turning embryos into "human organ manufacturing plant[s]."³⁰³ Furthermore, it is argued, cloning may lead to the loss of individuality and personhood since not one but two or more clones will exist, even if only at the cellular level. For some, an ethical response to cloning depends on an answer to the familiar "property or person?" question. There is no consensus on that issue: some consider clones to be the property of the donor, and even subject to commodification, while others argue for personhood. The clone, if developed to the level of an entire being, might face social stigmatization and become a member of a new "genetic underclass,"³⁰⁴ possibly labeled under a new family category — neither a daughter/son, nor a delayed sister/brother of the genetic contributor. Privacy is another serious concern, since embryos contain cells with genetically unique information, and clones would be identifiable as genetically identical.

There are practical problems with cloning, as well. Cloning is still an experimental procedure, so we must seriously consider the risks of genetic defects and potential harm to future children. Similarly, there are significant risks to gestational mothers, risks downplayed or silenced by academic and media reports.

In light of these different positions, one must find a balance between respect for the special status of the embryo and the interests of the people who suffer from disease, gestational mothers, as well as the interests of future children who may benefit or be harmed as a result. Harm can be defined not just in terms of the cloned individual, in part or whole, but also in terms of the societal value of what it means to be human. The use of cloning at all levels, it is argued, would lessen genetic diversity and therefore harm humankind as a whole in its evolution.

³⁰² D. Bueckert (quoting Tim Caulfield), "Ethicist says Canada should allow human cloning" (31 January 2001), online: CNEWS — Canada's Web Source for News and Information <http://www.canoe.ca/CNEWSscience0101/31_eth-cp.html>.

³⁰³ *Ibid.*

³⁰⁴ Media Interview of Alan Milburn, British Health Secretary, in M. Collett-White, "Britain to Ban Human Cloning" *National Post* (20 April 2001) A14.

IV. CONCLUSION

Reproductive technologies raise a myriad of legal, ethical and social issues with which society must contend. These include questions about who should have access to RTs, whether women should be inseminated with the sperm of men who are now deceased, whether gamete or embryo donors may revoke their consent, and how to control the creation or manipulation of embryos for reproduction or research. Finding answers to these issues is difficult, in part, because there is no social consensus concerning which acts and practices should be permissible. As we have suggested in this chapter, while some of the legal questions generated by reproductive technologies might be adequately resolved by applying existing common law principles and statutes, many feel that a direct legislative response is needed. Legislative intervention would ensure respect for the fundamental values of Canadian society, protect the public against risks to health and safety, and provide clear principles of law according to which potential disputes could be resolved.

Designing such a legislative response is a difficult enterprise. We need to assess the effectiveness of different types of law to answer problems raised by RTs. For example, the use of criminal prohibitions rather than more flexible regulatory regimes needs to be considered. In addition, there may be a danger in assuming that new laws enacted by Parliament or legislatures can adequately address all of the problems raised by RTs. It has been argued that the challenge posed by RTs "is to harness the law so as to mediate between moral imperatives and the therapeutic or non-therapeutic benefits of the advancement of science."³⁰⁵ How can we fashion a regulatory regime "which incorporate[s] a review of the ethical and social consequences of a technology"³⁰⁶ and also ensures safety and efficacy? Canadian federalism further complicates the possibility of a national and uniform approach to the regulation of reproductive technologies. In the absence of a legislated regulatory framework, the development of case law may be susceptible to differing interpretations and policy preferences in the different jurisdictions. Here, the traditional role of the federal government in regulating medical technology overlaps with the exclusive provincial role in the provision of medical services.

The commodification of gametes and embryos and the commercialization of human reproduction raise pressing concerns that cannot be left to market forces and an order of private law. Any regulatory regime must flexibly account for the social and biological dimensions of reproductive technologies, in light of the Canadian *Constitution* and evolving societal norms. At the same time, medical research and technological developments should not be overly constrained or

"chilled" because of regulation. The Canadian situation will likely be affected by developments outside Canada's borders, including the emergence of case law and regulatory regimes, such as the United Kingdom's *Human Fertilisation and Embryology Act, 1990*. Conflicting and inconsistent precedents from both Canadian and other common law jurisdictions are likely to leave a *de facto* situation of market regulation with private ordering as the default. Moreover, given the central role played by medical practitioners in offering and providing reproductive technologies, any form of piecemeal private ordering is likely to leave in place the medical model as the dominant model of decision-making. Once private ordering and market forces become entrenched, it may be very difficult to put in place an alternative statutory regime and a distinctive form of administrative regulation.

The Royal Commission and other commissions and panels have raised concerns about reproductive technologies. If reproductive technologies are defined as a response to a condition called "infertility," then it should be recognized that infertility, in that sense, is as much a social condition as a medical problem. Reproductive technologies are, among other things, a means to avoid passing on genetic and other hereditary diseases to offspring, and a means for women to reproduce without the assistance of male partners.

The draft AHRA, which will soon face debate and revision, provides an initial basis from which legislators might attempt to co-ordinate a comprehensive regulatory regime that respects the profound social consequences of reproductive technologies. Any such regime should carefully account for the responsible gatekeeping of new forms of family and the effects on personal and social lives. It remains to be seen whether a distinctive Canadian regulatory regime will be fashioned in this area.

³⁰⁵ P. Healy, "The Criminalization of New Reproductive and Genetic Technologies" in L. Weir, ed., *Governing Medically Assisted Human Reproduction: Report of an International Symposium* (Toronto: Centre of Criminology, University of Toronto, 1997) 65-71 at 70.

³⁰⁶ M. Hudson, "Societal Controls on New Reproductive Technologies: A Canadian Perspective" in L. Weir, ed., *Governing Medically Assisted Human Reproduction: Report of an International Symposium* (Toronto: Centre of Criminology, University of Toronto, 1997) 73-83 at 73.