Embryo Research

Researchers in the United States observed a human egg being fertilized in a glass dish (*in vitro*) for the first time in 1944. By the late 1960s, researchers in Great Britain were able to bring about fertilization of human eggs *in vitro* fairly reliably. This work led to the first live birth of a child having its beginnings outside the human body, which occurred in Britain in 1978. Since then, techniques for fertilizing human eggs have developed rapidly. Among the factors that have contributed to the development of this technique are the use of fertility drugs to stimulate human egg production and improvements in the procedures that enable sperm and egg cells to mature successfully *in vitro*.

One result of these developments is that more embryos* (or, more accurately, zygotes**) are created *in vitro* than are actually needed for assisted conception.[1] The existence of embryos *in vitro* has made it possible, for the first time in history, to conduct research on human zygotes

---

* There is a problem with terminology, as the term "embryo" is used in different ways. In the language of biologists, before implantation the fertilized egg is termed a "zygote" rather than an "embryo." The term "embryo" refers to the developing entity after implantation in the uterus until about eight weeks after fertilization. At the beginning of the ninth week after fertilization, it is referred to as a "fetus," the term used until time of birth. The terms embryo donation, embryo transfer, and embryo research are therefore inaccurate, since these all occur with zygotes, not embryos. Nevertheless, because the terms are still commonly used in the public debate, we continue to refer to embryo research, embryo donation, and embryo transfer. For accuracy, however, we also refer to the developing entity during the first 14 days as a zygote, so that it is clear that we mean the stage of development before implantation and not later.

** See discussion in this chapter (section on The Aims of Embryo Research and the section on The Ethical Uses of Human Zygotes in Research) on the use of the terms "embryo" and "zygote."

at this very early stage of development. Such research is less than 30 years old and was made possible only because the use of *in vitro* fertilization makes zygotes available. Conducted in many countries, including Canada, this research has facilitated advances in infertility treatments, provided insights into the early stages of human development, and increased our understanding of fertility and contraception.

The research also raises questions, however, about the moral and legal status of the embryo (meaning the zygote) and about how society's respect for human life should apply to this situation. What form of respect is owed to the zygote and at what stage of its development? What forms of research, if any, are consistent with respect for human life? What is the legal status of zygotes *ex utero*? Are they property or something else altogether? What legal or other rules should govern who has access to them and how they are treated? Should distinctions be made between *in vitro* and *in utero* zygotes? If a particular status is ascribed to embryos *in vitro*, how would this affect the status of zygotes *in utero*? These are some of the specific questions that have been raised in this area.

In general, concerns have been expressed about the potential impact of embryo research on women and on society. For example, some people are concerned that women may be pressured to donate zygotes not needed for implantation during IVF procedures for research, or to undergo fertility drug treatment to obtain eggs for research into fertilization. Some have also expressed concerns that development of the field could lead to an international trade in human zygotes, or that techniques currently used in animal embryo research, such as cloning and ectogenesis, could be applied to human beings. In addition, there is concern that the long-term social implications of embryo research are unknown; for example, could future applications of knowledge alter our current notions of humanness or parenthood? Can research be regulated in such a way as to prevent such misuse or abuse?

Embryo research in Canada has been conducted to date without a clear legal and public policy context. Research proposals are assessed on their individual merits by research ethics boards in hospitals and universities where research is going on. There is a growing public conviction, however, that consistent policies are needed to guide individual ethics committees. Because human embryo research is a relatively new field in Canada, the Commission had an unusual opportunity to examine relevant ethical and legal questions while the field is still young and to make recommendations that will anticipate rather than react to new developments. Commissioners believe it is important to seize this current opportunity to put in place limits and boundaries and to regulate within those boundaries, ensuring that only ethically acceptable, accountable use of technologies involving human zygotes occurs in Canada. During our consultations with Canadians the Commission heard a range of views about the acceptability and appropriate regulation of embryo research. Although many people expressed hope about the potential benefits of such

research, others expressed fears about the potential for harm and concern about the ethical and social implications.

To help assess the arguments presented to us, we commissioned various research studies to obtain as definitive a picture as possible of embryo research as it is practised in Canada and elsewhere. We also reviewed the legislation adopted in other jurisdictions and sought the views of theologians, ethicists, and legal scholars on the moral and legal status of the human embryo. In the remainder of this chapter, we document what we learned in consultations with Canadians across the country and from our inquiry into the current and future uses of human zygotes or embryos in research. We then review some of the laws, regulatory mechanisms, and government policies that have shaped research in this field. With this background, we discuss the ethical, legal, and social implications of embryo research. Our recommendations for policy conclude the chapter.

The Views of Canadians

Commission Survey

In the spring of 1990, the Commission conducted a national survey of Canadians to help us gauge attitudes toward various aspects of new reproductive technologies. We also conducted a later qualitative study involving 10 focus groups across the country in which participants were asked what they knew and thought about the use and disposal of sperm, eggs, and zygotes. The study revealed that participants had no ethical concerns about the freezing or disposal of sperm and unfertilized eggs or their use in research. By contrast, fertilized eggs were seen as having the potential for life or, by some, as being the beginning of life. As such, participants thought that the use of fertilized eggs in research should be restricted more than the use of sperm or unfertilized eggs.

Some participants argued that the techniques used in IVF should be modified to ensure that no surplus zygotes are created; they considered it unethical to produce fertilized eggs that cannot be transferred to a woman's body with the aim of establishing pregnancy. Others thought it was acceptable to produce surplus zygotes under certain conditions. According to the Commission survey, 63 percent of respondents would permit surplus

> If more ova are removed than can be reimplanted from a woman who is herself undergoing IVF, she should retain the right to decide whether the surplus are to be donated (at which time she relinquishes control), frozen, used for regulated research purposes or destroyed.
>
> *D. Day, Nova Scotia Advisory Council on the Status of Women, Public Hearings Transcripts, Halifax, Nova Scotia, October 17, 1990.*

zygotes to be frozen for later transfer to the woman from whom the egg came; 47 percent would allow surplus zygotes to be donated to another woman who is infertile; and 46 percent would permit their use in research in some circumstances. Almost all participants had many questions and concerns and called for some controls or limits in this area.

Submissions to the Commission

The Commission also sought the views of Canadians in public consultations and private meetings from Vancouver to St. John's and received many written submissions from individuals and groups. These consultations revealed that Canadians have a range of views on the question of when a human life begins, a life to which society has legal and moral obligations. Some argued that legal personhood should be recognized at fertilization, and hence that a zygote should not be subjected to research that is not for its own benefit. Other intervenors either argued that the developing human entity develops personhood gradually with gestational development or pointed to legal rulings by Canadian courts that it achieves personhood only at birth. They supported embryo donation and research but felt restrictions should be placed on researchers, such as ethical review of research proposals and prohibition of research beyond a certain point in development (proposing, for example, that research be prohibited beyond 14 to 17 days of development).

We also heard a range of views about the acceptable sources of embryos for use in research. Among those that accept embryo research, some thought research should be permissible only on zygotes not implanted during IVF; others believed zygotes could be created specifically for research, provided there were limitations on that research. Many women's groups disagreed with the creation of zygotes for research, stating that it could lead to the exploitation of women, including pressure to undergo ovulation induction to produce eggs to make zygotes.

Virtually all those who commented on these issues pointed out that traditional mechanisms of peer review and research ethics board review may not provide sufficient safeguards against inappropriate use of embryos in research. Many were of the view that the public, particularly women, should have more opportunity to participate in decisions about the restrictions or requirements that should apply to such research. The Commission heard many suggestions about how the public could participate in such

> We request that the law tolerate no treatment whatsoever of any human embryo as an experimental subject in the practice of either *in vitro* fertilization or *in vivo* fertilization. [Translation]
>
> *Brief to the Commission from l'Association féminine d'éducation et d'action sociale, November 1990.*

decisions, ranging from increased public representation on institutional ethics committees, to a multidisciplinary permanent advisory committee at the federal level, to a voluntary or statutory licensing authority with public representation.

> [In] experimentation and research, parents or researchers may not freely dispose of the physical integrity or life of the unborn child. Accordingly, corpses of human embryos and fetuses must be respected.
>
> *J. Penna, Roman Catholic Diocese of Saskatoon, Public Hearings Transcripts, Saskatoon, Saskatchewan, October 25, 1990.*

We also heard a range of views on the desirability of legislation as a means of regulating research in this field. Many doctors and researchers, as well as the Medical Research Council of Canada, argued that a voluntary system — under which research is monitored through federal granting agencies, provincial licensing bodies, research ethics boards, and peer review — provides effective protection while allowing the freedom needed to promote progress in knowledge and therapy. These intervenors argued that legislative controls might impede progress in research and therapy. Representatives of legal and human rights groups expressed concern about the absence of legal direction on issues such as "ownership" of zygotes, the storage and disposal of zygotes, and the interests and responsibilities of donors and physicians with respect to embryos.

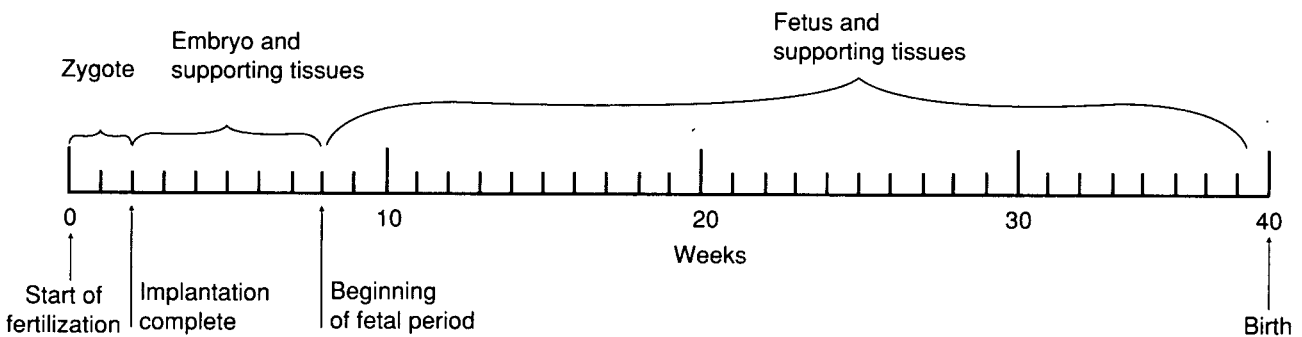
There was widespread agreement among all intervenors that any commerce or trafficking in human gametes or embryos should be prohibited, and that certain forms of research, such as the division of human zygotes ("cloning"), the formation of animal/human hybrids, and the gestation of human zygotes in the uterus of another species, were totally unacceptable.

These public consultations gave us a broad picture of the views and concerns of Canadians about embryo research. To evaluate these concerns, in the next few sections we discuss our findings from a series of studies examining the aims of embryo research, its future directions, its current practice in Canada, the source of embryos for research, and current regulations in Canada and abroad.

The Aims of Embryo Research

Nearly all documented human embryo research to date has taken place well before 14 days after fertilization (the stage by which a zygote created in a woman's body [*in vivo*] implants in the uterus) (see Figure 22.1). In fact, technical limitations make it difficult to keep a fertilized egg alive and developing *in vitro* normally after six days.

Figure 22.1. Stages from Fertilization to Birth



As we have outlined, there is a problem of terminology. Embryo research, embryo donation, and embryo transfer are not accurate terms, since these in fact occur at the zygote stage. The term "pre-embryo" has also been used to refer to the zygote. This is a more accurate term in some respects because, as discussed in Chapter 7 "The Biology of Human Reproduction," there are important changes in identity between the zygote and the post-implantation embryo (for example, 99 percent of the fertilized egg develops into supporting tissues, while 1 percent develops into the embryo proper). The term "pre-embryo" has been a source of controversy, however, as some people believe that it diminishes the humanity of the developing entity. To avoid this possible bias, we have chosen the more neutral term "zygote."

Evaluating whether research on zygotes is acceptable requires an understanding of the goals of this research. What sort of knowledge are researchers seeking to discover, and how will this knowledge contribute to human health? In this section, we outline the major types of embryo research and their objectives. Currently, biomedical research involving human zygotes is undertaken for one or more of the following reasons:

- to improve existing infertility treatments and develop new technologies for assisted conception;
- to learn more about human infertility (including implantation failure and ectopic pregnancy) and develop better ways to diagnose it;
- to detect and prevent genetic and chromosomal anomalies in human beings;
- to investigate new methods of contraception; and
- to advance knowledge about human development and its disorders.

We look at each of these in turn. Before examining them, however, it is worth noting that the question of what constitutes "research" is not straightforward. In the field of embryo research, it is difficult to distinguish between basic and applied research, between clinical investigation and new therapy. For example, research into new methods of fertilizing eggs *in vitro* or freezing zygotes has often gone hand in hand with clinical practice. It may be very difficult, therefore, to say whether the use of a new procedure for zygote freezing constitutes research or treatment improvements. Classifying embryo research according to whether it is clinical, pre-clinical, or basic is therefore next to impossible and not very meaningful. The Commission documented dozens of approaches to this problem. Although each system of classification has its own internal logic, they are often inconsistent with each other, and each suffers from the difficulties just outlined.

Although many commentators and international reports emphasize a distinction between therapeutic and non-therapeutic embryo research, for the reasons discussed below we found this an inappropriate distinction and

not useful for purposes of discussing the acceptability of research or what the public policy response should be. "Therapeutic" embryo research has been defined as research performed on a zygote to improve its chances of successful implantation and healthy development. Non-therapeutic research, on the other hand, is not intended to promote the developmental chances of a particular zygote; zygotes that have been the subject of non-therapeutic research are disposed of rather than implanted. As we have seen, some participants in the Commission's public hearings argued that therapeutic embryo research should be allowed, while non-therapeutic research should be prohibited.

The therapeutic/non-therapeutic distinction is common in other areas of biomedical research. In our view, however, this distinction cannot provide a basis for regulating research on human embryos. Research involving a zygote could have diagnostic or curative potential for that zygote only if it was subsequently transferred to a woman's uterus with the aim of establishing a pregnancy. However, transferring a zygote after it has been subjected to research poses unknown dangers for both the woman and the eventual fetus. This procedure should be allowed, therefore, only if there is evidence of its safety. The only way to establish such evidence would be through non-therapeutic research on zygotes, that is, observing *in vitro* the development of zygotes that have undergone a particular technique, to see whether they develop normally.

In other words, the only way to develop therapeutic embryo research is to allow for some non-therapeutic embryo research. Thus, the regulatory options are either to allow some forms of non-therapeutic research or to preclude research using zygotes altogether. Allowing therapeutic research while at the same time prohibiting non-therapeutic research would not be workable, nor would it be ethical, because of the risks it would create for women and children. In distinguishing between various types of embryo research, therefore, we found it more useful to classify by area of study than to talk about basic and applied research or therapeutic and non-therapeutic research.

Treating Infertility

The most common area of research using human zygotes is aimed at improving the success of IVF as a clinical treatment for infertility or testing new procedures for the treatment of infertility. Although the fertilization rate of human eggs exposed to sperm *in vitro* is between 70 and 80 percent, many fertilized eggs never develop to the stage at which they can be transferred to the uterus. In addition, there is significant attrition after transfer, with many zygotes not implanting, so that the average rate of live births per zygote transferred is only about 17.5 percent. Also, as is discussed in Chapter 20, most IVF practitioners transfer three or even four zygotes during each treatment cycle, with the goal of improving the chances

of a live birth; this is a significant factor in the increased rate of multiple pregnancies and premature births associated with IVF.

Improving the rate of live births would help reduce the need to transfer several zygotes. Research projects in various countries have therefore sought to improve the chances that transfer of a zygote will lead to a live birth. Among these projects are studies seeking to

- improve zygote freezing, storage, and thawing techniques;
- diagnose which gametes will fertilize successfully and which zygotes will result in live births;
- discover the optimal conditions for maturation and survival of gametes and zygotes *in vitro*; and
- assess the optimal stage of growth at which to transfer a fertilized egg and where in the woman's reproductive tract to place it (the uterus or the fallopian tube, for example).

Studies in zygote freezing include the comparison of various substances (cryoprotectants) and freezing techniques, with the aim of improving upon the current 50 to 70 percent rate for zygotes that survive freezing and thawing. Researchers are also studying how to freeze and thaw unfertilized eggs. If successful, this research would dramatically reduce the need to create and freeze surplus zygotes. The only way to test the safety of this technique, however, is to conduct research involving zygotes produced using frozen eggs that have been donated for research purposes. Eggs frozen in different ways are thawed and fertilized, and the chromosomes and rates of cleavage of the resulting zygotes are studied to see whether they develop normally.

One example of diagnostic research is the development of chemical gradients to select the healthiest sperm for insemination *in vitro* — but fertilization is the only way to test which gradient works best. Another example is the study of the metabolism of the zygote as a predictor of future viability.

An example of research into the optimal conditions for the survival and maturation of zygotes involves fertilizing donated eggs *in vitro* to study whether the use of different fertility drugs to induce ovulation has an effect on the likelihood of fertilization. In a British study, women having tubal ligations volunteered to undergo ovulation induction before the sterilization procedure. Their eggs were retrieved during the procedure and were fertilized *in vitro* to permit study of the effects of various fertility drugs on the resulting zygotes.[2] Again, fertilizing eggs may be the only way that research projects studying fertilization can be carried out.

Researchers are also testing new procedures to treat certain previously untreatable forms of infertility. Techniques are being developed, for example, to treat male infertility in which otherwise apparently normal sperm are unable to penetrate an egg's outer membrane. Several techniques have been investigated, including both chemical and mechanical

drilling through the egg's outer coat or shell (the zona pellucida) to ease the entry of sperm. Microinjection of a single sperm cell into the cytoplasm of the egg has also been attempted. Zona drilling has also been used to rupture the shell in the hope that it will improve the chance of implantation. Live births resulting from the use of each of these methods have been reported. Although these techniques may ultimately be used in treatment, their safety must first be assessed through embryo research on zygotes that are not subsequently transferred to a woman's uterus. Only if zygotes resulting from these experimental fertilization techniques are observed and assessed *in vitro* can it be known whether they develop normally, at least initially. A further phase of clinical research to assess any longer-term effects of these manipulations on the health of the potential individual born will also be needed before it can be viewed as "treatment."

Understanding Infertility

There is great interest in understanding the subtle mechanisms of human reproduction — for its own sake, but also to permit the development of better approaches to infertility and healthy reproduction.

In vitro study of human zygotes has shown that they manufacture and release numerous biochemical compounds. Very little is known about these growth factors released by the zygote and how they affect development and interaction with the woman's body. It is known that the zygote binds substances from its environment as it travels along the fallopian tube toward the uterus, but why it does so is not clear. Identification and functional analysis of these growth factors and chemical messengers may provide clues to understanding "unexplained" infertility. They may also help to define what is necessary for normal growth, both in laboratory culture and in the woman's uterus. Preliminary research has begun to reveal the metabolic behaviour of human zygotes; tests are being developed to show what type of and how much nutrient a zygote takes up from the medium in which it is being cultured.

Another area of human embryo research centres on the mechanisms and conditions necessary for successful implantation of the zygote in the wall of the uterus. This research may help explain why implantation fails, leading to relatively high rates of early loss or miscarriage. Understanding implantation may also help to explain ectopic pregnancies where no obvious tubal or structural defects exist. Ectopic pregnancy affects thousands of Canadian women each year, is a serious risk to their life and health, and remains an important clinical problem, in terms of both treating this medical emergency and the future fertility of a woman who experiences such a pregnancy (see Chapter 10, "Sexually Transmitted Diseases and Infertility").

Inherited Disorders

A new step in embryo research is the very recent development of "preimplantation diagnosis" techniques — that is, techniques for diagnosing the presence or absence of genetic disease in the human zygote. This experimental technique has been offered to women and couples at high risk of passing on a genetic disease, such as cystic fibrosis. Researchers at University Hospital in London, Ontario, are now evaluating the clinical feasibility of this procedure for women who are known carriers of a sex-linked genetic disease. This technique constitutes research at the current state of knowledge.

We discuss preimplantation diagnosis of genetic disease in future chapters; however, it is important to note its relationship to embryo research. For example, preimplantation diagnosis requires washing the zygote to remove surrounding cells, removing the zona pellucida, then gently lifting away one cell and analyzing its DNA to detect the particular gene. This "biopsy" technique was developed through research on zygotes, and any future clinical application of this procedure will depend on continued research into such biopsy techniques.

Regulating Fertility

Research on zygotes may be relevant to understanding new contraceptive methods. For example, the contraceptive RU-486, developed in the 1980s, works by countering the effects of the hormone progestin, which promotes the maturation of eggs. A potential risk of using RU-486 is that eggs might still mature and fertilize, despite the effects of RU-486, but develop abnormally. A study to assess the chances of this occurring involved recovering unfertilized eggs from women who volunteered to take RU-486 prior to undergoing laparoscopic sterilization and studying their maturation, fertilization, and cleavage *in vitro*.[3] The study showed that RU-486 did not affect fertilization and cleavage of zygotes, but further research is needed to evaluate whether RU-486 has any effect on developing embryos later.

Other research of relevance to the regulation of fertility involves studies on antigens and other proteins in the zygote as part of the search for contraceptives that work by provoking an immune response. This research may also throw light on the problem of recurrent spontaneous abortion.

Studying Human Development and Its Disorders

Scientists are investigating the mechanisms by which the cells of the early zygote — which have the capacity to give rise to any type of body tissue — differentiate into cells that are "committed" to be one type of tissue or another. Why do some cells give rise to the embryo itself and others give

rise to the placenta? Why do some cells then give rise to liver cells and others to brain cells? Elucidating these mechanisms is of great interest to basic biologists and scientists involved in human reproduction and may have relevance to our understanding of cell growth, differentiation, and cancer. Research to date has shown that certain observable shape differences in the zygote are correlated with later impaired development; chromosomal abnormalities have also been correlated with abnormal development of various kinds, but much more research will be required before these mechanisms are understood completely or even partially.

