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

V O L U M E 1

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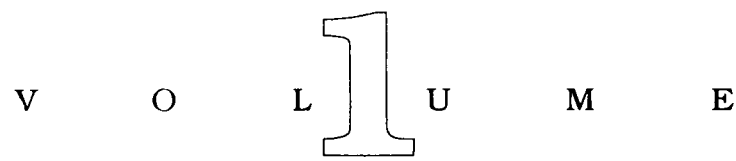

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Consistent with the Commission's commitment to full equality between men and women, care has been taken throughout this text to use gender-neutral language wherever possible.

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,

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Preface from the Chairperson

When Commissioners were given the task of recommending how new reproductive technologies should be handled in this country, we recognized that it was a complex and demanding task and that there were no easy answers. It is difficult because there is tension between the potential benefits the technologies can bring — which are to enable people to have a family and healthy children, goals important to most of us — and the potential harms to health and well-being they can also bring to individuals, groups, and social institutions.

We are facing unprecedented choices about procreation. Our response to those choices — as individuals and as a society — will say much about what we value and what our priorities are. It is therefore important that policies be based on very wide input and consultations. In this report, with our understanding deepened by the many views and perspectives we have heard and the evidence we have reviewed, the other Commissioners and I have made it clear what we believe our choices, as a caring society, should be.

We reached three overall conclusions about the delivery of new reproductive technologies. First, there is an urgent need for well-defined boundaries around the use of new reproductive technologies, so that unethical use of knowledge is not permitted. Second, within those boundaries, accountable regulation is needed to protect the interests of those involved, as well as those of society as a whole. Third, given the ongoing and, indeed, increasing pace of knowledge and development, a flexible and continuing response to evolving technologies that involves wide input from Canadians is an essential component of their responsible delivery.

We set three broad goals for our work: to provide direction for public policy by making sound, practical, and principled recommendations; to leave a legacy of increased knowledge for Canadians and others about new

reproductive technologies; and to enhance public awareness and understanding of the issues surrounding new reproductive technologies, so that ongoing public participation in determining the future of the technologies and their place in Canadian society would be facilitated.

The first goal has been achieved in the two volumes of this report. Our recommendations provide a detailed blueprint for how Canadians can deal with new reproductive technologies in this country, so that any use made of the technologies is in the service of our values. Throughout the report, we have made clear the evidence and the explicit framework we used to arrive at our policy recommendations — so as to make the reasoning behind our conclusions and recommendations evident.

The second goal has been fulfilled in the publication of the 15 volumes of research studies that accompany this report. The Commission developed and gathered an enormous and comprehensive body of information and analysis on which to base its recommendations, much of it available for the first time in Canada or indeed anywhere. The most qualified researchers in Canada participated in our research program — over 300 scholars and academics across the country representing more than 70 disciplines, including the social sciences, humanities, medicine, genetics, life sciences, law, ethics, philosophy, and theology.

Our third goal was to bring the issues before the public so as to encourage ongoing participation by Canadians in determining the future of the technologies and their place in our society. Although inquiries in other countries have addressed these issues and made recommendations, our Commission was the first that was able to consult widely and directly with citizens and benefit from substantial public input and participation. Many thousands of people attended public hearings or panel discussions, saw those discussions broadcast on cable television across the country, made written submissions, called our toll-free telephone lines for information or to express their opinions, talked to us about their own experiences with new reproductive technologies, or participated in research colloquia, workshops, and other consultations — in all, more than 40 000 Canadians participated. We sent out a newsletter, *Update*, and the research studies published in advance of this report were collected by academics, students, women's groups, and other groups working in this area and are available in libraries across the country. All these activities were important in helping us reach our conclusions, but they will also better equip Canadians to participate in and have input into how we will deal in an ongoing way with the issues as they evolve in Canada.

In a changing field of knowledge such as new reproductive technologies, new developments will require continuing attention by society regarding their implications and what needs to be done. Implementation of our recommendations will put in place the framework for this needed ongoing discussion, dialogue, limitation, and monitoring of the technologies.

Along with the other Commissioners, I wish to thank the very many Canadians who were involved in all facets of the Commission's work. Their contribution has been invaluable.

I would also like to acknowledge the efforts of a wide range of groups, for example the Canadian Coalition for New Reproductive Technologies, to have this Commission created, and the federal government for heeding their calls. We hope that the government will listen equally carefully to the calls for change that we make in this report and act promptly to implement our recommendations.

Appreciation and thanks are due to the researchers and to the external reviewers, who have given tremendous amounts of time, expertise, and thought to the Commission. I would also like to say how grateful I am to the Commission staff for their dedication, hard work, and commitment over the life of the Commission — they have gone many extra miles.

I would like to formally thank my four colleagues — my fellow Commissioners — for the spirit of collaboration, exploration, and cooperation with which they approached our work. We have all learned much and all felt a great responsibility to address the issues in as caring and wise a way as we can.

The issues this report has dealt with are important to us all. We hope governments and Canadians will use the detailed blueprint we have provided to make changes to the present unsatisfactory and harmful situation. Canada as a society can obtain benefits of technology for its members, but it also needs to protect them against harms from misuse.

We believe that, if we care about each other's well-being, the path we should take to deal with new reproductive technologies is clear. It is now up to governments and the people of Canada to decide whether they will take it. We believe it is critical that they do.

Patricia Baird

Patricia Baird

Chairperson
Royal Commission on New Reproductive Technologies

A Note on the Report

It is important that as many Canadians as possible, not just experts and academics, become aware of and understand the issues, so that they may participate in how we deal with new reproductive technologies in this country. In support of that goal, the Commission intends this report to be accessible to the general reader. The issues we are examining are complex and a certain amount of technical detail is unavoidable, but most of these details are provided in information boxes, which are set apart from the main body of the text.

In addition, quotations from the many groups and individuals who participated in the Commission's work are interspersed throughout the text; these reflect the extensive input the Commission received and the wide range of views we heard.

Executive Summary

The mandate of the Royal Commission was to examine how new reproductive technologies should be handled in Canada. Having children and healthy families are important goals to most Canadians, but some people cannot reach those goals without help. If there are technologies that can be used to help, a caring society should provide these. But there are misuses and harms, as well as benefits, that may come from use of the technologies — harms to both individuals and society.

We undertook our task by consulting very widely. As well as public hearings and submitted briefs, we had toll-free telephone lines, public surveys, and other avenues for Canadians to have input. In all, more than 40 000 people were involved in our work. We carried out a canvassing and examination of the issues that was extensive in both width and depth, with research projects and analyses in many disciplines, among them the social sciences, ethics, law, and medicine. More than 300 researchers at institutions across the country conducted projects for us.

We came to our conclusions in light of this widely based input and evidence, with three considerations in mind: a set of explicit ethical principles, the values of Canadians, and a conviction that offering any medical procedure as a service must be based on evidence that it works.

In spite of the existence of standards and guidelines recommended by various professional associations, we found that a varied patchwork of practices exists. Some practices are dangerous, such as donor insemination using sperm from donors who have not been tested for HIV. Some are harmful to the interests of the children born through the use of various technologies, such as the lack of records kept on their origins. Some are not respectful of women's choices, such as the finding that a woman's chance of being referred for prenatal testing varied more than fourfold across the country, despite the fact that women's attitudes toward testing varied relatively little. We found insufficient emphasis on the

prevention of infertility. We found some discriminatory practices in access to services, some clinics preparing to carry out procedures to allow surrogacy, and some commercial clinics existing to treat sperm to allow sex selection. Procedures are being offered as treatments without good evidence that they are effective, when they should be offered only in research trials. There are technologies on the horizon, such as embryo splitting and use of eggs from female fetuses for implantation. Our ethical analyses showed that some technologies and some uses of technology that are now possible or will be possible in the near future would contravene Canadian values.

It is clear that the situation with regard to the use of new reproductive technologies needs to be addressed; the issues will not go away — in fact, the field is growing, and potential uses are expanding. As this report went to press, the media were reporting the cloning of a human zygote. This vividly underscores the need to have in place a structure to deal with this evolving field in a way that takes into account the values and input of Canadians.

We conclude that government, as the guardian of the public interest, must act to put boundaries around the use of new reproductive technologies, and must put in place a system to manage them within those boundaries, not just for now, but, equally important, in an ongoing way. We therefore have two recommendations. First, we recommend legislation to prohibit, with criminal sanctions, several aspects of new reproductive technologies, such as using embryos in research related to cloning, animal/human hybrids, the fertilization of eggs from female fetuses for implantation, the sale of eggs, sperm, zygotes, or fetal tissues, and advertising for, paying for, or acting as an intermediary for preconception (surrogacy) arrangements.

Second, we recommend that the federal government establish a regulatory and licensing body — a National Reproductive Technologies Commission (NRTC) — with licensing required for the provision of new reproductive technologies to people. Only the federal government can set up such a system, and it is important that the government fulfil its responsibility to protect citizens and society by doing so.

Several requirements are common to all the technologies: the need for reliable information to guide policy and practice; the need for standards and guidelines for the organization and provision of services; the need for effective means to ensure compliance; and the need for accountability. The approach we propose builds on the best standards and practices of the medical specialties involved, which are already in use in some Canadian clinics. These standards should be expanded and should be embodied in a licensing system.

We recommend the NRTC be composed of 12 members, representing a broad range of experiences and perspectives. Consultation activities should be undertaken to further enhance public input and involvement.

Women should make up a substantial proportion — normally at least half — of the Commission's membership.

To ensure wide public input into the working of the system and to deal with setting policy as new issues evolve, we recommend that membership in the proposed NRTC should include persons with a broad range of experiences and perspectives, including the perspectives of those with disabilities, those who are infertile, and those who are members of racial minorities. A range of expertise should be represented, including reproductive medicine, ethics, law, and social sciences.

We recommend the NRTC have five areas of regulatory responsibility, in which the provision of services would be subject to compulsory licensing through five sub-committees established for that purpose. These areas are:

- sperm collection, storage, and distribution, and the provision of assisted insemination services;
- assisted conception services, including egg retrieval and use;
- prenatal diagnosis;
- research involving human zygotes (embryo research); and
- the provision of human fetal tissue for research or other specified purposes.

Licence hearings should be public, and a licence would be conditional on compliance with certain standards and stipulations of license. The major functions in these five areas of regulatory authority would be to:

- license, set standards, and monitor practice;
- collect, evaluate, store, and disseminate information;
- consult, help coordinate, and facilitate intergovernmental cooperation in the field; and
- monitor future technologies and practices and set policies for them.

In addition, we recommend the establishment of a sixth sub-committee, with primary responsibility in the field of infertility prevention. Its responsibilities would include the compilation and evaluation of data pertaining to the causes of infertility, the promotion of cooperative research efforts in Canada and internationally, and regulatory, public education, or other options for preventing or reducing the incidence of infertility.

With full implementation of these recommendations, a consistent country-wide system for the regulation of reproductive technologies and the provision of related services would emerge, with the following attributes:

- Assisted insemination, *in vitro* fertilization, and related infertility treatments would be provided only by licensed facilities, with national standards of service (related to matters such as counselling, informed disclosure and consent, standardized calculation of success rates, and

consistent record keeping) as conditions for obtaining and keeping a licence to provide these services.

- A national sperm collection and distribution system would be in place to ensure the availability of safe sperm, quarantined until donors are tested for infectious diseases, for use in assisted insemination in a medical setting or in self-insemination. The system would include comprehensive confidential record keeping on donors and recipients, with non-identifying information on the donor available to the recipient and child, and personal identification kept secure and available only in court-ordered cases.
- Prenatal diagnostic services would be provided only by licensed facilities, with national standards established and monitored through the licensing system. Prenatal ultrasound and testing of pregnant women's blood for congenital anomalies or genetic disease in the fetus would be provided only through provincially licensed or mandated programs. The structure would assure Canadians that genetic knowledge is applied in human reproduction in an accountable way and within acceptable limits — for example, not used for purposes of sex selection.
- A mechanism would be in place to facilitate multicentre trials and other research needed to assess the safety and effectiveness of reproductive technologies. It would promote interprovincial co-operation to mount the large-scale research projects needed to provide information on which to base health care service provision and resource allocation decisions.
- Once their risks and effectiveness had been assessed, infertility treatment and prenatal diagnostic services would be provided solely through provincial health care systems. Other treatments or procedures would be provided only in the context of research, with fully informed participation by volunteer research subjects and with rigorous protections for them. To preclude the development of commercial services, licensing conditions would include a stipulation that services not be offered on a for-profit basis.
- Annual reporting to the National Commission by licensed facilities would provide data that would allow evaluation of any long-term effects of treatments on the health of women or on their children.
- Any provision of fetal tissue for research would be licensed, so that it is used only in an accountable and ethical way according to guidelines, with permission for tissue use obtained separately from and subsequent to the decision to terminate a pregnancy.
- Any embryo research would be conducted only in licensed facilities, so that such research is carried out in an accountable and ethical way and in accordance with guidelines, including limitations on the

purposes for which research can be undertaken, and permitted only during the 14 days immediately following fertilization.

- A focal point for national action would be in place to support and encourage infertility prevention initiatives, to foster consultation and co-ordination of efforts among the many sectors involved, and to promote public education and research in Canada and internationally on the risk factors for and prevention of infertility.
- Canada would have a visible and continuing forum to monitor developments, promote public discussion, and develop public policy advice on the use of assisted reproductive technologies, prenatal diagnostic technologies, embryo research, research involving the use of fetal tissue, and other rapidly evolving or emerging technologies.

Getting There from Here

Commissioners are strongly of the view that the establishment of a National Reproductive Technologies Commission of the type we recommend must be an immediate federal priority. We believe that a National Commission presents the only feasible response to the clearly demonstrated need and justified public demand for coherent, effective, and appropriate national regulation of new reproductive technologies. The field is developing too rapidly, the consequences of inaction are too great, and the potential for harm to individuals and to society is too serious to allow Canada's response to be delayed, fragmented, or tentative.

A central goal of our recommendations is to enable individual Canadians to make personal decisions about their involvement with the technologies, confident in the knowledge that mechanisms are in place to assess their safety and effectiveness and to consider their ethical, legal, and social implications. Individuals have a responsibility to inform themselves as fully as possible before making such decisions, but government, on behalf of citizens, has a responsibility to ensure that inappropriate and unethical use of technology is prohibited and that the procedures and supports necessary for informed decision making are in place.

The regulatory framework we propose is essential to provide this assurance, but by itself it is not sufficient. Strong leadership and co-operation will be required among governments and professionals involved in the development and delivery of reproductive technologies, as well as among many other sectors of society. No group or institution can act effectively in isolation — partnership and cooperation among federal and provincial/territorial governments, professional organizations, patient groups, and other interested groups are critical.

Establishing such a system will take some time — although we should note that other countries have succeeded in putting their systems in place

within a relatively short period after their own inquiries. Nevertheless, some time will be required to appoint members of the Commission, establish and appoint its sub-committees, and carry out detailed implementation of the licensing system. Time will be needed to hold an initial round of licensing hearings, design secure record-keeping systems, and identify specific data collection methods and reporting forms.

The need for comprehensive action at the national level does not preclude the need for provincial and professional responses. Nor do provinces or the professions need to wait for a federal response before taking action themselves.

Provinces can take immediate steps to control the provision and proliferation of reproductive technologies in the health care system through the evidence-based approach we recommend. Practitioners now offering services can respond to the concerns Canadians raised before the Royal Commission and to the issues we have identified in the report. Professional associations can ensure that all their members are aware of the existing guidelines for practice and can promote more complete adherence to these standards among their members. Technology users and groups representing them can use the report of the Royal Commission to press for government and professional action. In the meantime, individual Canadians contemplating the use of reproductive technologies can use the information we have provided, ask questions, and request information from providers about the effectiveness, consequences, and potential risks of the technology use they are considering. Indeed, an informed public is the most effective bulwark against misuse or abuse of technology.

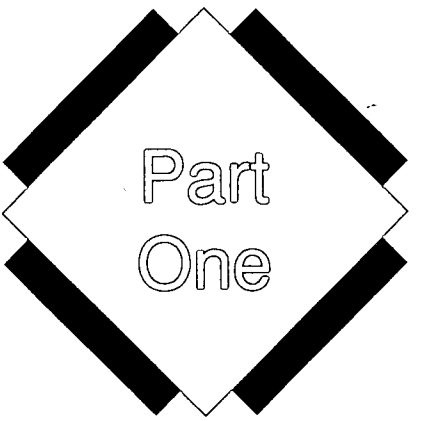
But all of these are only stop-gap measures. Government should act as the guardian of the public interest to set limits and to regulate the use of new reproductive technologies. No other body is sufficiently broadly based or has the mandate to do this. It is important that we put in place now the structures and an open, broad process to enable Canadians to deal with these growing dilemmas, dilemmas that affect individual lives and what kind of a society we are. How we use reproductive technology is not at root a medical matter, but a social matter that reaches into law, prevention, education, commerce, science, and research policy. Matters so important to women and children, in terms not only of their health but of their legal status and how they are viewed, cannot differ from province to province. The field is growing rapidly and Canadians want the government to act. There is clearly precedent — radio and television broadcasting is regulated and monitored through a licensing agency for the Canadian public interest. The area of reproductive technology use is at least as important to us as individuals and as a society.

Conclusion

Commissioners have set out a blueprint for how Canada, with its unique institutions and social make-up, can deal with new reproductive technologies, regulate their use, and ensure that future developments or use are in the public interest. Our blueprint requires action and leadership from the federal government, but also involves the participation and commitment of provincial governments, the professions, and many sectors of society. The approach we propose is feasible and practical, and we have laid out a detailed plan for how it can be accomplished.

The reasons for such action are compelling: the potential for harm to individuals and the need to protect the vulnerable interests of individuals and society. Adopting our recommendations will enable this protection, but will also allow scientific knowledge to be used to better the lives of many Canadians. Implementing the blueprint will demonstrate that we care about each other's well-being and recognize collective values with respect to the importance people attach to having children. At the same time, it will ensure that only ethical and accountable use of technology is made, and demonstrate that Canadians have wisdom, humanity, and compassion in the way they choose to use technology.

The Commission has done its work and indicated the path it believes should be taken. The next steps belong to the government and people of Canada.



New Reproductive Technologies and Canadian Society

A Comprehensive Response to Issues of National Importance

As Canadians living in the last decade of the twentieth century, we face unprecedented choices about procreation, placed before us by what has been described as a revolution in reproduction. Our responses to these choices will say much about Canada as a society — what we value, what our priorities are, what kind of society we want to live in.

New reproductive technologies now make it possible to unlink fertilization from sexual intercourse and pregnancy, allow embryos to exist for a time outside a woman's body, and permit characteristics of a fetus to be known early in pregnancy. New reproductive technologies therefore open up major ethical dilemmas for individuals and for society as a whole, because, like most technologies, they have the potential for both benefit and harm. They offer new options and potential benefits for the people who can use the technologies to form a family, but scientific and medical interventions in procreation also challenge us as a society to be able to recognize their significance and control their development. Would they further entrench existing inequalities or create new ones? How could they potentially alter definitions of parent, family, and generation? What is their potential effect on the way women are viewed in society?

The Appointment of a Royal Commission

Although the debate about new reproductive technologies dated from a decade or more earlier, by the end of the 1980s the time had clearly come for more extensive public information and discussion on new reproductive technologies and their implications for Canadian society. Calls for public discussion and recommendations for policy development came from many

sources, including women's groups, religious groups, legal and medical professional groups, federal-provincial/territorial working groups, academic organizations, and organizations of people with disabilities, as well as in forums such as international conferences on new reproductive technologies. Some of these organizations formed a coalition to advocate for the appointment of a royal commission; others supported the idea as a constructive way to deal with these complex issues.

In response to these developments, the Government of Canada appointed the Royal Commission on New Reproductive Technologies in October 1989 with a mandate to

> ... inquire into and report on 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 ...

The choice before Canadians is to decide to what degree our society will be driven by the pace of technological change, how to ensure that the further development of these technologies is conditioned by our priorities and values, and how those priorities and values will be identified and agreed upon. Technology is not beyond society's control. It can be shaped by policies adopted to guide our collective lives together and by personal choices in our private lives. This is the point from which the Commission began to explore its mandate, and it is the perspective that informs our recommendations. How we choose to use, or not to use, these technological capacities will shape society for our children and for their children. We need to evaluate the technologies and make decisions from the broadest possible perspective, using clear and explicit values and principles to guide our choices.

The Commission's Mandate

The establishment of the Commission therefore set in motion a comprehensive inquiry, based on a mandate that required the Commission to examine current and potential scientific and medical developments related to reproductive technologies, but also to go beyond them to consider

- the impact of the technologies on society as a whole;
- their impact on identified groups in society, specifically women, children, and families; and
- the ethical, legal, social, economic, and health implications of these technologies.

Although the past two decades have seen numerous examinations of certain aspects of new reproductive technologies in Canada and elsewhere, by and large these examinations did not include consideration of the causes and prevention of infertility, the use of prenatal diagnosis (PND), research

The Commission's Mandate

The **Royal Commission on New Reproductive Technologies** will be established "under Part I of the *Inquiries Act*" and will "inquire into and report on 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."

The Commission will examine, "in particular,

(a) implications of new reproductive technologies for women's reproductive health and well-being;
(b) the causes, treatment and prevention of male and female infertility;
(c) reversals of sterilization procedures, artificial insemination, *in vitro* fertilization, embryo transfers, prenatal screening and diagnostic techniques, genetic manipulation and therapeutic interventions to correct genetic anomalies, sex selection techniques, embryo experimentation and fetal tissue transplants;
(d) social and legal arrangements, such as surrogate childbearing, judicial interventions during gestation and birth, and 'ownership' of ova, sperm, embryos and fetal tissue;
(e) the status and rights of people using or contributing to reproductive services, such as access to procedures, 'rights' to parenthood, informed consent, status of gamete donors and confidentiality, and the impact of these services on all concerned parties, particularly the children; and
(f) the economic ramifications of these technologies, such as the commercial marketing of ova, sperm and embryos, the application of patent law, and the funding of research and procedures including infertility treatment."

—— *Order in Council No. P.C. 1989-2150*

involving human zygotes (or embryos*), or research involving the use of fetal tissue. Nor did they examine the broader context and implications of using the technologies — their social, health, and economic context, or

* 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.

their impact on the individuals and groups that make up society, particularly on women's health and well-being.

Central to the Commission's deliberations was how new reproductive technologies may affect women's reproductive health and well-being; their individual autonomy and scope for reproductive decisions; and their status, rights, and interests as members of society. Similarly, the Commission was concerned about the impact of the technologies on men, children, and families, and with ensuring that the technologies do not give rise to discrimination or exploitation related to socioeconomic, racial, or ethnic minority status.

Finally, given Canada's unique social make-up, the country's geography, our distinctive political and legal institutions, and our health and social systems, we had to evaluate new reproductive technologies and their implications from a Canadian perspective and to develop recommendations in light of our understanding of Canadians' collective values and attitudes.

The Commission's mandate was therefore broad and complex; we were asked to look at not only present technologies and procedures but also potential future developments, which meant also examining the implications of the technologies for future generations of Canadians.