Future Directions in Embryo Research

The areas of embryo and gamete research discussed in the previous sections are expected to remain the focus of research internationally for many years to come, but it is likely that new areas of study, such as the effects of people's age on the viability of their gametes, identification of hitherto undiscovered mechanisms that cause infertility, and the roles of viruses and chemical substances in causing congenital anomalies, may also be explored. Many aspects of this research could have important preventive and clinical applications. In addition, the study of stem cells derived from zygotes and cultured *in vitro* could yield information about cell division and its control, which could help researchers understand the proliferation of cancer cells.

Technology Transfer Between Animals and Humans

In discussing future directions in embryo research, it is important to distinguish human embryo research from animal embryo research. It is also relevant to consider the relationship between animal research and use of the technologies in human beings.

There are two issues with regard to technologies transferred from animals to human beings. In the first category of technologies are those that would be unethical in and of themselves if applied to human beings (such as ectogenesis, parthenogenesis, and inter-species crosses). Areas of current research with animal embryos include "cloning" by nuclear substitution, modification of the embryo's genetic make-up, parthenogenesis (creation of a zygote from the female gamete alone), fusion of female gametes, ectogenesis (development of a fetus to viability outside the uterus), and transfer of the zygote to another species for gestation. Transfer of these technologies for use with human embryos would be unacceptable. Use of human zygotes in this way would contravene the Commission's stated ethical principles and be contrary to the values of Canadians; indeed, such uses have been condemned by the various bodies that have

issued recommendations on research involving human embryos. We recommend prohibition of these.

In the second category are technologies that are not unethical in and of themselves, but whose use would be unethical if they were used in human beings for the same purposes as they are used in animals (for example, IVF done with the goal of producing many "high-quality" zygotes from one animal, to be gestated by less commercially valuable animals; or alteration of the genetic make-up of zygotes in order to produce a commercially valuable strain of animals). This category of technologies and techniques could be transferred ethically only if their goals were not transferred with them. It is in fact desirable to transfer knowledge gained through animal research to human beings, provided this knowledge and the technologies that result from it are applied in ethically acceptable and beneficial ways for women and for society.

It is in fact desirable to transfer knowledge gained through animal research to human beings, provided this knowledge and the technologies that result from it are applied in ethically acceptable and beneficial ways for women and for society ... If borrowing knowledge from animal studies contributes to ethically acceptable goals in human medicine, then it is appropriate and indeed desirable to use this knowledge.

In short, there has been, and will likely continue to be, a great deal of technology transfer between human medical research and veterinary research related to assisted reproduction. But it is important to remember that the aims of using reproductive technology in animals are very different from its goals when undertaken in human beings. In farm animals, the objective is not to circumvent infertility but to produce as many offspring as possible from a valuable selected animal or group of animals, with the goal of benefiting producers and consumers. IVF is used in cattle, for example, to obtain as many offspring as possible from commercially valuable genetic parents, using ordinary animals for many gestations. IVF zygotes are being used, for example, to establish entire populations of European cattle breeds in developing countries, by transfer to indigenous breeds for gestation. In our meeting with a large commercial breeding laboratory, Commissioners learned that frozen cattle zygotes are shipped around the world for this purpose. IVF in cattle is also used to produce large numbers of early cleavage-stage zygotes, which are used in studies of early development.

In human beings, by contrast, the ultimate goal is to maximize the probability of obtaining a viable and healthy pregnancy from use of a given technology. Although the conditions for which IVF is used in human beings have broadened, all are still concerned with remedying infertility, with the ultimate aim being to allow a woman to have a healthy child.

The goals of IVF in human beings and domestic animals, therefore, are very different. What IVF-related research efforts involving human and

animal embryos have in common is the goal of perfecting the various tools and strategies that make IVF and manipulation of the embryo possible in each species. In the view of the Commission, if borrowing knowledge from animal studies contributes to ethically acceptable goals in human medicine, then it is appropriate and indeed desirable to use this knowledge. Improvements in human IVF should not be refused simply because they originated in animal breeding. IVF has enabled people to circumvent infertility and to have a child. By itself, and as a medical intervention, this does not commodify or exploit women or reproduction.

But it is essential that the values underlying the use of these technologies in animals not be transferred along with the technologies. If a given line of animal embryo research has no beneficial or morally acceptable human application, the use of human zygotes for similar research should be prohibited. Given that there are vulnerable interests to be protected, and consistent with our guiding principles, we make recommendations later in this chapter that would ensure that only ethically acceptable use of these technologies is allowed.

It is essential that the values underlying the use of these technologies in animals not be transferred along with the technologies. If a given line of animal embryo research has no beneficial or morally acceptable human application, the use of human zygotes for similar research should be prohibited.

As discussed in Chapter 24, situations involving commercial interests in health care require that vulnerable individual or societal interests be protected by public policy or regulation. In agribusiness, the owner of the animal and the provider of reproductive technology services have commercial interests and goals; the animal itself has no recognized goals. The wider society has a general concern for animal welfare (so there are some regulations in place) and an interest in cheaper and better food products. In the human situation, however, there is no "owner" — the woman or couple have their own interests and goals but are not necessarily in a position to advance or defend themselves. Interposed here as well is the physician, who has a professional obligation to serve the interests and goals of the patient, but the interests of the patient may still be vulnerable interests in the face of commercial interests promoting technology. This means additional safeguards may be needed; adoption of our recommendations would put these in place. Our recommendations throughout this chapter would protect vulnerable interests by preventing inappropriate transfer of commercial technologies or goals from animal to human embryo research. Further detailed discussion of particular technologies being used in animals (such as zygote splitting, cloning by nuclear substitution, sex-selective zygote implantation, transgenic animals, ectogenesis) and our assessment of whether transfer is appropriate are

provided in Chapter 25. Accurate information on these techniques must be available for Canadians, as there is much misinformation in the public domain. An important aspect of the public policy response to embryo research is accountability, which requires that information be available to Canadians on what is being done in embryo research. Our recommendations include measures to bring this about — most importantly, the requirement that any facility conducting research on human zygotes/embryos be licensed and comply with conditions of licence.

Current Uses of Zygotes in Research in Canada

Although the future use of human zygotes in research is speculative, we wanted to determine how they are being used today in Canada. Early in our mandate, however, the Commission discovered there was no comprehensive information on how zygotes — or human reproductive tissues generally — are being used in research in Canada. We therefore undertook primary research to obtain these data. We sought to track the use of reproductive tissues — including gametes, embryos, fetal tissue, and placentas — to see how health care facilities, medical laboratories, and medical disposal firms are handling these tissues. In this section we discuss the use of gametes and zygotes; our findings regarding the use of fetal tissue and placentas are described in Chapter 31.

Handling and Use of Eggs and Embryos*

Because of the clinical circumstances in which human eggs are recovered and fertilized, and because of the specialized technologies required to sustain them outside the body, the facilities from which eggs and embryos can be obtained are limited. In Canada, fertilized and unfertilized eggs can be generated only in hospitals performing obstetric and gynaecological surgery and in clinics specializing in treating infertility. We decided to survey every health care facility in Canada that offers obstetric and gynaecological services, including those with fertility clinics attached to them.

Canada's hospitals and health care facilities offering obstetric and gynaecological services were surveyed between November 1991 and February 1992. Among the 642 facilities on which the survey results were based, 8 handled eggs and 8 handled embryos (for example, retained them for a patient's future fertility treatment or other treatment) (see research volume, *Treatment of Infertility: Current Practices and Psychosocial*

* The developing human entity is usually available only at the zygote stage. We use the term "embryo" in this section because it was the term used in the questionnaire of our research.

Implications). One facility reported retaining eggs for research purposes, and one reported retaining embryos for research purposes. None of the facilities reported providing either eggs or embryos to outside institutions, researchers, or agencies.

The questionnaire used in this survey did not ask about the movement of eggs or embryos *within* the facility. The location to which they would be sent most commonly within a facility, however, is the pathology laboratory. (All spontaneously aborted tissue, tissue from induced abortions, and tissue from surgical procedures are routinely examined in the pathology laboratory). The research team expressed concern that those designated to complete the questionnaire may not always have been the most knowledgeable about the distribution of reproductive materials by or within the facility.

Given this, and in an attempt to develop a clear picture of the use of human reproductive tissue in Canada, the Commission decided to conduct a follow-up survey with a sample of Canadian medical laboratories. Questionnaires were sent to 60 medical laboratories (primarily regional facilities affiliated with larger hospitals and universities), of which 48 (80 percent) responded. Of the 48 laboratories that responded, 2 reported handling eggs for purposes of pathology analysis, and 19 reported handling embryos (such as early pregnancy losses) for pathological examination. This shows there is some "internal" movement of eggs and embryos within hospitals and their associated clinics and laboratories, largely for pathological examination. However, these tissues are used for research purposes only very rarely — only one laboratory used embryos in research; none used eggs.

As a final check on the possible distribution of eggs and embryos, the Commission also conducted a survey of 23 medical waste firms (which included regional offices of larger national firms), of which 16 (70 percent) replied. None of the medical waste firms reported any handling of eggs or embryos, but much of what is disposed of through these waste firms is delivered to them in sealed containers, so that they may be unaware of the precise nature of the tissues handled.

The original survey of health care facilities as well as the follow-up survey of medical laboratories confirmed that there is relatively little human embryo research being conducted in Canada. Results from both these surveys identified one health care facility engaged in research on eggs, one facility engaged in research using embryos, and one medical laboratory involved in embryo research. Within these facilities, several distinct research projects have been undertaken. Research on embryos included studies of the development of cell motility, the process of division of embryonic cells *in vitro*, and the preimplantation diagnosis trial at University Hospital in London, discussed above. Research on eggs included a project analyzing unfertilized eggs for errors in chromosome number and structure; the frequency of chromosomal abnormality is then analyzed statistically for correlation with such factors as the woman's age, the use

of various fertility drugs, and heavy cigarette smoking. Another group is doing research on egg freezing.

It is evident that the data we were able to gather from these surveys are limited and inaccurate in various ways. For example, one of the more interesting results of the survey of health care facilities was that many hospital administrators seemed unaware of what their own institutions were doing with eggs or embryos. Moreover, respondents to both surveys may have interpreted questions differently. The survey asked about the use of eggs and embryos in "research," "treatment," and "pathology." But as we have seen throughout this report, these terms can be defined in various ways — new treatments and pathology analyses may be defined in certain contexts as "research" by some people but not others. Such data limitations are unavoidable in surveying areas that have never been surveyed before. We believe it is important to develop clear information on these questions, however, and our recommendations will help generate a better data base regarding the handling and disposition of eggs and zygotes in Canada.

Research by Pharmaceutical Manufacturers and Biotechnology Companies

There has been a persistent rumour, particularly in Europe, that human embryos are used by the pharmaceutical and cosmetics industries. Although investigations suggest that these rumours are unfounded,[4] we felt it was important to determine whether private sector companies in Canada are using eggs or embryos. The Commission surveyed all 67 member companies of the Pharmaceutical Manufacturers Association of Canada. Of these, 55 companies (82 percent) provided written responses. None reported any use of human eggs or embryos. One company is using human sperm. This research project ($100 000 annual expenditure) is being conducted in collaboration with a non-profit body outside Canada. It involves the use of sperm in research into a contraceptive method using the immune system.

The Commission also surveyed 26 biotechnology companies identified as potential users of human reproductive tissues. Of the 20 respondents (77 percent), none reported any research involving eggs or embryos. These findings lead us to conclude that little or no embryo research is being done by industry in Canada. This is consistent with the findings of a recent international study of embryo research. Partly in response to the rumours regarding the use of human zygotes in industry, the Council of Europe commissioned a survey of the commercial and industrial uses of human reproductive tissues. The study revealed extensive medical research involving zygotes, concentrated in England, France, the United States, and Australia, but there was no evidence of the use of embryos for commercial or industrial purposes.[5]

This could change. Industry respondents to the Commission's survey speculated that research involving human gametes or zygotes could be undertaken by the pharmaceutical industry in the next five years; research would likely focus on fertility controls for both men and women and more effective infertility treatments. It is important, therefore, to establish safeguards to ensure that research on zygotes in the private sector is regulated and that zygotes are not commercialized. Our recommendations later in this chapter are intended to address these issues.

Sources of Zygotes Used in Research

In Vitro Creation of Zygotes

The two potential sources of human zygotes for use in research are donations from women or couples being treated at fertility clinics and zygotes created specifically for research purposes. As we have noted, because the number of eggs that will fertilize *in vitro* is unpredictable, often all the eggs retrieved are exposed to sperm to help ensure that enough zygotes will be available for transfer to the uterus. As a result, more eggs are usually fertilized than can be transferred safely during that cycle. The extra zygotes may be cryopreserved for use in a future cycle if the current cycle is unsuccessful or if the couple plans to have more than one IVF child. If some zygotes turn out not to be needed, however, a couple may decide to donate them for research. Sometimes the zygotes intended for future use may be rejected for cryopreservation because of damage or an obvious anomaly, such as fertilization by more than one sperm; or cryopreservation may not be available. In these cases, too, the couple may decide to donate the zygotes for research.

The second potential source of zygotes is eggs fertilized expressly for the purpose of using the resulting zygote in research. This requires that donated gametes be available and that donors consent to this use of their gametes. This source of zygotes is less common, since women undergoing infertility treatment generally prefer to use their scarce eggs for their own treatment. However, women whose ovaries are being removed for medical reasons may be willing to donate any eggs that become available as a result of surgery.

Uterine Flushing

Zygotes can be "flushed" from a woman's uterus if less than seven days have elapsed since intercourse. This technique was first developed to recover zygotes from commercially valuable breeding livestock, with those recovered being transferred to less valuable stock for gestation. Only a limited number of uterine flushings have been performed in human beings — because of differences in uterine structure and the time between

fertilization and implantation, the procedure is much more dangerous and less successful in human beings. The procedure can result in ectopic pregnancy if the zygote is flushed into a fallopian tube, for example, instead of out of the body; or the zygote may implant in the uterus, leading to a normal (but unintended) pregnancy. Because of these risks to the woman, guidelines developed by the Canadian Fertility and Andrology Society and the Society of Obstetricians and Gynaecologists of Canada recommend against the use of uterine flushing to retrieve eggs and zygotes.

Potential Availability of Zygotes

Since the vast majority of eggs fertilized *in vitro* are intended for use in establishing a pregnancy, there is a relative scarcity of zygotes for research. If zygote freezing becomes a routine adjunct of IVF programs, the availability of viable zygotes for research is likely to decline further. On the other hand, as increasingly accurate, non-invasive viability tests for zygotes are developed, the availability of non-viable zygotes (that is, those unlikely to survive transfer and develop to term) for research may increase.

Some have raised the concern that the demand for zygotes for research purposes may affect women's clinical care, that women will be pressured to donate surplus IVF zygotes for research, or that women will be pressured to undergo unnecessary ovulation induction to produce eggs that can be fertilized for use in research. We have no evidence that this is occurring, but it is nevertheless important to have clear and appropriate safeguards in place to ensure that any demand for zygotes does not affect clinical care. Our recommendations later in this chapter address this need.

Alternatives to Research on Human Zygotes

Animal models have provided the starting point for most of the research areas described here. There is ample evidence, however, of the limitations of generalizing results from animal models to human beings. For example, it is now possible to freeze, thaw, fertilize, and transfer mouse eggs, and the resulting offspring are normal. Investigations into freezing human eggs have been far less successful, owing to subtle but critical structural differences between the eggs of the two species. Although animal models can provide insights for application to preliminary basic human embryo research, animal research alone is not enough; human embryo research is also needed to safeguard the health and well-being of women and the resulting children. Similarly, the use of human cell lines can provide important insights into certain questions, but it cannot eliminate the need for human embryo research.

Regulation of Embryo Research in Canada

On the basis of the evidence we assembled regarding the aims of embryo research, we believe that it can provide important health benefits. We are also aware, however, that allowing embryo research raises difficult ethical and legal questions and concerns. We need to determine whether it is possible to answer these concerns and acquire the benefits of embryo research in an ethically acceptable manner. In approaching this question, we looked first at the current state of laws and professional guidelines related to embryo research in Canada.

Legislation

No legislation directly regulates embryo research in Canada. Several federal and provincial inquiries have made recommendations in the area of embryo research (discussed below), but none has led to legislation.[6] In the absence of specific legislation, a variety of existing federal and provincial laws might apply. For example, provincial human tissue gift acts require the informed consent of tissue and organ donors to the use of tissue for research in certain contexts (for example, the transplantation of tissue from one person to another, or the post-mortem donation of tissue for transplantation, medical education, and research). These acts also preclude the buying and selling of human tissue. However, it is not clear that these laws apply to gametes or zygotes, which are often excluded, implicitly or explicitly, from legal definitions of "human tissue."

Hence, the legal requirements regarding the handling of zygotes are far from clear. In fact, the legal status of zygotes *ex utero* is itself unclear. As discussed in greater depth in Chapter 30, under Canadian law the embryo and the fetus are not legal persons before live birth. In law, what is not considered a "person" is often classified as "property," and recent court cases in the United States have characterized zygotes *ex utero* as the "property" of the gamete donors, at least for certain purposes.[7] Some IVF clinics in Canada have adopted this characterization in their consent forms, which state that couples enrolled in their programs are considered joint owners of the zygotes created from their gametes.

> Commissioners believe that it would be highly undesirable for zygotes or embryos to be characterized as property, with all the social and legal implications such a classification implies. Rather, we think that legal rules relating to the zygote and embryo should be designed to ensure that they are treated with respect as a form of potential human life.

However, the legal classification of zygotes and embryos has not yet been addressed explicitly by the courts in Canada.

Commissioners believe that it would be highly undesirable for zygotes or embryos to be characterized as property, with all the social and legal implications such a classification implies. Rather, we think that legal rules relating to the zygote and embryo should be designed to ensure that they are treated with respect as a form of potential human life.

An analysis prepared for the Commission suggested that a property model may be appropriate, since the core of property law is the idea of an exclusive right of control (see research volume, *Overview of Legal Issues in New Reproductive Technologies*). Characterizing embryos as property would vest exclusive control of gametes, and joint control over zygotes *ex utero*, in the gamete donors. This would protect donors' autonomy and privacy interests by requiring that they give their consent to any use of their gametes or zygotes for research (or indeed any other purpose). However, using a property law model for reproductive materials would have very significant drawbacks. A pure property law regime would give the "owners" of zygotes not only a right of control, but also all the other standard incidents of property ownership. For example, owners of property are generally allowed to give property away or sell it, bequeath it to inheritors, destroy it or experiment on it, store it, and share in the profits of research on it.

None of the reports reviewed by the Canadian Bar Association recommended a prohibition on experimentation. The general approach, typified by the recent report of the Law Reform Commission of Canada, is in favour of allowing experimentation on gametes and embryos, subject to certain restrictions. The advantages of increased knowledge, benefits to childless couples and therapeutic development outweigh concerns related to genetic manipulation and duplication of the species within the controlled experimental environment. The Canadian Bar Association is of the opinion that experimentation upon gametes and embryos is both appropriate and desirable.

Brief to the Commission from the Canadian Bar Association, November 1990.

These implications of a pure property law regime for embryos are clearly unacceptable. As discussed later in this chapter, there is clear international consensus that the buying and selling of zygotes are inconsistent with respect for human life, as are certain kinds of research involving zygotes. Moreover, the buying and selling of zygotes could promote the exploitation of women, the commodification of women and children, and the alienation of women from their bodies.

Some people suggest that zygotes could be seen as a unique kind of property in which the right to exclusive control applied, while the other

standard incidents of ownership, such as the right to sell one's property, would be restricted. These other incidents of ownership could be restricted either by explicit legislation or by allowing the courts gradually to develop a common law conception of the rights of ownership with regard to *ex utero* zygotes. This is, in effect, what is occurring in the United States, as the courts adapt property law to fit the distinctive situation of *ex utero* zygotes. However, as the U.S. experience shows, relying on the courts to develop a new definition of property rights with respect to *ex utero* zygotes is unpredictable and leads to a lack of uniformity, as judges in different states develop the common law in different directions. Moreover, courts are limited to the specifics of the case before them, whereas legislators can take into account a wider range of circumstances and interests.

We believe, therefore, that explicit legislation is needed to address the issue of control over zygotes *ex utero*, but we do not see property law as an appropriate model for thinking about who should have what kinds of decision-making powers with respect to them. We can address those issues directly, by asking why we think certain people should have particular powers of decision, and by seeing how this would affect the relationships of concern to us. Talking about "property" is not helpful here, because it gives rise to inappropriate assumptions about the interests and rights at stake.

The Law Reform Commission of Canada also argued that leaving these issues to be resolved on the basis of property law principles would be unethical. It recommended that Canadian lawmakers should

> develop special legal rules that will protect embryos but also permit the ethical debate to continue. Such rules could be developed on the basis of the written, signed consent of the producers [the gamete providers] given before the embryos are conceived ... [who should be] allowed to change their decision regarding the ultimate fate of the embryos before the embryos are used for the purpose for which they were intended.[8]

The Commission concludes that legal rules should be developed that adequately protect the interests of those whose gametes are used to create the zygote, including their right to understand fully and consent to the retrieval and subsequent use of their gametes and resulting zygotes. Our recommendations later in this chapter are intended to address these requirements.