The appointment of a royal commission was an opportunity to collect much-needed information, to foster the public awareness and debate that are necessary to create an informed social consensus, and, above all, to provide a principled framework for Canadian public policy on the use or restriction of these technologies. The Commission was thus placed squarely in the gap between technological development and policy development, with the task of helping to close it.

The Technologies

The term "new reproductive technologies," as used in the Commission's mandate, covers a broad range of conditions, technologies, procedures, and practices. By itself, the term is somewhat misleading, for it fails to convey the full scope of the Commission's mandate. Not all of the practices the Commission was asked to examine are new, not all involve technology, and not all are concerned with reproduction as it is usually understood.

Some of the practices the Commission was asked to examine are long-established. Assisted insemination (AI) in human beings, for example, has been practised in North America since at least 1884. Other practices, such as gene therapy, genetic alteration, and the use of fetal tissue for transplantation, are new but do not concern assisted human reproduction — which is the conventional understanding of what new reproductive technologies involve.

Some aspects of the Commission's mandate, such as infertility prevention, may require little technology; others, including prenatal

diagnosis and therapy, involve highly complex technologies. Practices such as preconception agreements (surrogacy) may involve assisted reproduction; their main implications arise, however, not from the technology used but from the ethical, legal, and social issues surrounding them. In short, the questions embraced by the Commission's mandate cannot be considered in isolation from one another, for they are interdependent at several levels, and decisions about one often have repercussions for another — hence the need for a comprehensive, multidisciplinary approach to our task and a comprehensive public policy response.

Structure of the Report

Our report is divided into three major parts. Part One describes the context for our inquiry and the major considerations that guided our deliberations — the ethical and scientific framework for our review and assessment of new reproductive technologies, as well as the societal values and attitudes toward reproduction and the technologies. Part One concludes with an overview of our proposals for a legislative and regulatory framework for Canada's comprehensive response to these issues. Implementing it will require concerted, collaborative efforts on the part of the federal government, provincial and territorial governments, the health care system, and other key partners.

Part Two is devoted to our examination and assessment concerning the four principal areas of our mandate: the prevalence, risk factors, and prevention of infertility; assisted human conception and alternatives to it; prenatal diagnosis and genetics; and research involving human zygotes, embryos, and the use of fetal tissue. Our detailed findings on these topics are set out in the 15 research volumes accompanying publication of this report. Here we present the conclusions emerging from our research and analysis and the policy recommendations flowing from them.

Part Three provides a summary of our recommendations, organized by area of responsibility for implementation. This summary illustrates the importance of concerted and collaborative efforts among numerous key participants in achieving the success of the approach to new reproductive technologies that we propose.

To organize its research, the Commission grouped the conditions, technologies, and practices referred to in its mandate under four broad topics: the prevalence, risk factors, and prevention of infertility; methods of assisted human reproduction; prenatal diagnosis techniques and genetics; and research involving human zygotes and embryos and involving fetal tissue. These four areas of inquiry are described briefly in the following pages and provide the structure around which Part Two of our report is organized. Throughout the report, and unless otherwise indicated, we use the term "new reproductive technologies" to refer to this full range of conditions, technologies, and practices, not solely to interventions intended to assist conception.

Prevalence, Risk Factors, and Prevention of Infertility

Developing policy with respect to the use of reproductive technologies requires a clear understanding of infertility and its causes. Is infertility the inability to conceive within a particular time limit, to carry a pregnancy to term, or to produce a living child? What causes infertility in women and men? How common is it? Is infertility on the increase among people in Canada? Can it be prevented? If so, how and in what proportion of cases?

The answers to these kinds of questions will help to determine society's response to infertility. Understanding the causes and considering how to prevent infertility in women and men are therefore crucial in establishing a context for the other, more technologically oriented issues in the Commission's mandate.

Some of the questions we examined do not involve technology; for example, adoption is often thought of as an alternative to the use of reproductive technologies for people who are infertile. Others, such as preconception agreements, may involve assisted insemination or *in vitro* fertilization (IVF) but need not do so. These questions are discussed in Chapters 16 (adoption) and 23 (preconception arrangements).

Assisted Human Conception

This area of our inquiry examined procedures intended to help individuals or couples to conceive a child. Our examination included the practices and procedures usually included in the conventional definition of new reproductive technologies: the use of fertility drugs, assisted insemination using partner or donor sperm, *in vitro* fertilization, sterilization reversal, and newer developments such as gamete intra-fallopian transfer (referred to as GIFT).

Some of these procedures and practices require associated technologies. Assisted human conception using IVF and GIFT, for example, may involve other procedures, including the use of fertility drugs, frozen sperm, and, sometimes, frozen zygotes. Thus, the Commission also examined subjects such as the short- and long-term effects of fertility drug use, as well as the techniques and practices of facilities collecting sperm for donation, and freezing, storing, and handling human zygotes.

Prenatal Diagnosis and Genetics

Prenatal diagnosis (which encompasses a range of procedures for detecting medically relevant characteristics of the embryo or fetus) includes techniques such as ultrasound scanning and amniocentesis. Newer developments are less familiar: chorionic villus sampling (CVS), preimplantation diagnosis, maternal serum alpha-fetoprotein (MSAFP) screening, prenatal predictive testing for diseases that occur later in life, and gene therapy are examples of the newer technologies the Commission examined.

Of particular significance with some of the newer developments is that they make information about the embryo available earlier, thereby allowing knowledge of its status — and thus, potentially, various interventions — at earlier stages of development.

Research Involving Human Zygotes, Embryos, and Fetal Tissue

Fetal tissue use includes research aimed at understanding human development and functioning, as well as research to determine whether fetal tissue or its derivatives can be used to treat human diseases. An example of the latter is research to determine whether transplants of tissue from this source will help people with neurological diseases such as Parkinson disease. Embryo research involves efforts to understand fertilization, implantation, and very early human development so that this knowledge can be used subsequently in medical treatment.

Research involving human zygotes and the use of fetal tissue is carried out in relatively few places in Canada; society therefore has an opportunity to consider the issues they raise as the technologies develop. The rapid pace of development in both fields, in Canada and elsewhere, makes their consideration a priority. (See Chapters 22 and 31.)

Broader Questions

The Commission was directed to examine the technologies in their medical, ethical, social, scientific, and research dimensions, as well as their economic and legal aspects. As well as examining these aspects we commissioned research on questions related to the origins, development, alternatives to, and implications of the technologies, so that we could develop a comprehensive and integrated picture. This process is described more fully in Chapter 6. In addition, the Commission was asked to consider several questions related to the field of human reproduction though not related specifically to new reproductive technologies:

- judicial intervention in gestation and birth;
- the legal status of reproductive material such as gametes (sperm and eggs), zygotes, and embryos; and
- the economic and legal implications of commercial marketing of human eggs, sperm, and embryos, the application of intellectual property law, and methods of funding both research into and provision of these technologies.

Organization of the Commission's Work

To fulfil our mandate and ensure a sound basis for our findings and recommendations, we sought to develop effective and innovative ways to

- consult with Canadians from all sectors of society and listen to their views and experiences on the issues surrounding new reproductive technologies;
- assemble solid information about and critical analyses of the technologies and their implications; and
- develop an integrated approach to our work, so that what we heard from Canadians would inform specific research and evaluation projects, while research findings in turn would suggest specific questions to be addressed through the consultation process.

The Commission organized its work around two major streams of activities: consultations and communications, and research and evaluation. Through these activities we were able to appreciate the scope and complexity of the issues covered by our mandate, consider the far-reaching implications of the technologies, take into account the values and attitudes that Canadians bring to the debate, as well as the evolving social fabric of the country, and recommend a comprehensive approach to the technologies that recognizes and accommodates the dynamic nature of society, technology, and the interaction between them.

The Commission set three broad goals for its work:

1. *To provide direction for public policy by making sound, practical, principled recommendations to help Canadians and our social institutions deal with the technologies now and to put in place mechanisms to ensure a continuing capacity to deal with them.*

In dealing with a subject with so many individual and social implications, we saw our task as being to offer recommendations that are principled, practical, and achievable, so that decision makers could formulate and implement sound policies in the interest of Canadian society now and in the future. We also wanted to provide the information and analysis that led to those recommendations. To do this required documentation and analysis of the nature, effectiveness, and health effects of the new reproductive technologies currently in use, focussing on their social, ethical, health, research, legal, and economic implications. We were particularly concerned with the ethical bases for social and individual decisions — bases not unique to reproductive technologies. In offering practical and workable proposals to governments and other institutions, organizations, and professions regarding regulation of new reproductive technologies, we hope that these proposals can serve as a prototype for other emerging health care technologies.

2. *To leave a legacy of increased knowledge in the field of Canadian and international experience with new reproductive technologies.*

Intelligent decisions require knowledge. The individual and societal choices surrounding new reproductive technologies must be founded on

information and analysis about the capabilities, limitations, and implications of these technologies. This involves not only medical and scientific information, but also analysis of the values and the social, political, and economic forces shaping the development of new reproductive technologies and, conversely, how new reproductive technologies may shape Canadians' attitudes and values.

To expand our knowledge base, we commissioned research and analysis examining the origins, current practices in Canada, and future implications of all the technologies falling within our mandate. To consolidate existing information, the Commission conducted an inventory of the current state of research, collating and centralizing information for use by all those with an interest in the field. Fifteen volumes of research findings accompany this report. Together with the submissions, they constitute an enormous body of research findings and testimony, our assessment of which provided the basis for our conclusions and recommendations.

3. *To enhance public awareness and understanding of the issues surrounding new reproductive technologies and to encourage public participation in determining the future of these diverse technologies and their place in Canadian society.*

In order to facilitate Canadians' participation in decision making at both the individual and collective level, we sought to expand the discourse around new reproductive technologies and to provide important information on the issues. To this end, our report is intended for the general reader, with only as much technical detail as is required to understand the implications of the technologies. We have also provided a chapter on the biology of human reproduction, definitions of terms used in each chapter, and a glossary at the end of the report. Readers with various degrees of expertise and familiarity with the technologies and the issues surrounding them who wish further detail may consult the 15 volumes of research studies.

The work of a royal commission is limited in certain ways inherent in its functions. A commission is not a permanent entity, so it cannot take on and manage research over the long term, deliver programs, or provide services. Nor can it ensure that its recommendations will be implemented — this is properly the function of elected governments and the democratic process. A royal commission's role is to clarify facts and issues, to analyze them from an ethical and social perspective, and to make principled recommendations chosen from among clearly described alternatives. The over-riding goal of the Royal Commission on New Reproductive Technologies was to do this for the consideration of the Government, Parliament, and the people of Canada.

Overall Results of Our Inquiry

After wide consultation with Canadians, ethical and social analysis of the implications, and careful examination of the scientific evidence relating to the current use of new reproductive technologies during the course of our mandate, the Commission has concluded that Canada must respond decisively and comprehensively to control development and use of these technologies; clear boundaries must be set and the technologies managed within these boundaries. As the Commission's detailed review of technologies and practices in Part Two of our report demonstrates, this response is necessitated by the technologies' profound ethical, social, health-related, and legal implications, both now and in the future.

The issues are not merely hypothetical; new reproductive technologies are already the subject of individual and systemic decisions about reproductive health, family formation, medical treatment, research, and health care resource allocation. Moreover, the field is evolving rapidly in Canada and elsewhere. As a society, we cannot turn back the clock. Nor can we live with the status quo, allowing the technologies to develop without clear societal direction grounded in collective values and priorities.

Canada must move forward into the new reality with a clear, coordinated approach that permits us to resolve and manage the critical issues involved. To allow Canada's response to be delayed or fragmented by the existing web of jurisdictional and administrative arrangements would, in the view of Commissioners, be a mistake of enormous proportions.

Canada must move forward into the new reality with a clear, coordinated approach that permits us to resolve and manage the critical issues involved. To allow Canada's response to be delayed or fragmented by the existing web of jurisdictional and administrative arrangements would, in the view of Commissioners, be a mistake of enormous proportions. Failure to intervene constructively and decisively would amount to an abdication of social responsibility and a failure of political will.

The Commission sees a need to set clear limits based on what society considers to be acceptable activities in the field of reproductive research and treatment; to establish a system for managing the technologies within these limits; and to provide a mechanism for continuing review and evaluation as ethical and scientific issues in this field emerge and evolve. These are the principal goals of our recommendations.

Our detailed recommendations throughout Part Two are proposed in light of a long process of deliberation and consultation. In the remainder of this chapter we describe the broader overall framework into which these

detailed and technology-specific recommendations fit. With such a framework in place, our recommendations point the way to ensuring that future developments in this crucial, complex, and rapidly developing field are in the best interests of individual Canadians and of Canadian society generally.

The Call for National Action

Throughout our public hearings, in the many submissions and briefs we received, and in the surveys we conducted across the country, we found consistent and widespread demand for national leadership and action in relation to new reproductive technologies. This demand was expressed by women and men with widely varying backgrounds, experiences, and circumstances, in all age groups, and in all provinces. Since the issues and interests involved are of far-reaching importance for Canadian society as a whole, this response is not surprising. It reflected a prevailing belief that unconstrained development of new reproductive technologies is not in the public interest, and that the research and application of these technologies require clear boundaries and effective and appropriate management within those boundaries.

> The federal government must establish structures that will ensure the sound, fair and equitable development of NRTs [new reproductive technologies], by guaranteeing that standards are set through a process that is as representative as possible, and making certain that these standards are enforced. [Translation]
>
> *Brief to the Commission from Le comité "Vieillir au féminin" de l'Université du troisième âge de l'Université de Moncton, January 18, 1991.*

The need for a broad national framework within which to manage reproductive technologies was confirmed by the following results from our research, analysis, and consultations carried out over the course of the Commission's mandate:

- Some uses of reproductive technologies should be prohibited, as they violate ethical principles and contradict values widely held by Canadians. We were led to this conclusion by our ethical analysis, as well as our review of inquiries into and experience with reproductive technologies in other jurisdictions in Canada and abroad.
- Collective principles and values of Canadians include, at the societal level, non-commercialization of reproduction, fair and equitable access to services, and responsible use of public resources. At the individual level, they translate to the need to seek to prevent harm and to protect the health and safety of present and future technology users, and to

ensure that they are fully informed of any risks and potential consequences of technology use.

- The status quo with respect to particular technologies is unacceptable from both an ethical and a medical perspective. Our review of evidence showed us that new and unproven medical procedures are being offered as treatment without the rigorous review and informed consent to which they should be subject; some practitioners are contravening guidelines established by their professional bodies; access to infertility treatment services is not equitable; and counselling and consent procedures for technology users are falling short of what is required.
- Our health care system cannot continue to respond to the demand for new medical technologies in the absence of clear evidence about their effectiveness. Such evidence constitutes a crucial component of the information necessary for individual decisions regarding treatment and collective decisions about resource allocation (including personnel, equipment, and facilities) needed to provide that treatment.
- More and better information on which to base informed choice and personal decision making with respect to reproductive health must become available. Our extensive consultations with Canadians revealed a need for public participation and public accountability in decision making; and a need for ongoing review of policies and decisions in the field of reproductive health and technologies.
- Canada's response to reproductive technologies must reflect constitutional values with respect to promoting equality and accommodating diversity, in the overall context of establishing congruence and consistency with Canadians' values and priorities and Canada's changing social fabric.
- Finally, no existing legislation or regulatory regime is broad enough and no public or private organization is equipped or has demonstrated the capacity to deal with all these questions in the comprehensive, timely fashion we believe is necessary.

Wide-Reaching Social, Ethical, and Public Policy Implications

The widespread call for national leadership heard by the Commission reflects a belief that it is unrealistic to expect self-regulating professional bodies, or the provinces, individually or together, to provide the necessary level of regulation and control on issues that transcend not only provincial but national and intergenerational boundaries and that have implications for all Canadians, regardless of where they live. It is the view of Canadians, and Commissioners' view as well, that given rapidly expanding knowledge and rapid dissemination of technologies, immediate intervention and

concerted leadership are required at the national level. This does not obviate the need for decisive action by provinces and professional bodies as well, but action at the national level must provide the leadership and impetus for a new approach to managing reproductive technologies.

Given rapidly expanding knowledge and rapid dissemination of technologies, immediate intervention and concerted leadership are required at the national level. This does not obviate the need for decisive action by provinces and professional bodies as well, but action at the national level must provide the leadership and impetus for a new approach to managing reproductive technologies.

Public calls for national leadership reflect Canadians' recognition that a field with such wide-reaching social, ethical, and public policy implications could never be dealt with adequately by a single government ministry or department, no matter how well intentioned — the ethical and public policy questions are simply too broad for such a response to be effective. In the view of most of those who appeared before us, the inadequacy of existing piecemeal approaches to regulating the technologies, together with their implications for the future of our society, place a particular onus on this generation of Canadians to take immediate steps to deal comprehensively and consistently with these issues of national importance. Indeed, the appointment of the Royal Commission on New Reproductive Technologies reflected this recognition that public policy development in this field required a broad, multidisciplinary approach.

Canadians recognize that national leadership will provide the particular kind of impetus that is necessary in new reproductive technologies to ensure that the ethic of care and values such as equality, non-commercialization of human beings, privacy, and informed choice are reflected in services, that adequate standards of care are achieved and maintained, and that goals such as public accountability and responsiveness in decision making are realized.

> We recommend that the federal, provincial, and territorial governments seriously examine the possibility of establishing a national organism for implementing reforms.
>
> *Brief to the Commission from the Law Reform Commission of Canada, November 21, 1990.*

In addition to calls for national leadership, many of the concerns we heard about the impact of new reproductive technologies took the form of calls for a moratorium on their development and use until such time as society is ready to deal with their implications.

Is a Moratorium the Appropriate Response?

The shortage of information on risks and effectiveness prompted calls during our public hearings for a moratorium on the development and use of new reproductive technologies. In the public debate that continued throughout our mandate, most intervenors who raised this issue expressed concern about women's inadvertent or uninformed exposure to risk because of lack of information and insufficient control over practices and procedures. It was in this context that some witnesses proposed a moratorium on the use of new reproductive technologies.

There was no consensus on what form a moratorium should take. Some intervenors spoke of legislative measures to suspend particular medical practices or types of research concerning reproductive technology, with the goal of allowing our collective knowledge and careful consideration of the issues to catch up to the developments themselves. Others used the term moratorium to mean a permanent halt to all current and future activity in an area of research or medical practice. Still others talked of maintaining activities at current levels without further expansion until results have been established and assessed. Opinion also varied on what technologies or research areas should be subject to a moratorium. Few aspects of reproductive research, assisted reproduction, prenatal diagnosis, gene therapy and genetic alteration, or research involving the use of fetal tissue were exempt from proposals to suspend or cease activity.

Calls for a moratorium are understandable in a field where the ethical and social implications are so far-reaching and knowledge is evolving so quickly. The Commission recognizes that there are certain technologies or areas of research that should be prohibited outright. Our recommendations later in the report reflect this recognition. However, we consider the imposition of a general moratorium inappropriate for several reasons:

- Some technologies and some uses of technology are beneficial. To deprive fully informed people of services that have been shown to make a difference in outcomes — services that may represent their only hope of having a biologically related child or of avoiding the birth of a child with a genetic disease or severe disabilities — would be inappropriate.
- It would be hard to ensure that only the specific activities covered by a research moratorium were put on hold and that necessary reproductive, endocrinological, or immunological research was not halted. This is because the boundaries between various research areas are not always clear, and because knowledge acquired through one type of research may have far-reaching beneficial applications in other fields that become apparent only later.
- A moratorium on research in Canada would not stop such research from occurring elsewhere; research results in other countries could

easily be transferred and applied in Canada, just as they are now. This could have two consequences: first, it would be difficult to assess what the benefits and risks of an "imported" technology would be if applied in the Canadian clinical context, because it would not have been tested under Canadian conditions and controls. Second, Canada could become guilty of "ethical dumping" — taking the moral high road by banning research but later benefiting from the results of research conducted elsewhere and imported into medical practice in Canada.

- Leading researchers and research-oriented practitioners might leave the country, threatening the existence of Canadian centres of excellence, in which research and practice that have benefited Canadians have been linked.

Clearly, it is important to examine the concept of moratoria — what they are, what they can do, and when they are appropriate. However, a general moratorium is neither desirable nor feasible. The Commission believes that the best response in the area of new reproductive technologies is twofold: first, determining whether some forms of treatment or research are so ethically questionable, medically risky, or socially harmful that they should be banned. In cases where analysis shows that a practice or particular type of research violates fundamental ethical principles, or there is clear information that the potential for harm from a given practice is much greater than any anticipated benefit, a complete prohibition is the appropriate response. The second part of the response is to put in place mechanisms to manage research and treatment found to be potentially acceptable if they are carried out in an ethical, controlled, and accountable way. The result of this twofold response would be the establishment of boundaries, with unacceptable forms of research or treatment being prohibited, and potentially beneficial research or treatment activities being regulated and shaped by a publicly accountable body. Our recommendations reflect this stance.

We believe that the overall framework and the specific measures we propose not only will be capable of addressing the kinds of public concerns that gave rise to calls for a moratorium but will do so with greater precision and effectiveness than would be available through a general moratorium. At present, however, Canada has no mechanism for implementing such measures in a comprehensive, coordinated, and continuing way. Filling this regulatory void is the object of our recommendations in the remainder of our report.

A Matter of National Concern

As we were reminded repeatedly by the many groups and individuals that appeared before the Commission, the issues raised by new

reproductive technologies defy neat categorization as solely a health problem, solely a legal problem, or solely an ethical problem. The research, development, and use of new reproductive technologies involve national concerns that cut across social, ethical, legal, medical, economic, and other considerations and institutions. This characteristic of new reproductive technologies generates the need for a distinct regulatory and organizational response — one capable of responding to and dealing with the issues in a comprehensive way.

New reproductive technologies are, in many ways, unique in Canada's health care system, in that they are administered under the jurisdiction of the provinces and territories, but, because of their profound social, ethical, and legal implications, raise issues that require national attention. Few individuals or families in this country are not touched in some way by new reproductive technologies.

> Considering the overarching nature, profound importance, and fundamental inter-relatedness of the issues involved, we consider that federal regulation of new reproductive technologies — under the national concern branch of the peace, order, and good government power, as well as under the criminal law, trade and commerce, spending, and other relevant federal constitutional powers — is clearly warranted.

Just as the technologies themselves are highly complex, requiring careful and intelligent management, so are the ethical and social questions surrounding their use. A host of difficult issues and questions needs to be dealt with and resolved. A recurrent concern voiced to the Commission in our consultations with Canadians was that there is no single authority overseeing developments in the area of new reproductive technologies.

The Commission believes that the issues associated with new reproductive technologies must be resolved on a national basis. As we have already suggested, and as will become increasingly evident in our review of technologies and practices in Part Two of this report, it is not an exaggeration to say that chaos characterizes the regulation of the technologies in Canada today. The research, development, and application of new reproductive technologies are occurring in the absence of an overall framework for monitoring or controlling these developments. To allow this situation to continue is not in the interests of Canadians, and is not, in the Commission's opinion, an acceptable option.

Comprehensive Policies and Regulation Are Required

As it stands, no comprehensive law is in place, and no entity, public or private, has overall responsibility in this area. Existing family, health, contract, commercial, and related legal regimes apply to new reproductive technologies largely by inference, if at all, and few or no court cases have been decided. Thus, society lacks guidance on issues such as the status,

liabilities, and responsibilities of participants; access to treatment; informed consent; privacy and confidentiality; and the boundaries between acceptable and unacceptable practices, procedures, and treatments.

For instance, prevention of infertility is not a health policy priority in Canada at present, and there is no coherent or comprehensive public policy response to factors that may put fertility at risk — for example, reproductive hazards in the environment and the workplace. Medical coverage of infertility treatments and access to them vary across the country and from clinic to clinic, there is marked variation in standards and practices, and there is no comprehensive system of keeping records on these treatments and their outcomes. Canada now depends on a patchwork of laws to address the bewildering challenges of medically assisted procreation. Other than the Yukon, Newfoundland, and Quebec, no province or territory has made provision for the unique situations created by the use of donated gametes, so that the legal status of the parents and children involved remains unclear. Similarly, with the exception of a provision in the Quebec *Civil Code*, there are no laws anywhere in Canada specifically governing preconception arrangements. Despite the existence of guidelines on prenatal diagnosis, a woman's access to this testing depends largely on the values and beliefs of her physician, which vary substantially from region to region, and from specialty to specialty. Canada has no national policy regarding the use of fetal tissues, and, in its absence, Canadian researchers rely on undocumented and unregulated individual agreements with facilities providing abortions.

> Accreditation and quality assurance functions [for IVF programs] should clearly be operated at a federal level. Furthermore, a registry could only effectively operate as a national registry.
>
> *D. Mortimer, Ontario Medical Association, Public Hearings Transcripts, Ottawa, Ontario, September 18, 1990.*

Issues such as these are too important to our society, their fundamental social, moral, legal, and ethical implications too profound, to be left to be resolved by a fragmented and disjointed sector-by-sector or province-by-province approach. The protection of the public interest, the well-being and interests of women, the creation of children, and the formation of families are national issues that must be addressed at a national level. Though not directly involved in the delivery of new reproductive technology services, the federal government has a critical role to play — that of facilitating societal inquiry, education, and reflection on new reproductive technologies, and then following this through with responsible regulation that is national in scope.

We believe that it is important that the approach of the 1980s, when many uses of new reproductive technologies proliferated with little control,

does not continue in the future. Through our consultation activities, and through this report, we have brought forward and consolidated a considerable amount of information that will assist in ensuring this situation is rectified.

> In Canada today, the development of IVF and related technologies can most charitably be described as anarchic.
>
> Provincial/territorial and federal levels of government have exercised little control or regulation concerning NRT practice and research. The medical profession and governments have done little in the way of formulating standards for the testing and monitoring of NRTs, thereby facilitating the confusion between research and treatment that marks NRTs.
>
> ... a national body [should] be established to review and approve research proposals, set ethical standards, set national standards of informed consent for NRT research and therapy, standardize data collection on NRTs, and monitor service access and provision.
>
> *Brief to the Commission from the Canadian Advisory Council on the Status of Women, March 1991.*

Given what we learned through extensive consultation, data collection, and analysis over the life of our mandate, we share the widely held public view that new reproductive technologies raise issues of a magnitude and importance that not only warrant but *require* a national response. We reject the argument that new reproductive technologies as a general matter should continue to be subdivided into component parts and left to the provincial legislatures, or delegated to self-governing professional bodies, for regulation on a province-by-province or even an institution-by-institution basis. Considering the overarching nature, profound importance, and fundamental inter-relatedness of the issues involved, we consider that federal regulation of new reproductive technologies — under the national concern branch of the peace, order, and good government power, as well as under the criminal law, trade and commerce, spending, and other relevant federal constitutional powers — is clearly warranted.

> The government [should] show leadership in this area [of creating] and perhaps emphasizing the importance of a national registry.
>
> *N. Barwin, Planned Parenthood Federation of Canada, Public Hearings Transcripts, Ottawa, Ontario, September 19, 1990.*

We recognize that the constitution assigns wide legislative jurisdiction to the provinces in the field of health. However, there is a clear basis for seeking national action in this area. In particular, Parliament has authority, under the national concern branch of the federal peace, order, and good government power, to regulate matters

going beyond local or provincial interest that are of inherent concern to Canada as a whole.

Peace, Order, and Good Government

The Supreme Court has decided that the peace, order, and good government power can be invoked in support of federal legislative action, provided the matter Parliament seeks to regulate is of genuine national concern and possesses a degree of singleness, distinctiveness, and indivisibility that renders federal regulation compatible with provincial control over matters within their legislative jurisdiction.

The Supreme Court has held that provinces' ability to deal with a matter effectively through cooperative action, and the effect on extraprovincial interests of a province's failure to regulate the intra-provincial aspects of the matter, are of particular relevance, since it is the inter-relatedness of the intra- and extraprovincial dimensions of the problem that creates the need for single or uniform legislative treatment. We are firmly of the belief that new reproductive technologies, as defined in our mandate, meet the criteria established by the Supreme Court, so that federal intervention under the peace, order, and good government power is constitutionally justified.

New reproductive technologies possess a conceptual and practical integrity and distinctiveness. Their fundamental object is human reproduction, with all its distinct historical, social, and ethical implications. Viewed as a biological function, reproduction is easily distinguishable from other matters of human health. It has particular social significance, has particular ethical, political, and economic dimensions, and creates particular legal relations and responsibilities. Thus, although health issues are certainly involved, numerous other individual and societal issues converge in reproductive technologies, necessitating a broad, inclusive approach to dealing with them.

Focussing on human reproduction, new reproductive technologies are clearly identifiable and distinct from other areas of medical science, technology, research, and health service. Assisted conception services, for example, and the research, technologies, and medical interventions they involve, are not designed to cure illness or disease in a traditional pathological sense, but rather to address the problem of involuntary childlessness — a condition whose significance and implications for the individuals involved, and for society as a whole, are of a predominantly social rather than medical character. Prenatal diagnosis services, research involving human zygotes and the use of fetal tissue, and prenatal genetics research also have distinct ethical and social significance owing to their unique relationship to human reproduction. More than any other aspect of health-related technology or service, the research and application of new reproductive technologies have significance beyond the individuals directly involved.

Public control over the development and use of new reproductive technologies is therefore necessary to safeguard a wide range of interests. Some relate directly to the health and well-being of the individuals involved. Others relate to the welfare of particular groups such as women, for whom reproduction has always had particular social, economic, and legal consequences. Still others relate to the well-being of Canadian society as a whole, including that of future generations, and have implications beyond Canadian borders.

> Decisions about who will get how much of what in health care are made mostly in an ad hoc fashion, with different motives operating for the different levels of decision makers. Although some mechanisms exist for influencing technological adoption and diffusion, such as regulation under special programs for the purchase of expensive technologies ... or fee-for-service schedules that signal what services can be provided and how much the payment will be, ... policy mechanisms at present are neither coordinated nor applied consistently to ensure predefined and publicly articulated health goals. Moreover, prospective assessment of the consequences of technology decisions has not been part of the decision-making process.
>
> *A. Kazanjian and K. Cardiff, "Framework for Technology Decisions: Literature Review," in Research Volumes of the Commission, 1993.*

All of these interests are inter-related. It is hardly surprising, therefore, that at the level of both policy and practice, the effectiveness of regulation of one dimension of new reproductive technologies will depend greatly on the effectiveness of regulation of other dimensions of the technologies. For example, as the discussion in Part Two of our report makes clear, a legislative policy requiring disclosure of information about the medical and social family history of children born through assisted conception involving donated gametes (eggs or sperm) would be rendered meaningless by a failure to ensure that proper records on the donors are compiled and maintained. Similarly, requiring full and informed consent to any assisted conception intervention would be ineffective without information being available about the health status of donors or the safety of drugs and procedures. It would be ineffective to prohibit the donation of gametes or zygotes for research without being able to control the ultimate research use of such entities. And, similarly, a legislative policy discouraging or prohibiting preconception (surrogacy) arrangements would be compromised by a failure to ensure that practices surrounding embryo transfers are regulated appropriately.

Failure to regulate some or all aspects of new reproductive technologies in one province or region would also adversely affect the interests that such regulation seeks to promote elsewhere. Indeed, as we have indicated, detrimental consequences such as variations in access and

practices and inadequate record keeping have occurred already. Moreover, policies and practices that tended to allow the commodification of children or commodification of women's reproductive functions in one province would have significant social consequences that could not be confined to any particular jurisdiction where commodification was deemed acceptable. Allowing or ignoring the practice of preconception arrangements in one province while it is prohibited elsewhere would have a harmful impact, not only on the gestational mothers and other women in the province in question, but on Canadian women generally. Such permissiveness in one jurisdiction — quite apart from the "reproductive tourism" it would encourage — would convey tacit acceptance, or even affirmative state sanction, of a practice that is likely to undermine the value, dignity, reproductive capacity, and bodily integrity of Canadian women. Again, because of the great mobility of Canadians, failure to impose adequate controls on the safety of assisted conception technologies in one province or region would inevitably have social, health, and economic consequences as those affected moved elsewhere.

Some would argue that interprovincial variations in levels of access to, and control over, new reproductive technologies are an unavoidable fact of life in Canada, and that regional variations are one of the prices we pay for a federal system designed, in part, to accommodate diversity — and indeed this is true for many areas of our collective lives. In our view, however, the exacerbation of existing interprovincial discrepancies in access, monitoring, and control as the pace of technological developments accelerates — together with the fact that citizens in provinces with insufficient regulation may suffer harm and the fact that the technologies have social implications that are not containable within the boundaries of a single province — make new reproductive technologies a matter of national concern.

Some countries have already put in place nationally based measures to deal with the issues raised by new reproductive technologies; this enabled the Commission to learn from experiences elsewhere. The real difficulties in implementing a national system to regulate new reproductive technologies should not be underestimated, but other countries facing similar difficulties have established bodies to oversee developments in this area and have had them functioning within a relatively short period of time.

For instance, the British government established the Human Embryology and Fertilisation Authority to regulate all aspects of new reproductive technologies throughout the United Kingdom, including licensing of all clinics providing infertility-related services or conducting embryo research. Australia, which has a federal system of government, as does Canada, has opted for a national body, the Australian Health Ethics Committee, to encourage and enhance public debate on the ethical aspects of the technologies. France has created the National Advisory Committee for Health and the Life Sciences, the world's first permanent ethics committee, as well as a national self-regulating body, La Fédération

Française des Centres d'Étude et de Conservation des Oeufs et du Sperme humains (CECOS), while Denmark has a National Ethics Council.

In summary, the significance of research, development, and use of new reproductive technologies for Canadian society as a whole; the national as well as international character of the issues involved; the inter-relatedness of their intra- and extraprovincial dimensions; and the potential effects of provincial failure to regulate the intraprovincial aspects of the subject, taken together, indicate the need for national uniformity in legislative treatment rather than provincial or regional diversity. To safeguard the individual and societal interests involved, we believe that regulation of new reproductive technologies must occur at the national level, although provincial and professional involvement will be essential to the success of this endeavour. Only then will it be possible to overcome an increasing fragmentation of regulatory control and the difficulty of monitoring as practices and technologies expand and multiply.

The Commission therefore proposes that federal legislation be passed making some uses of the technologies illegal, thus establishing boundaries around what Canada considers acceptable use. To manage technology development and ensure only appropriate use within these boundaries, we propose the establishment of a National Reproductive Technologies Commission (NRTC) to fulfil policy, regulatory, and licensing functions in relation to specific activities in this field. We have also made relevant recommendations to the provinces and to professional and other bodies, which are essential partners in making the approach we propose workable and effective. An overview of the proposed regulatory framework is set out in Chapter 5, and further details are provided in the chapters devoted to our review of the specific conditions, technologies, and practices that our mandate asked us to examine. In Part Three, we provide the reader with an overview of how our recommendations work together, organized along the lines of who would be responsible for their implementation.

In the next three chapters, we set out the ethical and scientific principles that guided our review of current uses of the technologies and that provided a framework for reaching our conclusions and recommendations. In Chapter 5 we describe the broad outlines of our recommendations for establishing boundaries around the technologies whose use we consider acceptable and for managing them within those boundaries in an ethical and accountable way.

Social Values and Attitudes Toward Technology and New Reproductive Technologies

Technology sparks strong emotions and debate among Canadians. The debate about technology has been intensified, however, by rapid changes in society, in Canadians' values and attitudes in general, and in the context of increasing globalization. Broad changes in society and the changing status of technology as a driving force in society come together in providing the framework within which reproductive decisions are made, individually and collectively. Commissioners were committed to understanding new reproductive technologies in this Canadian social context, including such factors as sexism, racism, poverty, and other sources of discrimination. We believe that Canadians' values and attitudes must inform any policy decisions in this area.

To gauge Canadians' general attitudes the Commission conducted a series of national surveys measuring Canadians' familiarity with and values in areas related to new reproductive technologies. In total, representative samples involving more than 15 000 Canadians took part in personal interviews, focus groups, phone interviews, and/or answered written questionnaires. As well, Canadians from across the country attended public hearings and private sessions, sent written submissions or letters of opinion, and gave us their thoughts on our toll-free telephone lines. In all, more than 40 000* individuals contributed to the work of the Commission. Their contributions added immeasurably to the depth and the breadth of our understanding of Canadians' perceptions of technology in general and new reproductive technologies in particular, providing an

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* Our consultations, communications, and research are discussed in Chapter 6, "Developing a Comprehensive Picture of Technologies and Practices."

important guide to, and source of wisdom about, the limits of what is ethically acceptable.

From Canadians' input, from survey research, and from analytic research projects, the Commission gained a sense of the values and attitudes that will carry Canada into the twenty-first century and that must form a context for all public policy decisions. We discuss these trends in the first part of this chapter. An over-riding theme emerging from this discussion is the need to consider reproductive technologies from the perspectives of the various groups and individuals who make up Canadian society. Therefore, in the second part of the chapter, we examine the impact of new reproductive technologies on these various sectors and groups. The issues concerning new reproductive technologies are not uniform, nor is Canadian society: both are diverse. Here we provide an overview of these complex issues, and we examine the implications of this diversity in much greater detail in Part Two of our report.

Technology and Society

Society has become fascinated by and dependent on science and technology, yet most people would be hard pressed to explain how many technologies work, let alone the scientific principles that underlie them. Scientific and technological advances have expanded the knowledge gap between technology experts and technology consumers. As a result, although public attitudes of 40 years ago — captured in the phrase "better living through modern technology" — are still prevalent, there are also increasing concerns about scientists "playing God" and technologies "tampering with nature." There is a growing unease on the part of some that the "genie has been let out of the bottle," and technology will never be "contained" again.

People are also recognizing that technological developments can give rise to unexpected problems, some of them very difficult to solve. Environmental degradation resulting from use of agricultural and industrial technologies is one example of unanticipated technological fallout. This has led to greater awareness that the cost of achieving short-term goals is sometimes long-term damage to the physical environment and resource base. By analogy, the complexity and delicacy of the human reproductive system necessitate a strong element of caution when scientific or technological intervention is contemplated, because of the risk of unintended or unforeseeable consequences. For example, the Commission heard from many people with concerns about the potential of reproductive technologies to change the genetic make-up of individuals and to change social relationships. Some people expressed concerns that technology in general, and medical developments in particular, are moving too fast for society.

National Surveys of Canadians' Attitudes Conducted by the Commission

Reproductive Technologies — Qualitative Research: Summary of Observations (*Angus Reid Group*)

Between May 15 and May 27, 1990, researchers conducted telephone interviews with a representative cross section of 1 503 Canadians. Respondents were asked about their knowledge, opinions, and perceptions concerning new reproductive technologies and the ethical, social, and economic issues concerning them.

Social Values and Attitudes of Canadians Toward New Reproductive Technologies (*Decima Research*)

Between December 1991 and July 1992, researchers conducted phone interviews with a representative sample of 7 664 Canadians, 2 722 of whom also completed a written questionnaire, which asked about the importance of family and children in the lives of Canadians, perceptions of social pressure to have children, and feelings and attitudes toward new reproductive technologies. The survey was controlled for demographic factors such as age, ethnicity, and region. Researchers also investigated the specific attitudes of Aboriginal peoples and members of racial and cultural minority communities by conducting 10 focus groups with members of these communities.

Canada Health Monitor (*Price Waterhouse*)

The Canada Health Monitor is an ongoing, semi-annual telephone survey of the Canadian population. One of its main purposes is to track the attitudes and behaviour of Canadians in a number of health-related areas, and each Canada Health Monitor survey has a "special theme" to investigate a specific subject more deeply. During 1991, two surveys (Canada Health Monitor #6 and #7) were devoted to "Health Issues Affecting Women." The Commission helped design a number of survey questions to determine attitudes toward the use of new reproductive technologies, attitudes toward adoption, and attitudes and perceptions of issues related to health care and the Canadian health care system. Canada Health Monitor #6 surveyed a representative sample of 2 723 Canadians, 15 years of age and older, between August and November 1991, with additional interviews on February 27 and 28, 1992. Canada Health Monitor #7 surveyed a representative sample of 2 725 Canadians, 15 years of age and older, between December 1991 and February 1992.

Survey of Ethnocultural Communities (*Shyla Dutt*)

This survey of 100 key representatives from ethnospecific and ethnocultural women's communities sought out the views and unique concerns of those sectors of the population with regard to new reproductive technologies. The qualitative summary of results showed that attitudes expressed by organizations reflected patterns similar to those in the general public.

An ambivalence toward technology was also apparent in the Commission's survey of values and attitudes. Although attitudes toward technological developments in general were quite positive, the data suggest that respondents tend to be more wary of specific procedures arising from these developments. A clear majority — 70 percent — said they welcomed new scientific developments, and 60 percent said they do not fear the impact of scientific developments (versus 30 and 40 percent who expressed reservations or fear). However, the number of respondents expressing caution, fear, or scepticism, when added to the number who said they had insufficient information on which to base an answer, rose to about half of all respondents as the survey questions became more specific ("I worry that medical science is moving too fast for our society to maintain control over its use"; "I worry that the medical technologies used to assist people to have children are not safe enough").

Ambivalence was again evident in responses to this statement: "I believe that even though there are some processes of human life, such as birth, that we increasingly know more about, we are not meant to alter these processes." Forty-two percent of respondents agreed with the statement, while 37 percent disagreed; the remaining respondents were neutral. What is noteworthy is that respondents were more likely to agree strongly (22 percent) than to disagree strongly (14 percent).

A national survey of ethnocultural communities also revealed a certain hesitation toward technology. Here too there was a strong feeling that medical science is moving too quickly for society to be able to control it. In addition to these concerns, minority groups expressed fears that technology could be used to exploit their members or to divide their communities. In discussions with Aboriginal people, Commissioners heard concerns that traditions passed on for centuries could be threatened.

There was strong agreement for the suggestion that "medical science is moving too fast for our society to have control over its use" ... Those who had placed a higher value on preventing infertility also felt uncomfortable about the speed of medical innovation.

There was virtually unanimous support for the statement "our community is more concerned with access to basic health care and overcoming discrimination than with technology to assist in reproduction." Only one respondent disagreed.

S. Dutt, "Survey of Ethnocultural Communities on New Reproductive Technologies," in Research Volumes of the Commission, 1993.

In summary, the Commission's surveys of values and attitudes found that most Canadians are supportive of using technology to help people have children, even while having some concerns about the problems associated with their present or potential use. Concerns revolved around the health risks of the technologies and a general sense that technology is moving too

fast at too great a cost to society. As we learned during our public consultations, Canadians are also aware of the ethical dilemmas raised by the existence of the technologies. Although in some cases this range of concerns led to calls for a moratorium on new reproductive technologies, as discussed in Chapter 1, many respondents, despite their concerns, did not want to deny the potential benefits of the technologies to those who wish to use them. For example, 73 percent of those surveyed agreed with the statement that "if the technology to assist people to have children is available, people should have the right to use it." In addition, there is a small group of Canadians who find new reproductive technologies unacceptable in principle and who believe that the risks to society far outweigh the potential individual benefits from their use.

Unquestionably, the challenge for Canadian society is to gather information about how specific technologies affect individuals and social groups, so that the attendant medical and psychosocial risks and benefits can be identified. This is particularly important for technologies that affect human biological processes and have the potential to affect how our society evolves.

Globalization

Technological development results in the blurring of national boundaries. This globalization received relatively little attention in earlier inquiries into new reproductive technologies. As with many endeavours that depend on the growth and dissemination of knowledge, what happens in the field of new reproductive technologies in one country affects developments in other countries — no country can isolate itself from events elsewhere in the world. We need to know how the actions of other countries with respect to the technologies may influence developments in Canada and how Canadian actions can influence other countries. Several aspects of globalization raised important issues for the Commission.

For instance, research done in one area of the world results in medical procedures and knowledge being exported to other areas through international conferences, journals, and movement of personnel — the scientific and medical community is global in membership and scope. It would be an abdication of ethical responsibility, however, to condone unethical research carried out elsewhere in the world, while prohibiting it in one's own country, and then to permit the results to be used to benefit one's own population. This "ethical dumping" has been criticized for exposing people in less developed countries to risks for the benefit of those in the developed world.

Given increased globalization and its implications, international cooperation is needed in the area of reproductive technologies, in forms such as harmonization of national regulations and record-keeping systems. Canada has an opportunity and a responsibility to contribute to the debate on the ethical, legal, social, and economic issues and their relevance in an

international context. We believe that the appointment of this Commission — involving a commitment of time and resources thus far unmatched by any other country and leading to development of an extensive program of public consultation and original research — was a significant step in this direction.

> With respect to the orientation of research and services and restrictions on practices, what we are recommending is that an international committee be set up under the auspices of a worldwide organization, the WHO [World Health Organization] for instance, which would exercise control at the international level over the orientation of research and restrictions on practices. This issue, which is being discussed here in Canada, in France, in the United States, is one that should be debated throughout the world — we cannot allow it to be discussed by only the industrialized countries. [Translation]
>
> *C. Coderre, Fédération des femmes du Québec, Public Hearings Transcripts, Montreal, Quebec, November 21, 1990.*

Equality

As attitudes toward technology and society are changing, so too are Canadians' notions of equality and tolerance. This is reflected not only in constitutional and legislative arenas, such as the introduction of the *Canadian Charter of Rights and Freedoms* and various human rights laws, but also in workplace and other policies designed to promote more equitable opportunities for participation in society.

To gain a greater understanding of Canadians' general outlook with regard to a sense of tolerance and equality, the Commission's national survey of values and attitudes included several items asking about the principle of equality, attitudes toward immigration and the extent to which Canadians welcome others to our society, tolerance levels for homosexual relationships, and general attitudes toward women and women's role in society.

Most Canadians surveyed believed that all people should be treated equally. In fact, 90 percent agreed with the statement that "every individual should be treated equally regardless of ethnic origin, colour, religion, sex, age, or mental or physical disability," with over two-thirds of respondents strongly agreeing with this statement.