Professional Guidelines

In the absence of legislation, the only existing Canadian policy related to embryo research is the voluntary guidelines of the Medical Research Council. In its 1987 report on *Guidelines on Research Involving Human Subjects*, the MRC endorsed "non-therapeutic" embryo research, for up to 14 to 17 days following fertilization, if approved by a local research ethics board. It recommended that zygotes not be created solely for research purposes and that embryo research be undertaken only to improve

knowledge and treatment of infertility.[9] Compliance with these guidelines is a requirement only when the research in question is funded by the MRC, but the guidelines have also been adopted widely by research institutions, universities, hospitals, and other granting agencies in Canada.

Although the MRC guidelines have served Canada well to date, we believe that additional measures are needed. For example, they do not provide much guidance about how informed consent should be sought for embryo research, or about appropriate standards for handling and storing human zygotes. Moreover, research ethics boards are likely to differ in the way they approach decisions regarding embryo research, giving rise to potential inconsistencies. As well, local research ethics boards may lack the expertise to evaluate certain kinds of research proposals and may be unduly vulnerable to pressure from advocacy groups. Furthermore, there is no mechanism for centralized record keeping regarding embryo research, so the public can know what is occurring in this field, and the MRC guidelines do not apply to research not funded by universities or government bodies.

Some of the limitations with respect to research ethics boards are being addressed. For example, the Royal College of Physicians and Surgeons recently established the National Council on Bioethics in Human Research (NCBHR), funded by the MRC, to assist in the implementation of MRC guidelines. It is intended, in part, to function as the voluntary and unofficial standard-setter for university research ethics boards.[10] However, the efficacy of this mechanism is not yet clear. Although the NCBHR has lay input, it is still established and funded by the medical research community, and it is not yet known whether this mechanism will be seen by the public as capable of resolving conflicts of interests in the public interest, or as assuring adequate public input. Moreover, these guidelines and review mechanisms do not apply to research done in settings where there is no research ethics board — for example, in industry.

> The same ethical guidelines that apply to medical experimentation on humans and the use of human tissues for experimentation, transplantation or other therapies should apply to the embryo and foetal tissues. Thus the only embryo experimentation and research that is ethically defensible is that which will potentially benefit the embryo itself.
>
> *J. Bromley, Fort Smith Pro-Life Group, Public Hearings Transcripts, Yellowknife, Northwest Territories, September 12, 1990.*

For these and other reasons, we believe that embryo research should be evaluated in a national context, as well as at the local level. Most federal and provincial inquiries in Canada that have addressed embryo research have emphasized the need for standardized and centralized monitoring of it. Some recent reports have endorsed a system of national standards and national approval of embryo research and/or national accreditation or

licensing for facilities where such research occurs.[11] This is also true of the 1990 report of the two major associations of professionals involved in embryo research (the Canadian Fertility and Andrology Society and the Society of Obstetricians and Gynaecologists of Canada).[12]

Regulation of Embryo Research Internationally

The Commission also reviewed current public policies on embryo research in other countries; for a detailed discussion, see Appendix 1. Our review revealed a range of responses to this issue: some countries allow non-therapeutic research for up to 7 or 14 days (provided the zygote is not subsequently transferred for implantation), while others ban it; some countries restrict research to surplus zygotes, while others allow the creation of zygotes for research purposes.

In other areas, however, there is consensus. For example, it is widely agreed that certain forms of embryo research are inherently impermissible (for example, cloning; formation of cross-species hybrids). Moreover, it is widely accepted that if embryo research is to occur, it must be subject to limitations such as the following:

- the research project must be approved by an ethics committee;
- the informed consent of the embryo or gamete donors must be obtained before donation;
- zygotes that have been the subject of research cannot be transferred to a woman's uterus;
- research on human zygotes is permissible only if the information sought cannot be obtained in any other way (for example, research using animal embryos or cell lines);
- zygotes must not be bought or sold; and
- the aim of embryo research should not be commercial profit.

Moreover, as in the Canadian inquiries, there seems to be a trend internationally toward some form of national monitoring of embryo research, through legislation, licensing, or accreditation. We have examined these international models carefully in considering our recommendations.

Issues and Recommendations

The Commission's guiding principles, elaborated below as they pertain to embryo research, helped to shape the Commission's recommendations about the kinds of embryo research that should be permitted in Canada,

the limitations that should be imposed on embryo research, and how these activities should be regulated.

As discussed earlier in this chapter, the use of zygotes in medical research has the potential to provide important medical knowledge and to improve the quality of health care for Canadians. To the extent that such research can help alleviate harms and the effects of disease, then it promotes ethically valid goals. Zygotes are not, however, simply "things" to be used however we like. They are connected to the human community in many ways. Human zygotes come from a human source — indeed, from particular human beings; they share certain basic biological qualities with human beings; and they may have the potential to become fully developed human beings. To treat a zygote as merely a thing would be to deny the reality of these connections.

In deliberating about zygote and embryo research and in applying our guiding principles, we took these considerations into account. We sought to allow for the attainment of the benefits of increased medical knowledge, while ensuring that these benefits are obtained only in a way that respects the connections between zygotes and the human community and that avoids undermining our sense of respect for the dignity of human life.

We have divided our recommendations into six areas: the ethical uses of zygotes in research; obtaining zygotes and informed consent; the use of zygotes following research; the funding of embryo research; commercialization; and accountability.

The Ethical Uses of Human Zygotes in Research*

At the heart of the debate on the ethics of research involving human zygotes are fundamental questions about when a developing entity acquires a distinctive moral status and how we ought to treat it as a result. According to the chairperson of the Warnock Commission, this is the most important issue raised by the reproductive technologies.[13] We agree that it is a vital issue, partly because of its relationship to other issues that are equally fundamental to our mandate, such as the rights and status of women, the interests of families, and the collective interests of society at large.

Canadians have differing views on the moral status of the zygote and embryo. Although there is strong agreement on a commitment to the principle of respect for human life, Canadians differ about what form that respect should take and what level of protection is owed to human life at its different stages of development. There is also a wide range of answers to these questions in the history of moral philosophy.

Some people argue that human life acquires full moral status at the moment of fertilization. Others argue that moral status changes and

---

* See Annex for dissenting opinion.

increases as a fertilized egg achieves the various stages of development from zygote to embryo to fetus and, eventually, to a child. Various stages of development have been proposed as marking a crucial change in moral status, including sperm penetration of the egg, syngamy, implantation, development of the primitive streak, development of sentience, quickening, viability, and birth. Each of these various "marker events" has been said to be relevant in assessing the moral status of the zygote, embryo, fetus, or child.

Commissioners recognize that no amount of deliberation on our part will definitively answer the question of the moral status of the embryo. Philosophers and theologians have grappled with the issue for centuries, as have scientists, legal scholars, and politicians in our own time. As noted by one researcher who prepared a paper on this issue for the Commission,

> Definitions of "person" or "human being" ... are imbued with subjective considerations ... that in turn are informed by differing cultural standards, parental teachings, and religious pronouncements, regarding the morality of certain practices ... Consequently, arguments, evidence, and other forms of justification may be advanced in support of a particular understanding of the concept of personhood or humanhood, but the evaluation itself can neither be proven nor disproven.[14]

Although there is no way to "prove" any particular view on this question, we believe it is important to state clearly our position on the ethics of embryo research and to explain our reasons for rejecting alternative views.

We believe that the moral status of the embryo before day 14 after fertilization does not preclude research under certain defined conditions. We judge that given clear and stringent protections and regulation, it is ethically permissible to conduct research on human zygotes up to this stage, and that such research is in fact an essential part of ensuring the quality of health care and thus the safety and well-being of patients. We recommend the 14-day limit on research for several reasons: it recognizes the developmental stage at which the primitive streak appears, establishing the start of one or more distinct entities; it is also the point at which the zygote has normally completed its implantation in the uterine wall; and it is the most widely accepted international standard for embryo research.

We are aware that many Canadians will disagree with this conclusion. Many intervenors in our public hearings told us that embryos should be treated with respect because they are living entities with the potential to develop into full members of the human community; hence, they should be accorded the same legal protection against potentially harmful research as children or adults. We considered this argument very carefully and respect the depth of conviction of those who advance it. We share the concern that zygotes be treated with due respect. It is clear that the zygote is human, in the sense of having the genetic, biochemical, and cellular composition of the species *Homo sapiens*. Similarly, there is no doubt that the zygote is alive, although it is not viable outside a woman's reproductive tract for

more than a few days. Zygotes are further connected to humanity because they may have the potential to become human beings. (A zygote does not necessarily have the potential to become a human being, as a significant percentage have a genetic make-up that means they could never develop to that stage, as discussed in Chapter 7.) These criteria alone confer a degree of moral status on the fertilized egg, even at its earliest stages of development. As a living entity that may have the potential to become a human being, a measure of respect and protection should be extended to it.

However, as noted in Chapter 30, Canadian law does not recognize embryos or fetuses as "persons." Embryos may have the potential to become persons, and we agree that this is grounds for treating the embryo with respect. But the idea of potentiality is complex, as is the relationship between potentiality and moral status. Potentiality has been used to justify different, even contradictory, policies on embryo research. It is appealed to not only by advisory bodies or policies banning embryo experimentation after fertilization or syngamy,[15] but also by those that allow experimentation for 7 or 14 days.[16] This suggests that the idea of potentiality is not simple or straightforward. In the debate over embryo research, it has been interpreted in at least two very different ways.

First, those who defend the 14-day limit argue that potentiality is not an all-or-nothing matter. They adopt the principle of graduation, according to which the zygote/embryo/fetus deserves more respect as it develops, up until viability or birth, at which point it becomes a full member of the moral community. In this view, various forms of research are acceptable at early stages, since the zygote is a potential human being only in a very remote sense. As development progresses, however, this potential comes closer to being realizable, and at some point non-therapeutic research would violate the respect owed a potential human being. Fourteen days is often chosen as the dividing line, since this marks the development of the primitive streak, which fixes the individual identity of the embryo and forms the basis for its nervous system.

We are sympathetic to this line of argument, but we do not agree that the 14-day limit on research should be understood exclusively in terms of the development of potentiality. In natural conception, a zygote starts the process of implantation in the woman's uterus at about 7 days after fertilization; *if implantation does not occur around that time,* the possibility of successful implantation and development *in utero* soon disappears. Zygotes *in vitro* actually *lose* their potential to become human beings after 14 days. Focussing exclusively on potentiality, therefore, would suggest that there is no moral objection to research involving zygotes *in vitro* after day 14. If we consider it permissible to do research on zygotes only when they have little or no potential to become persons, then, it can be argued, this tells us that research on zygotes should occur only *after*, not before, 14 days.

The 14-day limit does not rely, therefore, solely on a measurement of potentiality. A 14-day-old embryo *ex utero* deserves moral respect not for what it *can* become, but rather for what it *has already* become. After 14 days zygotes are closer to humanness, not in the sense that they have greater potential to become a human being, but in the sense that they have already developed two key components of a fully formed human being — a fixed individual identity and the precursor of a nervous system. (Researchers have not to date been able to keep human zygotes developing normally *in vitro* beyond 7 days, so there is no realistic possibility, for the foreseeable future, of experimenting on zygotes that have reached the stage of individuation.)

Those who argue for a complete ban on any embryo research not intended to benefit the particular zygote offer a different interpretation of the zygote's potential. In this view, the potential of the zygote is clear from fertilization, and the process of development is continuous. There is no marker event that is so significant that it justifies distinguishing the level of respect owed a zygote at different stages of development. As the Australian Senate Select Committee stated, from conception the zygote "may be properly described as genetically new human life organised as a distinct entity oriented towards further development," and so "the stance and behaviour proper to adopt towards it would include not frustrating a process which commands respect because its thrust is towards the further development of a biologically individuated member of the human species."[17]

We do not accept this view. Again, one difficulty is that the sense in which a zygote is a potential person is very remote. At day 4 a zygote may have the potential to become a person, but it is not *likely* that this will in fact occur, even in the most propitious circumstances. The probability of a zygote developing to birth depends on many factors, but generally half of all eggs fertilized *in vivo* do not result in a live birth (see Chapter 7). The likelihood is far smaller in the case of *in vitro* fertilization, as only about 17.5 percent of transferred zygotes result in a live birth.

People's intuitive commitment to respect for potentiality is unlikely to hold in circumstances where the likelihood of realizing that potential is so remote. As the British Royal College of Obstetricians and Gynaecologists observed, large numbers of fertilized eggs are aborted spontaneously, and "it is morally unconvincing to claim absolute inviolability for an organism with which nature itself is so prodigal."[18]

A second difficulty lies in determining the point at which the "new life" first exists. People who see fertilization as a critical landmark for assigning full moral status must decide at what point in the process of fertilization this "personhood" occurs. Is it the entry of the sperm? pronuclei formation? syngamy? or the "turning on" of the genes?

Historically, the passage of the sperm through the egg cell wall was often identified as the point at which a new life came into existence. However, recent advances in embryology have established that it takes about 24 hours after fertilization for the nuclei of the egg and sperm to

break down and for the chromosomes of the egg and sperm to come together on a common spindle. When this process is complete, "syngamy" is said to have occurred. Hence, many proponents of this argument now identify syngamy as the point at which development begins, on the grounds that this is when genetic identity is established.[19]

However, as discussed in Chapter 7, individual embryonic development cannot be said to have begun until the appearance of the primitive streak, after the fourteenth day following fertilization. Before this stage of gestation, the developmental singleness of the zygote has not yet been established. Occasionally two or even three primitive streaks may form within a single embryonic plate. Conversely, but more rarely, what initially appears to be twins may combine into a single embryo. Furthermore, some fertilized eggs have a genetic constitution that means they will develop into tumours or into empty sacs, so no embryo develops at all. (This is termed "blighted ovum" and is a very frequent finding in early spontaneous abortions.) Hence, it is only with the development of the primitive streak that individuation occurs. It is therefore inaccurate to identify syngamy as the moment at which a specific individual human being comes into existence, since the process of establishing this identity continues after syngamy.

In addition, the subtle changes gametes undergo before and during fertilization and syngamy are steps in a developmental process that begins before fertilization. Moreover, the entire process of development from unfertilized gamete through fertilization to syngamy is both continuous and highly regulated by the reproductive cells involved. Thus, the process by which human life develops its potentiality begins before fertilization.

In summary, the complexity of these processes and of the notion of potentiality means that the moral status of the zygote or embryo cannot be seen simply as a function of its potentiality. We believe that they deserve respect because of their connections to the human community; potentiality is one form of connection, but not the only one and not necessarily the most important one. Zygotes are connected to the human community by their past and their present, not only by their potential future. As we have seen, these forms of connection may run in opposite directions. Zygotes at a later stage of development may be closer to the human community than earlier zygotes in terms of their present characteristics, but farther away in terms of their future potential. In this case, the future of the zygote (its potential) is less important, morally speaking, than its present stage of development.

The 14-day limit, we believe, respects all these forms of connection. It also recognizes the legitimate value of medical knowledge and the need to find a morally acceptable compromise in a pluralistic society in which there are various views about the relative importance of different stages of embryo development. People disagree about issues such as the role of potentiality, the importance of individuation, or the value of medical

knowledge, and the 14-day limit is a prudent and legitimate compromise among these differing views and interests.

Indeed, many recent reports that adopt the 14-day limit place less emphasis on the idea of potentiality and more emphasis on the idea that this limit is simply a reasonable compromise among varied interests and perspectives. For example, the British Columbia Branch of the Canadian Bar Association argues that "Although arbitrary, the limit is at a natural point of evolution when the embryo would implant in the womb and satisfactorily balances the concerns against genetic engineering and in favour of beneficial experimentation."[20] The Medical Research Council points out that the recommended limit of about 14 days may accord with a "pragmatic sense of ethical acceptability."[21] Moreover, the 14-day limit has now become the international consensus. As the Law Reform Commission of Canada notes, "given the current state of knowledge, it is appropriate to agree to a standard that enjoys broad international support, if only to ensure that research done in Canada will be as respected as that done in the rest of the world."[22] Similar statements about the importance of international consensus on the 14-day standard can be found in the reports of the Canadian Bar Association, the Conseil d'État in France, various Australian state committees, the American Fertility Society, and many others.

> Zygotes are connected to the human community by their past and their present, not only by their potential future ... The 14-day limit, we believe, respects all these forms of connection.

Some people consider this limit arbitrary, and indeed it is — just as many other rules or limits adopted by society are necessarily arbitrary — the speed limit, for example, or the amount of time allowed to appeal a court decision. The decision to establish a limit of 14 days does not rest on any precise assessment of a specific single criterion, such as potentiality, to determine the degree of moral status. However, the fact that so many recent reports have endorsed the 14-day limit suggests that it has found widespread acceptance, based on its complex balancing of interests and views. We believe that in a pluralistic society, this approach is reasonable, and indeed is the only realistic basis for resolving certain ethical issues. In light of these considerations, the Commission recommends that

183. Approved research on human zygotes/embryos be restricted to the first 14 days of development.

Although research on zygotes in the first 14 days is ethically permissible, any such research must always respect the zygote's connections to the human community. Commissioners believe that certain

kinds of research, such as cloning and formation of cross-species hybrids, deny these connections and so violate basic norms of respect for human life and dignity. These are unacceptable and should be prohibited. We found widespread agreement on this among Canadians.

As noted earlier and discussed in detail in Chapter 25, forms of zygote manipulation that would be unethical in human beings are being researched in the context of animal embryo studies. These include "cloning" by nuclear substitution, parthenogenesis (creation of a zygote from the female gamete alone), fusion of female gametes, ectogenesis (development of a fetus to viability outside the uterus in an "artificial womb"), and transfer of zygotes to another species for gestation. These manipulations may serve valuable scientific and commercial purposes. However, transfer of these technologies to human zygotes would contravene the Commission's ethical principles, would be contrary to the values of Canadians, and has been condemned by the various bodies that have issued recommendations on research involving human zygotes.

Certain kinds of research, such as cloning and formation of cross-species hybrids ... violate basic norms of respect for human life and dignity. These are unacceptable and should be prohibited. We found widespread agreement on this among Canadians.

The idea that human zygotes could be incubated and develop to term in an artificial womb is seen as reprehensible by most Canadians. Even in the unlikely event this were possible, its pursuit would dehumanize motherhood; some have even suggested it could lead to "baby farms." Equally forceful objections apply to the idea of transferring human zygotes to the uterus of another species, cross-species fertilization, or cloning by nuclear substitution, all of which would deny the zygote's connections to the human community. The Commission therefore recommends that

184. Human zygote/embryo research related to ectogenesis, cloning, animal/human hybrids, and the transfer of zygotes to another species be prohibited, under threat of criminal sanction.

Commissioners also believe that no research involving the genetic alteration of human zygotes or embryos should be permitted or funded in Canada. Genetic alteration need not be a violation of the zygote's moral status, if it is done to treat a genetic disease diagnosed through preimplantation diagnosis. However, we believe that the risks of such a procedure far outweigh its potential benefits, and that there are safer and more appropriate ways for couples to manage the risk of passing on a

genetic disorder. (We discuss our views on this matter in Chapter 29.) The Commission recommends that

185. Research involving genetic alteration of human zygotes or embryos not be permissible.

Finally, we considered the question of whether zygotes should be created for research purposes. On the one hand, we believe that this would create the danger of promoting instrumentalization of zygotes, thereby potentially undermining commitment to respect for human life and dignity. On the other hand, it is not clear whether we can distinguish effectively between zygotes that become available because they are "surplus" to the needs of couples undergoing IVF treatment and zygotes created specifically for research. Some commentators argue that the distinction is unworkable, since doctors can stimulate the maturation of more eggs than are needed for purposes of IVF by using fertility drugs. According to a submission to the Australian Senate Select Committee, "any intelligent administrator of any IVF program can, by minor changes in his ordinary clinical way of going about things, change the number of embryos that are fertilized. So in practice there would be no purpose at all in enshrining in legislation a difference between surplus and specially created embryos."[23]

Moreover, some important forms of embryo research can be done only if unfertilized eggs are donated specifically for research. For example, studies on new fertilization techniques — such as changes in the fluid in which unfertilized eggs are kept before being mixed with sperm — would be impossible if research was permitted only on surplus zygotes, because some aspects of fertilization can be understood only by carrying out fertilization.

In the light of these considerations, Commissioners conclude that it is acceptable for zygotes to be created for research purposes, provided that appropriate research safeguards are in place. The conditions to be met include the following:

- informed consent of the gamete donors must be obtained before donation;
- a zygote that has been the subject of research not intended to benefit that zygote is not to be transferred to a woman's body;
- research is permissible only if the knowledge sought cannot be obtained through studies on animal embryos or cell lines;
- the research must be done in a facility licensed for such research;
- the aim of the research is to benefit human health, not to seek commercial profit; and
- no egg retrieval procedures are undertaken specifically to obtain eggs for this purpose; only eggs retrieved during procedures already being performed for the health of the woman can be used.

These conditions are discussed in greater detail below.

Obtaining Zygotes and Informed Consent

Although most of the public debate about embryo research has centred on the moral status of the embryo, other important ethical issues have been raised as well. These include respect for the autonomy of the donors whose gametes are used to create the zygote. We are particularly concerned about the possibility that the pursuit of embryo research could put pressure on women and couples enrolled in IVF programs to donate eggs or zygotes for research.

> The question of what you do with an embryo clearly is not the doctor's decision. I think it has to be the decision of the patient.
>
> *D. Cumming, Department of Obstetrics and Gynaecology, Faculty of Medicine, University of Alberta, Public Hearings Transcripts, Edmonton, Alberta, September 13, 1990.*

The principle of autonomy says that every individual has a right to control his or her own body, subject to the limits imposed by law. In the context of embryo research, this principle would give gamete donors a right to prohibit any use of zygotes created from their eggs or sperm, since they have a unique moral interest in the use of their genetic material. They are also entitled to full disclosure of the risks and benefits of potential uses of their gametes. Thus, the informed consent of gamete or zygote donors must be required for all decisions about the storage and disposition of zygotes. Their consent will necessarily be circumscribed by legislation and regulations pertaining to embryo research. For example, donors could not consent to donate gametes or zygotes for research that is illegal. The Commission recommends that

186. Clinics and researchers be permitted to use human zygotes for research only with the fully informed consent of the persons who have donated the gametes used to create the zygote.