The majority of Canadians felt that equality between the sexes in terms of opportunities has not yet arrived. In our survey, for example, 69 percent of those interviewed agreed with the statement that "the opportunities for women are not equal to the opportunities for men in our society," while 18 percent disagreed and 13 percent neither agreed nor disagreed. Seventy-six percent of respondents indicated that they believe that women gaining more power and influence in the workforce has a positive impact on society, while 6 percent said that the impact has been negative, and 16 percent saw the impact as neither positive nor negative.

Survey respondents not only agree with the concept of equality of all individuals, most also believe that, as a society, Canadians welcome new immigrants from around the world. Two-thirds of respondents strongly agreed (30 percent) or agreed (36 percent) with the statement, "Canada welcomes people from different races, religions and cultures into society."

Although most people surveyed said they believed in the concept of equality, responses to specific issues of tolerance and acceptance varied. For example, with regard to acceptance of homosexual relationships, 35 percent of respondents believe they are acceptable; 21 percent had no opinion one way or another; 16 percent said they are unacceptable; and 27 percent found them totally unacceptable.

Pluralism and Diversity

Recognition of the need for more equitable participation in national life is reflected in increased awareness about human rights. The cumulative effect of these changes is that a more diverse range of voices is beginning to be taken into account in Canadian affairs. As a society based on immigration, Canada has seen a dramatic broadening of its cultural make-up, particularly in the past 30 years. Succeeding waves of immigrants are transforming labour markets, schoolrooms, and neighbourhoods of Canada's cities, especially in the large urban centres. Along with this greater cultural diversity have come new perceptions and new attitudes toward family, kinship, and parenthood.

> It is our firm belief that it is our duty to future generations that we take actions today that are directed towards ending existing inequalities in society. We see the role of this Commission to recommend just such actions, actions that protect the interests of the most exploited and oppressed sectors of our society today.
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> *S. Thobani, Immigrant and Visible Minority Women of British Columbia, Public Hearings Transcripts, Vancouver, British Columbia, November 26, 1990.*

The trend toward diversity tells us something about what twenty-first-century Canada will be like and has significant implications for society's response to new reproductive technologies. For example, ethical questions related to use of some of the technologies will not be resolved by referring to an unchanging common set of social beliefs, assumptions, and values. Nor can we assume that established ways of setting priorities, making decisions, developing policies, and delivering services will be adequate to the task of accommodating Canadians' diverse aspirations and goals. Yet this is precisely what more and more Canadians expect of their systems and institutions — that they should not only listen to a more diverse range of voices but also embrace and accommodate diversity through their structures, personnel, and

decisions. As Canada becomes more heterogeneous, it will become increasingly important to make core values transparent and to ensure that consensus on technologies takes into account the diverse nature of the country.

Empowerment

There is a general belief in Canada that decisions about technology in general, and new reproductive technologies in particular, should be made in the context of common values and opinions, and with full public participation. Our inquiry into new reproductive technologies was sensitive to this growing trend toward empowerment.

"Empowerment" literally means the investing of power and authority. For many Canadians, the word has come to mean enabling or equipping individuals or groups to have power, with the aim of creating and fostering relationships of equals in society. Several developments reflect this new attention to equality in social relationships. Both nationally and internationally, the past two decades have seen greater emphasis on personal and collective rights. Individuals and groups have become more vocal with respect to their desires and priorities. In turn, such institutions and systems as governments, health care, and education have been striving with varying degrees of success to become more responsive to people's diverse expectations. Empowerment goes beyond this, however; it also requires active participation by these systems' clients and users in decisions that affect them.

On an individual level, empowerment is evident in the development of social trends with particular relevance to the Commission's mandate. Many Canadians are attracted to alternative forms of health and social services, for example, because they are seen as more empowering of the individual than traditional approaches to medical treatment. There has also been significant growth in self-help and mutual support groups dealing with issues once considered the domain of medical and other professionals. In response, people working in medical settings are increasingly endorsing empowerment and are changing their approach to include more information and greater involvement of patients in their own care.

During our public hearings we heard over and over that Canadians want more information to support their decisions about new reproductive technologies. In focus groups, submissions, and private meetings we heard repeatedly about a changing approach to making decisions about medical care, an approach that underscores individuals' need to comprehend their situation, to reflect on it, to understand the risks and benefits of medical treatment, to have all options explained to them, and to be counselled and supported throughout the decision-making process.

The empowerment of individuals thus has implications for traditional doctor/patient relationships. Individuals are no longer as accepting or trustful of "experts," particularly in fields such as medicine where the

consumer movement has influenced people's perception of how they can participate in their own care. We found that Canadians are demanding a relationship with practitioners in which they are fully informed of their options — options that may include non-medical, non-interventionist approaches. Users of programs and services want relationships based on partnership rather than the focus on expert opinion that previously characterized such relationships.

> The fact of the matter is that the disability community feels as though doctors are a real problem, not just in this particular context but in general.
>
> *S. Day, Canadian Disability Rights Council, Public Hearings Transcripts, Vancouver, British Columbia, November 28, 1990.*

The move to empowerment has also given rise, however, to a common perception that access to specific medical treatments is a right, regardless of whether a treatment is appropriate or likely to work or what the costs might be. With respect to new reproductive technologies, individuals often demand access to treatments and technologies as a right, seemingly without regard to the social implications or financial consequences for the health care system. Changes in attitudes and ways of relating to societal institutions therefore present both opportunities and problems, with implications for how and through what structures new reproductive technologies are made available.

> The right to have children is not like the right to have an object or an animal. Children are persons and must be treated as persons. The right to have children is, therefore, better understood as the right to take advantage of opportunities that are open to everyone as a matter of course. When those opportunities are not present, then society has an obligation to assist those who lack the opportunities. When such a lack can be remedied by the development or application of reproductive technologies, then society has a *prima facie* obligation to develop and apply them. However, any societal action in this regard must always be with an eye to the fact that children are persons.
>
> *Brief to the Commission from the Canadian Medical Association, February 1991.*

Advocacy groups present another facet of empowerment. In the health care sector, consumer groups and individuals with a shared condition or situation have organized to press for change in policies, programs, or services, to increase public awareness of an issue or problem, or to demand more effective participation in decisions that affect them. The rise of advocacy groups also reflects more extensive social participation by previously marginalized groups. Policy and law makers are

being asked to ensure that the diverse interests, perspectives, and expectations of these various constituencies are taken into account when priorities are set and decisions are made.

Thus, empowerment is both an individual and a collective phenomenon. It is the objective of demands from many individuals and groups — especially but not only women — for a greater voice in decisions that affect them. At the same time, it results in a call for not only individuals but also governments, institutions, the health and education systems, and professionals to be accountable for what they do.

Empowerment has far-reaching implications for policy making. The number of voices at the table has increased, often making it more difficult to reach consensus, and potentially creating unrealistic expectations and heightening social conflict. Frustration with the complexity of trying to reach consensus has sometimes resulted in a backlash against empowerment, expressed as a desire to return to a time when decision making was simpler. Empowerment and participation do complicate the process of governing and of providing services. Nevertheless, equality is now entrenched as a constitutional principle, and Canada has accepted and institutionalized diversity and encouraged individual and group efforts to pursue autonomy, empowerment, and human dignity, even though their achievement is seldom uniform or easy. Pluralism is now enshrined in our constitution: multiculturalism, bilingualism, and the rights of certain groups — specifically women and Aboriginal peoples — are all recognized in the Charter. Society's institutions and decision-making processes must also recognize and incorporate it.

Medicalization

The term medicalization describes a social process — occurring over time — in which behaviours or conditions previously considered outside the realm of medicine became defined as medical concerns. Medicalization has eased suffering, cured disease, saved lives, and enabled couples to have healthy children. Increasing empowerment, however, has created resistance to what some perceive as excessive medicalization. Some think medicalization has contributed to a loss of autonomy by women over their bodies and their reproductive functions and that it has promoted a narrowly defined medical view of complex social problems. As scientific and technical knowledge about women's physiology and reproductive functions expands, so too does the pressure to define

> The medicalized nature of new reproductive technologies (NRTs) ... must be dismantled and reconstructed based on a [holistic] approach to health.
>
> *Brief to the Commission from Students, Women's Studies Course, University of Calgary, April 11, 1991.*

women's experiences in medical terms and to respond to their problems with technical solutions.

The phenomenon of medicalization is illustrated clearly in the evolution of social attitudes and medical practices with respect to women's reproductive experience. Appropriately or inappropriately, many aspects of women's reproductive lives — childbirth, contraception, abortion, premenstrual syndrome, and menopause — have moved into the medical domain. Certain communities are doubly affected by this shift — Aboriginal Canadians, for example, told Commissioners that the medicalization of reproduction has the potential to undermine traditional Aboriginal approaches to fertility, pregnancy, and childbirth..

As with the expansion of technology in other human endeavours, the application of medical technologies to reproduction raises questions about power relationships and who controls the technologies and their use. A key issue in the medicalization of women's reproductive lives is the unequal distribution of power inherent in the doctor/patient relationship. The patient has less technical and medical knowledge than the physician and may tend to surrender personal decision making. This power imbalance places a heavy responsibility on physicians to be aware of its potential consequences and of the need to make information available to patients and to support their decision making without directing it and without infringing on their dignity and autonomy. This is particularly relevant in situations where power imbalances are exacerbated by the fact that the patient is female and the doctor is male. The greater the vulnerability of the patient, the greater the physician's responsibility to use her or his power in the service of the patient.

Even though the goals espoused in the Hippocratic oath involve putting the interests of the patient first, the power imbalance is of concern because the best interests of the woman and what she values may not always be identical to the physician's interests and values. For example, studies have shown that when given full information on which to base a decision about treatment, patients tend to be much more averse to risk than clinicians are;[1] they also may value even the successful outcomes of intervention less than clinicians do.

There are also concerns that the increasingly routine use of some technologies will make it difficult to refuse their use and so will reduce women's scope for decision making and control over their own reproduction. For example, some types of prenatal tests, developed originally to detect disabling conditions in the children of high-risk couples, are now being used more generally and are becoming a routinely offered part of prenatal care. As discussed further in Part Two of our report, some women may feel pressure to have the testing once it becomes routine, despite having religious, cultural, ethical, or other reservations.

One challenge that lies ahead is to increase scientific understanding of reproductive concerns while situating issues of reproductive technology in a larger social context and safeguarding women's personal control over

issues that affect them directly and significantly. In some cases of childlessness, the most appropriate response may be medical. In others, individuals and society may be served better by consciously pulling back from medical and technological approaches — we may need to "de-medicalize" our approach. Determining when and how to do this, based on the potential impact of technologies, is one of the issues that has occupied the Commission and should continue to occupy society in the future as existing technologies evolve and new ones develop.

Another fear is that medicalization tends to generate its own momentum — even to the point, some feel, of creating a technological imperative. Some witnesses argued, for example, that new reproductive technologies promote feelings of "obligatory fertility," making it difficult for women to refuse treatment or stop it once begun, and that the technologies are therefore limiting rather than expanding their choices. Alternative non-medical responses, such as adoption, foster parenting, or a decision to accept childlessness, may appear inadequate or unacceptable, they said, when compared to the resolution hoped for from the technologies.

On the other hand, testimony before the Commission also showed that medicalization and medical technology have given some women options that otherwise might not have been available. Many couples who are infertile who appeared before the Commission welcomed knowing there was a medical reason for their condition and said that the availability of the technologies helped them resolve their feelings about it, knowing that everything that could be done had been done. Other positive aspects of a medical approach to infertility include greater attention to the origins of infertility, including environmental causes; recognition of infertility as more than just a "woman's problem"; increased options and alternatives for people who are infertile; and earlier and more precise diagnosis and treatment of infertility problems, with greater likelihood of effective treatment for some causes.

Impact of New Reproductive Technologies on Canadian Society

The trends that have emerged in Canadian society all point to the need for a new approach to decision making about technology, including new reproductive technologies. In an increasingly diverse society, where the interests of more groups and individuals are recognized and attended to, it is becoming more difficult to reach consensus on the difficult issues that must be resolved in all areas of life. This includes decision making about the health care system and new reproductive technologies, as we discuss in Chapter 4. It also raises the issue of the impact of new reproductive technologies on individuals, on identifiable social groups, and on society as

a whole. The increasing diversity of Canadian society means that we cannot make assumptions about the impact of new reproductive technologies on society as a whole. Different groups will be affected in different ways by the technologies, and in the remainder of this chapter we discuss the concerns that came to the attention of the Commission through our public hearings, consultations, and research program. In particular, we examine the concerns about the potential of the technologies to affect the health and well-being of women in Canadian society.

> The social management of motherhood is characterized by a certain inconsistency. While the planet as a whole tries to cope with overpopulation, in Canada our governments continue to worry about falling birth rates. They encourage Canadian women to produce more Canadians and place limits on immigration. People who have the means to have children but are not prepared to pay the price and choose not to have any are often judged as selfish. Access to abortion is barred to women whose health is not at risk. At the same time as governments develop policies to encourage higher birth rates, they make cuts in the social programs on which more and more women and children depend.
>
> *Brief to the Commission from the New Brunswick Advisory Council on the Status of Women, October 19, 1990.*

We were directed to examine the impact of the technologies on some groups, such as women, children, and families, by the terms of our mandate. Within these main groups, we also looked at other groups, such as people with disabilities and members of racial, ethnic, and cultural minorities, because the nature of their status in Canadian society may result in their being affected differently by the technologies. This section gives a brief overview of this impact. Because the technologies themselves differ as well, with diverse consequences for users and for society, this limits the generalizations that can be drawn. These effects will be examined in greater detail in our discussion of particular technologies in Part Two of our report.

Impact on Women

The diversity of women's views about new reproductive technologies reflects their various circumstances and experiences. Through the Commission's extensive communication channels, such as toll-free telephone lines, focus groups, roundtables, surveys, and other information vehicles, as well as in our public hearings, we heard the views of many women, sometimes speaking as individuals, sometimes speaking on behalf of their communities.

Women's Reproductive Health and Well-Being

Canadians are raising serious and thoughtful questions about the nature of reproductive technologies and their impact on women's health and well-being. As Commissioners, we had to consider the strong belief on the part of some Canadians that new reproductive technologies are needed to address important problems and that such technologies have opened up new choices for women. In this view, any attempts to curtail development of the technologies are unwarranted, because such an approach assumes that women are not the best judges of what is good for their own reproductive health and well-being. If use of these technologies is restricted "for women's own good," what other areas of women's health care or access to other kinds of services could be affected next?

As well, however, Commissioners had to consider the strong concerns of others about the harmful effects of the technologies on women, individually and collectively. These concerns take several forms. We heard from women that they have not been involved in decisions about the development of new reproductive technologies and the provision of services, and that women's interests have not been represented in the boardrooms and professional forums where these decisions are made. Some feel decisions have been made about technologies and services without considering their adverse consequences for women's autonomy as individuals and their status and value as members of society.

> We understand the urgency felt by women who suffer from infertility, but we also think that the technologies present such enormous questions for our society we have to look at [them] from a broad social perspective, and particularly from a collective perspective as women.
>
> *J. Rebick, National Action Committee on the Status of Women, Public Hearings Transcripts, Toronto, Ontario, October 29, 1990.*

Some of those testifying before the Commission believe that the technologies have not been developed to serve women or to improve their health and well-being; rather, the technologies have increased the ability of doctors and others to control reproduction (medicalization of reproduction). If technologies are to be used in a way that respects women's reproductive autonomy, it is argued, the entire approach to reproduction must change — infertility should be prevented in the first place where possible, and basic reproductive health care should be provided. Indeed, it was argued that greater priority should be given to improving the social and economic conditions of women generally, as only then could new reproductive technologies be used in a way that respects women's reproductive autonomy and sexual equality.

> I was struck by the discussion this morning of how difficult it is to get women talking about NRTs when the bread and butter issue is [the] economic situations of women in Newfoundland and Labrador — it seems to be the chief and overriding issue concerning our lives.
>
> *Roundtable Discussion, Public Hearings Transcripts, St. John's, Newfoundland, October 15, 1990.*

There was also debate about the impact of new reproductive technologies on reproductive choice. Some women believe that in the area of reproductive health, more choice is not necessarily better; they see the availability of such technologies as in fact limiting their choices by making it easier for people to judge women's behaviour and decisions. In this view, society has a collective responsibility to women, which may require limiting choices by individual women if these choices promote harmful social perceptions of womanhood or detrimental attitudes toward women as a group.

Some women think that because women's bodies and social status could be put at risk, women should have the primary role in determining whether new reproductive technologies are socially desirable and, if so, how they should be provided and regulated. Because of women's lack of involvement, they said, new reproductive technologies have been developed by exploiting the genuine desires of those who are infertile, as means by which physicians and researchers achieve career advancement and financial gain — all at the expense of women who experience adverse physical, emotional, or financial consequences as a result of the technologies.

Some women believe strongly that the development and use of new reproductive technologies is a consequence of women's unequal status in society. Just when women are making strides toward independence and equality, it is argued, the advent of new reproductive technologies serves to reinforce the image that women are mothers and nurturers first and foremost. Some analysts contend that new reproductive technologies contribute to devaluation of women in society because they emphasize the societal belief that women's primary role, and the only role for which they should be valued, is reproduction.

We heard that new reproductive technologies could also undermine a holistic view of women's health, if they are delivered in a way that deals only with body parts. This possibility was particularly evident in discussions of commercial preconception agreements, which could contribute to women being seen as "wombs for hire." Similar concerns were expressed about commodification of human reproductive tissues and processes — that is, treating women and children as objects or means to an end rather than as ends in themselves, thereby devaluing their humanity and dignity.

In discussions with Canadians we found concern that focussing public attention and resources on new reproductive technologies could divert attention from reproductive health concerns that affect the majority of women: research into prevention of sexually transmitted diseases (STDs), many of which can lead to infertility; research into and the availability of safe and effective contraception; the availability of safe and effective abortion; family planning services; elimination of workplace hazards to reproductive and general health; health promotion activities; and pre- and post-natal care. New reproductive technologies were seen to shift scarce research and health care dollars from these other health concerns.

This view emphasizes the need to focus public attention and resources on reproductive health care as a continuum. If assessed within the framework of women's reproductive health care needs as a whole (from puberty to post-menopause), new reproductive technologies could be seen as one of many reproductive health issues. Given that avoidance of reproductive dysfunction is one of the objectives of reproductive health care, society could seek to eliminate the preventable medical conditions that lead to infertility. In this view it would preclude the need for people to seek treatment in the form of new reproductive technologies.

Concerns from Particular Groups of Women

Many women from different groups expressed concern over access to both basic health care services and new reproductive technologies. These women had concerns specific to the personal and collective issues within their group.

Aboriginal women told us about the lack of basic health and education services and felt that these should take priority over new reproductive technologies. They also said that new reproductive technologies must be offered in ways that are culturally and linguistically appropriate to the communities being served. Aboriginal peoples have unique ways of viewing children in their communities, resulting in different ways of dealing with childlessness, such as custom adoption (where the child remains in the community and in contact with her or his family and cultural origins).

> I believe that there should be national standards but I would also make a fervent plea that those standards reflect the diversity of people in Canada. Those standards should not be used in my mind as a controlling mechanism but one that would respect the interests of people like the aboriginal people in Canada ... who are at this time and have always been very concerned about maintaining themselves as distinct national peoples in Canada.
>
> *M. Dion Stout, President, Indian and Inuit Nurses of Canada, Public Hearings Transcripts, Ottawa, Ontario, September 20, 1990.*

Some felt new reproductive technologies could undermine such traditional approaches.

Women from racial, ethnic, and linguistic minority groups told us they often have difficulty gaining access to basic health care services and information in culturally appropriate ways. Such basic services, they told us, should be the priority and are generally more important than access to new reproductive technologies. Where new reproductive technologies are provided, intervenors said, there should be equal access to the technologies, without either individual or systemic discrimination. They feared that they may be denied the benefits of these technologies and instead encouraged to control their fertility.

There were concerns throughout the country that access to new reproductive technologies is easier for affluent white couples, and that minority or low-income people are seen as less deserving of access. Indeed, for women who are economically disadvantaged, access to basic health care services is a priority, but we heard the view that if new reproductive technologies are to be made available there should be equal access regardless of income. Also, linguistic and cultural barriers often reduce access to the technologies for many. In fact, in focus groups, submissions, and presentations, many intervenors identified a need for culturally and linguistically appropriate counselling and information.

Intervenors also noted the disproportionately negative impact of judicial intervention in pregnancy on women from racial and ethnic minorities (discussed in Chapter 30). Some said that minority women are more vulnerable to judicial controls such as court-ordered sterilizations or other interventions. Some noted women's vulnerability to pressure from sex selection

> New reproductive technologies have the potential to radically change the way we think about reproduction, sexuality and parenting. However, there are existing biases that are already operating and have determined the way in which NRTs are applied.
>
> The values which presently make an impact on NRTs are largely those of the medical establishment, who are predominantly male, disability-phobic, white, middle class and heterosexual. For example, in vitro fertilization is presently accessible only to qualified women; that is, women under 40 who are in a stable, long-term heterosexual relationship and who can afford the expense.
>
> IVF candidates must conform to stereotypical notions of what kind of woman makes a good mother. Women with disabilities, poor women, single women and lesbians do not quite fit this conception of the ideal wife and mother.
>
> *B. Van't Slot, Women's Network, Public Hearings Transcripts, Charlottetown, Prince Edward Island, October 16, 1990.*

in some cultural communities (discussed in Chapter 28). Still others underlined the danger of exploitation of women of lower socioeconomic status through preconception arrangements (Chapter 23) or through financial incentives for reproductive functions such as egg donation (see Chapter 21), emphasizing the potential for dual exploitation because of both socioeconomic status and minority status. These particular concerns were accompanied by broader concerns about the difficulty of assessing the implications of the technologies for groups or communities in the absence of more extensive public knowledge and discussion about them.

Single women and lesbians fear that restrictive access to assisted insemination may deny them the opportunity to have children by this means. Medicalization of assisted insemination and restrictions against self-insemination are seen as unnecessary impediments to access to safe sperm for self-insemination.

Women in rural and remote areas are concerned about geographic distances and travel costs. They are also concerned that devoting scarce resources to new reproductive technologies may divert them from more urgent health care requirements. We discuss these and other issues of equitable access to services in greater detail in Part Two in the context of our examination of specific technologies.

Women who have had negative experiences with reproductive interventions sounded warnings about unexpected consequences of technology. They cautioned that reproductive interventions used today may have negative health repercussions in future and emphasized the need for data about the short- and long-term psychological and physical health risks of new reproductive technologies and their overall safety and efficacy.

At the same time, women with fertility problems and women at risk of passing on a genetic disease emphasized their needs and their ability to make decisions in their own best interests, provided they have complete and accurate information about associated risks and expected outcomes. Women with fertility problems talked about the importance to their lives in the long term of having children, and stressed their desire for more public awareness of the emotional and societal issues related to infertility and its prevention and possible treatment. Reproductive freedom, they asserted, was dependent upon equal access to the technologies as well as information and counselling for those who are infertile. They identified difficulties in access due to cost of treatment and availability of services.