Donors' consent should be provided in writing, and consent must be as informed as possible. The Commission recognizes that it may not always be possible to predict all possible research uses in advance. Nevertheless, all information available about the particular research use must be disclosed to donors.

There is increasing recognition that discussions of embryo research cannot take place in abstraction from the health and well-being of the women who produce the eggs. Doing research on zygotes could put women enrolled in IVF programs under pressure to consent to donate unused eggs or zygotes. This pressure could be particularly acute if the creation of zygotes for research purposes were prohibited. Women or couples could feel compelled to donate zygotes so as not to be seen as uncooperative or because they believe that to refuse could cost them their place in the IVF

program. Such situations, if they arose, would clearly contradict principles of autonomy and medical ethics.

In addition, the ethic of care tells us that a woman should not undergo the risks of invasive procedures unless they offer the possibility of benefit to her. This is why surgical procedures intended only to retrieve eggs for research should not be permitted. A fully informed woman having surgery for other reasons and who agrees to donate eggs would not be subject to any additional risk from egg retrieval; we therefore consider this ethically permissible. However, procedures specifically to retrieve eggs for research from women not already undergoing surgery for other reasons would not be ethically acceptable. The Commission recommends that

187. A woman's or couple's consent to donate zygotes generated but not used during infertility treatment for research never be a condition, explicit or implicit, of fertility treatment. Potential donors must be informed that refusal to consent does not jeopardize or affect their continuing treatment in any way.

and that

188. Zygotes be created for research purposes only if gametes for this purpose are available without conducting any additional invasive procedures.

Some commentators suggest that the only way to ensure that women in IVF programs are not pressured to donate unused eggs or zygotes is by banning embryo research altogether. We do not accept this view. On the contrary, we believe that prohibiting research on zygotes could create a situation where women are subject to new IVF techniques whose safety has not been adequately tested.

For example, legislation in the Australian state of Victoria does not permit testing of the chromosomes of zygotes produced using new techniques such as micro-insemination and egg freezing. If these zygotes were subsequently implanted in women, the outcome for the developing fetus and the woman carrying it would be unknown. Preventing non-therapeutic research on embryos would therefore mean that women were subject to additional risks from new procedures.[24] As the MRC observes, "It may be viewed as unethical not to conduct supportive research designed to assess and improve the safety and efficacy of such procedures as *in vitro* fertilization and embryo freezing. Without such research, therapeutic advances become limited and haphazard."[25] The Commission concurs, and we believe that women's health and autonomy are best protected by carefully circumscribing and regulating, rather than prohibiting, embryo research.

Use of Zygotes Following Research

If eggs are being fertilized and the resulting zygotes frozen or biopsied in experimental ways as part of research to improve IVF techniques or preimplantation diagnosis techniques, it is impossible at the outset to know whether or how this would affect the normal process of zygote development. If such a zygote were transferred to a woman's uterus and a pregnancy established, the resulting child could be born with anomalies or impaired functioning.

At some point in the development of knowledge, however, it will be necessary to conduct clinical trials of new fertilization, freezing, or preimplantation diagnosis techniques. The children born as a result would be vulnerable to unknown risks. To minimize these risks, we believe that any research that involves transferring zygotes that have been manipulated must be preceded by research on animal zygotes and embryos, as well as on human zygotes that are not subsequently transferred in the uterus, to establish that the procedure is feasible and of acceptable risk. There should be full disclosure to the adults participating in the research, and any such proposal would have to be approved by the National Reproductive Technologies Commission. The Commission recommends that

189. Human zygotes that have been subjected to manipulations of any kind for research purposes not be transferred to a woman's body. If knowledge reaches the point where manipulations are likely to increase the woman's chances of conceiving or be of a therapeutic nature, application to conduct a clinical trial in a licensed facility should be made to the National Reproductive Technologies Commission.

and that

190. No transfer of zygotes that have been the subject of research be undertaken without the approval of the National Reproductive Technologies Commission.

Funding Embryo Research

The focus of most international debate has been on concerns about embryo research. It is equally important to understand, however, why this research is needed in the first place. All else being equal, there are valid reasons to fund research related to areas in which treatment is being

provided. If IVF is being offered as treatment, it is desirable to engage in research to help ensure its safety and efficacy. However, we cannot research all conditions and treatments, so choices have to be made about where to allocate resources. These decisions have to be made in light of the priority assigned to other calls on limited research funds — for example, prevention and health promotion research.

Is embryo research an important health priority? What benefits are expected from embryo research? Where do these benefits fit within our larger health care priorities? This is a matter of some debate. Some argue that to ban such experimentation would go against the interests of humanity. Others argue, however, that almost all the information currently acquired through embryo research could be acquired in other ways.

We believe that, depending on its aim, embryo research can provide important benefits not available through other research means.[26] We concur with the position embodied in the MRC guidelines, which state that the purpose of proposed embryo research is "a critical element" in deciding whether such research is acceptable.[27]

Policies in some countries require that embryo research be directed only to improving infertility treatment; others have a broader definition of allowable research. As noted earlier, improving infertility treatment is likely to remain the most common aim of embryo research. However, we believe that embryo research may also prove useful in studying contraception and fertility; it could also promote women's health by improving knowledge about the causes of ectopic pregnancy and other threats to women's reproductive health and about how to reduce the incidence of spontaneous abortion. Since we recommend below that all facilities involved in human embryo research be licensed by the NRTC, which would monitor research projects done anywhere in the country, we do not believe it is necessary to specify further restrictions in law on the aims of research.

Public funding of embryo research is appropriate, provided the research is duly approved by institutional ethics boards using a clear framework developed by the NRTC and conducted in a licensed facility.

We believe that public funding of embryo research is appropriate, provided the research is duly approved by institutional ethics boards using a clear framework developed by the NRTC and conducted in a licensed facility. In this area, as in any other decision about public funding, granting agencies should be guided by the principle of the appropriate use of resources. Hence, they should ensure that the research will benefit our understanding and treatment of human health and should weigh these benefits against the benefits of alternative uses of the funds. However, since we propose that the conditions for receiving a licence to conduct human embryo research include that the research must benefit human health and that the information sought cannot be obtained in other ways,

we see no reason why support for embryo research in licensed facilities should not qualify as an appropriate use of public funds.

Indeed, public funding can help ensure that public priorities are respected in this area of research. According to the U.S. Office of Technology Assessment, the former ban on federal funding of embryo research in the United States meant that questions fundamental to an understanding of human reproduction remained largely uninvestigated by U.S. researchers; research into the efficacy and risks associated with infertility treatments such as IVF and GIFT also remained largely uninvestigated. For these reasons, the Commission recommends that

191. Research projects involving the use of human zygotes and carried out in licensed facilities be eligible for public funding.

Commercialization

As we have emphasized throughout this report, it is inappropriate for decisions involving human reproduction to be motivated by the prospect of financial gain. Thus, the buying and selling of gametes and zygotes would be unacceptable, and we recommend their prohibition. This prohibition is essential, not only as a matter of respect for human dignity, but also to protect anyone who might be pressured or induced to sell gametes or zygotes. However, fees to recover the cost of related services, such as freezing, storage, testing, handling, and transport, may be acceptable. The Commission recommends that

192. The sale of human eggs, sperm, or zygotes be prohibited, under threat of criminal sanction.

In addition to prohibiting the buying and selling of zygotes, we also wish to make it clear that human zygotes, embryos, and fetuses are inappropriate subject matter for intellectual property protection. Inherent in the moral point of view and respect for human life is abhorrence of any recognition of property interests of one human being in another; as entities that may have the potential for human life, zygotes should not be patentable.

Prohibiting the patenting of human zygotes or embryos does not necessarily preclude the patenting of innovative products derived from embryo research. For example, embryo research may lead to the discovery or development of cell lines with important diagnostic or therapeutic uses, and if patent protection were available, private companies might provide funds for this research that would not be available from public funding sources. Allowing patenting in this context raises important issues that

require further consideration and study leading to policy decisions. We discuss these issues, and the principles that should underlie patent policy, in Chapter 24.

Accountability

Society has a right and a responsibility to ensure that embryo and zygote research is circumscribed by appropriate ethical boundaries. At present, however, there are no specific federal or provincial/territorial laws governing embryo research in Canada. Proposals for embryo research are reviewed by local ethics review boards, but these differ in composition, expertise, and approach, and their deliberations and decisions are not always made public. Moreover, if embryo research were to occur in the private sector, it might escape ethical review entirely.

Commissioners believe that the implications of embryo research are so profound that they warrant a shift from the current system of medical and scientific self-regulation toward a more active regulatory system in the context of policy making with greater public participation. The principle of accountability suggests that the public has a right to know what is going on in this area and to be assured that research complies with social and ethical as well as medical and scientific standards.

We believe that a more open and participatory system would not only promote more informed public debate, but would also provide the greatest protection against misuse. One essential ingredient of such a system is the availability of clear and accurate information — information that should be provided on a regular basis by a body without a particular vested interest. The debate about embryo research is not only about whether such research is acceptable in principle, but also about whether it can be regulated appropriately in practice. Many Canadians share the concern of the Working Party on Human Fertilisation and Embryology of the Church of England, which questioned whether "society possesses the maturity as well as the means for restricting research work within acceptable bounds."[28] We believe that society does have the wisdom and the will to establish and enforce these limits. We therefore need to put in place the means to do so — an open and participatory system of national regulation and monitoring to prevent abuse and to provide public

The implications of embryo research are so profound that they warrant a shift from the current system of medical and scientific self-regulation toward a more active regulatory system in the context of policy making with greater public participation. The principle of accountability suggests that the public has a right to know what is going on in this area and to be assured that research complies with social and ethical as well as medical and scientific standards.

assurances that misuse or abuse is not occurring. The Commission therefore recommends that

193. All research using human zygotes be subject to compulsory licensing by the National Reproductive Technologies Commission.

Such licensing would not replace institutional ethics committees in universities and hospitals. Rather, it would serve as an additional and nationally consistent check on the acceptability of research using human zygotes before its commencement. It would also ensure that private sector researchers are subject to the same oversight as those in the public or quasi-public sector. Licensing by the NRTC would also afford a greater degree of public accountability than professional self-regulation, reassuring Canadians that embryo research in this country is not violating widely held social values and norms.

Facilities that applied and met the NRTC's licensing conditions would receive a licence to conduct research using human zygotes for a period of five years. Once the clinic was licensed, it would then seek approval for individual projects from a local institutional ethics review board, which would use guidelines drawn up by the NRTC to assess such proposals. We do not consider it necessary to require researchers to obtain a separate licence for each research project.

We believe that this combination of national licensing of facilities and local approval of projects in the context of clear NRTC guidelines would provide the most appropriate blend of safeguards and flexibility for human embryo research in Canada. Since one of the conditions of licensing, discussed below, would be that the research facility provide an annual report to the NRTC on its research projects, it would be possible for the NRTC to ensure that local ethics review boards across the country are applying the basic principles and guidelines consistently in their assessments of individual projects. Publication of such information in the NRTC's annual report would allow for public education and feedback on the issues surrounding embryo research and its evolution in practice.

Commissioners believe, however, that the extra risks to women and children involved in any research that involves transfer of a zygote that has been subject to manipulation warrant an extra level of approval. The Commission therefore recommends that

194. Any research project involving the transfer of a zygote that has been subject to experimental manipulation receive approval from both a local research ethics board and the National Reproductive Technologies Commission.

In summary, Commissioners conclude that the area of embryo research has far-reaching implications for all of society and therefore warrants a comprehensive response. We recommend that the federal government use its legislative powers to establish boundaries around this area of research and to set limits on what is acceptable and then, within those limits, to put in place regulation ensuring appropriate and accountable use. Both Commissioners and the Canadian public are concerned that measures be put in place that ensure any embryo research that is carried out is conducted in the best interests of women, children, and society. The details of the licensing regime we recommend in this regard are set out below.

Licensing Requirements for Research Using Human Zygotes

The Commission recommends that

195. Licensing requirements for zygote/embryo research apply to any physician, centre, or other individual or facility using human zygotes in research. Both experimental and "innovative" therapies for human zygotes should fall under the rubric of research. Any individual or institution engaged in such manipulation would therefore be subject to licensing.

196. Engaging in research using human zygotes without a licence issued by the National Reproductive Technologies Commission, or without complying with the National Commission's licensing requirements, as outlined below, constitutes an offence subject to prosecution.

and that

197. The National Reproductive Technologies Commission establish a permanent Embryo Research Sub-Committee,* with responsibility for developing standards and guidelines to be adopted as conditions of licence and for overseeing the implementation of the National Commission's licensing program.

The Commission recommends that

198. The following requirements be adopted as conditions of licence for zygote/embryo research:

(a) All approved research must be restricted to the first 14 days of development of the human zygote.

(b) The use of surplus human zygotes for research purposes is permissible, provided the prior informed consent of the donors has been obtained. Consent to the use of surplus zygotes for research must not, however, operate as a condition of participation in an assisted conception program.

(c) The creation of human zygotes specifically for research purposes is permissible. The use of invasive procedures specifically to retrieve eggs for purposes of creating zygotes for research is, however, prohibited; only eggs retrieved during procedures already being performed can be used.

(d) Standard gamete donor information materials and consent forms should be developed by the Embryo Research Sub-Committee of the National Reproductive Technologies Commission.

---

* This is termed the Embryo Research Sub-Committee, as this is how such research has been referred to in the public debate. As we have noted, the research is actually done at the zygote stage. However, the term Embryo Research Sub-Committee should be read to refer to both zygote and embryo research.

(e) Proper documentation showing the source of gametes, and signed donor consent forms, must accompany all gametes used to create zygotes for research. This documentation must be retained in the documentation relating to the research project and kept in a secure manner to protect confidentiality and the privacy of donors.

(f) Human zygotes that have been subject to manipulation of any kind for research purposes cannot be transferred to a woman's body without the specific approval of the National Reproductive Technologies Commission, and then only in the context of a clinical trial. Such approval should be contingent on the ability to demonstrate that the manipulations in question are likely to increase the woman's chances of conceiving or be of a therapeutic nature. The Embryo Research Sub-Committee would act in concert with the Assisted Conception and Prenatal Diagnosis Sub-Committees in reviewing any such application.

(g) All research on human zygotes must be undertaken only for purposes of promoting understanding and treatment of human health. No such research may be undertaken for commercial gain.

(h) The objectives of research on human zygotes should be achievable only through the use of human zygotes.

(i) Research involving genetic alteration of human zygotes is not permissible.

(j) Any research project involving the use of human zygotes undertaken by a licensed researcher or facility must be approved by a local institutional research ethics board. Guidelines for approving such research projects should be developed by the Embryo Research Sub-Committee. The onus would be on researchers to demonstrate that the proposed research complied with the guidelines.

(k) Individuals or facilities engaging in human embryo research report to the National Reproductive Technologies Commission on their activities in a standard form annually, and that a summary of such projects be included in the National Commission's annual report. The data required annually should include, for example, a summary of each research protocol, documentation of research ethics board approval, the number of zygotes involved, the facility or source from which they were obtained, and funding source(s) for the research.

(l) Individuals or facilities engaging in human embryo research be required to apply to the National Reproductive Technologies Commission for licence renewal every five years.

(m) Human embryo research licences be revocable by the National Reproductive Technologies Commission at any time for breach of the conditions of licence.

The Role of the Embryo Research Sub-Committee

It is useful to reiterate the Embryo Research Sub-Committee's other functions, given its crucial role in ensuring adequate and accountable oversight of this increasingly important area of research. Given that the field will continue to evolve, as well as its implications for society, the Embryo Research Sub-Committee will have a crucial role in maintaining vigilance and promoting public dialogue about the directions such research should be allowed to take and how collective values and goals should be embodied in decisions about it.

The Embryo Research Sub-Committee would be established and chaired by the NRTC. It would be one of six permanent Sub-Committees, along with those dealing with infertility prevention; assisted conception services; assisted insemination services; prenatal diagnosis; and the provision of fetal tissue for research and other designated purposes. Like National Commission members themselves, we recommend that at least half the Sub-Committee members be women, and that all members be chosen with a view to ensuring that they have a background and

demonstrated experience in dealing with a multidisciplinary approach to issues, as well as an ability to work together to find solutions and recommend policies to address the difficult issues raised by research on human zygotes in a way that meets the concerns of Canadian society as a whole.

As well as setting and revising the licensing requirements for human embryo research to be applied through the NRTC licence hearing process, the Sub-Committee would also

- develop standard information materials and standard requirements for donor consent forms to be used in all research projects;
- establish guidelines to be applied by institutional research ethics boards in reviewing and approving embryo research projects;
- analyze the data and information provided about projects and practices to help in the Sub-Committee's guideline- and standard-setting activities;
- discuss and develop policy on new issues and problems as they arise, monitor new research techniques, and ensure appropriate levels of regulation on an ongoing basis;
- work together with members of the Assisted Conception and Prenatal Diagnosis Sub-Committees in approving clinical trials involving the transfer of human zygotes that have been subject to manipulation; and
- promote public awareness and debate regarding human embryo research in Canada, through the publication of the NRTC's annual report, the circulation of draft discussion or policy papers for comment, or direct consultation with the public, as required.

In addition to enhancing public awareness and debate by providing more and better information about research using human zygotes currently under way in Canada, public accountability in this area would be promoted by the composition of the Embryo Research Sub-Committee. This should include both NRTC and outside membership, with a multidisciplinary make-up, including membership from the relevant medical and research communities as well as from groups familiar with the reproductive health concerns of women and other key segments of the public. Such broad representation will, we believe, enhance public confidence that any research undertaken on human zygotes in Canada reflects widely shared social concerns and values.

Conclusion

In summary, the Commission concludes that the use of human zygotes in research can be considered acceptable when that research is

directed to promoting understanding of human health and disease and developing treatment. However, any use of human zygotes must be within the strict guidelines we have outlined — which include clear limits on the way zygotes or eggs are acquired (informed consent, no invasive procedures specifically to retrieve eggs for research) and handled, as well as limits on the purposes for which research is conducted. Moreover, there must be a national system of licensing for this research, to ensure its compliance with ethical, legal, and scientific standards. Certain kinds of research would be expressly prohibited, and research would be permissible only up to 14 days after fertilization.

A consistent theme throughout our report has been the ethical imperative of providing treatment only if risks and effectiveness are known or in the context of research to obtain this knowledge. We have determined that *in vitro* fertilization should be offered as treatment for women with fallopian tube blockage, and that IVF for other diagnoses be considered a research priority. Commissioners consider that offering this treatment without also allowing research aimed at improving its safety and effectiveness would be unethical. In other words, prohibiting research on human zygotes would create a situation where the health of women and their children was put at risk, because it would close off an avenue to knowledge that could contribute to the development and evaluation of safer, more effective ways of performing IVF. We therefore believe that research involving human zygotes not only is acceptable but is an important component of the ethical provision of IVF and related techniques of assisted conception. It is for these reasons that we have determined that such research should be permitted within the framework of licensing, ethical review, public accountability, and other safeguards we recommend.

Appendix 1: Current Public Policies on Embryo Research in Eight Countries

Great Britain

Embryo research in Britain is now governed by the *Human Fertilisation and Embryology Act*, which was introduced in 1989 and passed in 1990. Under the act, all embryo research must be approved by the new Human Fertilisation and Embryology Authority. This body has the authority to issue three types of licences, one of which is a research licence to permit the creation of zygotes and their use for approved research projects, as well as such use of surplus zygotes. These licences must be renewed each year. Research is permitted only up to 14 days after fertilization, and a zygote that has been the subject of research cannot be transferred to a woman's

uterus. The informed consent of the zygote donors is required, and certain kinds of research are expressly prohibited, including trans-species fertilization.

This system of statutory licensing replaces the Voluntary Licensing Authority (VLA) (which changed its name in 1989 to the Interim Licensing Authority), an interim body established by the medical profession in the wake of the Warnock Committee's report (1984).

Australia

Because medical research falls under state jurisdiction in Australia, most public policy regarding embryo research exists at the state level. Three of the six Australian states have recently enacted legislation covering embryo research.

The state of Victoria passed the *Infertility (Medical Procedures) Act* in 1984. It permits research on surplus zygotes with the informed consent of the zygote donors if properly approved by a state licensing body, but it prohibits the creation of zygote for research purposes. Regulations under the act set limits on the permissible aims of research. Uncertainty about the definition of an embryo led to a legislative amendment in 1987, which specifies that a fertilized egg becomes an embryo only at the point of syngamy (that is, the actual coming together of chromosomes of sperm and egg), which occurs 22 to 24 hours after the sperm has penetrated the egg. This means that researchers can fertilize eggs solely for the purpose of research, if the research is performed before syngamy.

The other two states to pass legislation covering embryo research are Western Australia (*Human Reproductive Technology Act, 1991*) and South Australia (*Reproductive Technology Act, 1988*). Both effectively prohibit embryo research not intended to benefit the particular zygote that is the subject of the research.

The other three states do not yet have legislation. However, they did establish inquiries that covered embryo research. The New South Wales report endorsed embryo research for up to 14 days, as well as the creation of zygotes for research purposes; the Tasmania report rejected all embryo research; the Queensland report left the issue undecided. There is no indication that legislation is imminent in any of these states.

Given the wide range of state responses to this issue, there has been considerable pressure for the federal government to legislate in the area. Several federal reports have recommended that restrictions on embryo research be applied uniformly across the country through a system of national licensing of IVF and related research. However, no system for statutory national regulation has yet been implemented. In 1985, a private member's bill was introduced in the federal Senate to prohibit embryo research under the *Criminal Code*, but it did not receive legislative approval.

The only existing federal policy is the voluntary guidelines of the National Health and Medical Research Council (NHMRC), developed in

1982. According to these guidelines, embryo research is permissible for up to 14 days if approved by a local institutional ethics review board, and zygotes can be created solely for the purpose of such research. These guidelines are binding only on researchers who receive funding from the NHMRC. However, the NHMRC guidelines have been adopted by the medical profession itself. In the absence of a national system of statutory licensing, the Fertility Society of Australia set up its own system of voluntary licensing. Adherence to the NHMRC guidelines is required to receive a licence from the Reproductive Technology Accreditation Committee. However, this too is a voluntary system; there are no professional or legal sanctions against researchers who do not seek a licence.

United States

No federal regulation or legislation in the United States directly concerns embryo research, other than a de facto moratorium on the public funding of such research. Although several federal reports have endorsed the ethical permissibility of embryo research, and the legitimacy of its public funding, the institutional mechanisms required for processing funding requests do not exist. This may change under the new Clinton administration, which lifted a similar ban on public funding of fetal tissue transplantation research.

There is some regulation by both state governments and the medical profession. The Ethics Committee of the American Fertility Society recommended in 1990 that research on human zygotes, for up to 14 days, be considered ethically acceptable, with the consent of the donor and if reviewed by a properly constituted institutional review board. Creating zygotes for research purposes is also allowed, under certain circumstances. These guidelines are purely voluntary.

Several states have enacted legislation that deals with embryo research and research involving the use of fetal tissue. Most are concerned with research on aborted fetuses, and their relevance to research on zygotes *in vitro* is unclear. The state of Louisiana passed legislation specifically to prohibit the creation of zygotes for research purposes, but this was struck down as unconstitutional by a federal court, partly on the grounds that the legislation was too vague (for example, the term "experimental" was not defined).[29] Other states prohibit the donation of fetuses or zygotes for research.

Germany

In 1986, a draft law to regulate embryo research was introduced in the German legislature. In October 1990, after several years of debate, the *Embryo Protection Act* was passed; it came into force in January 1991. This act prohibits the creation of zygotes for research purposes and prohibits

non-therapeutic experimentation on surplus zygotes. It also prohibits cloning, the creation of chimeras, and preimplantation diagnosis. Zygotes can be created *in vitro* only to bring about a pregnancy in the woman whose egg is used to create the zygote. Once created, zygotes can be frozen and used for future pregnancy attempts by the woman whose egg was used originally to create the zygote.

The act allows an exception to this ban on embryo research for zygotes that are dead or incapable of development. However, if the zygote displays "developability," then research is limited to non-invasive observation that does not affect the possibility of successful implantation. Although the act states that an embryo exists only from the point of syngamy, it extends protection to the fertilized egg before this point. It states that for the first 24 hours after penetration by the sperm, before syngamy, the egg shall be assumed to be capable of development and hence protected from experimentation.

France

The current system of voluntary licensing for reproductive technology centres, established by the French government in April 1988, does not specifically cover embryo experimentation. However, a non-binding moratorium was placed on preimplantation diagnosis by the National Advisory Committee on Ethics for the Life and Health Sciences in 1986 and was reaffirmed in 1990.

Two major government reports have recommended comprehensive legislation, including the regulation of embryo research. In its 1986 report, the Conseil d'État endorsed embryo research for up to 14 days, subject to a system of case-by-case authorization by a national ethics committee. The creation of zygotes for research purposes was deemed impermissible, as were certain forms of research such as ectogenesis, cloning, and parthenogenesis. A 1989 draft bill, known as the *loi Braibant* and based on the Conseil d'État report, was never passed.

Subsequently, the Task Force on Biomedical Ethics and Life Sciences released a report entitled *Aux frontières de la vie.* It recommends the initiation of a legislative debate on whether embryo research should be allowed. If the National Assembly accepts embryo research, the task force recommends that such research then be required to comply with the following conditions: (1) there should be no production of zygotes solely for research purposes; (2) there should be no transfer of a zygote that has been the object of experimentation; and (3) the consent of donors should be required. Similar proposals, though with a seven-day limit on embryo research, were made by the National Advisory Committee on Ethics for the Life and Health Sciences in 1989. In March 1992, the *Projet de Loi #2600,* which deals with the donation and use of human body parts, stipulated that zygotes be donated only for therapeutic reasons. However, further details about what is meant by this are not provided, and in fact this bill,

as well as two others submitted to the National Assembly in March 1992, have been put on hold during the recent change of government in France. Another committee has been established to look at the issue, and its report is due by the end of 1993.

Spain

The Spanish Law 35, *Health: Assisted Reproduction Techniques*, was passed in November 1988. It was largely based on the Report of the Special Commission set up by the Spanish legislature to study IVF and assisted insemination. The Spanish law allows research on non-viable surplus zygotes for up to 14 days, and on viable zygotes provided it is "applied research of a diagnostic character or if it has a therapeutic or prophylactic purpose." It is left to scientists to determine non-viability, but generally this would be when the zygote fails to cleave or when there are more than two pronuclei. The creation of zygotes for research purposes is forbidden. Research involving cloning, parthenogenesis, or genetic manipulation is not allowed.

Sweden

The Swedish *In Vitro Fertilization Act*, introduced in January 1989, sets out the conditions under which embryo research may be undertaken. Research is permitted up to 14 days after the fertilization of the egg, but only if the research is related to the improvement of IVF techniques. Couples may consent to the use of unused zygotes for research. Research projects must be approved by an ethics committee.

Norway

The Norwegian Act No. 628, passed in 1987, prohibits embryo research. This law may be amended to allow for research up to seven days after fertilization. When the bill was originally drafted, the minister of health suggested the seven-day limit, but this was not accepted by the legislature. A legislative committee of inquiry is now looking at embryo research issues.

General Sources

Benjamin, M. *Splitting the Difference: Compromise and Integrity in Ethics and Politics*. Lawrence: University of Kansas Press, 1990.

Betteridge, K.J., and D. Rieger. "Embryo Transfer and Related Technologies in Domestic Animals: Their History, Current Status, and Future Direction, with Special Reference to Implications for Human Medicine." In Research Volumes of the Royal Commission on New Reproductive Technologies, 1993.

Boué, A. "Spontaneous Abortions and Cytogenetic Abnormalities." In *Progress in Infertility*, 3d ed., ed. S.J. Behrman, R.W. Kistner, and G.W. Patton. Boston: Little, Brown and Company, 1988.

Edwards, R.G. "The Galton Lecture, 1982: The Current Clinical and Ethical Situation of Human Conception In Vitro." In *Developments in Human Reproduction and Their Eugenic, Ethical Implications*, ed. C.O. Carter. Proceedings of the Nineteenth Annual Symposium of the Eugenics Society. London: Academic Press, 1983.

Handyside, A.H., et al. "Birth of a Normal Girl After In Vitro Fertilization and Preimplantation Diagnostic Testing for Cystic Fibrosis." *New England Journal of Medicine* 327 (September 24, 1992): 905-909.

Litman, M.M., and G.B. Robertson. "Reproductive Technology: Is a Property Law Regime Appropriate?" In Research Volumes of the Royal Commission on New Reproductive Technologies, 1993.

McLaren, A. "Human Embryo Research: Past, Present, and Future." In Research Volumes of the Royal Commission on New Reproductive Technologies, 1993.

Owen, K.D., and Z. Rosenwaks. "Current Status of *In Vitro* Fertilization and the New Reproductive Technologies." *Current Opinion in Obstetrics and Gynecology* 4 (June 1992): 354-58.

Singer, P., et al., eds. *Embryo Experimentation*. Cambridge: Cambridge University Press, 1990.

SPR Associates Inc. "Report on a Survey of Use and Handling of Human Reproductive Tissues in Canadian Health Care Facilities." In Research Volumes of the Royal Commission on New Reproductive Technologies, 1993.

SPR Associates Inc. "Report on a Follow-Up Survey of Use and Handling of Human Reproductive Tissues (Survey of Medical Laboratories and Medical Waste Disposal Firms)." In Research Volumes of the Royal Commission on New Reproductive Technologies, 1993.

Steptoe, P.C., and R.G. Edwards. "Birth After the Reimplantation of a Human Embryo." *Lancet* (August 12, 1978): 366.

Walters, W. "Personhood and the Human Embryo." In *Moral Priorities in Medical Research: The Second Hannah Conference*, ed. J.M. Nicholas. Toronto: The Hannah Institute of the History of Medicine, 1984.

Specific References

1. Whereas researchers in the 1970s might have been able to retrieve and fertilize one egg per cycle, doctors today can retrieve 5, 10, or more eggs per cycle and expect a 70 to 80 percent fertilization rate. As a result, many human zygotes exist for at least a brief period outside the human body (*ex utero*) in Canada. An *ex utero* zygote will die within a day or two if it is not transferred to a woman's body. Only a few embryos can be implanted without risks to the woman and to the children if they survive; this means that unless the remaining zygotes are frozen and stored they will not survive.

It is impossible to calculate the exact number of *ex utero* zygotes, in part because there are no precise data on the average number of eggs retrieved or the average fertilization rate. However, a variety of sources suggest that an average of six eggs is retrieved per cycle and about 70 to 80 percent of these eggs fertilize. This would mean that in Canada in 1991 approximately 13 500 zygotes were created through the retrieval and fertilization of eggs for 3 000 *in vitro* fertilization patients. Of these 13 500 zygotes, just over half were transferred with the aim of establishing a pregnancy. This leaves some 6 000 *ex utero* zygotes that were not transferred, though many of these would not have been viable, would not have shown normal cell division, or would have had anomalies that meant they could not have developed further. Some were also frozen.

2. Templeton, A.A., et al. "Oocyte Recovery and Fertilization Rates in Women at Various Times After the Administration of hCG." *Journal of Reproduction and Fertility* 76 (2)(1986): 771-78. It is important to note that the women involved in this study were also the subjects of research, since the ovulation induction was not done for their personal direct benefit.

3. Messinis, I.E., and A. Templeton. "The Effect of the Antiprogestin Mifepristone (RU 486) on Maturation and In-Vitro Fertilization of Human Oocytes." *British Journal of Obstetrics and Gynaecology* 95 (6)(June 1988): 592-95.

4. Council of Europe. Select Committee of Experts on the Use of Human Embryos and Foetuses. *Report on the Use of Human Foetal, Embryonic and Pre-Embryonic Material for Diagnostic, Therapeutic, Scientific, Industrial and Commercial Purposes.* Strasbourg: Council of Europe, 1990, para. 74-75.

5. Ibid., para. 107.

6. Legislation on embryo research has been considered in Quebec. In 1989, following the report of its Working Committee on New Technologies in Human Reproduction, the Quebec Department of Health and Social Services proposed a supervisory framework for embryo research that would require official approval for current projects and prohibit trade in embryos or the creation of human embryos solely for the purpose of research. Legislation was being considered by the Quebec Justice Department, but as of September 1992 no such legislation had been presented.

7. Most recently, *Davis v. Davis* (1989) WL 14 0495 (Tenn. Circ), also *Davis v. Davis* 15 Fam L. Rep. (BNA) No. 46, at 2097 (Blount Country Cir. Ct. Tenn., Sept. 26, 1989).

8. Law Reform Commission of Canada. *Medically Assisted Procreation.* Working Paper 65. Ottawa: Minister of Supply and Services Canada, 1992, p. 141.

9. Medical Research Council of Canada. *Guidelines on Research Involving Human Subjects.* Ottawa: MRC, 1987.

10. For a discussion of the role of the NCBHR, see Dossetor, J.B., and J.L. Storch. "Roles for Ethics Committees in Relation to Guidelines for New Reproductive Technologies: A Research Position Paper." In Research Volumes of the Royal Commission on New Reproductive Technologies, 1993.

11. The reports of the Law Reform Commission of Canada (*Biomedical Experimentation Involving Human Subjects*, 1989), the Working Committee of the Quebec Department of Health and Social Services (*Rapport du comité du travail sur les nouvelles technologies de reproduction*, 1988), the Bar of Quebec (*Rapport du comité sur les nouvelles technologies de reproduction*, 1988), the Ontario Law Reform Commission (*Report on Human Artificial Reproduction and Related Matters*, 1985), and the Canadian Bar Association, British Columbia Branch (*Reproductive Technologies*, 1989), generally support the substance of the MRC guidelines (that is, the 14-day limit, the need for donor consent and for local research ethics board approval, the unacceptability of transferring zygotes that have been experimented on, and the limitations on certain forms of research — for example, cloning). However, they all recommend more systematic regulation and monitoring of embryo research, to ensure that these guidelines are being respected and applied consistently.

12. Canadian Fertility and Andrology Society and the Society of Obstetricians and Gynaecologists of Canada. Combined Ethics Committee. *Ethical Considerations of the New Reproductive Technologies.* Toronto: Ribosome Communications, 1990, pp. 43-45.

13. Warnock, M. *A Question of Life: The Warnock Report on Human Fertilisation and Embryology.* Oxford: Basil Blackwell, 1985, p. xvi.

14. Baylis, F.E. "The Ethics of Ex-Utero Research on Spare 'IVF' Embryos." Ph.D. dissertation, University of Western Ontario, London, 1989, p. 69.

15. See Australia. Tasmanian Government. *Report of the Committee to Investigate Artificial Conception and Related Matters.* Tasmania: Government Printing Office, 1985.

16. United Kingdom. Committee to Review the Guidance on the Research Uses of Fetuses and Fetal Material. *Report* (The Polkinghorne Report). London: HMSO, 1989.

17. Australia. Senate Select Committee on the Human Embryo Experimentation Bill 1985. *Human Embryo Experimentation in Australia.* Canberra: Australian Government Publishing Service, 1986, para 3.7.

18. Royal College of Obstetricians and Gynaecologists. *Report of the RCOG Ethics Committee on In Vitro Fertilisation and Embryo Replacement or Transfer.* London: RCOG, 1983.

19. Buckle, S. "Arguing from Potential." In *Embryo Experimentation*, ed. P. Singer et al. Cambridge: Cambridge University Press, 1990, p. 95.

20. Canadian Bar Association, British Columbia Branch. *Report of the Special Task Force Committee on Reproductive Technology of the British Columbia Branch, The Canadian Bar Association.* Victoria: The Association, 1989.

21. MRC, *Guidelines on Research Involving Human Subjects.*

22. Law Reform Commission of Canada. *Biomedical Experimentation Involving Human Subjects.* Working Paper 61. Ottawa: Minister of Supply and Services Canada, 1989.

23. Australia, *Human Embryo Experimentation in Australia,* para. 3.31.

24. Gaze, B., and K. Dawson. "Who Is the Subject of the Research?" In *Embryo Experimentation,* ed. P. Singer et al. Cambridge: Cambridge University Press, 1990.

25. MRC, *Guidelines on Research Involving Human Subjects,* p. 34.

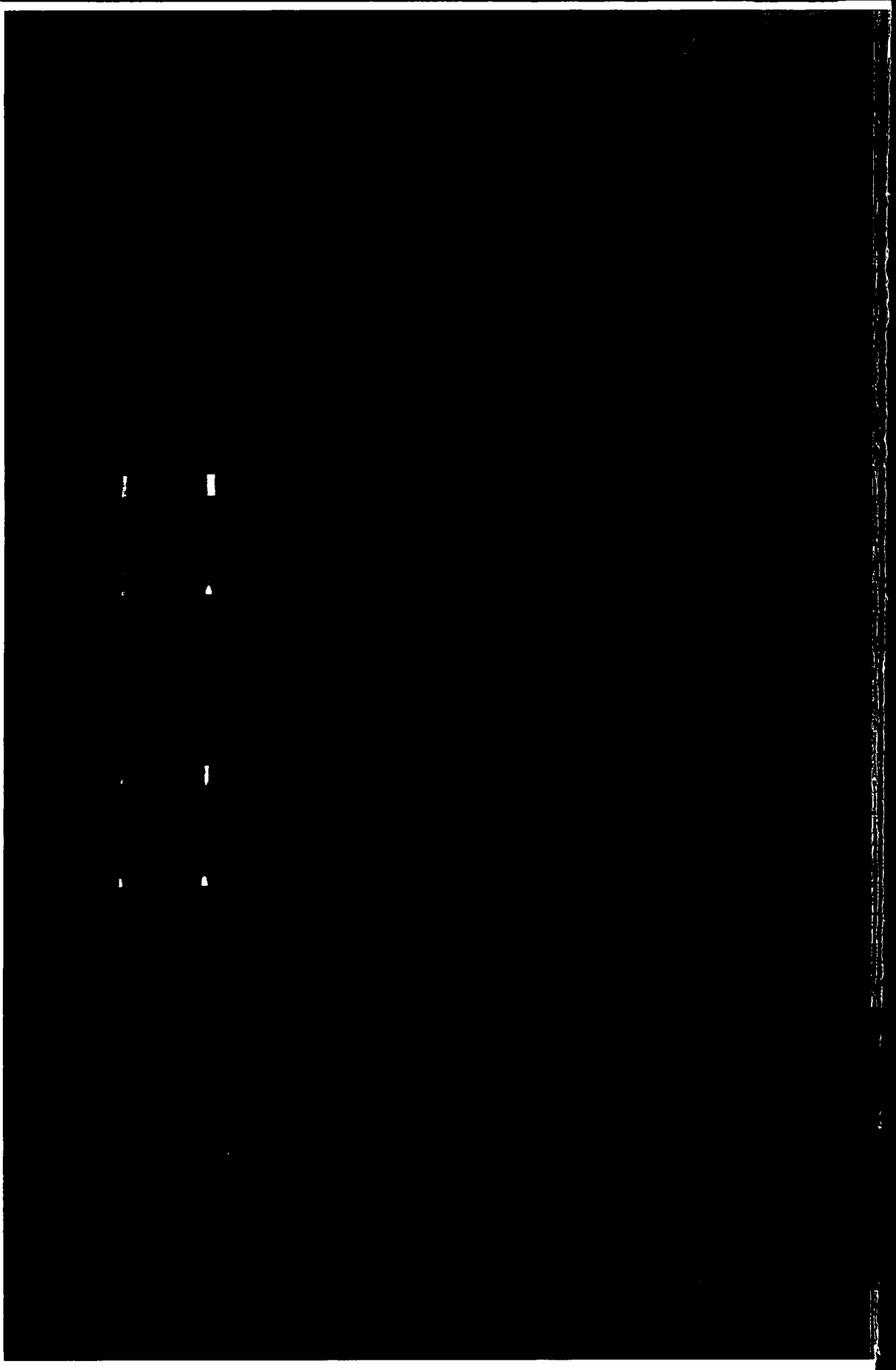
26. For accounts of the aims of recent embryo research, and why embryo research is necessary to achieve those aims, see Interim Licensing Authority. *IVF Research in the UK: A Report on Research Licensed by the ILA,* 1989; and Trounson, A. "Why Do Research on Human Pre-Embryos?" In *Embryo Experimentation,* ed. P. Singer et al. Cambridge: Cambridge University Press, 1990.

27. MRC, *Guidelines on Research Involving Human Subjects.*

28. *Personal Origins: The Report of a Working Party on Human Fertilisation and Embryology of the Board for Social Responsibility.* London: CIO Publishing, 1985, p. 137. Similarly, the Family Law Council of Australia suggests that once we allow the creation of embryos for research, we will start down a slippery slope, and that "no end can be set on the dangers" (Australia. *Creating Children: A Uniform Approach to the Law and Practice of Reproductive Technology in Australia.* Canberra: Australian Government Publishing Service, 1985, p. 84).

29. *Margaret S. v. Edwards* 794 F.2d 994 (5th Cir., 1986).

DATE DUE



Royal Commission on
New Reproductive Technologies

Commission royale sur les
nouvelles techniques de reproduction

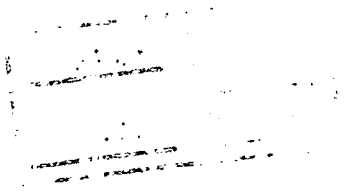
PROCEED WITH CARE

FINAL REPORT
OF THE
ROYAL COMMISSION ON
NEW REPRODUCTIVE TECHNOLOGIES

VOLUME 2

PROCEED WITH CARE

VOLUME 2



PROCEED WITH CARE

FINAL REPORT
OF THE
ROYAL COMMISSION ON
NEW REPRODUCTIVE TECHNOLOGIES

VOLUME 2

Printed and bound in Canada

This Report is available in both official languages as a set or as individual volumes.

Available in Canada through your local bookseller
or by mail from
Canada Communications Group — Publishing
Ottawa, Canada K1A 0S9

CANADIAN CATALOGUING IN PUBLICATION DATA

Canada. Royal Commission on New Reproductive Technologies

Proceed with Care: Final Report of the Royal Commission on New Reproductive Technologies

Issued also in French under title: Un virage à prendre en douceur.
Complete work consists of 2 v.
ISBN 0-660-15359-9 (set)
ISBN 0-660-15365-3 (v.1); 0-660-15366-1 (v.2)
Cat. no. Z1-1989/3E (set);
Z1-1989/3-1E (v.1); Z1-1989/3-2E (v.2)

1. Human reproductive technologies — Canada. 2. Infertility — Treatment — Canada. 3. Human reproductive technologies — Canada — Moral and ethical aspects. 4. Infertility — Treatment — Canada — Moral and ethical aspects. 5. Embryology, Human — Canada. I. Title. II. Title: Final report of the Royal Commission on New Reproductive Technologies.