As is clear from this brief review of testimony before the Commission, not all women see the development and use of new reproductive technologies in the same way. This is not surprising, given the diversity of women's backgrounds, experiences, and life circumstances. From one perspective, the existence of the technologies offers women who are infertile, families at risk of congenital anomalies or genetic disease in their children, or individuals suffering from Parkinson disease some hope and an opportunity to improve their well-being.

From another perspective, however, discussions of new reproductive technologies should focus on broad societal concerns and the interests of women as a social group. In this view, the good of society as a whole rather than the choices of individuals should guide the assessment of such technologies. The collective interests of women as a social group should take precedence over the interests of individual women, the argument continues, the interests of society as a whole over the interests of families at risk. Consequently, the criteria to evaluate the use of new reproductive technologies should be the probable effects on women's autonomy, equality, and status in society. Still others argued for evaluation of new reproductive technologies with the best interests of the resulting child and families in general as the paramount consideration.

On reflection, it is clear that these are not separable alternatives: both individual and collective interests must be taken seriously in a humane and caring society. We have sought to demonstrate this in the chapters that follow.

Impact on Children

Children born as a result of reproductive technologies were the second group identified in the Commission's mandate. Technologies using donated gametes (eggs, sperm, or both) are creating new kinds of family and social relationships. Traditional notions of biological and kinship ties are called into question as a result, because the concept of family has never before included the situations that are emerging through the use of new technologies.

In addition to social relationships, we are concerned about the possible impact of these technologies on the health, emotional well-being, legal status, and economic circumstances of children and their families. These effects will differ from technology to technology and with the circumstances under which a given technology is used. Each of these areas is considered more fully in Part Two.

The other groups that must be taken into account in considering the impact of the use or non-use of new reproductive

> Historically, the family unit has been premised on the "traditional" family form existing as a result of a legally sanctioned marriage. The principles and definitions governing the law of filiation assume that reproduction occurs within either a marital relationship or a stable heterosexual relationship and it usually perpetuates this bias. In addition, the rules of law reflect an assumption that reproduction occurs only through sexual intercourse, an assumption greatly challenged by the various forms of assisted reproduction.
>
> *E. Sloss and R. Mykitiuk, "The Challenge of the New Reproductive Technologies to Family Law," in Research Volumes of the Commission, 1993.*

technologies include couples who are infertile; couples at risk of congenital anomalies or a genetic disease in their children; and donors of sperm, eggs, and embryos and their families. The consequences for these individuals may be physical, psychological, financial, and legal; these effects vary significantly with the type of technology used, yet significant gaps remain in our knowledge of the exact nature and extent of these consequences.

There is a dearth of information about, for instance, the direct outcomes of being conceived through assisted reproduction. Physical outcomes are important to monitor, but there may also be emotional and psychological outcomes to being born through the use of assisted methods of conception. For instance, we know very little about the effect on a child's sense of identity and belonging of being born through assisted insemination using donor sperm or following *in vitro* fertilization using donated eggs. Very often, these practices are surrounded by secrecy, with many parents not wanting to tell their children about their biological origins.

Little is known about the long-term outcomes of being born through donor insemination (DI) — a Commission study of donor insemination found only one published follow-up study (carried out in Japan in 1968) of children conceived through DI. Other reports about the long-term outcomes tend to be based on case studies or very small samples. Once again, without concrete information, all we can do is infer from what we know about children in analogous situations — adoptees. We know now, for example, that adopted children often experience a powerful urge to seek information about their biological parents and to know about their genetic and cultural heritage — "genealogical bewilderment" was a term coined as long ago as 1952 to describe the adjustment problems experienced by a substantial proportion of adopted children who had no information about their biological origins.

Impact on Family Structure

Many of the recent changes in society converge in a single social structure: the family. The "traditional" family (two parents and a child or children) was for many generations the most common family structure in Canada. However, an array of new family forms has emerged during this century. Family forms that were once rare or socially unacceptable — one-parent families, common-law unions, blended families, same-sex couples, childless couples — are becoming more common. It has become more common and widely accepted for both parents to work outside the home. The increasing diversity of Canadian society means that the Eurocentric notion of the nuclear family is less dominant than it once was. Perceptions about the importance and nature of family relationships are changing. These new family forms are the result of emerging trends in family formation. Factors in these changes include a trend toward marrying at a later age; a decline in the total number of marriages; and rising rates of divorce and remarriage — all of which have implications for fertility and

therefore for new reproductive technologies.

In the Commission's national survey of values and attitudes, we explored some attitudes toward these various family forms. Results of the focus groups conducted in preparation for the survey indicated that a heterosexual married couple with children was what most participants considered to be a family; other family structures were acknowledged, but what was fundamental to most participants' perceptions of a family was the presence of children.

> We are particularly concerned about the family, which is the main building block of our society. Any society for that matter. If Canada is to be strong we must build strong families. The family is now facing new and confusing pressures. The breakdown of the family unit is a significant reason in our view for the disorder we are witnessing in our nation at the present time.
>
> *H. Hilsden, Pentecostal Assemblies of Canada, Public Hearings Transcripts, Toronto, Ontario, November 20, 1990.*

For example, when asked whether a man and a woman living common law without children constitutes a family, in the national survey 47 percent said it does not, while 24 percent said it depends, and 25 percent said it does. A homosexual couple without children was considered a family by 13 percent of respondents, whereas a homosexual couple with children was considered a family by 37 percent of respondents. Our survey found that, overall, women are more accepting than men of a wider range of family forms. A single man or woman with children was considered a family by 65 percent of those surveyed. These responses suggest the importance of the presence of children in defining a family. Further, our survey of ethnocultural communities revealed that children were seen as important in carrying on cultural and ethnic heritage.

Although the traditional family is still considered the social norm, this perception is changing gradually. Research has demonstrated little support for the contention that any one family structure is essential for the well-being of children. In fact, studies point to other factors — such as the environment of the family (its economic and emotional well-being), the quality of relationships within the family, the time and energy family members have to devote to family life, and the availability of support systems in the form of extended family and networks of friends — as being more important to a child's well-being than any particular family structure.

In discussions with members of visible minorities, Aboriginal communities, and the general public, the consensus was that no one single type of family structure was ideal for the well-being of children. As one participant noted, "What is important is how you bring them [the children] up ... and the morals you teach them." There was a sense that the family is the vehicle through which values are passed on to children. Examples we heard of specific values that should be communicated and learned

through the family included respect for others, self-respect, decency, how to work hard, and religion.

If "traditional" families continue to be seen as the norm, however, society may decide to restrict access to new reproductive technologies to those who conform to this view, despite the fact that non-traditional families are increasingly common. New reproductive technologies could play a role in facilitating the addition of children to non-traditional families as well as to traditional families.

> Aboriginal children were perceived as the greatest gifts given to aboriginal women by the Creator. Children were always given privileged and special status in the North American aboriginal family. They were showered with affection, kindness and attention not only by their biological parents, but by all clan members, siblings, and members of the extended family.
>
> *M. Dion Stout, President, Indian and Inuit Nurses of Canada, Public Hearings Transcripts, Ottawa, Ontario, September 20, 1990.*

Impact on People with Disabilities

People with disabilities are also concerned that the use of such technologies may heighten negative societal attitudes toward disability generally. In particular, they think the use of prenatal diagnosis to identify fetuses with anomalies, possibly leading to abortion, creates a dangerous environment for people with disabilities. As testing becomes more common, will parents face societal disapproval if they knowingly bring a child with disabilities into the world? There are also concerns that the focus on prenatal diagnosis may divert resources from providing support to people with disabilities and their families. These issues are examined in greater detail throughout our discussion of prenatal diagnosis in Part Two.

> Will disabled women who are the poorest of the poor be able to gain access to the infertility clinics? Are the clinics even wheelchair accessible? What if a deaf woman came in and needed sign language? Would a doctor [look] at the same old stereotypes of disabled women and feel that they should not even try to have a baby? And many people feel that way when disabled women even think of getting pregnant.
>
> *P. Israel, DisAbled Women's Network Canada, Public Hearings Transcripts, Toronto, Ontario, October 31, 1990.*

For women with disabilities, new reproductive technologies raise two main concerns: access to services, and the effects of prenatal diagnosis on society's attitudes toward disability. Many women with disabilities have the same desire to bear children as others and argue that they should have equal access to technologies where

they are provided. Indeed, the very nature of some disabilities may mean that women will require assistance in order to have children. Thus, they said, disability should not be a factor used to screen out potential candidates for services involving new reproductive technologies.

Impact on Society

In light of the potential for new reproductive technologies to affect society as a whole, certain questions arise. How will they change our understanding of how to relate to each other as members of society? How will we define social relationships such as families, parents, siblings, and generations? The Commission is concerned with these questions not only as they affect current relationships in society but also as they affect how our society evolves. Our assessments of the potential harms and benefits of new reproductive technologies covered a broad range of considerations, including, among others, the need to avoid harm to future generations from either using or failing to pursue a given technology or practice. This is particularly relevant, for example, when we consider the potential of some of the technologies, such as research involving the use of fetal tissue to treat diseases that affect many Canadians.

> The scope and magnitude of the issues before this Commission [are] truly staggering. What you are attempting to examine goes to the heart of what we are as humans. The questions raised by these new technologies [challenge] each of us in very fundamental ways about our views of life, ethics and morality. The solutions we find will define us as individuals and as a society.
>
> *A. Lie-Nielsen, Executive Director, Prince Edward Island Council of the Disabled, Public Hearings Transcripts, Charlottetown, Prince Edward Island, October 16, 1990.*

Although the individuals on whom new reproductive technologies have a direct impact remain a minority in society, their collective experiences still have the capacity to influence broader societal values and norms, just as the collective experiences of any identifiable social group can influence how society perceives and responds to a particular issue. For example, how society views and values adoption has been affected by the collective experience of those involved in it. Adoption was once shrouded in secrecy, with a certain social stigma attached — for the adoptive parents, for the adoptee, and for the woman who "gave up" or "surrendered" a child for adoption. Increasingly, however, public calls by adoptees for access to information about their biological parents, as well as media stories about how adoptees have re-established relationships with biological parents — often encouraged by their adoptive parents — have expanded our understanding of the social circumstances that lead to adoption.

Similarly, the increasing number of children born through assisted insemination or *in vitro* fertilization has created greater awareness of these ways of having children and is influencing how society sees these children; it may also result in different views on the technologies that brought them into being. We need to consider what impact, if any, there will be on the demographics of the family. Is it likely that the number of single-parent families or non-traditional two-parent families will increase because of increased availability of donor gametes? How would children be affected as a result? Various individuals and groups are bound to see these issues in different ways, depending on their position or status in society, their values, their knowledge of the technologies, their interests in the use of the technologies, and a host of other factors.

In the absence of specific laws and regulations — which are society's concrete expression of collective decisions — decision making by individuals, practitioners, and public policy makers will be shaped by an interplay of individual and group views and perceptions about technology in general. This interplay also will affect how specific laws and regulations are eventually made. But experience shows that laws and regulations tend to lag behind knowledge and knowledge-based developments by a decade or more, just as the process of change in social institutions lags behind changes in social realities. Furthermore, by the time change in law occurs, new developments may well have rendered it obsolete.

Thus, there is an ongoing iterative process — the origins and use of new reproductive technologies have implications for society, which in turn shape decisions about provision of and access to the technologies. As these decisions are implemented, a fresh set of social conditions evolves in which new or modified technologies may develop, and new societal responses will be required.

> We are filled with compassion for the infertile couple who wants to have a child and cannot give birth through the normal, natural process. These couples should have recourse to alternative methods of reproduction.
>
> We have outlined our concerns in this brief, as we are apprehensive about the speed with which these new techniques are evolving.
>
> The Committee is focusing on the consequences, both good and bad, of NRTs on future generations. We wanted to bring up concerns in connection with a social issue. Even though, because of our age, we are not directly affected by NRTs, we believe that they will have an impact on the family structure. [Translation]
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> *Brief to the Commission from Le comité "Vieillir au féminin" de l'Université du troisième âge de l'Université de Moncton, January 18, 1991.*

A New Approach to Decisions About Technology

As we have seen throughout this chapter, new reproductive technologies have a varying impact on different sectors of society; members of some sectors are affected much more directly and profoundly than others, but some changes will affect all of society. Depending on whether and how some technologies are used, they could contribute to making Canada a more caring or a less caring society. Public policy should be developed with these implications in mind; this is the perspective that informed the Commission's approach to assessing the technologies and developing our recommendations.

Society does not have to be driven by technological change; we have choices about how to control technologies to ensure that, if they are used, it is in beneficial ways and in ways that avoid or minimize their adverse consequences. It is society's responsibility to see to it that knowledge gained from science develops in a way that is beneficent, along directions most likely to have humane and advantageous consequences.[2]

New reproductive technologies are a specific instance of this general position — that society has a responsibility to determine the place and uses of technology. From the Commission's perspective, society's approach to technology must be balanced in its orientation and solidly grounded in experience and identified needs. Despite growing unease about technology, particularly when it touches on the life sciences and medicine, and deep concern that new powers to intervene in human lives yield the potential for abuse or inappropriate application, it is possible to approach these issues based on careful examination and weighing of the evidence.

This approach identifies several considerations: first, society's need and responsibility to control the development and use or non-use of technologies in light of broader ethical, social, economic, and other concerns; second, within this context of societal control, the need for individuals to be able to make informed choices with respect to their own use or non-use of a technology. Dealing with technology effectively and appropriately means taking the broad view (all of society) and the long view (over more than one generation) without losing sight of the individual. This suggests that more voices and perspectives than before need to be involved in making decisions about technology — among others, members of the public, experts, and those experiencing or affected by the technologies.

Between the extremes of unquestioning acceptance and outright rejection of new reproductive technologies is an approach based on a step-by-step examination of evidence regarding the origins, current practices, outcomes, and implications of, and alternatives to, specific technologies. The result may be that some technologies are encouraged, others are regulated or restricted, and some are banned altogether. This evidence-based evaluation must be done in the context of the technologies' broader

implications for individuals and for society as a whole. If we ignore their implications, or allow them to proceed without discussion of their positive and negative aspects, new reproductive technologies could bring about changes that contradict or clash with society's values and beliefs, and we will become a less tolerant and caring society as a result.

The Commission intends to contribute to the social debate about the implications of new reproductive technologies by promoting public discussion of their social impact that is well informed and based on accurate information. We have tried to ensure that the needs and interests of all groups and individuals in society have been taken into account in our discussions and thinking about new reproductive technologies to minimize, whenever possible, any inadvertent negative consequences. We frame the discussion in terms of our guiding principles, with the ethic of care as a context, as we set out in Chapter 3, and have focussed on evidence-based medicine, as discussed in Chapter 4. We intend to provide a policy-oriented approach to new reproductive technologies that can also be used as a framework for developing public policy on other emerging technologies. We are confident that this approach can increase the likelihood that new reproductive technologies are provided and used only in ways that coincide with the values and priorities of Canadian society and that, where they are used, they are used responsibly and with care.

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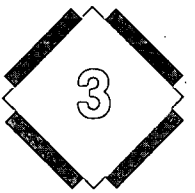

What Guided Our Deliberations: Ethical Framework and Guiding Principles

Given the range and complexity of the issues before us, it was vital to develop a way for Commissioners with varying backgrounds and life experiences to approach the technologies — to establish a framework for decision making. How new reproductive technologies are controlled and regulated will affect the way people think about their rights and responsibilities to each other and to future generations. It was therefore necessary for Commissioners to develop an explicit and consistent ethical approach to examining these implications and making decisions; it would also enable us to make clear to others the reasoning and basis for our recommendations.

The process through which we developed this approach and the shape it took are the subject of this chapter, which describes the ethical framework and guiding principles that informed and infused our deliberations as we worked toward our recommendations. Our goal is to ensure that the reasoning behind our recommendations is clear to policy makers, to those working in the field, and to Canadians generally. As we examine individual technologies and the issues they raise in Part Two of our report, the relationship between the ethical principles described here and the real-life dilemmas facing individuals and society as we consider the use or non-use of technologies will also become clear.

We considered two basic approaches. One approach involves choosing an overarching ethical theory, such as utilitarianism, natural law, or contractarianism. These theories, which are examined in greater detail in research studies and background papers prepared for the Commission (see research volume, *New Reproductive Technologies: Ethical Aspects*), postulate a single overarching rule or ideal that can be used to resolve moral debates. A second approach uses a broader ethical orientation —

called the ethic of care — and, within that orientation, a set of guiding principles to serve as a prism for moral deliberations.

We adopted the second approach. Three factors influenced our decision. First, adopting a single overarching theory generally requires rejecting the others when in fact they have substantial areas of agreement — for example, as we discuss later, a commitment to a moral point of view. In addition, the relative merits of these theories have been the subject of philosophical debate for centuries — there is no reason to think that this can be resolved in the near future, and certainly not by this Commission.

Second, there are immense difficulties in applying general theories to the complex issues raised by new reproductive technologies. It is often extremely difficult to draw a direct, clear, and uncontroversial line from the very general concepts found in a given ethical theory to the specific circumstances of particular ethical decisions. The long distance from theory to application can often create irresolvable differences. Indeed, the level of disagreement *within* each of these schools of thought on particular issues of reproductive technology is often as great as the level of disagreement *between* the various schools.

Finally, overarching ethical frameworks like utilitarianism or social contract theory often are premised, in one way or another, on an understanding of human nature that sees people as individuals first and foremost, protecting their own interests against the encroachment of others. Yet human beings are connected to one another in families, communities, and social bonds of all sorts. People connected in these ways care for one another and seek one another's welfare, knowing that people cannot enjoy rights and interests by themselves. In our view, an ethical perspective that gives priority to this mutual care and connectedness and tries to foster it is particularly helpful. The ethic of care means that a large part of ethical deliberation is concerned with how to build relationships and prevent conflict, rather than being concerned only with resolving conflicts that have already occurred.

Obviously, conflict cannot be prevented entirely; no ethical stance could ensure that. It is therefore important to have not only an ethical perspective that fosters care and community but also guiding principles to cast light on issues when conflicts do arise. Each principle sheds a different kind of light on the options available. Reaching moral decisions often involves considering more than one of these principles, as usually more than one will be relevant to the situation. Moral reasoning requires consideration of whether and how each of the principles applies, all within the overall perspective of the ethic of care. This approach seeks to prevent adversarial situations whenever possible; yet the guiding principles are in place to act as a sort of bottom line of social justice when all else fails. The reasons that led the Commission to adopt this approach are discussed in more detail in this chapter.

One of the difficulties we saw with adopting one traditional overarching ethical theory was that it would focus attention on the differences between the various theories. We thought it was more useful to focus on what these theories have in common, including a commitment to a moral point of view. All the traditional overarching theories agree that there is such a thing as a moral perspective on issues — a perspective that is distinct from a self-interested or economic perspective — and that it is defined by some notion of equal respect for persons.

From a narrowly self-interested or economic point of view, some people's lives may not matter to others, because they are unable to harm or benefit them. From a moral point of view, all people matter in and of themselves. It matters how well their lives go, and if our decisions affect their well-being, then we must take that into account. Adopting a moral point of view thus requires sympathetic attention to people's interests and circumstances, understanding how things look from their perspective, and taking account of their well-being. The ethic of care resonates with the moral point of view common to all these ethical theories.

The Ethic of Care and the Guiding Principles Approach

Commissioners believe that the approach offered by the ethic of care and our guiding principles gives the most insight into the particular issues the Commission is examining. It provides the greatest opportunity for preventing adversarial situations and offers the possibility of finding agreement on specific issues, even among those who adhere to different overarching ethical theories. The theoretical development of the ethic of care is taking place in many different contexts: in secular mainstream ethics, in feminist theory, and in religious thinking. We have drawn on all these sources to enrich our understanding. Of course, promoting the ethic of care is not entirely new — to a degree it has been reflected over the centuries in various formulations of medical ethics and the duty of physicians.

> The Commission should commit itself to a stated set of guiding principles and use these principles in its ethical deliberations. If there is a broad consensus in favour of each of these principles, then this approach will add considerable credibility to the Commission's conclusions, since these will be seen as neither ad hoc nor merely the result of logrolling among competing interests.
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> *L.W. Sumner, reviewer, research volumes of the Commission, 1992.*

The Ethic of Care

Although there are differences of emphasis among the ethical thinkers from whose work we have drawn, the ethic of care holds, broadly speaking, that moral reasoning is not solely, or even primarily, a matter of finding rules to arbitrate between conflicting interests. Rather, moral wisdom and sensitivity consist, in the first instance, in focussing on how our interests are often interdependent. And moral reasoning involves trying to find creative solutions that can remove or reduce conflict, rather than simply subordinating one person's interests to another. The priority, therefore, is on helping human relationships to flourish by seeking to foster the dignity of the individual and the welfare of the community.

Where intervention is necessary, its aim should be creative empowerment so that, as far as possible, everyone is served and adversarial situations do not arise. At the very least, intervention must, in this view, avoid causing harm to human relationships. The traditional first principle of medicine, non-maleficence (do no harm), is thus applicable not only to medical practice but to intervention in society generally and is made into a positive commitment to empowerment. The concept of non-maleficence goes beyond simply avoiding actions that might cause harm, to taking steps to prevent harm and create conditions in which harm is less likely to occur and beneficial results are the more likely outcome.

The Guiding Principles

Although most would agree with the goals of the ethic of care, it is less than immediately obvious how these goals can be implemented in practice. Without some further development, the theory remains vague — benign but ineffectual. This is widely recognized by its proponents, who therefore adopt basic principles of justice — often those developed within traditional ethical theories — as a means of applying an ethic of care.

Accordingly, while adopting the ethic of care as an orienting ideal, the Commission found it useful to identify eight principles of special relevance to our mandate that enable decisions to be made that give concrete expression to the ideal of care. The principles are to be found in ethical theory generally and

> We live in a scientific and technological culture. Our lives are not only filled with the products of science and technology but both pervade our society as ways of making sense of the world. We see things as problems according to a certain rationale and we expect technology to fix them. Our approach lacks vision and guiding principles, sensibility and accountability.
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> *A. Burfoot, private citizen, Public Hearings Transcripts, Montreal, Quebec, November 21, 1990.*

biomedical ethics in particular. They are also consistent with what we heard in testimony and submissions from Canadians and with the values and principles implicit in the reports of inquiries in other countries. The eight principles are individual autonomy, equality, respect for human life and dignity, protection of the vulnerable, non-commercialization of reproduction, appropriate use of resources, accountability, and balancing of individual and collective interests.

There is some overlap among these eight principles. For example, the principle of non-commercialization of human beings and human reproduction is largely a conclusion from the other principles, such as equality, protection of the vulnerable, and respect for human life and dignity. Similarly, the appropriate use of resources is often connected to the principle of accountability, and the promotion of autonomy is often seen as requiring equality of access to health care. It may be possible to combine these related principles, although perhaps at the price of losing sight of important issues. Conversely, it may be possible to divide up some of these principles into even finer categories. However, the eight principles seem to capture ethical considerations that are both important and relatively distinct. Since these principles informed our deliberations and infuse our reasoning in the rest of our report, we give a brief account of each of them in the following pages. Moreover, there is no hierarchy here; no principle automatically trumps any other. Different principles are considered as they apply to specific issues.