RG133.5C2 1993 618.1'78 C94-980002-3

The Royal Commission on New Reproductive Technologies and the publishers wish to acknowledge with gratitude the following:

- Translation Services, Government Services Canada, for their contribution to the translation of this report and related studies. Special thanks are due to the Privy Council Translation Service, the Scientific Translation Service and the Montreal Health and Criminology Translation Service. We also gratefully acknowledge the contribution of the Parliamentary Documents Translation Service to the revision and preparation of the French version of this report.
- Canada Communications Group, Printing Services
- Biomedical Communications at the University of British Columbia

Consistent with the Commission's commitment to full equality between men and women, care has been taken throughout this text to use gender-neutral language wherever possible.

Royal Commission on
New Reproductive Technologies

Commission royale sur les
nouvelles techniques de reproduction

TO HIS EXCELLENCY
THE GOVERNOR GENERAL IN COUNCIL

MAY IT PLEASE YOUR EXCELLENCY

By Order in Council dated October 25, 1989, we were requested to inquire into and report upon current and potential medical and scientific developments related to new reproductive technologies, considering in particular their social, ethical, health, research, legal and economic implications and the public interest, recommending what policies and safeguards should be applied.

We have been honoured to have the responsibility of working to fulfil this mandate, and beg to submit our Final Report in each official language.

Respectfully submitted,

Patricia Baird
Patricia Baird, Chairperson

Grace M. Jantzen
Grace Jantzen

Bartha Maria Knoppers
Bartha Maria Knoppers

Susan E.M. McCutcheon
Susan E.M. McCutcheon

Suzanne Rozell Scorsone
Suzanne Rozell Scorsone

November 15, 1993
Ottawa, Canada

P.O. Box/C.P. 1566, Station/Succursale "B", Ottawa, Canada K1P 5R5, (613) 954-9999 Fax: (613) 954-9998

Biographical Notes on Commissioners

Dr. Patricia A. Baird is a paediatrician, professor in medical genetics at the University of British Columbia, and a member of the Population Health Program of the Canadian Institute for Advanced Research.

Grace M. Jantzen is currently a Reader in Philosophy of Religion, Department of Theology and Religious Studies, King's College, University of London, England.

Bartha Maria Knoppers is an Associate Professor, Faculty of Law, at the University of Montreal, and a Senior Researcher with the Centre de Recherche en Droit public de l'Université de Montréal.

Susan E.M. McCutcheon began her career as a teacher, and was active in the business community. She currently takes part in several community organizations, and holds several corporate directorships.

Suzanne Rozell Scorsone is spokesperson for the Archdiocese of Toronto on family and women's issues, and is the Director, Office of Catholic Family Life. Dr. Scorsone is an anthropologist.

Contents

Volume 1

Volume 2

Part Three: Overview of Recommendations

Part Four: Annex, Glossary, and Appendices

Annex: Suzanne Rozell Scorsone

Glossary

Appendices

Tables

Figures

Preconception Arrangements

Preconception arrangements (often referred to as surrogacy or contract motherhood) provoked considerable debate in testimony and submissions before the Commission. For some, prohibiting the practice raised issues of personal liberty and reproductive freedom. Others saw it as a practice that reduces the human experience of reproduction to a commercial transaction, evoking unsavoury images of "wombs for rent" and children as products or commodities. In particular, Canadians told us that they oppose the involvement of brokers and others with a commercial motive in such arrangements. Still others opposed the practice as degrading to women, relegating them to a status in society based solely on their reproductive capacity.

The Commission gathered information to assess the practice of preconception arrangements in several ways. We spoke with people who have participated in preconception arrangements. We investigated the practices surrounding preconception arrangements and the involvement of the various parties. We examined the ethical and legal issues raised by preconception arrangements, considered the psychosocial effects of preconception arrangements on the children and on the participants, and deliberated on the implications of the practice for society at large. We also surveyed Canadians' views on these arrangements. Finally, we investigated how other jurisdictions have dealt with preconception arrangements and their reasons for doing so. (See the research volume, *Social Values and Attitudes Surrounding New Reproductive Technologies*, for the results of these investigations.) Our conclusions and recommendations with respect to preconception arrangements are based on consideration of all these aspects.

Preconception Arrangements: What They Are

Various terms have been used to describe arrangements whereby a woman undertakes to conceive and bear a child with the understanding it will be raised by someone else (the "commissioning" man, or couple). These terms include surrogacy, surrogate motherhood, contract motherhood, and intrauterine adoption. The Commission uses the term "preconception arrangements" to describe all such situations, referring to the fact that, unlike adoption, agreement to transfer custody and parental rights is reached before the child is conceived.

Types of Preconception Arrangements

Genetic-gestational arrangement: The gestational mother is impregnated with the sperm of the man from the commissioning couple through assisted insemination; the resulting child is the genetic child of the gestational mother and the commissioning man. The commissioning woman becomes the child's social mother.

Gestational arrangement: An embryo created from the egg and sperm of the commissioning couple is implanted in the gestational woman, who becomes pregnant and gives birth. The child is the genetic child of the commissioning couple and is not related genetically to the woman carrying the fetus and giving birth.

Commercial arrangement: The commissioning couple pays fees to the woman and/or to a broker to cover the cost of facilitating the agreement and the expenses of the gestational woman; a written contract between the couple and the woman is usually involved.

Non-commercial arrangement: No broker or fees are involved, although a contract may be involved and the commissioning couple may agree to cover expenses; such arrangements usually occur between family members or close friends.

Such a practice — couples who are infertile seeking a woman to assist them in having a child to raise — is far from new, dating back at least as far as the earliest biblical times; the difference today is that procedures such as assisted insemination and *in vitro* fertilization remove the need for sexual intercourse.

The circumstances under which a commissioning couple seeks a preconception agreement vary considerably. The commissioning woman might have been treated unsuccessfully for infertility, or might have had difficulty carrying a fetus to term. Alternatively, the woman might be at risk of passing on a genetic disease to her child or might have a medical condition that makes pregnancy inadvisable. Preconception arrangements

enable the couple to have a child that is genetically related to the commissioning man or, more rarely, to both members of the couple.

However, the practice is not limited to couples who are infertile or childless. The literature contains instances, for example, of preconception arrangements being used when the commissioning woman's infertility was the result of voluntary sterilization or menopause, when the couple already had a child or children, and when one or both members of the couple already had adopted or biological children in a previous relationship. As well, there are examples of single men and unmarried couples receiving children through preconception arrangements.

Though difficult to document, these arrangements appear to be growing in number; in some jurisdictions there are now professionals (lawyers, physicians, and others) whose practice concentrates solely on facilitating such arrangements. In the United States, preconception arrangements resulted in the birth of an estimated 4 500 children between 1975 and 1990 and have led to the development of a range of profit-making organizations devoted to this activity. From what little evidence is available, it appears that commercial brokers do not operate in Canada.

Categories of Preconception Arrangements

Preconception arrangements usually fall into one of two categories, depending on the source of the egg and the techniques used. Genetic-gestational arrangements are the most common type. Assisted insemination is used to inseminate the gestational mother with the commissioning man's sperm. A physician usually performs the procedure, although self-insemination is also possible.

Gestational arrangements are where the gestational woman is not the source of the egg, and they require the involvement of a physician because of the technical nature of the procedure. The commissioning woman undergoes an egg retrieval cycle (see Chapter 20), and the eggs are fertilized *in vitro* using her partner's sperm. The resulting zygotes are then transferred to the gestational woman for implantation. This usually requires that both women take fertility drugs — to produce eggs in the commissioning woman, and to ensure that the two women's cycles are coordinated, maximizing chances of implantation. Less commonly, sperm from a donor could be used, or the egg could be donated by a third woman, thus totally separating the genetic, gestational, and social aspects of "parenthood."

Although they are less common than the genetic-gestational type, the number of solely gestational arrangements is rising. In the United States, such arrangements account for a large proportion of some clinics' business. To take one example, in 1990 more than 50 percent of clients at the Center for Surrogate Parenting in Beverly Hills, California, were participating in

gestational arrangements. At present this is not being done in Canadian infertility clinics, although there have been reports that two are considering it.

Preconception arrangements also differ according to whether the gestational mother is paid for her participation and whether the parties have known each other before undertaking the arrangement.

In commercial preconception arrangements, the gestational mother receives payment in the form of fees and expenses. Commercial arrangements can be facilitated by a third party, called a broker, or they may take the form of a private agreement between the commissioning couple or man and the gestational woman. The fee can be paid to the broker, who passes on a portion of it to the gestational woman, or directly to the gestational woman.

Non-commercial arrangements occur between a commissioning couple and another woman, often a family member or close friend. Because these arrangements are private, involve fewer people, and may not become public knowledge unless they lead to litigation, relatively less is known about the nature and extent of non-commercial arrangements. The gestational woman may receive payment to cover her personal or other expenses during or related to the pregnancy.

Current Practices

The Commission found little empirical research on preconception arrangements in Canada and elsewhere. Documenting the practice is difficult because of the private nature of these arrangements; much of what we know about them comes from anecdotal accounts. Such information as is available pertains mainly to commercial arrangements; there is little published evidence about non-commercial arrangements. One of the Commission's goals was therefore to determine the extent to which preconception arrangements are occurring in Canada.

The most common type, genetic-gestational arrangements, does not require the involvement of medical professionals; however, when there is such involvement, it can take place in a physician's office and be recorded in a way that preserves secrecy. Arrangements involving a relative or friend as the gestational mother are generally kept private because of the legal uncertainties, as well as apprehension about the reaction of others to the arrangement.

The only effort to date to gauge the prevalence of preconception arrangements in Canada was a 1988 study for the Law Reform Commission of Canada. The study estimated (conservatively, in the authors' view) that there had been at least 118 cases of preconception arrangements involving one or more Canadian participants. Details about these arrangements are

scarce, however, as the cases were generally reported by someone not involved directly in the arrangement.

The Commission surveyed programs and services being offered by the 27 fertility clinics across Canada. From our data there was no evidence that any Canadian fertility clinics are currently involved in preconception arrangements. The practice may be occurring in physicians' offices outside clinics, but we have only anecdotal accounts of this. The Commission found, however, that one Toronto clinic plans to offer gestational preconception arrangements. The clinic's consent forms are being given final legal review, and the procedure is being reviewed by various hospital and university committees. One other program outside Ontario also reported considering preconception arrangements involving *in vitro* fertilization.

A survey undertaken for the Commission demonstrated that patients undergoing treatment at fertility clinics would consider a variety of approaches in trying to have a child, including preconception arrangements. Six percent of *in vitro* fertilization patients and 5 percent of people undergoing assisted insemination (using partner's sperm) would consider preconception arrangements in the future, although none of the respondents who had had assisted insemination using donor sperm would contemplate a preconception arrangement. Three percent of patients receiving other fertility treatment would consider preconception arrangements in the future.

Commercial Arrangements

Commercial agreements are difficult to document, because they, too, are not usually public knowledge. The 1988 study for the Law Reform Commission of Canada found that of the 118 cases of preconception arrangements examined, 42 took place in Canada and 76 involved U.S. agencies. In 13 of the cases involving U.S. agencies, Canadians were serving as gestational women; in 62 cases, the Canadians were commissioning couples; and, in one case, a Canadian single man had received a child.

Non-Commercial Arrangements

Information about how non-commercial preconception arrangements are handled is extremely limited. The Commission heard directly from several people who had participated in non-commercial arrangements. Anecdotal accounts suggest that the typical case would involve a relative (often a sister) or close friend of a woman who is infertile being inseminated with her partner's sperm, usually without medical involvement. The gestational mother may have pregnancy care and deliver the child in hospital under the commissioning woman's name and health insurance number, register the birth using the commissioning woman's name (the

father does not have to be named on the birth certificate), and relinquish the child to the commissioning couple upon leaving the hospital.

Ways of Dealing with Preconception Arrangements

To date, Quebec is the only Canadian jurisdiction to have enacted specific legislation regarding preconception arrangements; no other provincial statutes deal explicitly with preconception arrangements. Section 541 of Quebec's revised *Civil Code* provides that all agreements for procreation or gestation for payment are null and void.

Apart from these provisions, preconception arrangements remain in a legal void in Canada. In the absence of specific legislation, existing law in several fields, including family law, adoption law, and contract law, may apply to preconception arrangements. The extent to which these laws apply is not clear, however, as there are no official reports of litigation concerning preconception arrangements in any Canadian jurisdiction.

Family Law

The provisions of existing family law could affect preconception arrangements in two ways: (1) the legal status of the agreement and (2) the determination of the legal parentage of a child born as a result of a preconception arrangement. There is certainly a body of legal opinion that states that legitimizing preconception arrangements would be inconsistent with existing family law principles. This is because a contract that provides in advance for handing over a child at birth would be at odds with fundamental principles of family law — that custody must be determined according to the best interests of the child and that parental authority and obligations cannot legally be "contracted away" in anticipation. Adults cannot simply transfer custody of a child at their whim; the child's best interests must guide decisions and actions in this respect.

In Ontario, for instance, family law would appear to make preconception arrangements void because the law gives the courts ultimate power to decide the custody of a child, even where parents have made an agreement in that regard. Since custody is determined in the best interests of the child, a preconception agreement made before the child's birth would be void, because it could only have been made in the interests of the adult participants — the best interests of the child could not have been known. Further, any attempt to transfer maternal rights is subject to adoption law, which forbids payment for adoption and requires a seven-day waiting period before the birth mother can give consent to adoption. Finally, Ontario law makes it illegal for a third party to receive payment for negotiations or arrangements with a view to a child's adoption.

Other provinces have similar provisions in their family law acts. In no province or territory have these provisions been tested in the context of

preconception arrangements, however, so the degree to which the courts would apply them to preconception arrangements is unknown.

The second major impact of family law is in the determination of legal parentage. Despite family law provisions that would appear to make preconception arrangements illegal, the fact remains that children are being born through such arrangements. Establishing their legal parentage is vital both for them and for the other participants in the process, as it affects the rights and obligations of the parties with respect to custody, access, support, and inheritance. Unfortunately, current family law in most jurisdictions in Canada does not always provide clear guidance on the question of legal parentage. By contrast, Quebec, Newfoundland, and the Yukon have specified the legal parentage of children born as a result of assisted conception techniques in the revised *Civil Code*, the *Children's Law Act, 1988* and the *Children's Act, 1986*, respectively. These provisions would presumably apply to children born through assisted conception in the context of preconception arrangements.

Contract Law

The freedom to contract is not unrestricted; the courts may refuse to enforce a contract on the basis of such legal concepts as misrepresentation, inequality of bargaining power, and incapacity of an individual to enter into legal relations for such reason as mental incompetency, and on the basis of public policy considerations. The Commission's research indicates that the courts would probably find preconception contracts contrary to public policy and therefore null and void under existing law. In particular, these arrangements contravene public policies reflected in provincial/territorial legislation across Canada prohibiting for-profit exchanges involving children, requiring proof of parental unfitness before parental rights are terminated, and requiring the surrender of children in such situations to appropriate child welfare authorities.

For these reasons, preconception contracts would likely be deemed unenforceable by the courts, regardless of whether payment was involved, although this interpretation is by no means certain. In the *Baby M* case in the United States, for example, a trial judge ruled that preconception agreements were not contrary to public policy, but this finding was later reversed on appeal. To establish legal certainty, all provinces and territories (except Quebec, which will do so as of January 1, 1994) would have to pass laws clarifying the legal status of these arrangements. If contracts are deemed unenforceable, however, the principles of family law again come into play. The parties' parental status would be determined under provincial family law independently of the contract and perhaps in a manner different from what was intended by the parties to the contract. Most significantly, the best interests of the child test would prevail.

Proposals for Change

Given the considerable uncertainty about the legal status of preconception arrangements in Canada, there have been several proposals for law reform in this area. The Ontario Law Reform Commission's *Report on Human Artificial Reproduction and Related Matters*, released in 1985, is one of the few reports in the world to endorse the practice of preconception contracts, and it generated considerable controversy in this regard. The report's authors believed that the practice would carry on regardless of the state of the law and that its potential dangers would increase if it were driven underground by making it illegal. They therefore proposed a regulatory scheme to govern such agreements. The Ontario government has not implemented the recommendations.

The Canadian Bar Association, on the other hand, recommended in its brief to the Commission that preconception arrangements be handled, as far as possible, under existing adoption law. Under this proposal, preconception contracts would not be illegal, but they would be enforceable only if the birth mother wanted to relinquish the child. As in adoption, she would have a period of time after the birth in which to make the decision. The Canadian Bar Association recommended further that if the gestational mother decided not to relinquish the child, the commissioning couple should not have any visitation or access rights. The Canadian Bar Association submission does not make any distinction between the different types of preconception arrangements (genetic-gestational, gestational, commercial, or non-commercial) in its recommendations.

In its working paper on medically assisted procreation (1992), the Law Reform Commission of Canada recommended that preconception contracts be null and void and that acting as a paid intermediary in such arrangements be a criminal offence.

The Uniform Law Conference of Canada proposed in 1991 that all provinces deem the woman who gives birth, not the woman who produced the egg, to be the mother. This would clarify the identity of the legal mother of children (their "maternal filiation") born through preconception arrangements. It is also important for the well-being of the child, however, that the identity of the man who has legal responsibility as father be clarified; the Uniform Law Conference of Canada report did not recommend a means to do that.

International Experience

Preconception arrangements have been of concern in many countries, and several have enacted legislation or policies to deal with the practice. The Commission examined the response of the United Kingdom, Australia, the United States, and France to see what lessons, if any, might be relevant to the Canadian context.

The Commission's review showed that the trend internationally has been to discourage and even criminalize commercial preconception arrangements. Outright legislative bans on preconception agreements are rare, but most jurisdictions that have taken a position do prohibit commercial arrangements, primarily by making it illegal to advertise for a gestational woman, to act as a broker or intermediary (even if no commercial motive is involved), or to pay for or accept compensation in any form in connection with a preconception arrangement. Most jurisdictions have taken pains, however, not to institute measures penalizing the gestational woman.

The other measure proposed or adopted most frequently to discourage preconception arrangements is to make the contract between the gestational mother and the commissioning man or couple legally unenforceable; in other words, the gestational woman could not be forced by a court to give up the child if she changed her mind about fulfilling the terms of the contract. The element of uncertainty this introduces for commissioning couples and brokers is thought to be an effective means of discouraging such arrangements.

Views on Preconception Arrangements

The Commission's review of the debate on preconception arrangements is based on several sources: the range of views expressed by Canadians in our public hearings, in submissions to the Commission, and in surveys conducted for the Commission; other research we commissioned on the topic; and the published reports of other organizations and jurisdictions that have examined the issue.

We found that opinions on this issue are diverse and difficult to catalogue, ranging from outright opposition to the practice, whatever form it might take, to acceptance and even encouragement of the practice by public policies to regulate it, to enforce contracts, and to provide medical services in support of it. Ranged between these positions are those who oppose commercial arrangements but would tolerate non-commercial arrangements, particularly in cases where the commissioning woman's health was the reason for seeking a preconception arrangement; those who would find commercial arrangements acceptable if certain safeguards or regulations were in place; and those who would not encourage or participate in a (non-commercial) preconception arrangement themselves but would not prohibit others from doing so. We examine this range of positions in the next three sections.

An Unacceptable Practice: The Arguments Against Commercial Preconception Arrangements

Those who hold that commercial preconception arrangements should be prohibited believe that they are inherently exploitive; that they treat children as commodities; that they are dehumanizing and degrading to women and their reproductive capacity; that they are harmful to the participants and to children born as a result of these arrangements; that they foster harmful social attitudes about the role and value of women, children, and families; and that they reinforce and perpetuate sexual inequality in our society. They also point out that such arrangements have significant implications for the gestational woman, who agrees on signing the contract to restrict her behaviour in certain ways (for example, with respect to smoking and drinking) and to abide by the commissioning couple's requirements for her pregnancy care (for example, to undergo tests such as amniocentesis). These arguments are examined in the next few pages.

> Criminalizing the decision of a woman to serve as a so-called "surrogate mother" ... would in fact focus all of the enforcement efforts on the woman. And as enforcement efforts in other areas of law have demonstrated, women are easily made vulnerable by that in ways that other parties are not.
>
> *K. Lahey, Ontario Advisory Council on Women's Issues, Public Hearings Transcripts, Toronto, Ontario, October 29, 1990.*

Potential for Exploitation

Concerns about the exploitive nature of commercial preconception arrangements stem from several sources, in particular the social and economic disparities between gestational women and commissioning couples and the disproportionate assumption of risks and obligations by the parties to a preconception contract. These inequalities in power and resources, it is argued, make gestational women vulnerable to exploitation, no matter how willing they might be to participate, because they can never negotiate on an equal footing with the other parties.

A recurring concern we heard was that women willing to undertake gestational arrangements for others would be those who are economically vulnerable — that a woman who was well off financially would be most unlikely to agree to be a gestational mother. That this is often the case was borne out by our research, which revealed significant socioeconomic differences between commissioning women and gestational women. Although reliable data on participants are scarce, the information available shows that gestational women are younger, less well educated, and of lower income than commissioning couples. The study for the Law Reform

Commission, for example, which examined data on 32 commissioning couples, found that their overall age is much older than that of the gestational women; the youngest commissioning man, at age 35, and the youngest commissioning woman, at age 34, were both older than the oldest gestational woman, who was 33.