> Any decision on the regulation of new reproductive technologies must endeavour to balance the interest of all members of society at the same time though the council believes that any policies which are developed must be grounded on the principle that women have the absolute right to decide what happens to our body and to determine our own choices with respect to reproduction and reproductive health care.
>
> *W. Williams, The Provincial Advisory Council on the Status of Women, Newfoundland and Labrador, Public Hearings Transcripts, St. John's, Newfoundland, October 15, 1990.*

Individual Autonomy

By individual autonomy we mean that people are free to choose how to lead their lives, particularly with respect to their bodies and their fundamental commitments, such as health, family, sexuality, and work. Clearly, this is not an unqualified principle. Individual autonomy does not include the freedom to harm others, to use force to coerce them, or to undermine social stability. Moreover, restrictions are sometimes placed on people's freedom of action in circumstances if it is determined that they lack the competence necessary to make reasonable decisions. However, a defining feature of modern culture is that individuals are seen as having the right (and the responsibility) to

decide what kind of life they want to lead. From this principle it follows, for example, that actions or decisions that affect people's health, bodily integrity, security, and identity require informed consent.

Equality

The principle of equality means that every member of the community is entitled to equal concern and respect. The view that the well-being of each person matters and matters equally precludes any social practice that reflects or perpetuates the assumption that some people's lives are worth less than others. Adopting the principle of equality keeps this tenet in view.

> Our interpretation of the principles governing human rights in Canada and the current thinking of the leaders in Canadian family law lead us to the following conclusion: all citizens should be equally eligible for medically assisted reproduction services.
>
> Any legitimate restrictions, relating to economic factors or the distribution of scarce resources, should not be used as an excuse for discrimination on the basis of marital status or sexual orientation, but should be implemented in a manner that respects human rights and the basic principles of justice. [Translation]
>
> *G. Létourneau, Président, Commission de réforme du droit du Canada, Public Hearings Transcripts, Montreal, Quebec, November 21, 1990.*

The principle of equality forms the basis for our particular concern with ensuring that the interests and concerns of Canadians in all their diversity are taken into account in decisions about new reproductive technologies. This is why we have examined specifically how the technologies affect women, members of racial and ethnic minorities, people with disabilities, Aboriginal people, and lesbians. We recognize that achieving equality sometimes requires special steps to ensure that groups that have experienced discrimination in the past are placed on an equal footing with other members of society. This is particularly relevant in discussions of access to services, because services must be not only accessible but also designed to take into account the diversity of needs, expectations, and abilities in the populations they are intended to serve.

Equitable access to public services such as health care and education is based on this principle. We heard from many Canadians that they believe treating people with equal respect requires equitable access to basic services. Non-discrimination in access to these services has also become part of Canada's constitutional and legal environment through prohibition of discrimination on the basis of sex, race, and other grounds in the *Canadian Charter of Rights and Freedoms* and in human rights legislation.

Respect for Human Life and Dignity

All forms of human life (and indeed human tissue in general) should be treated with sensitivity and respect, not callousness or indifference. Although the law does not treat zygotes, embryos, and fetuses as persons, they are connected to the community by virtue of their origins (having been generated by members of the community) and their possible future (their potential to become members of the community). Not only all persons but also zygotes, embryos, and fetuses should be treated with appropriate respect because of this. In Part Two of our report we discuss more specifically how this principle applies to zygotes, embryos, and fetuses (see Chapters 22, 30, and 31).

Protection of the Vulnerable

Vulnerability relates to power imbalances, and this principle requires that the welfare of those who are less capable of looking after themselves or who are open to exploitation for various reasons be given special consideration. The most common example concerns the welfare of children. Since children cannot look after all their own needs, parents have the authority to make decisions for them. However, this authority is a trust, to be exercised for the benefit of the children, and the state is responsible for ensuring that this trust is kept. Vulnerability to exploitation may also arise from a person's socioeconomic status, membership in a minority group, or disability. Safeguards exist to ensure that adults who are temporarily or permanently unable to make competent decisions are not ignored or taken advantage of; someone is appointed to make decisions on their behalf and must act in their best interests. Society also has a responsibility to ensure that vulnerability is reduced where possible and that those who are vulnerable are not manipulated or controlled by those in positions of power and authority.

Non-Commercialization of Reproduction

Two concepts are relevant to our discussion of this principle: commercialization and commodification. By commercialization we mean activities involving the exchange of money or goods and intended to generate a profit or benefit for those engaging in this exchange. By commodification we mean the treatment of human beings or body tissues and substances as commodities — as means to an end, not as ends in themselves. Thus, commercialization necessarily includes commodification, but commodification need not entail a profit motive.

Commissioners believe it is fundamentally wrong for decisions about human reproduction to be determined by a profit motive — introducing a profit motive to the sphere of reproduction is contrary to basic values and disregards the importance of the role of reproduction and its significance in our lives as human beings. Commodifying human beings and their

bodies for commercial gain is unacceptable because this instrumentalization is injurious to human dignity and ultimately dehumanizing. We therefore consider commercialization of reproductive materials and reproductive services to be inappropriate.

However, as we discuss in Part Two of our report, there may be a legitimate role for commercial interests in certain aspects of reproductive health care — for example, in the development of drugs and medical devices or in certain ancillary services such as storage and transportation. But, for the reasons just discussed, it is important to place strict limits on the extent of commercial involvement in this field and particularly to guard against inappropriate commodification of human tissues, products, and processes. It may sometimes be appropriate to treat human tissues, including reproductive tissues, as means to an end — as in research or therapy intended to benefit people — provided this occurs under strictly defined conditions that ensure respect for the source of the materials or tissues. But it is never appropriate to treat human reproductive tissues or substances as objects of commerce or commodities on which there is a profit to be made.

> First, we strongly believe that neither bodies, nor gametes, nor human embryos, nor any part of our reproductive potential, should be considered fungible or marketable commodities. Permitting the exploitation, conditioning and distribution of the seeds of life, human embryos and infants, in accordance with market forces, ignores the principles of human dignity and individuality.
>
> We demand that the principle of no charge for services that has always guided Canadian law and policy on blood and organ donations be upheld, and we recommend that marketing of gamete and embryo transfers be prohibited. [Translation]
>
> *G. Létourneau, Président, Commission de réforme du droit du Canada, Public Hearings Transcripts, Montreal, Quebec, November 21, 1990.*

Appropriate Use of Resources

The principle of appropriate use of resources recognizes the existence of diverse needs and finite resources, which requires that resources be used wisely and effectively. Resources used to help some people in one way become unavailable to help other people in other ways. Decisions about the provision of programs, procedures, or technologies must therefore be made in accordance with clearly defined public policy priorities. Society must establish its health care priorities, for example, and strive to maintain them in difficult political and economic times. As we discuss in Chapter 4, this will require a shift in attitudes on the part of Canadians, a new orientation in the health care system, and a new approach to medical

treatment. Our recommendations concerning the importance of evidence-based medicine, the need for assessment and evaluation of uses of technology in medical practice, and the appropriate roles for prevention and acute care are premised in part on this fundamental principle of making the most appropriate use of available resources.

Accountability

The principle of accountability means that those who hold power, whether in government, medicine, technology, or other fields, are responsible for the way they use that power. This entails the conviction that Canadian society has a right — and a responsibility — to regulate and monitor how reproductive technologies are used to ensure that our values, principles, and priorities are being respected. In the past, these functions have been assumed through the self-regulation of the professions. But as we will see in subsequent chapters, there is increasing dissatisfaction with self-regulation as the sole method of ensuring accountability, because it is seen as an approach in which people from outside the professions have little role in the development or enforcement of policies and codes of practice. The implications of new reproductive technologies are so profound that demands for more active public participation in their regulation are clearly legitimate. Although medical self-regulation does oblige professional organizations to act in the public interest, a self-regulating profession is not necessarily best equipped to assess the social, ethical, and economic implications of the technologies and may be insufficiently accountable to those whose needs they are meant to serve, particularly in the absence of a broader regulatory system.

Balancing Individual and Collective Interests

This principle reflects our belief that both individual and collective interests are worthy of protection, and that individual interests do not automatically take precedence over collective interests, or vice versa. The individual interests with which we are concerned include those of women or couples seeking assisted conception or prenatal diagnosis services, those of gamete donors, and those of children born as a result of a new reproductive technology. The

> Here in the Northwest Territories where Dene and Inuit peoples predominate, community life is built around family life. Child bearing is considered a gift and a privilege. Infertility is indeed a tragedy for many childless couples, and we affirm the right of such couples to pursue methods of child bearing which do not jeopardize the inherent value, rights and dignity of the persons involved.
>
> *L. Hudson, Tawow Society, Fort Smith, Public Hearings Transcripts, Yellowknife, Northwest Territories, September 12, 1990.*

collective interests include those of society as a whole, as well as those of identifiable groups within society, such as women, children, people with disabilities, and members of racial and ethnic minorities. We discuss the application of this principle later in this chapter.

What We Heard: Support for This Approach

Ethical issues were the focus of many of the interventions and submissions we received during our consultation process. There was a widespread public perception that the ethical implications of reproductive technologies require greater attention and a more systematic response than they have received to date.

Some of the individuals and groups we heard from presented their ethical reasoning in the form of specific principles. These principles varied from sector to sector and, to a lesser extent, within each sector. No social grouping had a single approach to ethical issues — their priorities, applications, and belief systems varied. However, we saw evidence of extensive support for the guiding principles we adopted. Although different groups focussed on different principles, the principles are complementary rather than competing; the eight principles we identified thus reflect widespread consensus in Canadian society on the ethical basis that should guide decision making.

> We must bear in mind that the principle of respect for individuals is proclaimed in the Universal Declaration of Human Rights and the constitutions of most countries. It is recognized as a key principle.
>
> Its theoretical grounds are the same as the basic principles of bioethics:
>
> 1. the principle of respect for individuals and their autonomy;
> 2. the principle of compassion;
> 3. the principle of justice or equity.
>
> These three principles are the basis of the right to privacy, to free and informed consent, to confidentiality, and to justice. [Translation]
>
> *Y. Grenier, private citizen, Public Hearings Transcripts, Montreal, Quebec, November 21, 1990.*

Indeed, these principles were endorsed by a very broad range of groups — professionals and laypeople, women and men, religious and secular groups, members of racial and ethnic minorities, people with disabilities, doctors, and patients. That these principles were endorsed by groups with diverse experiences and interests confirms our belief that they capture important ethical considerations. Moreover, principles similar to those we adopted have been found useful in other inquiries regarding new reproductive technologies. Many of the international inquiries we examined appeal to principles of

autonomy, respect for human life and dignity, and protection of the vulnerable. There was also considerable support for principles of non-commercialization and equitable access.

Finally, there is a growing trend in the bioethics literature to the guiding principles approach. Our review of the literature revealed the following principles at the core of bioethics: beneficence (and non-maleficence), justice, informed consent, respect for human life and dignity, honesty, and confidentiality. The differences between these principles and our own stem from the fact that bioethics developed originally to deal with the relationship between doctor and patient, whereas our principles are intended to deal with broader issues of public policy as well.

Given this level of consensus, we believe that the guiding principles we adopted provide concrete and constructive guidance with respect to the issues raised by new reproductive technologies.

Applying the Guiding Principles

Setting out the guiding principles is only the first step; many questions of priority setting and application remain. Each principle points to a legitimate concern that may be applicable to groups that are affected by new reproductive technologies. To apply the principles, therefore, we also need to identify the individuals and groups that are potentially affected by the use or non-use of these technologies. How each decision and recommendation will affect them needs to be considered explicitly. Moreover, as we discussed in Chapter 2, all of society is affected indirectly, whether by the social and ethical precedents that are established or by the fact that resources are directed here rather than elsewhere. Identifying the range of groups to be considered, in conjunction with the guiding principles, enabled us to take a comprehensive and consistent approach to decision making. Ensuring that we have given proper consideration to all those affected by the technologies provides the basis for morally responsible recommendations.

There is, of course, a danger of oversimplification in describing the guiding principles approach in this way; it is not a magic formula for resolving all moral disputes. There will be disagreements about the interpretation of the guiding principles and about the extent to which one or another applies in particular cases. Some of these disputes may not be resolvable. Although there is consensus on the principle of respect for human life and dignity, for example, Canadians are deeply and seemingly irresolvably divided over how to interpret that principle. Where we encountered such differences in preparing our report, we used our guiding principles to help identify and explain the nature of the disagreement as clearly as possible.

We believe, however, that many disputes are resolvable by a variety of means. First, many of the ethical concerns that arise about the use of reproductive technologies do so because some people believe that the use of these technologies will lead, over time, to disastrous social consequences for women, families, and people with disabilities, among others. Others believe that these negative effects will not occur because society is capable of preventing abuse through regulation. This is an important dispute, but it is a dispute more about facts than about values. To some extent, the dispute can be resolved by generating and disseminating better information and by establishing a system of public accountability that gives all groups in society a say in the future development of these technologies. The development of the Commission itself is a step in this direction.

Some debates can be left for future decision-making bodies. Given that the technologies are changing constantly and that not all have reached a stage of development where we know enough about them to make informed decisions, some decisions about future development or use cannot be made at this time. Establishing decision-making bodies with clear mandates and responsibilities for making and reviewing decisions in light of the latest available evidence has worked well in other jurisdictions.

Finally, some options will be more appropriate or feasible than others in light of Canada's legal, political, economic, and cultural context, existing institutions and practices, as well as our obligations as a member of the international community. Although ethical arguments are of fundamental importance, public policy must also recognize the existence of social and economic constraints, and these may help narrow the range of feasible options. Adopting a guiding principles approach does not guarantee a satisfactory resolution of all moral issues. It does, however, illuminate the ethical implications of new reproductive technologies and provide a clear and constructive approach for evaluating these implications and establishing public policy in light of them.

Individual and Collective Interests

The need to balance individual and collective interests arises in all areas of public policy. But the conflict can be especially poignant in the area of reproductive technologies, and in this we faced some of our most difficult decisions.

Defining the Problem

On one hand, the interests of people who are infertile, people at risk of having children with a genetic disease or severe anomalies, or people with diseases that may be treatable using knowledge from zygote or fetal tissue research are important and deeply felt human concerns. On the

other hand, we cannot ignore the obligation of society to weigh the broader implications of making available medical services in these areas, to allocate scarce resources in an appropriate manner, and to monitor and regulate health care so as to assure the safety of the population and future generations.

We do not accept the view, sometimes expressed, that liberal democracy differs from some other forms of government because individual rights always take precedence over the interests of the collectivity. Canada's constitutional history demonstrates unequivocally that in a liberal democracy, individual rights can be limited when the aim is to protect important societal interests. Indeed, we believe that framing a need or desire in the language of "rights" may not be the most helpful way of approaching this issue.

The ethic of care involves an outlook premised on seeking creative ways to accommodate diverse interests. It requires balancing individual and collective interests to forestall, as much as possible, competitive or adversary stances. We believe that weighing individual and collective interests in this way (facilitated by our guiding principles and considering the range of individuals and groups affected) may lead to more humane and caring policies.

We uphold the value of rights. There are many examples of how rights can promote people's self-respect and mobilize them to remedy injustices — the women's movement, the civil rights movement, and the development of human rights instruments through bodies such as the United Nations are among the prime examples. But it is also important to recognize that different people's rights overlap, that rights are subject to various limitations, and that rights usually come with responsibilities attached. To claim a right does not by itself resolve policy issues — or resolve how to assess whether a given claim is indeed a right. Moreover, although rights are important, they can be understood only within a larger context of societal limitations and individual responsibilities. And this leads us back to questions about the proper relationship between individual and collective interests.

Throughout our deliberations and in formulating our recommendations, Commissioners have sought to understand the nature of individual rights, interests, and responsibilities, as well as the interests and responsibilities of society as a whole. We have also sought to understand, as part of the balancing process, the rights, interests, and responsibilities of various groups in Canadian society. Finally, we have sought to reflect on these issues from the general perspective of the ethic of care.

The Role of the Charter

The *Canadian Charter of Rights and Freedoms* sets out a range of individual rights, including the right to life, liberty, and security of the person, the right to equality, and the right to freedom of expression and

association, among others. These represent and protect the legitimate aspirations of individuals and groups, and the Supreme Court is empowered to strike down government legislation and policies that violate these aspirations.

Individual rights are qualified by other sections of the Charter, reflecting Canada's approach to the continuing tension between individual and collective. For instance, section 1 of the Charter says that any right in the Charter can be limited in ways that are "demonstrably justified in a free and democratic society." But to be demonstrably justified, these limits cannot be based on mere convenience or prejudice. Where there is a legitimate social objective, and where reasonable limits on individual rights are necessary to achieve that societal goal, then the good of the collective can be held to limit the rights of the individual. Similarly, section 33 of the Charter, the notwithstanding clause, allows governments, as the elected representatives and the expression of the will of the collective, to limit individual rights for the good of society. Any decision on the part of a government to limit individual rights in a particular piece of legislation is temporary, however, and subject to review after five years.

Individual rights are also qualified by the existence of a third category of rights: the rights of specific groups within Canadian society. The rights of Aboriginal and multicultural communities are protected (sections 25, 27, and 35), as are the rights of linguistic and religious groups (sections 23 and 29). There is also constitutional protection for programs that may limit the rights of the individual in order to redress collective wrongs to historically disadvantaged groups.

These sections of the Charter provide some protection to government policies that are aimed at promoting the interests of specific groups from a rigid insistence on individual rights. In these and other ways, the Charter both affirms and limits individual rights. It insists that individual rights cannot be limited for reasons of convenience or prejudice, but it recognizes that valid societal interests can justify some limitation on them. Thus, the Charter both expresses and reflects a uniquely Canadian framework for relations between individuals and the state. Its introduction both was based on and accelerated a trend toward acknowledging pluralism and rights-based participation in Canadian society. We believe that an interpretation of rights that balances individual and collective interests remains deeply rooted in Canada's political culture and is applicable to public policy decisions in the areas covered by our mandate.

Given its significant impact on the relationship between governments and citizens, it is not surprising that the Charter raises various issues in relation to the regulation of new reproductive technologies. For example, section 7 (which guarantees "life, liberty, and security of the person") has implications for the right to informed consent before medical treatment, including the right of pregnant women to refuse unwanted medical treatment; for issues surrounding gamete donors' rights to privacy and the locus of control of the use of their gametes; and for the right of children

born through the use of new reproductive technologies to learn about their social and medical histories. Section 15 raises the issue of the permissibility of restrictions on access to new reproductive technologies based on an individual's age, marital status, sexual orientation, economic status, or other prohibited grounds of discrimination. This does not necessarily mean that courts would find that discrimination had occurred — in the case of age, for example, medical grounds may make this appropriate.

> The legislation [should] include underlying principles and establish a framework and process for assessing the appropriateness of new technologies as well as ongoing research. The principles would include, the rights of women to control their own reproductive destiny; the rights of individuals to make their own decisions based on all information; the right to accessibility of treatment for everyone; the non-commercialization of reproductive services, and an assurance of compliance with equality guarantees and the *Charter of Rights and Freedoms*.
>
> *B. Suek, Charter of Rights Coalition/ Manitoba, Public Hearings Transcripts, Winnipeg, Manitoba, October 23, 1990.*

As well as providing a benchmark against which government policies and legislation can be tested and challenged, the existence of the Charter has altered the way some Canadians think about government policy. As a result, law is seen by some as an agent of social policy, rather than a technical tool for administering government policy; legal judgements are seen as the way to resolve conflicts between individual and collective interests.

Situations Where Individual and Collective Interests May Differ

There is no inherent conflict between individual and collective interests. On the contrary, a community can flourish only when its individual members are flourishing, and individuals can flourish only within a larger social context. It is important for society to care for its members, to ensure that it is a society worth belonging to. In some situations, however, protecting the interests of some individuals would be harmful or prohibitively costly for the rest of society.

In some cases, the pursuit of an individual's objective may be inherently detrimental to collective values or requirements for public health and safety. In other cases, an individual activity may be tolerable if it occurs rarely but harmful to society if it crosses a certain threshold and becomes more commonplace. In yet other cases, solving the legitimate problems of an individual may require so great an investment of societal time, energy, and resources as to affect our ability to meet other societal needs. For example, some people think that heart/lung transplants should

not be publicly funded because there are other more pressing unmet medical needs, and they think the cost of these operations is so high for the likelihood of benefit that society could spend the money more effectively elsewhere, providing greater benefit to a greater number of people.

There is an important distinction between the third and the first two cases, specifically that there is nothing socially harmful about the individual's desire for the surgery. On the contrary, the operation is good from both an individual and a collective point of view, and so society would provide it if possible. Unfortunately, it may not be possible, given the full range of health priorities. Fulfilling the individual desire would not harm the collective good, but it would not contribute much compared to other possible uses of scarce resources — thus, its "opportunity cost" may be too high. Some have argued that the Charter can be interpreted as imposing an affirmative duty on the state to make new reproductive technologies available, so that those who are unable to become parents in the usual way can enjoy the same reproductive "rights" as other members of society. It is highly unlikely, however, that the courts would uphold such claims, given the broader social interest in providing basic health care for all Canadians and the existence of finite resources with which to do so.

It is not always easy to distinguish among the situations in which individual and collective interests may differ, because the three categories (inherently detrimental, threshold situations, opportunity costs too high) are often connected in the context of a particular reproductive technology and are sometimes mixed together in the public debate. Furthermore, full information on the cost and likelihood of success of particular procedures may not be available initially, making decisions more difficult. But it remains important to distinguish among these different objections, because the appropriateness of a particular policy depends in large part on the category of situation it is intended to address.

Individual Rights and Social Interests

Individual and group rights claims made under the Charter must be taken into consideration as well as societal interests. As the discussion throughout our report makes clear, the impact of new reproductive technologies extends well beyond the individuals directly involved in their use. The research, development, and application of new reproductive technologies affect not only the prospective biological and social parents, but the children born as a result of their use, women as a group, and society as a whole. The presence of group and societal interests may well qualify the right to become a parent through the use of new reproductive technologies and condition the other individual rights involved.

It is impossible to formulate a rule about whether the interests of individuals or society are more important. Rather than subordinating one to the other, it would be more appropriate to say that each qualifies and shapes the other and that a delicate balance is required. Thus, a strategy

that encompasses both individual and social interests should always be the first and preferred approach. Moreover, it is potentially misleading to talk about "individual versus collective" conflicts, as if all uses of reproductive technologies could be lumped together or resolved in the same manner.

There is no single formula for weighing individual and collective interests that would allow us to resolve all these issues. Rather, we need to look at given situations on their merits and consider how individual interests affect society's values, norms, and resources, and vice versa. As we deliberated, we were acutely aware of the need to take individual, group, and societal interests into account, in line with both our ethical principles and the requirements of the Charter. Our thinking and recommendations with respect to the individual technologies and the ethical issues they raise are discussed in Part Two.

Conclusion

The Commission saw one of its responsibilities as promoting informed public debate on new reproductive technologies. In deciding how to approach our ethical deliberations, therefore, we felt it was important to adopt a perspective that draws upon the language and principles of Canadian public debate. Our aim was neither to mirror the existing views of Canadians nor to transcend them radically. Rather, we hope to improve public understanding and the capacity to engage in social debate by identifying shared ethical principles in a considered approach that can help to guide future public policy making. We hope that our approach will help Canadians see how profound the implications of reproductive technologies are and why it is so important to ensure that, if they are used, they are used in an ethical manner. Nor need this approach be limited to the new reproductive technologies — it offers a perspective that society could apply to other emerging technologies and other social policy issues.

The Commission saw one of its responsibilities as promoting informed public debate on new reproductive technologies. In deciding how to approach our ethical deliberations, therefore, we felt it was important to adopt a perspective that draws upon the language and principles of Canadian public debate.

Setting public policy also requires careful attention to and consideration of the values and attitudes of Canadians. Many of these values and attitudes are embodied in the Constitution, particularly in the Charter. At the same time, the opinions Canadians hold may sometimes differ from how the Charter is applied in particular cases. This is sometimes the case with equality issues, for example, where public opinion on a given question may differ from the values entrenched in section 15 of

the Charter. The legitimacy of public policies is therefore a function of both their consistency with constitutionally entrenched values and their congruity with the values and attitudes of a broad range of Canadians.

This brief sketch of the Commission's guiding principles conveys our ethical stance in somewhat general and abstract terms. Their full dimensions and nuances and how the principles apply will become clearer as we explain our reasoning and recommendations with respect to specific technologies and the real-life decisions to which they give rise in Part Two of our report.

Just as important as the ethical basis for individual and societal decisions about the use or non-use of new reproductive technologies is society's capacity to implement our collective decisions. How are Canadian systems and institutions structured to implement society's decisions? How are priorities set, policies established, and services designed and delivered? Do they currently have the capacity to respond to the demands of public policy making in an increasingly diverse, knowledge-based society on the verge of the twenty-first century? What changes, if any, are needed? Understanding Canadian systems and institutions was an important part of the context for our study of new reproductive technologies. Among all the systems that will be affected by our recommendations, the health care system is the central one. This is where ethical dilemmas, medical decision making, and service delivery converge. The next chapter of this part of our report is devoted to an overview of the health care system as the context within which the provision of reproductive technologies is possible.

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New Reproductive Technologies and the Health Care System

The state of Canada's health care system and what the place of new reproductive technologies should be within it were the subjects of extensive and detailed debate before the Commission in our public hearing and consultation processes. Much of this debate centred on whether reproductive technologies should be offered within the health care system, whether offering them would place an unwarranted burden on an already overburdened system, and whether attention to these technologies would divert health care resources from other pressing needs, whether in reproductive health or other areas. While sharing many of the concerns we heard, Commissioners approached the issues from a somewhat different perspective, asking how we could reconcile the great importance people attach to having children with the need to manage the health care system responsibly, given the many legitimate claims on its resources, without overburdening it.

The importance of the health care system to Canadians was abundantly clear from our consultations and research: the system is a source of national pride, it is an important factor in people's lives, and it is a tangible way in which our society expresses mutual support and caring for its members. The health care system is a symbol of strongly held Canadian values, reflecting the fact that we think individuals should be treated equally in the face of disease or injury. In many ways, the health care system helps to define Canadians

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and how we see ourselves, and it evolved as it did only because of the values we hold collectively — hence the importance of managing the system responsibly and not overburdening it with functions or responsibilities that should lie elsewhere. At the same time, the evidence before the Commission is that Canadians attach great importance to having children; not only people who are infertile but the vast majority of Canadians want to have children and anticipate having them in their lives. How should we reconcile these two goals if, as in the case of new reproductive technologies, one might have the potential to undermine the other?

Commissioners concluded that Canada has the capacity to develop a response that reconciles these two goals. If having children is important to most Canadians, as we have found it is, and if safe and effective means exist to help people who would otherwise not be able to have children to do so, then the ethic of care directs us to take this into account in societal decisions about how our collective resources are allocated, including those allocated to the health care system.

It would be unethical, however, to offer services or assistance in the form of unproven procedures or treatments. It would be irresponsible to devote public resources to such procedures in the absence of knowledge about their risks and effectiveness, and about their costs and benefits relative to other approaches to solving the problem and other calls on the available resources. A rational framework is needed as the basis for making such decisions.

What was required, therefore, was a means of determining whether these procedures could be provided ethically — with reasonable assurance about their risks and effectiveness — and whether doing so represented an appropriate use of public resources. Our approach was to adopt the concept of evidence-based medicine.

Evidence-Based Medicine

The evidence before the Commission suggests that a significant proportion of medical care is ineffective, inefficient, or unevaluated. (Similarly, much of the care provided by dentists, chiropractors, nurses, social workers, and many others practising in the general field of health care has not been evaluated.) This situation has clear implications for the quality of care people receive and for inefficient or less than maximal use of limited resources. Evidence-based medicine — that is, medical practice and management of the health care system based on knowledge gained from appropriate evaluation of treatments and their results — offers a way to correct this situation. To date, however, the massive investment of time and resources in new medical technologies and treatments has not been balanced by an equal commitment of resources for their assessment and evaluation. We know a great deal about the inputs to the system — the

resources used, number of beds, numbers of patients treated — but relatively little about results — the health status of patients following treatment.

New reproductive technologies in particular have brought these concerns to the forefront. Individuals and groups representing a broad range of interests told the Commission about their concerns that reproductive technologies are being introduced without adequate research into their effectiveness, the risks associated with them, and their short- and long-term effects on health. Some of women's previous experiences with reproductive health care have fuelled concerns about safety, particularly with respect to the potential for unanticipated consequences. For example, when technologies and drugs such as the Dalkon Shield®, diethylstilbestrol (DES), and thalidomide were first introduced, researchers and physicians alike believed they were effective and did not involve high risks. As we know now, however, there were unexpected and devastating consequences for women and their children. These experiences offer hard-learned lessons about the need for evaluation before wide dissemination of medical treatments, for full disclosure to patients about known or potential risks, and for the continuing collection of data on the results of treatment.

> Decisions regarding technology are made daily by practitioners, administrators, and policy makers. Ideally, decisions regarding health technology should be based on evidence from comprehensive assessment — that is, information on the safety, effectiveness, costs, and ethical, legal, and social implications of the particular technology under consideration. Reality proves otherwise; the large majority of technological innovations in health care are in use long before any systematic assessment has taken place. Sometimes, at the second- or third-generation level, technologies are found to be ineffective, or even unsafe, after belated assessment.
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> *A. Kazanjian and K. Cardiff, "Framework for Technology Decisions: Literature Review," in Research Volumes of the Commission, 1993.*

When these concerns are added to broader concerns about the potential of new reproductive technologies to affect human relationships and society generally, it is clear that Canadians are demanding a systematic and rational approach to decisions about whether the use of new reproductive technologies is acceptable and, if so, whether and under what conditions their provision should occur within the health care system. In the Commission's view, evidence-based medicine is the first component of a rational approach to decisions about the funding of medical care. As the health care system is currently structured, however, there are barriers to implementing this approach. Moreover, increasing financial and other pressures on the system have created a situation where change — even change generally agreed to be necessary — is difficult to effect.

Commissioners therefore recognized that we had a social responsibility to ensure that our recommendations contribute to developing effective and equitable health policy while maintaining the integrity of that system and, indeed, improving its capacity to deliver services if possible. At the very least, we felt a responsibility not to erode a system that is meeting Canadians' medical needs and generally fulfilling our expectations about its role in our collective life.

Evidence-Based Medicine: Medical practice based on data and assessment of whether procedures or treatments are of benefit for their intended purpose.

In devoting a chapter to the health care system the Commission is acknowledging that our recommendations will not be implemented in a vacuum. If new reproductive technologies are to be made available, it will be in the context of a health care system that is already under considerable pressure. Given the cost of providing new reproductive technologies and associated services and programs, we must consider the issues in light of these pressures, asking ourselves questions about outcomes, priorities, and equity in allocating public health dollars and delivering services. Decisions about providing new reproductive technologies must clearly be part of this broader process of deciding what the health care system should or should not be called upon to do. Evidence-based medicine offers a way to establish the effectiveness and risks of procedures or medications before they are made available generally; if effectiveness and risks have not been established, treatment should be provided only in the context of research until this information can be generated. The long-established practice is that those receiving procedures that are in the category of research must be fully informed of their experimental nature and consent to the procedures in knowledge of this. Evidence-based medicine also offers a more rational and equitable way of allocating public health dollars by suggesting which treatments are beneficial to people at what cost to the system and which are ineffective or overly costly given their likely benefits.

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Thus, like the ethical framework created by our guiding principles and the ethic of care, evidence-based medicine shaped the Commission's approach to assessing the various forms of infertility treatment. It too provided a prism through which to view the technologies and to determine whether their provision within the health care system was ethically acceptable and constituted an appropriate use of resources.

> On this issue, we must rethink our methods of evaluating technology. Our "technology assessment" usually covers only a few features, and does not, for example, look into how subsequent users of a technique will change it. And usually, our assessment is carried out by people who are already favourably disposed toward the technique. [Translation]
>
> *H. Doucet, Faculté de Théologie, Université Saint-Paul, Public Hearings Transcripts, Ottawa, Ontario, September 18, 1990.*

Beyond this, however, it became clear as our work proceeded that the ethical and practical approaches we were developing as a basis for assessing new reproductive technologies have broader application in the health care system. Our approach would make it possible for Canada's response to new reproductive technologies not only to avoid being part of a problem — in the sense of overburdening, distorting, or undermining the system — but to be part of a solution by contributing to the system's capacity to continue to deliver effective health care services in a fair, rational, and cost-effective way. Strategies to achieve these goals are the common threads running through Part Two of our report as we examine the various technologies and recommend approaches to dealing with them.

In the remainder of this chapter, we examine the current state of Canada's health care system as an important part of the context for our inquiry and for implementation of our recommendations. The approach inherent in evidence-based medicine is evident already in many of the issues and proposed solutions emerging in the health care field, as pressures on the system create incentives for policy makers and other decision makers to look at what the system is doing, whether it is doing the right things, whether it is doing things well, and how to alter patterns of resource allocation in light of the answers to these questions.

Health Care and Health

Most Canadians equate medical care and treatment with better health; we tend to place great faith in the power of surgery, drugs, and medical technology and believe that having more health care services will result in healthier people. Medical care may be critical and even life-saving for those who are acutely ill, and some treatments of chronic illness are of clear benefit; however, the capacity of medical care to produce a healthy population is, in fact, relatively limited. Medical treatment is important and even essential in certain situations, but it is only one of the determinants of overall health.

We know this for at least two reasons. First, research in Canada and elsewhere shows clearly that there is a direct relationship between health status and income. The higher the income, the longer and healthier the life, despite the fact that medical treatment is available and used throughout the country, and even when smoking, nutrition, and other factors are taken into account. In the aggregate, low socioeconomic status, not lack of health care, is the greatest correlate of poor health. Second, research in Canada, the United States, and elsewhere shows that the rate of use of certain medical procedures, including certain types of surgery, varies very widely between similar communities, yet high use makes no appreciable difference to health status. Medical care is available to and used by people in all segments of Canadian society; therefore, it is clear that most of the difference in health status between groups of people is not attributable to the medical care system. These facts, coupled with current pressures on the health care system, make it timely to reassess the contribution and limits of medicine.

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Notwithstanding the facts about health care and health status, the prevalent belief that the availability and use of medical care are central to health has led to massive amounts of our collective resources being allocated to the medical system. Yet money spent to provide medical care is then unavailable for purposes such as affordable housing, education, income security, and environmental protection, which also have a great potential impact on the overall health of the population. Allowing these other determinants of health to deteriorate by devoting insufficient resources to them is risky. We have reached the point where, paradoxically, the further allocation of dollars to health services could actually have detrimental effects on health.

What is an informed society willing to pay? How much spending on health care is "enough"? The fact is that under the current method of allocating resources to health care, we simply have no accurate way of knowing. There may be enough resources already allocated to the health care system to continue to provide effective existing treatments, as well as to accommodate effective new technologies, provided we can identify and stop providing the minimally effective or demonstrably ineffective interventions now being funded. At present, however, we have little evidence on which to base this determination, because much of medical care has never been evaluated, and resource allocation decisions have not been made on the basis of the evaluation information that does exist.

The role of medical care is vital and, if used appropriately, of great value in our lives. But not all medical care is of equal value in achieving health. As evidence and awareness of these facts expand, there are increasing calls within the health care system and in the broader community to recognize the limitations of medicine and to acknowledge and support other ways of achieving health. To do this, we need to discover whether and under what conditions treatments work — that is, to demonstrate their effects on health — and then to manage the health care system in light of this evidence.

As we will see, while generally applicable throughout the health care system, this approach is particularly relevant to new reproductive technologies. It would be useful to know, for example, the relative effectiveness — in terms of both individual health and cost to the health care system — of a chlamydia prevention program and an *in vitro* fertilization program. (Chlamydia, the most common sexually transmitted disease among women in their late teens and early 20s, can lead to pelvic inflammatory disease [PID], which in turn may lead to fallopian tube blockage — a principal reason for the use of *in vitro* fertilization.) The urgency of adopting an evidence-based approach has become particularly evident as pressures on the health care system have mounted in the past decade.

Pressures on the Health Care System

Canadians are generally satisfied with the quality of our medical care system, but concern is surfacing about whether the system can continue to respond to current pressures on it without buckling under the strain. These pressures include the rising costs of care and the tendency to expand the boundaries of the system — in response to both practitioners' treatment patterns and patients' expectations — as new technologies become available or as medical solutions are sought to problems once considered outside the system's purview. In the absence of evidence on the effectiveness of treatments, the health care system is vulnerable to pressure groups; politically astute patients and service providers, in alliance, not only may be making the system responsive to real needs, but also may be pushing the system in directions that are not sustainable and that society collectively does not want.

> Canada's health care system is therefore at an important crossroads. If we can learn to manage it better, it can continue to play an important and respected role in Canadian life. If we do not, we run the danger of allowing the system to be eroded by these pressures, with deteriorating standards, less access, and social inequities the likely results.

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Growing Use and Costs

Several factors have generated rising costs for the health care system. The number of older Canadians, for example, has increased steadily in the past two decades; moreover, there has been an increase in per capita use of health care services and medications by elderly Canadians. This greater use is attributable in part to the absence of more appropriate community-based supports; many residents currently in nursing homes and many patients in acute care hospitals, whatever their age, could be released tomorrow if a system of home care and community-based day programs were in place.

Another factor that has created pressure on the health care system is the disproportionate increase in the number of physicians relative to the increase in the general population. Between 1981 and 1991, the number of doctors practising in Canada rose by 38 percent, while the population grew by just 12 percent. Recognizing the pressures this creates on the system, provincial ministers of health agreed recently to reduce enrolment at the country's medical schools by 10 percent as part of a nation-wide agreement. The aim of this policy is not just to contain costs but to use our collective resources more appropriately and effectively. There is no good evidence that the increase in number of physicians per capita is a good use of resources and results in better care for patients.

> Along an alternative line of questioning, there would appear to be a relatively high level of pessimism about the presence of potentially costly situations facing the health care system. For example, over 80% of respondents surveyed agreed that many use health services unnecessarily and 70% felt that doctors often prescribe unnecessary medication. It would appear that a majority (69%) also feel that hospitals are overutilized and that home care approaches are sufficient for many individuals.
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> *M. de Groh, "Reproductive Technologies, Adoption, and Issues on the Cost of Health Care: Summary of Canada Health Monitor Results," in Research Volumes of the Commission, 1993.*

Fee-for-service reimbursement, which is the way most doctors are paid, has also contributed to rising costs. As gatekeepers of the health care system, physicians control access to diagnostic testing and hospital and medical services; in fact, service providers (physicians), not consumers,

largely determine the extent of use. The fee-for-service arrangement can lead to an increase in the number of services provided or create an incentive for physicians to select hospital or medical services over other forms of care. This is an extremely complex issue of system design, and one that simplistic solutions will not resolve. Putting physicians on salary, for example, would not necessarily ensure greater levels of evaluation and accountability in the system or a more rational allocation of resources within it.

The fact remains, however, that under the current system physicians are not accountable for the cost implications of their treatment decisions; they respond rationally to a system that does not ask or expect them to consider the cost of various approaches to treatment or the alternatives offered by non-medical approaches. This tendency is reinforced when patients expect more diagnostic and treatment services and equate expensive and technology-dependent approaches with "better" medicine. The news media and word of mouth also play a role in expanding public knowledge and hence the potential demand for treatment, especially the newer and more technology-intensive forms of care.

The technologies themselves are not responsible for rising costs, however. Rather, it is their application and patterns of use that lead to spiralling costs. Some technologies may in fact have the capacity to reduce costs in specific areas of medical care, provided they are used only where they have been demonstrated effective for the purpose in question.

Indeed, the proliferation of new medical technologies has been seen as another source of rising health care costs. It is true that these technologies have developed and spread rapidly in recent decades — new imaging technology, transplant technology, and intensive life support, as well as the technologies that are the subject of the Commission's mandate. Diagnostic procedures have also proliferated. Some of them are technology-based, and some of them are used routinely without evidence that they make any difference to health outcomes. In addition, tests and services are sometimes provided to enable physicians to defend against subsequent litigation, although "defensive" medicine remains less of a problem in Canada than in the United States. The technologies themselves are not responsible for rising costs, however. Rather, it is their application and patterns of use that lead to spiralling costs. Some technologies may in fact have the capacity to reduce costs in specific areas of medical care, provided they are used only where they have been demonstrated effective for the purpose in question.

In summary, patterns of medical treatment and technology use, the disproportionate increase in the number of physicians, and the lack of accountability in the fee-for-service reimbursement system — all have contributed to cost pressures in the health care system. The problem is compounded by declining economic growth. Although health care spending

by governments rose during the expansionary 1970s, relative to overall growth in the economy it remained steady or increased only slightly. Financing the expansion of the health care system during the 1970s did not create cost pressures because the economy was expanding — health care spending and gross domestic product rose in tandem and at roughly comparable rates. By the 1980s, however, with slower overall economic growth, the same rates of increase in health care spending that had been acceptable in the 1970s became unmanageable; the question of how to finance health care in an economy with little or no growth began to create serious and mounting pressures to contain costs.

> The technology of monitoring of pregnancy and birth may at first glance be simple, but in fact it involves the complex field of medical practice and hospital organization.
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> *Brief to the Commission from the Toronto Birth Centre, March 31, 1992.*

Government Expenditures on Health Care

The cost to governments is only part of the cost of health care in Canada. Health care costs also include what Canadians spend on dental care, eyeglasses, prescription and non-prescription drugs, chiropractors and other alternative caregivers, supplementary health insurance, and other health-related expenses, as well as health insurance premiums (in those provinces that still have them) and health levies or taxes on employers. Many of the solutions proposed to ease resource pressures involve attempting to reduce the cost to governments. These solutions include off-loading some of the cost to governments by requiring others — patients, employers, or insurance companies — to pay more. Increasing the proportion of health care costs borne by these private payers is a dangerously simplistic response. The issue is not how much the health care system costs governments, but how much it costs our economy as a whole. Resources devoted to health care — whether they come from the pockets of taxpayers, employers, insurance companies, or governments — are resources unavailable for allocation to other social priorities or investment in other parts of the economy. The other issue here is that most cost shifting — for example, through user fees — goes against the ethos of distributing health

Increasing the proportion of health care costs borne by these private payers is a dangerously simplistic response. The issue is not how much the health care system costs governments, but how much it costs our economy as a whole. The other issue here is that most cost shifting — for example, through user fees — goes against the ethos of distributing health care resources according to need rather than ability to pay.

care resources according to need rather than ability to pay. Simply shifting the burden from one group of payers to another, then, will not solve the problem; other remedies are needed.

Federal and Provincial Responsibilities for Health Care

In practice, responsibility for the health and well-being of Canadians is shared by the federal and provincial governments. Under its peace, order, and good government power, the federal government can regulate aspects of health and welfare that are of national concern. Pursuant to its criminal law power, the federal government can prohibit practices and products that are dangerous to health. The federal government is responsible for health, safety, and environmental regulation in areas of federal jurisdiction, such as interprovincial transportation and telecommunications. It delivers health services to status Indian and Inuit persons, to members of the Canadian armed forces, and to people in federal institutions, such as penitentiaries. Through its spending power, the federal government conducts health research and public education and significantly subsidizes provincial health care services. Finally, the federal government has the power to ratify international treaties and to participate in other international health and welfare initiatives.

Health care delivery is a matter of provincial responsibility, pursuant to provincial jurisdiction over hospitals and health professions, and matters of local or private concern. The provinces and territories administer the costs of medical and hospital care through health insurance plans and through their general budgets and regulation. They also finance a range of other health care services, including home care, community health centres, and non-physician services, such as physiotherapy and occupational therapy, delivered in health care settings. The provinces and territories are also involved in public health promotion. Pursuant to their jurisdiction over property and civil rights, the provinces are responsible for occupational health and safety, environmental regulation, and the regulation and licensing of health care facilities and health care professionals, including nurses and physicians.

In the midst of these developments, provincial governments are grappling with a new pressure: declining federal cash contributions to health care costs. Provincial and federal governments have shared the cost of health care through various formulas and arrangements negotiated periodically since the late 1950s. Initially, the federal contribution was determined by what the provinces actually spent to provide health care services. This arrangement proved unsatisfactory both for the federal government, which wanted a greater degree of predictability in the amount of transfers to the provinces, and for the provinces, which wanted greater flexibility to set their own spending priorities and to determine how the federal contribution would be spent.

The formula was therefore changed in 1977 with the passage of the *Federal-Provincial Fiscal Arrangements and Established Programs Financing Act*. Since 1977, then, federal contributions to health and post-secondary education have been in the form of "block funding," with no link to

The *Canada Health Act*

Although health care services are administered and delivered by the provinces and territories, they are subsidized by the federal government under various federal laws and according to criteria set out in the *Canada Health Act*. The act, which came into effect in 1984, confirms the criteria and conditions that must be in place for provincial and territorial health care systems to be eligible for federal funding. These criteria are public administration, comprehensiveness, universality, portability, and accessibility.

Public administration means that the health care plan in the province or territory must be administered on a non-profit basis and by a public authority. *Comprehensiveness* refers to the fact that most services provided by hospitals and medical practitioners are insured. *Universality* means all residents of a province or territory are entitled to insured health care services. *Portability* means that Canadians moving from one province or territory to another or visiting temporarily continue to be protected by health insurance. *Accessibility* refers to the provision of insured health care services without financial impediments.

Under the act the federal health minister has the authority to penalize any province that fails to comply with the criteria, the most severe sanction being to reduce or withhold federal transfer payments to the province.

Although the national health care law is based on the fundamental principle of public funding for "medically necessary" services, a survey conducted for the Commission found that no province or territory has defined this term operationally.