Commercial Preconception Contracts

The Commission examined preconception agreements drafted by U.S. commercial agencies. They contained some or all of the following provisions:

1. The gestational woman agrees to become pregnant using the commissioning man's sperm, to carry the fetus to term, and then to relinquish her parental rights and transfer custody of the child to the commissioning couple.
2. The gestational woman and her husband (if she has one) promise to take all steps necessary to have the commissioning man's name entered on the child's birth certificate as the father, and the gestational woman's husband agrees to renounce any legal presumption that he is the child's father.
3. The commissioning couple promises to pay the gestational woman a specified sum (usually U.S.$10 000) when her maternal rights are terminated by a court order and provided he has custody of the child.
4. The parties agree that the specified fee can be reduced significantly if the woman miscarries or gives birth to a stillborn child. In the *Baby M* arrangement, for example, the gestational woman was to receive no payment if miscarriage occurred in the fourth month or earlier, and $1 000 if the fetus miscarried after the fourth month or was born dead.
5. The gestational woman promises that she will undergo amniocentesis.
6. The gestational woman agrees that she will not abort the fetus but that, if the commissioning couple decides on the basis of the amniocentesis results that they do not want the child to be born, she will have an abortion.
7. The gestational woman promises not to form a parent-child bond with the fetus.
8. The gestational woman agrees not to drink alcohol or to take any non-prescription, prescription, or illicit drugs without the permission of a physician specified in the agreement and otherwise to adhere to all medical instructions of the attending physician.
9. Should custody of the child be awarded to anyone not related to the commissioning couple (such as, for example, the gestational woman), the gestational woman and her husband promise to reimburse the commissioning couple for all sums they are ordered to pay in child support.
10. Should the commissioning man die before the child's birth, the gestational mother agrees to renounce her parental rights and to transfer custody of the child to his wife, if any. Should he not be married or should his wife also die before the child's birth, the gestational woman agrees to transfer custody to the person the commissioning couple has named in the arrangement.
11. The commissioning couple agrees to pay specified expenses incurred by the gestational woman, such as medical, hospitalization, laboratory and therapy expenses, travel, accommodation, and child care costs.

As a group, commissioning couples had a higher level of education than the gestational women; 88 percent of commissioning men and 79 percent of commissioning women had post-secondary degrees, compared to only 17 percent of gestational women. This was reflected in occupations, with commissioning couples more likely to be professionals and to have higher incomes. Given the fees involved ($20 000 or more where fees to a broker and the gestational woman are involved), only the affluent can afford a preconception arrangement, so they are a highly select group and not typical of the general population.

Research in this area is of limited reliability in several respects; sample sizes were small, and the Law Reform Commission of Canada study was conducted in 1988. It showed nevertheless that most of the gestational women surveyed were married, usually to someone in a blue-collar occupation, most were of Protestant background, and almost all were Caucasian. Most of the women had not finished high school or had only high school education, and many did not work outside the home. The anecdotal accounts the Commission heard support this description of the situation of gestational mothers and their partners, suggesting that they tend to be of a lower socioeconomic status than commissioning couples and that payment is a major factor in their decision to participate.

> Commercial surrogacy contracts constitute a form of baby-selling; if the mother were merely providing the service of gestation, the mother and father would have equal rights to the child once the gestation was over and the child was born. The fact that many contracts stipulate that a reduced fee be paid to the mother if the product [her child] is "defective" makes it clear that gestation is merely a means to the end of a healthy baby.
>
> *Brief to the Commission from the Canadian Research Institute for the Advancement of Women, September 20, 1990.*

Indeed, this contention is borne out by the experience of one broker in the United States. Only one woman a year came forward to be a gestational mother when arrangements were made on a volunteer basis. Once the broker began to offer payment, the number rose to 20 women per year within two years. Without the financial incentive, then, it can safely be assumed that there would be far fewer willing gestational women.

The inequalities between the gestational woman and the commissioning couple are reinforced by the involvement of brokers. Despite the neutrality of the term "broker," implying an intermediary between the parties, in fact commercial brokers usually represent the interests of the commissioning couple, who pay the broker's fee of U.S.$10 000 to $16 000. The inequality of the parties is then confirmed by the terms of the standard contract, in which the gestational woman agrees

to accept all the risks of assisted conception and pregnancy — up to and including her own death — while abiding by behavioural and other rules established by the contract — including the requirement to submit to medical diagnosis and treatment at the commissioning couple's discretion.

The commissioning couple, by contrast, is obliged only to complete payment on delivery of the child and relinquishment of the gestational woman's maternal rights and transfer of custody. They can refuse to accept the child if it proves not to be the genetic offspring of the commissioning man, and there have even been reported cases of commissioning couples refusing to accept the child because it was of the "wrong" sex or had a congenital anomaly or disability.

> One of the most severe results these technologies can have for women is the emergence of a class of professional female breeders, causing women, especially the unemployed, economically stressed, less educated, immigrant, and visible minority women, to be exploited and abused. It is these women who will be manipulated to benefit white upper middle class Canadian women. You ... must insure that these women are protected and respected under the law.
>
> *B. Lee, National Organization of Immigrant and Visible Minority Women of Canada, Public Hearings Transcripts, Moncton, New Brunswick, October 19, 1990.*

Preconception contracts were of particular concern to many of the groups representing minority women who appeared before the Commission. They told us that they fear increased exploitation of lower-income women, a disproportionate number of whom are members of minority groups. The advent of purely gestational arrangements, moreover, raises the possibility of minority women being used by white couples to gestate their children, both here in Canada and in developing countries. This concern was raised, for example, by Immigrant and Visible Minority Women of British Columbia:

> The idea that women would be so poor as not to have any other options than making their living by producing babies is, of course, repugnant ... [S]teps must be taken to ensure that surrogate motherhood is not undertaken for profit and that the legal and ethical issues are seriously addressed.
>
> *D. Ellis, Canadian Federation of Business and Professional Women's Clubs, Public Hearings Transcripts, Toronto, Ontario, October 29, 1990.*

> With the rise of commercial surrogacy, and on the basis of current experience, we foresee devastating consequences for all poor women and for women of colour who are disproportionately represented among the poor ... We recommend that this Commission call for a ban on surrogacy. The costs in the increased potential for exploitation of women

> of colour by far outweigh any benefits that might accrue to affluent couples. *(S. Thobani, Immigrant and Visible Minority Women of British Columbia, Public Hearings Transcripts, Vancouver, British Columbia, November 26, 1990.)*

These concerns were given substance by reports that at least one U.S. broker is bringing women to the United States from overseas to act as gestational women; these women are not paid beyond their travel and living expenses, resulting in much lower costs for the commissioning couple. The same broker is also exploring the possibility of initiating the pregnancies overseas and bringing only the resulting children to the United States.

Non-financial forms of exploitation are also a danger, as many groups appearing before the Commission emphasized.

Dehumanizing and Degrading to Women

Apart from the question of whether commercial preconception arrangements are inherently exploitive, witnesses asked the Commission to consider the dehumanizing and degrading aspects of such agreements for the individual women who participate and for women generally:

> In the standard surrogacy arrangement the woman who ovulates, conceives, gestates, labours, and delivers a baby is not called "the mother." She is a mere "surrogate." The presumption is that the real mother is the wife/partner in the infertile couple. We feel this is very degrading to the woman involved. *(J. Lewicky, Alberta Federation of Women United for Families, Public Hearings Transcripts, Calgary, Alberta, September 14, 1990.)*

These aspects are certainly apparent in the contracts gestational mothers are asked to sign, which require them to waive their right to refuse medical treatment — a right guaranteed under the provisions of the *Canadian Charter of Rights and Freedoms* that protect every individual's "life, liberty and security of the person." Moreover, other values inherent in the Charter, such as women's right to autonomy and dignity (implied in section 7) and equality (section 15), would be offended by state legitimation or enforcement of preconception contracts:

> To ensure that the mother provides an appropriate environment for her "product," strict regulations are often placed on her diet, exercise, and intercourse with the male partner. The contracted mother may also be required to undergo medical treatment, including ultrasound, amniocentesis, and abortion, regardless of her wishes. Her right to refuse medical treatment is thus denied by the contract. If surrogacy contracts are made legally enforceable, a dangerous precedent will be set for the rights of all pregnant women. *(Brief to the Commission from the Canadian Research Institute for the Advancement of Women, September 20, 1990.)*

Harm to Participants and Children

Proponents of preconception arrangements downplay the concept of harm to the gestational mothers, arguing that they are free to decide whether to participate. Other witnesses, however, questioned this premise, pointing out that the circumstances surrounding such arrangements have the potential to lead to pressure or even coercion of women by husbands or partners in the interests of adding to the household income. Even without direct coercion, they felt that, given the disparities in the income and social status of gestational women and commissioning couples, the choice, in practice, is not "free." Family pressures in non-commercial situations may also undermine a woman's ability to decide freely whether to participate.

There may also be significant psychological implications for gestational mothers even if they have participated willingly. Pregnancy produces physical and hormonal changes in a woman's body that can affect her emotions and therefore have the capacity to alter her relationships with her partner and any other children she has. These changes may also affect her own thoughts and feelings about what she is doing and the fetus she is carrying. These effects cannot be predicted precisely before pregnancy begins; yet preconception contracts often require gestational mothers to certify in advance that they will not form a maternal bond with the fetus during the nine-month gestation period and will relinquish all ties to the child soon after birth.

> Surrogacy contracts are not really a procedure — we cannot really say that they are a new reproductive technology, but we have to look into them just the same because they are becoming very prevalent in our society. We of course feel that they must be prohibited. Surrogacy contracts are another way of further partitioning the maternity experience, and another way of trading with women's bodies. We consider this a totally exploitive practice and we recommend that it be banned. [Translation]
>
> *C. Coderre, Fédération des femmes du Québec, Public Hearings Transcripts, Montreal, Quebec, November 21, 1990.*

Some who have investigated the practice contend that many gestational mothers seriously underestimate the emotional and psychological costs of giving up the child. In fact, there is a substantial body of medical, gynaecological, and psychological literature to support the view that the bonding that takes place during gestation should not be underestimated and that any forced separation between mother and child may result in lasting harm to the mother.

Some U.S. brokers have reported that gestational women tend to deny that the child they are carrying is their own and to see it as "belonging" to the commissioning couple. There is anecdotal evidence, however, that

women who relinquish a child with little distress at the time can later suffer from the experience. The long-term effects of relinquishment simply are not known, although an analogy can be drawn to studies focussing on adoption. The evidence suggests that the effects of relinquishment, including long-lasting grief, may be common to both practices.

If, on the other hand, the gestational mother decides not to relinquish the child, she may then have to cope with guilt or other feelings evoked by denying the commissioning couple the child they had anticipated. She could also face a court case over custody. Even if her attempt to keep the child is successful — whether because the commissioning couple does not challenge it or because she wins the custody case — she then faces the prospect of raising the child of another man with her husband or partner — or alone — with all the potential for strain on family relationships and finances that would entail.

Commercial preconception arrangements diminish women's status as equal members of society by giving credence to a perception of women as being of value for a reproductive capacity that can be bought and sold.

For commissioning women, the benefits of such arrangements are not unambiguous. Society attaches great importance to the genetic link between fathers and children, and the woman may perceive this as pressure to agree to the man's desire to have a genetically related child. She may believe, for example, that this is something she "owes" her husband because of her feelings of inadequacy at not being able to carry his child herself. Several commissioning women have also reported difficulty dealing with what many would consider a fundamentally unacceptable situation — in essence, their husband having a child with another woman. In short, the voluntary participation of commissioning women, like that of gestational mothers, may be in doubt. Commissioning women too risk being coerced, even if the pressures are subtle, into agreeing to a preconception arrangement.

Other sources of strain can arise as the couple raises the child. Although with arrangements involving zygote transfer to a gestational woman both members of the couple would be related to the child, in most instances this is not the procedure used. As in donor insemination for male infertility, just one member of the couple is genetically related to the child born as a result of a genetic-gestational arrangement. With donor insemination, it is the woman who is related to the child; with preconception arrangements using assisted insemination, however, it is the man. As discussed in Chapter 19 on the use of donor gametes, this may result in the perception that the couple's relationships with the child are unequal. The child may also become a symbol and constant reminder of the woman's infertility.

> A sign of the deeply personal aspect of procreation can be seen in the cruelly painful, tangled relationships brought about by surrogate motherhood cases ... The law must not attempt to replace this base of family relationship with its own arbitrary structure.
>
> *L. Moreau, Office of Marriage and Family Formation, Archdiocese of Vancouver, Public Hearings Transcripts, Vancouver, British Columbia, November 27, 1990.*

Although they are not participants in the arrangement, the resulting children can also be affected profoundly by it. First, they have been created not as ends in themselves but to serve the needs of others and, at least in part, to fulfil the financial goals of the broker and possibly those of the gestational woman and her partner as well. Second, there is the issue of multiple parenthood when genetic, gestational, and social roles are separated as a result of a preconception arrangement — a situation that we know, based on experience with adoption, can have a significant impact on a child's personal and emotional development and sense of identity.

Commercial preconception arrangements are too recent a practice for there to be adults who began their lives under these circumstances. There are, however, several potentially harmful psychosocial implications for the children. Although the child may be very much wanted and loved, he or she has nonetheless been "bought at a price," which could make the child feel like a commodity that can be bought and sold, and create pressure for him or her to live up to his or her "purchase price."

> The experience of maternal-fetal bonding during pregnancy and childbirth is unpredictable for the gestational mother. Where such bonding occurs, no woman should be expected to surrender custody of her child.
>
> *Brief to the Commission from the Canadian Advisory Council on the Status of Women, March 1991.*

Brokers have a service-oriented approach — their client is the commissioning couple, and the child is seen as a "product," as evidenced by the fact that the couple can opt out of the contract if the "product" is "defective." Also consistent with this approach is the fact that brokers generally do not screen prospective parents to ensure that the children will be going to suitable homes; ability to pay is the only prerequisite.

Finally, we have to consider the potential for conflict within families — for example, as a result of disapproval of the arrangement on the part of non-participating family members — and the effects this may have on children who feel, rightly or wrongly, that their existence is the source of the conflict.

The family of the gestational mother is also affected by her pregnancy. If she has other children, they see the child being given away and reportedly wonder whether they too could be relinquished by their parents. Her partner, if she has one, must make allowances for the physical and psychological changes of pregnancy, at the same time perhaps feeling resentful or jealous that his wife is carrying another man's child. Finally, the gestational mother's parents may be affected by the loss of a child that they see as their grandchild.

Social Harms

Beyond the impact on those directly concerned, commercial preconception arrangements have an impact on society and on social perceptions of the role and value of women, families, and children. Many witnesses told the Commission, for example, that they fear that these arrangements will reinforce a social definition of women in terms of their ability to bear children and the perception of their bodies as vessels or tools designed to serve the interests of others.

We heard many concerns that preconception arrangements will alter society's understanding of parenthood, family, and parental responsibilities, reducing parenthood to a transaction — a deal depending solely on the will of the adults who make it — with the child as the product of the deal. This is clearly contrary to any notion of children as ends in themselves, as human beings with their own dignity and identity. Society's view of children could be altered irrevocably as a result, with children being seen as a product, a commodity that can be bought and sold. By contrast, the trend in human rights over the past two decades has been toward increasing recognition of children as persons in their own right, not as parental property.

> Surrogate motherhood ... does nothing to enhance the view that women are equal to men, to being persons in their own right, but, rather, demoralizes and dehumanizes women. Children become assembly line commodities, "factory-built" and exploited.
>
> *R. Murray, Prairie Prolife of Portage la Prairie, Public Hearings Transcripts, Winnipeg, Manitoba, October 24, 1990.*

Sexual Inequality

Finally, we heard from Canadians that preconception arrangements perpetuate inequalities between men and women in our society, because they reinforce the idea that women's value is defined by serving men's needs and that men have a right to control women's bodies.

We live in a society that has been based, historically, on the idea that women's primary role is motherhood and that men have legal rights over

women's bodies. Many of those who oppose commercial preconception arrangements do so on the grounds that they perpetuate the assumption that women's role and value in society are defined by their sexual and reproductive functions and reinforce the notion that men have a right to control these functions.

The principle of equality means that every member of the community is entitled to equal concern and respect. Commercial preconception arrangements diminish women's status as equal members of society by giving credence to a perception of women as being of value for a reproductive capacity that can be bought and sold.

> The production of children for sale logically extends a particular condition of women that is historically longstanding: the commodification of their bodies. Pornography provides a useful analogy for understanding the meaning of "surrogate" motherhood. The commodification of women is at the core of both pornography and prostitution, in which women put their bodies, or, more precisely, body parts, up for sale as market objects.
>
> *C. Boodram, Edmonton Branch, Canadian Federation of University Women, Public Hearings Transcripts, Edmonton, Alberta, September 13, 1990.*

An Acceptable Practice: The Arguments for Commercial Preconception Arrangements

Those who believe that preconception agreements are an acceptable practice and warrant public policy support tend to argue from one of two general perspectives: the perspective of personal autonomy and rights or the perspective of medical necessity.

Personal Autonomy

The essence of the first argument is that a right to participate in a preconception arrangement is inherent in the right of couples to be free from state interference in their right to reproduce by sexual intercourse, which is protected by principles such as marital privacy and liberty. Proponents of this argument thus assert that there is a right to procreate, that those who cannot do so through sexual intercourse are entitled to use any other means at their disposal, and that people are entitled to the assistance of the state in exercising this right.

A second element of this perspective is the argument that a woman has a right to control her own body. Provided she is making a fully informed and free choice, it is argued, the state should not interfere in a woman's decision about whether to become a gestational woman:

We strongly believe that a woman has the right to make the decision if she chooses to be a surrogate. *(E. Mertick, Alberta Advisory Council on Women's Issues, Public Hearings Transcripts, Edmonton, Alberta, September 13, 1990.)*

Medical Necessity

Several physicians' organizations and other groups appearing before the Commission saw assisted insemination and *in vitro* fertilization in support of preconception arrangements as acceptable and medically justifiable responses to certain types of infertility (such as an absent or malformed uterus) or medical conditions in the commissioning woman (severe hypertension, diabetes, or heart condition):

> We are not necessarily recommending surrogacy. We are simply pointing out that under the right conditions, it may be that a woman with a disability would be assisted through a surrogacy arrangement.
>
> *Y. Peters, Canadian Disability Rights Council, Public Hearings Transcripts, Vancouver, British Columbia, November 28, 1990.*

We are in support of surrogacy in medically valid circumstances, that is a woman who has her uterus removed for some condition, who is not able to carry a child, who may have some condition that she would pass on to her child that would be life threatening to the child ... We neither support surrogacy for non-medical indications, nor do we support the commercialization of surrogacy agreements where valid medical indications may exist. *(R. Reid, Society of Obstetricians and Gynaecologists of Canada and Canadian Fertility and Andrology Society, Public Hearings Transcripts, Montreal, Quebec, November 22, 1990.)*

[We are not suggesting] that surrogacy is either right or wrong ... [The question is] whether or not a true need exists for this technology. Many women find themselves incapable of reproducing due to loss of uterine function as a result of surgical intervention for malignant disease, especially carcinoma of the cervix, which affects women in the child-bearing ages. These women are frequently in the prime of child-bearing age and are suddenly deprived of uterine function but not of ovarian function. Such women are ideal candidates for surrogacy in order to achieve their own genetic offspring. *(A. Yuzpe, Department of Obstetrics and Gynaecology, University of Western Ontario, Public Hearings Transcripts, London, Ontario, November 2, 1990.)*

Commercial Arrangements Unacceptable, Non-Commercial May Be Acceptable

The Commission also heard testimony from Canadians who find the commercial aspects of preconception arrangements abhorrent but take a

different approach to private, non-commercial arrangements. Several witnesses drew this kind of distinction between commercial and non-commercial arrangements:

> It has been an occasional practice cross-culturally and since time immemorial for women to bear children for other women known to them personally. These latter arrangements do not involve payment and often provide for continued interaction of all parties. [We do] not believe these arrangements pose problems for public values or the status of women. However, these non-commercial arrangements should be distinguished from the socially novel practice of commercial preconception contracts involving third-party mediation between a woman and other parties desiring children. *(Brief to the Commission from the Canadian Advisory Council on the Status of Women, March 28, 1991.)*

Other witnesses who made this distinction pointed to two factors: the danger of driving a practice underground by making it illegal, and reluctance to deprive people of an option that might permit them to form a family.

The second factor reflects the view of significant numbers of Canadians, according to surveys conducted for the Commission. The surveys revealed that opinion about preconception arrangements varies considerably with the type of arrangement involved (commercial or non-commercial) and the circumstances that lead people to seek a preconception arrangement. There was, however, no consensus on whether and what types of preconception arrangements should be permitted.

> If I have made at all clear what it has been like to be in my shoes lately, I do hope that you won't recommend an end to what my sister and I have done. Surrogacy, when done without exploitation of anyone, has, I believe, a place in this society.
>
> *Private citizen, Public Hearings Transcripts, Vancouver, British Columbia, November 26, 1990.*

One survey, for example, asked respondents whether a couple should consider a preconception arrangement if the woman had a medical condition that would be life-threatening if she became pregnant. Half the respondents (49 percent) disagreed with a preconception arrangement as the solution, 31 percent agreed, and 19 percent were neutral on the issue. In another survey, 58 percent of respondents disapproved and 23 percent approved of a preconception arrangement in the situation where the woman was infertile and the man's sperm was used to impregnate another woman.

The surveys showed that many Canadians do not wish to close the door on preconception arrangements, even if they would not participate themselves or would not advise others to do so. For example, 46 percent of respondents answering a general question (the situation of the couple was not described) said that a person who is infertile should be able to consider the use of a preconception arrangement; 30 percent said this is

something the person should not consider, and 24 percent remained neutral on the issue.

Finally, the surveys showed that a majority of respondents (61 percent) do not believe that preconception arrangements are likely to have a significant impact on society, largely because they will not be used very often. This no doubt reflects the fact that a large majority of respondents said that they would not participate in a preconception arrangement; 90 percent of women surveyed said that it was unlikely they would become a gestational mother in such an arrangement, giving such reasons as "I couldn't give away a baby I gave birth to" and "I wouldn't undergo pregnancy and birth unless it was my child."

Recognition that it would be virtually impossible to enforce a law prohibiting private, non-commercial preconception arrangements is reflected in this and similar testimony:

> It should be emphasized that the Council does not endorse surrogacy as a means of obtaining a child. It does recognize, however, that surrogacy does exist and feels that any effort to ban it would merely send the practice underground ... [I]f it goes underground and is something over which there is no control whatsoever, the children and the women will be victims ... we don't see this as an ideal situation. *(L. Newson, National Council of Women of Canada, Public Hearings Transcripts, Saskatoon, Saskatchewan, October 25, 1990.)*

Given this situation, some witnesses argued, the best approach is to try to reduce the opportunities for abuse or exploitation and to provide for the interests of any children that are born:

> Our attitude is that surrogacy per se is not something that should be specifically encouraged, but also it should not be banned altogether. Therefore the general conclusion we reached ... is that non-commercial, non-binding arrangements that of necessity must be based on generous, sincere motives should not be criminalized or otherwise banned ... We would acknowledge, therefore, the evidence of the existence of this practice and provide an appropriate legal response. *(J. Dillon, Canadian Bar Association, Public Hearings Transcripts, Vancouver, British Columbia, November 27, 1990.)*

Still others saw dangers in tolerating even non-commercial arrangements between close family members:

> No, we do not accept surrogacy between sisters. We consider that the commodification of the human body is absolutely to be condemned. This is a basic ethical principle, but we believe that even in the case of sisters, it opens the door to other things. [Translation] *(L. Fortin, Les Cercles de Fermières du Québec, Public Hearings Transcripts, Montreal, Quebec, November 22, 1990.)*

The Commission's Assessment

As the preceding sections make clear, preconception arrangements raise ethical and legal issues that are neither straightforward nor easy to deal with. As Commissioners listened to the continuing debate about this practice, one conclusion became evident: proponents and opponents are not likely to change each other's minds about the ethical and social dimensions of preconception arrangements. Views on preconception arrangements are based on fundamentally different convictions about human nature and about how the world works or ought to work; therefore, assessments of the actual or potential implications of preconception arrangements for women, for children, for couples, and for our evolution as a society also differ.

Commercial Arrangements

Using our ethical framework and standards, the Commission finds commercial preconception arrangements offensive on several grounds.

First, they offend human dignity by commodifying women's reproductive capacities and commodifying children; they contradict the principle that human reproduction should not be commercialized in any way. Second, we see actual and potential harms for families, for individual women and children, and for specific groups within society. Finally, we believe that public policy that condones or supports the establishment of adversarial relationships is fundamentally flawed; public policy should seek instead to support and encourage humane, non-conflictual family and social relationships. Any attempt to legitimize or support commercial preconception arrangements through public policy would represent the antithesis of this goal.

Commodification of Children and Reproduction

The fundamentally repugnant aspect of preconception arrangements is that they instrumentalize human beings through the deliberate act of creating a child for the express purpose of giving it up, usually in exchange for money. The premise of commercial preconception contracts is that a child is a product that can be bought and sold on the market. The moral point of view requires that people be treated as ends in themselves, not as a means to the ends of others. We must therefore uphold the value of children in and of themselves. Children are not a commodity, nor are they instruments to be used to serve the purposes of others. The commodification of children entailed by preconception arrangements ignores these essential values.

Moreover, commercial preconception arrangements commodify women's reproductive functions and place women in the situation of alienating aspects of themselves that should be inherently inalienable. A

preconception contract obliges the gestational mother to sell an intimate aspect of her human functioning to provide someone else with a genetically related child; the capacity to become pregnant and bear a child is reduced to a marketable service. We do not allow people to give up their freedom and become slaves, even if they make a choice to do so, because of our collective conviction that this would negate the value we attach to human dignity and the inalienability of the person. Similarly, assigning a commercial value to the human function of reproduction would result eventually in a new and, in our view, undesirable social understanding of the value and dignity of women, their reproductive capacity, and their bodily integrity.

Commercial preconception contracts by their nature — the exchange of money for a child — contradict one of the fundamental tenets of the Commission's ethical framework. On these grounds alone, we could recommend prohibition of such arrangements, since we believe that all public policy in this field should be based on the principle of non-commercialization of reproduction.

A preconception contract obliges the gestational mother to sell an intimate aspect of her human functioning to provide someone else with a genetically related child; the capacity to become pregnant and bear a child is reduced to a marketable service.

The evidence is clear that in commercial preconception contracts the principal motivation of both the broker and the gestational woman is money. Far from being the idyllic situation portrayed by brokers — gestational woman as "altruistic angel" giving the gift of a child to a couple who is happy but infertile — commercial preconception contracts are business transactions. The child is a product being sold by one party and bought by the other.

Harms to Individuals

The Commission heard strong arguments that preconception arrangements are detrimental to the autonomy of gestational mothers. We concur. Far from enhancing the gestational woman's autonomy, as some have argued, the practice circumscribes and dictates the gestational woman's behaviour by specifying contractual obligations, including the obligation to be treated by medical personnel selected by the commissioning couple, to have an abortion if the commissioning couple so decides, and to renounce her maternal feelings and rights even before conception. Again, we believe there is clear evidence of the potential for coercion and exploitation of gestational women because of the disparities in power and resources between gestational women and commissioning couples.

A commissioning couple uses a woman as a vehicle to serve their own ends. As the New York State Task Force on Life and the Law observed, they

seek the birth components of gestation from the gestational woman while denying the personal, emotional, and psychological dimensions of her experiences and self. If she succeeds in denying her emotional responses during this profound experience, she is dehumanized in the process. If she fails, her attachment to the child produces a conflict that cannot be resolved without anguish for all involved.

> Children are not a commodity, nor are they instruments to be used to serve the purposes of others. The commodification of children entailed by preconception arrangements ignores these essential values. Moreover, commercial preconception arrangements commodify women's reproductive functions and place women in the situation of alienating aspects of themselves that should be inherently inalienable.

Moreover, informed choice is a necessary component of autonomy. As we have seen, however, brokers arranging preconception arrangements are not neutral intermediaries; they act in the interests of the commissioning couple. If the gestational mother has her own lawyer, it is often one recommended by the broker. Furthermore, since so little is known about the psychosocial effects of these arrangements on the participants and the resulting child, the woman's decision cannot be made in light of all the information that might influence it. All these factors undoubtedly undermine her capacity to exercise informed choice in deciding to enter a preconception arrangement.

We also conclude that concerns about negative psychosocial consequences for the gestational mother are well founded, particularly because it is impossible for her to predict, at the time she signs the contract, how she will feel about fulfilling its terms after the child has been born.

Even if fully informed choice were possible, society has established certain limits on what people are free to make choices about. Such situations are rare but central to our definition of the kind of society we want to live in. Thus, in a caring society, personal autonomy is not a value that trumps all others, and society may see fit to place limits on the exercise of free choice when the choice concerns an activity that society regards as fundamentally incompatible with values such as respect for human dignity and the inalienability of the person.

We heard the view that preconception arrangements enhance women's autonomy by giving substance to their right to control their own bodies — by allowing them to decide for themselves the meaning and social implications of their ability to bear children. We reject this argument. Although they are strongly held values, freedom and autonomy do not include the right to engage in activities that will result in harms to others, particularly, as in this case, to the child that is eventually born; the limits of autonomy become apparent when its exercise will harm others, as the commodification of children most certainly does.

Harm to children born as a result of these arrangements cannot be ignored. Commissioners reject the argument that these harms could be outweighed by the opportunity for life, as this argument assumes the very factor under deliberation — the child's conception and birth. We concur with the assessment of the New York State Task Force on Life and the Law: "The assessment for public policy occurs prior to conception when the ... arrangements are made. The issue then is not whether a particular child should be denied life, but whether children should be conceived in circumstances that would place them at risk." Nor do we see any practical way of protecting the interests of the child that will eventually be born or even of ensuring that they are taken into account in negotiating and concluding a preconception arrangement.

> In a caring society, personal autonomy is not a value that trumps all others, and society may see fit to place limits on the exercise of free choice when the choice concerns an activity that society regards as fundamentally incompatible with values such as respect for human dignity and the inalienability of the person.

Commercial preconception arrangements do produce benefits — but the benefits are to brokers and commissioning couples at the expense of the interests of vulnerable women and of children who had no part in the arrangement.

Harms to Society

We agree with those who argued that commercial preconception arrangements have potentially negative consequences not only for individuals but also for women collectively and for other groups in society. These arrangements reinforce social attitudes about motherhood as the role that defines women's status and value in society. Furthermore, preconception arrangements could create broad social harms by diminishing the dignity of reproduction and undermining society's commitment to the inherent value of children.

Even if the number of commercial preconception arrangements to date has been relatively small, over time such arrangements would be bound to have a detrimental effect on the way society perceives women, children, and reproduction generally.

In short, we reject the notion that public policy can be based on a description of procreation in terms of a market production model — which is, essentially, that such arrangements should be permissible and legally enforceable because commissioning couples are willing to pay and gestational women are free to sell their labour. Second, we do not accept that the freedom to procreate automatically assumes a right to state support — whether in the form of enforceable contracts or publicly supported medical services — for the exercise of that right. Finally, we

reject the arguments of proponents because they are premised on incomplete or inaccurate depictions of preconception arrangements, making them an inappropriate basis for public policy, which must take into account not only the interests of the participants, but also the other interests affected, including those of the resulting child, as well as the potential for individual and/or social harm.

> We reject the notion that public policy can be based on a description of procreation in terms of a market production model — which is, essentially, that such arrangements should be permissible and legally enforceable because commissioning couples are willing to pay and gestational women are free to sell their labour.

We also reject the argument of medical necessity. We find it unacceptable that one party — the gestational woman — should be called upon to bear all the medical risks of pregnancy and birth, and possibly those of *in vitro* fertilization and zygote transfer, while all benefits accrue to the commissioning couple. In no other circumstances does society accept that a healthy person be placed at medical risk for the benefit of someone else for money, even when that condition is life-threatening. In this case, the commissioning woman's infertility is *not* life-threatening.

The commonly understood motivation for commissioning couples to enter into a preconception arrangement is because the commissioning woman is unable to conceive and/or carry a fetus to term. This makes preconception arrangements appear as a last resort when infertility is untreatable or treatment has been unsuccessful. As we have seen, however, this is not always the case; not everyone who seeks a preconception arrangement is involuntarily infertile, a member of a couple, or even of childbearing age. But even in cases where it is true, preconception arrangements are not an acceptable remedy.

Goals of Public Policy

As we have argued elsewhere in this report, one goal of public policy in the field of new reproductive technologies should be to seek to prevent conflict — or, at the very least, to avoid knowingly setting up situations where conflict is bound to result. Instead, we would seek to foster healthy family and social relationships through such means, for example, as promoting greater social acceptance of family ties based on other than a genetic component.

The Commission recognizes the value of public policy that supports people's attempts to establish families, and we uphold women's right to autonomy. We believe, nevertheless, that preconception arrangements can cause damage to children, families, and society as a whole and can actually limit, rather than enhance, women's autonomy. We recognize the genuine and legitimate desire of couples who are infertile to have children; but this

should not take precedence over the best interests of children, which lie in not being the object of a contract, agreement, or paid transaction.

We believe further that preconception arrangements contradict the ethic of care, as they result — inevitably and intentionally — in the breaking of parental bonds and in strain on family relationships. They can also result in long, acrimonious conflict, in court and in the media, between the gestational woman and the commissioning couple; far from preventing conflict, preconception arrangements actually make conflict more likely.

In reaching our conclusions, we also took into account the Commission's public hearings, consultations, and surveys, which illustrated the ambivalence of Canadians' attitudes toward commercial arrangements. Canadians have seen what has happened in the United States, where several cases have come to public attention through bitter custody disputes, and do not want to see these events repeated here. At the same time, as we saw in our survey of people across the country, Canadians attach great value to having children and appear reluctant to deny others the opportunity to have a child, even if it means permitting a practice they do not condone or would not engage in themselves. It is not clear, however, that public opinion about preconception arrangements is based on a full understanding of their nature and implications, because much of the public information about them comes from brokers or others with an interest in portraying the practice in a positive light.

In some circumstances a preconception arrangement may seem a reasonable response to a particular situation. For example, where a woman has a serious health problem that prevents her from carrying a pregnancy, she might seek a gestational woman to carry a fetus conceived using the commissioning woman's eggs and her partner's sperm. Given the broader social harms we have described, however, we do not believe that using another woman's reproductive capacity is justifiable even in this situation, as difficult as it might be for the individuals involved to accept their inability to have a genetically related child.

> Even if a regulatory system could be designed to overcome these obstacles, the deepest and most serious harms of preconception arrangements would remain. No regulatory system could remedy the basic affront to human dignity occasioned by the commodification of children and the commercialization of reproduction.

We do not deny that a public response in the form of regulation could help to control some of the pressures and abuses identified with respect to preconception arrangements — for example, by requiring the provision of independent legal advice for gestational women or by making counselling mandatory for all parties to an arrangement. We are sceptical, however, that any regulatory scheme could ensure that all parties were able to make free and informed choices. Moreover, a regulatory approach by its nature would invite disputes and conflict.

Even if a regulatory system could be designed to overcome these obstacles, the deepest and most serious harms of preconception arrangements would remain. No regulatory system could remedy the basic affront to human dignity occasioned by the commodification of children and the commercialization of reproduction.

Non-Commercial Arrangements

The Commission's conclusions with respect to non-commercial preconception arrangements between family members or close friends are similar. We do not believe such arrangements should be undertaken, sanctioned, or encouraged. The motivation might be sincere and generous, but the arrangement still results in the commodification of a child and the reproductive process. Even if no money is involved, no one should have the right to make a "gift" of another human being; this is offensive to the human dignity of the child.

Non-commercial arrangements present the potential for coercion in the form of family pressure to participate. They also give rise to the possibility of damage to family relationships before or after the child is born, as well as even greater potential for confusion on the part of the child, because of continuing contact between the birth mother and the commissioning couple. Moreover, the arrangement still results in a healthy woman being placed at medical risk for the benefit of someone else.

At the same time, we recognize that the practice may continue to some degree and so demands a public policy response, particularly because of the uncertainties surrounding the legal status of a child born as a result of such an arrangement and the need to ensure that the child's best interests are served. We wish to make it clear, however, that our recommendations in this latter regard are not intended to sanction the practice, but simply to recognize that it is probably going to occur and that, in the absence of public policy, significant harm to children could result.

Recommendations

Commissioners are strongly of the view that preconception arrangements are unacceptable and do not warrant state support in any form that would signal acceptance or encouragement of them. We do not advise sanctions with respect to gestational mothers, however, as this would simply compound their vulnerability. While we recognize the vulnerability of couples who are infertile and their emotional needs, we believe that making payment for such arrangements should be prohibited. We also believe it is essential, in particular, to prohibit others from assisting in such arrangements — for example, brokers and physicians — by criminalizing the knowing provision of assistance. With these principles

in mind, the Commission reviewed the options available and came to the following recommendations to prohibit commercial preconception arrangements.

Our first goal is to ensure that the status of this practice is uniform across the country, to discourage people from travelling to parts of the country where it is permitted. Evidence before the Commission shows that arrangements can take place across provincial/territorial borders. Thus, prohibition only at the provincial level would not be effective with respect to such arrangements. Hence, we sought a comprehensive, uniform, and effective approach to preconception arrangements across the country. This can be achieved by prohibiting certain activities aimed at facilitating such arrangements for gain. Accordingly, the Commission recommends that

199. The federal government legislate to prohibit advertising for or acting as an intermediary to bring about a preconception arrangement; and to prohibit receiving payment or any financial or commercial benefit for acting as an intermediary, under threat of criminal sanction. It should also legislate to prohibit making payment for a preconception arrangement, under threat of criminal sanction.

This proposed criminal prohibition will serve as an effective deterrent to commercial preconception arrangements. Given our recommendations with respect to donor insemination and *in vitro* fertilization (donor insemination restricted to anonymously donated sperm collected by a licensed facility, *in vitro* fertilization restricted to licensed facilities and offered only for diagnosed fallopian tube blockage), physicians too would be barred from participating in any such arrangement.

Second, statutory provisions making preconception contracts unenforceable would operate as a strong deterrent to the practice, because they would generate uncertainty for the commissioning couple, whether or not a broker has been involved. Such provisions would ensure that the gestational woman could not be compelled by a court to give up custody of a child born as a result of a preconception agreement. The Commission therefore recommends that

200. Provinces/territories amend their family law legislation to specify that all preconception agreements, whether or not they involve payment, are unenforceable against the gestational woman.

Commissioners do not wish to leave the impression that we consider non-commercial arrangements acceptable or to imply that non-commercial

arrangements have no potential to harm individual women, the status of women generally, children and families, or society at large. However, we believe that the most effective way to deter non-commercial arrangements is to provide for penalties for third parties who facilitate preconception arrangements. The Commission recommends that

201. Self-regulating professional bodies, such as provincial colleges of physicians and surgeons and provincial law societies, adopt strict codes of conduct, disciplinary measures, and severe penalties, including loss of licence to practise, against members involved in brokering or performing assisted insemination, *in vitro* fertilization, or zygote/embryo transfer to facilitate a preconception arrangement.

and that

202. Any facility knowingly providing assisted conception procedures in support of a preconception arrangement lose its licence to provide assisted conception services.

It is important to ensure that the interests of any resulting children are protected. In particular, establishing their legal parentage is vital for the children and for the other participants, as it affects the rights and obligations of the parties with respect to custody, access, support, and inheritance. Without clarification of legal parentage, children could be deprived of the support they are owed and become subject to the trauma of protracted litigation. For these reasons the Commission recommends that

203. All provinces/territories that have not already done so amend their family law legislation to ensure that a woman who gives birth to a child is considered the legal mother of the child, regardless of the source of the egg.

204. As in the case of adoption, the birth mother be allowed to relinquish her maternal rights only after a minimum waiting period following the birth of the child.

and that

> **205. In any dispute over custody arising from a preconception arrangement, the best interests of the child prevail over the interests of the adults involved.**

Finally, in support of our international obligations, Commissioners believe that Canada should demonstrate leadership by supporting policies aimed at achieving an international ban on preconception arrangements. Given that Canadians could go to other countries, particularly the United States, to seek arrangements not permitted in this country, we believe that such a step is needed on the part of the international community to prevent the exploitation of women and the commodification of children. Adopting a domestic policy would be the first step toward this goal; encouraging other countries to adopt similar measures would reinforce and extend it.

The extent to which Commissioners deplore the practice of preconception arrangements is evident in our determination to recommend strong measures to discourage these arrangements and to penalize those who would seek to benefit financially from them. Our goal is to halt commercial practices entirely and to discourage others from participating in these arrangements. We recognize the value Canadians attach to having a genetically related child. In our view, however, this value cannot be upheld in the face of the other values that would have to be sacrificed. A caring society has an obligation to ensure that individual actions — even those intended to benefit others — do not generate greater social harms, and that public policy works to support and foster healthy family and social connections, not to undermine them or set them up to fail.

Preconception arrangements illustrate the ethical dilemmas posed by situations where both benefits and harms can result from a practice. In this case, however, the benefits to a few individuals are far outweighed by the harms to others and to society that are likely to result. This is why we have adopted such a strong stand against preconception arrangements. Taken together, Commissioners believe, the measures we propose will have a strong deterrent effect on preconception arrangements and, in particular, on third-party activities in this area, but without compounding the vulnerability of participants.

General Sources

Decima Research. "Social Values and Attitudes of Canadians Toward New Reproductive Technologies." In Research Volumes of the Royal Commission on New Reproductive Technologies, 1993.

de Groh, M. "Reproductive Technologies, Adoption, and Issues on the Cost of Health Care: Summary of Canada Health Monitor Results." In Research Volumes of the Royal Commission on New Reproductive Technologies, 1993.

Eichler, M., and P. Poole. *The Incidence of Preconception Contracts for the Production of Children Among Canadians.* Report prepared for the Law Reform Commission of Canada. Toronto: Ontario Institute for Studies in Education, 1988.

Guichon, J.R. "'Surrogate Motherhood': Legal and Ethical Analysis." In Research Volumes of the Royal Commission on New Reproductive Technologies, 1993.

Law Reform Commission of Canada. *Medically Assisted Procreation.* Working Paper 65. Ottawa: Minister of Supply and Services Canada, 1992.

New York State Task Force on Life and the Law. *Surrogate Parenting: Analysis and Recommendations for Public Policy.* New York: The Task Force, 1988.

Ontario Law Reform Commission. *Report on Human Artificial Reproduction and Related Matters.* Toronto: Ontario Ministry of the Attorney General, 1985.

SPR Associates Inc. "An Evaluation of Canadian Fertility Clinics: The Patient's Perspective." In Research Volumes of the Royal Commission on New Reproductive Technologies, 1993.

Stephens, T., and J. McLean. "Survey of Canadian Fertility Programs." In Research Volumes of the Royal Commission on New Reproductive Technologies, 1993.

Uniform Law Conference of Canada. *Proceedings of the Seventy-Third Annual Meeting, Regina, 1991.* Toronto: ULCC, 1991.

Williams, L.S. "Legislation, Inquiries, and Guidelines on Infertility Treatment and Surrogacy/Preconception Contracts: A Review of Policies in Seven Countries." In Research Volumes of the Royal Commission on New Reproductive Technologies, 1993.