Health care services are referred to collectively as a "system," a term that implies an integrated whole, but in fact most provinces' systems are composed of many diverse parts with few formal links among them. In effect, most provincial "systems" represent the sum total of many individual decisions made by diverse groups of practitioners in a range of health care settings.

provinces' actual spending patterns. The provinces and territories receive per capita grants from the federal government in the form of transfers of tax points (that is, they are given a percentage of tax revenues), with the remainder made up in cash. The proportion of the transfer that consists of cash varies from province to province, depending on the tax points they receive. The federal minister of health can enforce compliance with the five principles of the *Canada Health Act*, the ultimate penalty being the withholding of the federal cash contribution until the province breaching the act corrects the situation.

As part of its strategy to reduce the deficit, the federal government introduced the *Government Expenditures Restraint Act*, which became law in February 1991. The *Restraint Act* limits annual growth in federal transfers to the provinces under the *Contributions Act* by a formula — growth in gross national product (GNP) less 3 percent (with adjustments for changes in a province's population). Because the tax revenue percentage

portion of the transfer is calculated first, the remaining cash portion declines if income tax revenues rise more quickly than GNP growth less 3 percent. Income tax revenues have generally risen more quickly than this; as a result, it has been estimated that within 10 to 15 years under the current formula, the cash portion of federal transfers will disappear entirely (sooner in some provinces than in others, because of the relative proportion of tax points and cash in their transfer arrangements).

Dwindling federal cash transfers for health care (and post-secondary education, which is covered by the same legislation) have the same effect on provincial treasuries as any other decline in revenues. Provinces have to decide whether to respond by cutting back, either in the health care system (for example, by de-insuring some services or closing facilities) or in other programs; financing spending through borrowing; or raising additional revenues through taxation or other means.

Importantly, the cash transfers are virtually the only tool available to the federal government to exert influence over provinces' compliance with the five criteria set out in the *Canada Health Act*. This means that phasing out these transfers through the current formula makes it more difficult — some would argue impossible — for the federal government to maintain a strong presence in the health care system and ensure compliance with the *Canada Health Act*. Either there will be no federal contribution to hold back, or the amount will be so minimal as to provide no incentive for provinces to adhere to the *Canada Health Act* criteria with respect to such issues as user fees. The federal government has stated that it intends to maintain its leverage through other funding mechanisms, but it is difficult to see what mechanisms will remain at its disposal once the full effects of the *Restraint Act* are felt. This is of great concern to Canadians — who showed a high level of commitment to the five principles in the *Canada Health Act* in surveys conducted for the Commission.

This collapse of a strong central cohesive force, coupled with the other pressures on the health care system described earlier in this chapter, raises fears that universality and accessibility will be eroded, leading to development of a two-tier system — one publicly funded, and one available to those who can pay for it. We think it very important, therefore, that the federal government consider how to maintain its capacity to require provincial compliance with the criteria of the *Canada Health Act* and to introduce the mechanism necessary to do so.

We think it very important, therefore, that the federal government consider how to maintain its capacity to require provincial compliance with the criteria of the *Canada Health Act* and to introduce the mechanism necessary to do so.

Concern about the pressures on the system has also led to debate about what the boundaries or limits of the health care system should be if

we are to keep universality intact so that all Canadians can continue to benefit.

The Limits of the System

We heard extensive testimony reflecting growing recognition that there are limits to what the health care system can achieve and limits on the demands to which the system is capable of responding. Two major types of boundaries are being discussed in current debates about the health care system: its external limits and its internal limits.

In reproductive technologies, as in other health fields, the external limits of the system are generally defined by provincial health insurance programs. As legally defined in the *Canada Health Act*, the health care system includes only medically necessary hospital and physician services. But in reality, provincial systems include both medical care and health care. Defining the external limits of the medical care system means determining what kinds of problems are appropriate for it to treat. For example, is alcoholism a problem that requires medical treatment? Are learning disabilities? Is smoking cessation?

Services considered to be "medically necessary" are covered by provincial and territorial health insurance plans, which vary across the country; the types of problems deemed appropriate for medical attention are determined by what the province or territory (and tradition) considers to be medically required. In a way, these plans set the external limits of the health care system, but they differ slightly by jurisdiction — thus, there is no universally applicable definition of the external limits of the health care system. In Ontario, for example, provincial health insurance covers the cost of *in vitro* fertilization, whereas other provinces' plans do not; that is, Ontario's policy is to include IVF within the boundaries of the health care system. Provinces that do not insure IVF have made the decision to keep this procedure outside the boundaries of their health care systems. This means it is available in those provinces only to those able to pay for it.

Several questions arise when we try to define external limits. What can the medical care system realistically be expected to accomplish? Do such services represent the most appropriate strategy to deal with a given problem? What is more properly the responsibility of other systems – such as education, social services, income support, or health promotion?

Unless the issue of external limits is addressed, the boundaries of the medical care system could expand indefinitely. This is unrealistic, not only financially but conceptually. Expecting it to respond to all problems not only places unreasonable burdens on that system but, importantly, detracts from its ability to deal properly with the issues that are clearly within its mandate — to provide effective treatment for medical conditions.

Once a decision has been made to insure a service, the internal limits of the system — who receives treatment and under what circumstances — are defined by practitioners and institutions. If it is agreed that a specific

problem is medical in nature and therefore should come within the ambit of the medical care system, the next decision is whether treatment should be offered to all those affected by the problem, or whether there should be limits or criteria for determining who gets treatment. It may be generally agreed, for example, that blocked arteries to the heart constitute a medical problem and should be treated within the health care system. But what should the internal limit be? Should all persons with this diagnosis have surgery? Or should it be limited to those for whom there will be an appreciable increase in length and quality of life? Similarly, should everyone diagnosed with infertility receive *in vitro* fertilization? Or should it be limited to those cases where medical history, diagnosis, and other relevant considerations suggest that the likelihood of a live birth is greater?

> The concept of health has expanded tremendously, far beyond the capacity of the public sector to undertake responsibility for it. The public sector has undertaken responsibility for health *care*, fairly narrowly defined. The more you expand the definition of health and then go from there to say that anything that contributes to health is in some way a public responsibility, the more you load up the state with responsibilities that it *can't* fulfill; that many of its citizens do not think are legitimate for it to fulfill ... The state can't take responsibility for all the things that contribute to health. And that's especially important it seems to me for the area of new reproductive technologies.
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> *R.G. Evans, reviewer, research volumes of the Commission, 1992.*

Decisions about the system's boundaries have significant implications for the cost of medical care. This has been recognized by many jurisdictions, and one, Oregon, has attempted to respond to this issue. In order to extend Medicaid coverage to most state residents below the federal poverty line, the state decided to narrow the boundaries of what treatments and services would be covered. More people will be covered for medically high priority services, rather than covering more procedures for fewer people. A commission consisting of physicians, consumers, and representatives from the public health and social services sectors undertook the task of ranking more than 700 services in order of importance, with the understanding that, if funding is insufficient, services will be eliminated, starting at the bottom of the list. The value attached to each procedure was determined using research into effectiveness, a formula considering cost and benefit, public hearings, and survey data.

Although IVF was one of the treatments ranked, as we explain in Chapter 20, there were methodological problems that meant it may have been given a falsely low ranking. Nevertheless, the general approach is one that many people feel will lead to a more stable, humane, and effective way of distributing health care resources, while reducing the provision of services that are medically ineffective and are not valued highly by the

community. They say that it is only a matter of time before Canada is forced to adopt a similar approach to providing health care services. Others have said, however, that the project rations health care only for some of the population — those who are poor — and will have a disproportionately negative impact on poor women and children, because people who can afford private insurance are not affected. They say that because of this, prioritization is an unfair and inappropriate method for distributing health care, which could lead to a distortion of the doctor/patient relationship and to poor care.

There are important differences between Canada's health care system and the system in Oregon. Nevertheless, it is clear that we need to use resources effectively to avoid, for as long as possible, a rationing approach to cost containment. A better approach to relieving pressure on the health care system is to reorient it to obtain better value for money — value in this situation being defined as the health achieved through the expenditure of dollars on the medical care system. This is an approach the Commission endorses — not only because it offers a means of using resources wisely while maintaining services of the quality Canadians have come to expect, but also because reorienting the system to reflect principles such as effectiveness and value for money is a way to manage the system to withstand the pressures that might otherwise cause it to break down. Reorienting the system in this way will not remove the need to make tough choices — but the fiscal boundary at which choices occur will be farther out.

The System's Limits and New Reproductive Technologies: The Issues of Access

Decisions about the external and internal limits of the health care system are clearly relevant, then, to new reproductive technologies. For instance, should infertility be considered a condition that requires medical attention? If so, who should have access to treatments made available within the system? The complex issue of access to new reproductive technology services has two components — availability and accessibility.

Availability concerns the external limits of the health care system — whether services are provided at all through Canada's publicly funded system. Ethical issues and questions about the broad allocation of resources to and within the health care system often figure in availability debates. Decisions about whether a given service should be made available must necessarily be made in light of how delivery can be effected, but for the most part availability decisions revolve around whether, in principle, it is appropriate to provide the service at all.

Accessibility of services deals with the issues of to whom they are available and what the limitations are. These wide-ranging issues of organization and delivery include who can deliver the service, where it is delivered (both geographically and in which health facilities), what quantity

of services is provided, how a service is paid for, the medical conditions for which it is provided (the internal limits previously discussed), and any other operational factors influencing whether or how a person obtains the service.

The Commission's research showed that the provision of new reproductive technology-related services in Canada is not uniform with respect to either aspect of access. Services are available in some regions but not in others. Eligibility criteria vary from place to place, resulting in differential access to such services as do exist. Testimony before the Commission showed how this unevenness is affecting Canadians seeking treatment.

> One basic thing is that the health care system is not immune to the kinds of biases reflected in the general society. In fact, those social biases have worked their way right through the system.
>
> *Discussion with Health Economists, Transcript, Vancouver, British Columbia, April 25, 1991.*

As the Commission's deliberations proceeded, it became clear that access to new reproductive technologies is one of the broad issues touching several aspects of our mandate and one that must be resolved with reference to Canadian values and health care priorities. It raises questions about the boundaries of the health care system — and hence the demands on it and the cost of sustaining it — but also issues of social justice, equality, and fairness. It also raises questions of the relationship between the need for standards of care and provincial jurisdiction in setting these standards. We believe, however, that these health care issues are primarily national in nature because of their profound social implications. We therefore return to these questions of access in the context of our examination of each of the technologies in Part Two. Here we present our overall conclusions and how we arrived at them.

Coming to recommendations about access to reproductive technologies involved several inter-related considerations for the Commission that necessitated a step-by-step approach. First, the Commission considered whether the technologies should be available at all in Canada: this involved individual assessments specific to each technique or procedure that factored in our guiding principles, what Canadians told us about the significance of the technology in their lives and its implications for them individually or as members of a particular segment of society, and our findings about safety and efficacy. If we determined on this basis that a technology should be available, the next consideration was whether it should be offered as a medical treatment through the publicly funded health care system and, if so, under what conditions. We made this determination through an evidence-based assessment of whether the procedure was actually of benefit for its intended purpose, whether it could be provided at acceptable levels of risk and within a framework of

appropriate regulation, and whether its inclusion in the health care system represented a wise use of public resources in and of itself and relative to other public health priorities.

Finally, if we determined that a procedure should in fact be offered as a medical treatment within the medical care system, we looked at the factors that determine access to procedures within that system. This means examining such issues as equitable access, as defined by both the *Canadian Charter of Rights and Freedoms* and the *Canada Health Act*, and the kinds of barriers to access that could arise — for example, geographical distance, linguistic or cultural factors, financial considerations, and so on.

Our conclusions, as will become evident in Part Two of our report, are that

- if safe, ethical, and effective means are available to help Canadians achieve the goal of having a healthy child, then as a caring society we should consider how to devote our collective resources to doing so;
- if procedures have been demonstrated to be safe and effective, and if we have determined as a society that they should be available, then we must be prepared to commit public resources to their provision through the health care system; to do otherwise would be to ignore Canadians' values with respect to non-commercialization of reproduction and equity and fairness in access to treatment, and, as we will show in subsequent chapters, to undermine the publicly funded health care system by imposing uncontrollable burdens on it; and
- if a procedure is to be provided through the public health system, access to it must be determined by medical criteria and in accordance with the principles established in the *Canada Health Act*, the *Canadian Charter of Rights and Freedoms*, and human rights legislation.

If safe, ethical, and effective means are available to help Canadians achieve the goal of having a healthy child, then as a caring society we should consider how to devote our collective resources to doing so.

Emerging Issues in Health Care

Among the responses to pressures on the health care system are several with relevance to new reproductive technologies. These issues — which have been gaining prominence in recent debates about the dimensions and goals of the system — include quality control in medical care, the appropriate allocation of resources for acute care relative to

prevention, increased information and choice for users of the health care system, privacy and confidentiality, and greater opportunities for participation in individual and collective decisions about health care.

Quality Control

Evidence-based medicine is essential to the concept of quality control in the provision of medical services. The Hippocratic oath directs the physician to work for the benefit of the patient and not to do harm; this means both refraining from actions that are likely to harm and seeking actively to avoid harm or prevent it from occurring. To avoid or prevent harm, it is essential to ensure quality control, a broad concept encompassing the need to "do the right things" as well as the need to "do things right." Yet serious problems with respect to quality control have been identified in the health care field. We discuss how issues of quality control relate to new reproductive technologies and make recommendations regarding them throughout Part Two of our report.

Quality control is an issue for Canadians not only in relation to reproductive technologies but also with regard to medical care generally. Canadians told us they are concerned both about the safety of drugs and procedures and about the long-term health effects on technology users and their children.

A first element of quality control, sometimes referred to as quality assurance, is setting standards for appropriate care, comparing current practice to these standards and, if necessary, adjusting practices to bring them into line with standards, then adapting or adjusting standards as knowledge evolves. There is a need for clear guidelines in this area. As we will see, physicians' use of treatments varies, and there is inconsistency in how and why individual reproductive technologies are used. Nor is responsibility for developing and monitoring adherence to guidelines clearly established.

A second important element of quality control is making sure that only effective treatments — treatments that work — are used. Preventing harm requires finding out how well a treatment works and what its potential risks and side effects are before using it widely. Techniques used to evaluate treatments range from randomized clinical trials to the informal methods of individual physicians. No technique is universally applicable for every medical technology — sometimes simpler approaches are sufficient, and frequently it is best to derive evidence from several techniques. The crucial point is that some sort of systematic evaluation needs to be in place. Unfortunately, this is often not the case.

Moreover, the results of evaluation may not always be used appropriately. For example, clinical trials to test effectiveness and identify risks may result in a treatment being approved for use for a clearly defined set of indications — that is, the specific medical circumstances in which its use was tested. Once a treatment has been approved for use and becomes

more widely known, however, often it is used to treat an expanding range of people with other indications — without any evidence that it will do any good. When this happens, the benefits of the treatment in terms of overall health improvement in the population decline. Further, the safety and effectiveness that were established for the treatment's original use may not apply to these new and wider uses. Similarly, once drugs have been tested for safety and effectiveness and approved for use, there is no monitoring to ensure that the drugs are being used in the way and for the purposes for which they were tested and approved.

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As we have seen, however, a more serious problem than limited evaluation is no evaluation at all. It is estimated that between 30 and 80 percent of all medical therapies, including surgeries, have never been rigorously evaluated. This is not to say that conducting such evaluations is easy — on the contrary, the design and execution of needed evaluations may be very difficult, but they must be done. Moreover, management of the health care system must be based on these efforts: information from evaluations must be reflected in clinical practice and in resource allocation decisions.

The Commission saw several examples of the benefits of this approach. The Canadian Collaborative CVS-Amniocentesis Clinical Trial Group, for example, conducted multicentre randomized control trials in the introduction of two different techniques for prenatal diagnosis — amniocentesis and chorionic villus sampling. These were international pioneering initiatives that have helped set the standard for introducing and assessing prenatal diagnosis technology and controlling its further dissemination on the basis of study findings (see Chapter 26).

Apart from examples such as these, which are the exception rather than the rule, the far more common sequence is for medical treatments or technologies to be introduced and disseminated through a gradual process. First, promising reports appear in the medical literature. Then, professionals adopt the innovation and the public begins to expect it as media reports and word of mouth make it more widely known. Next, the innovation tends to become a standard part of the care offered by many practitioners. Only then are large-scale clinical trials of some innovations conducted and the results disseminated. Critical evaluations of these studies may or may not result in further discussion of the potential risks and benefits of using the technology or procedure. Finally, medical consensus develops, either discrediting the procedure or generally accepting it. Such a process is precisely how many forms of pregnancy and childbirth care were introduced, with scientists only now conducting

extensive evaluations of the results of these practices and discovering that significant numbers of them either should be discontinued or need more investigation before their benefits (or lack of them) can be determined.

Decisions about which services are publicly supported through provincial health insurance coverage have been influenced historically not by evaluation results but by lobbying, media coverage, and emotional appeals. Many Canadians continue to believe, however, that funding and diffusion of health care technology are rational, consistent across provinces, facilities, and practitioners, and closely related to effectiveness. In fact, analysis of patterns of technology use shows that the inherent attributes of a given health technology (effectiveness, safety) are not related in any consistent way to its diffusion. Moreover, health care technology diffusion is not related consistently to the prevalence of disease. Not surprisingly, this situation is of great concern to governments, which now want to be able to make empirical, evidence-based decisions about how much of which technologies or procedures should be provided.

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Support for a more rational approach is growing, accelerated in part by recognition of the need to make most effective use of finite resources. Two provinces, for example, have established health technology assessment offices, and a joint federal/provincial/territorial body, the Canadian Coordinating Office for Health Technology Assessment (CCOHTA), was instituted by the country's health ministers in 1989. The Quebec government set up the Conseil d'évaluation des technologies de la santé in 1988, while the government of British Columbia established the Office of Health Technology Assessment through a grant to the University of British Columbia in 1990. The University of Manitoba also has a unit within the Department of Community Health Sciences devoted to health services research and

> Appropriateness of technology including the provision of health promotion and illness prevention programs must be a major concern given the country's pre-occupation with quality care, cost effectiveness and health care ethics.
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> *A. Baumgart, National President, Canadian Nurses Association, Public Hearings Transcripts, Ottawa, Ontario, September 20, 1990.*

analysis, the Manitoba Centre for Health Policy and Evaluation. Then, in January 1992, the Conference of Deputy Ministers of Health adopted an eight-point set of policy directions that is tantamount to a national health strategy. One of the eight points is the development of national clinical guidelines to reduce the provision of unnecessary medical treatments. CCOHTA also reports annually to the Conference of Deputy Ministers of Health on its work. In addition, the Ontario Ministry of Health and the Ontario Medical Association recently established (1992) the Institute for Clinical Evaluative Sciences to conduct research on the accessibility, quality, and efficiency of medical services in the province.

All medical interventions involve a weighing of the potential risks and benefits; there are no risk-free situations. It is clear, nevertheless, that appropriate medical care can be provided only if evidence collected through clinical trials and other appropriate forms of evaluation is available to guideline setters, practitioners, and funders. Evidence alone is not sufficient, however; it must be translated into funding decisions, guidelines, behaviour, and practice.

The Commission's approach to examining reproductive technologies rested on the premise that safety and efficacy must be demonstrated before judgements can be made about the appropriateness of providing or not providing treatment. Before such a judgement is made, treatment provided in the absence of evidence should be considered research, not therapy. This raises questions about when medical technologies cease being experimental procedures and become therapeutic treatments, as well as who is qualified to make this distinction and how such decisions should be made. This gap is being filled by a new term — "innovative therapy" — the practice of which requires no scrutiny by research ethics boards. Because borders of innovative therapy are not clear, the possibility arises that this rubric could be used to circumvent the structures, regulations, ethical oversight, and protections that apply to research involving human subjects.

Treatment provided in the absence of evidence should be considered research, not therapy.

The protections afforded by categorizing a procedure as research include (1) review and approval by the research ethics committee of the institution (hospital, university) where the research is being conducted; (2) specific requirements for obtaining informed consent from participants; and (3) inability to charge participants for services received as research. Relevant concerns that are dealt with in this way include certain ethical aspects, such as the information needed by people before they give their consent to participate in research, and how the privacy and the confidentiality of information about them generated by the research will be protected. Thus, whether a procedure is designated "research" or "treatment" has very important practical implications. Research is

important — it is irresponsible to provide treatment if it is not also accompanied by research aimed at assessing the results of treatment and improving practices. However, in this field we see no useful place for the category "innovative therapy" — in fact, people consenting to such procedures should have the protections afforded by categorizing the procedures as research.

One of the issues that arises inevitably in discussions of quality control is the cost of evaluations, particularly when techniques such as clinical trials are involved. In the Commission's view, it is reasonable to recommend that provincial ministries of health fund such trials, mainly because it is the responsibility of these ministries to manage the health care system on behalf of taxpayers, making wise use of resources and appropriate decisions about which services should be included in the system. It is from their budgets that treatments, if demonstrated effective, will eventually be paid for, and such trials will provide evidence on which to base rational resource allocation. It is the view of Commissioners that ministries of health should demand rigorous technology assessment before agreeing to fund services through the publicly supported health system and should be prepared to fund such assessments in the interests of providing better medical care and a better managed health care system.

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Provinces might well be able to share the cost of such trials and avoid duplication by coordinating their efforts. In addition, we believe that the federal government, through our proposed National Reproductive Technologies Commission, should fund some of the most urgent clinical trials and work with the provinces to identify areas where sharing of cost and information would contribute to the rapid assembly of sufficient data on which to base health care service and funding decisions.

Over the years, ministries of health have made decisions to include specific procedures or services within the health care system before they were assessed properly, relying on the various professional colleges and professional associations to set guidelines for practice and on the cooperation and discipline of individual practitioners to refrain from using them in unproven ways. In the past, ministries may not have seen much benefit in investing in technology assessment (for example, funding trials), largely because they saw little indication that the evidence produced by such research actually influenced or changed medical practice. However, under the licensing system we propose for assisted conception services and other reproductive technologies, the structure and mechanisms will be in place to ensure that the evidence produced by clinical trials does lead to

changes in practice and to control of inappropriate use of technologies and procedures. This is a cogent reason for ministries of health to fund both initial assessment and continuing evaluation of technologies in the reproductive sphere.

A quality control question separate from whether the technologies work is whether they have short- or long-term health effects that should determine the evolution of practice — for example, whether the circumstances or conditions under which a treatment is provided should change in light of knowledge gained by providing the treatment to large numbers of people over a significant period of time. Assembling this knowledge requires various monitoring and follow-up techniques, such as the reporting system and the record linkage approach we suggest with respect to the long-term health effects on women and children of assisted conception techniques (see, for example, Chapter 18, where we explain the concept of record linkage as a means of tracking long-term health effects of technology use in greater detail). Monitoring and follow-up of this type provide a way to close the quality control loop, by ensuring that knowledge gained through practice is fed back into the process of revising, adapting, and updating guidelines and standards of practice.

Acute Care and Prevention

How the health care system values and allocates resources between medical care and preventive efforts is another emerging issue. Consensus is emerging on the need for a shift in resource allocation between illness care on the one hand and illness prevention and health promotion on the other, but the appropriate dimensions and timing of such a shift are not yet entirely clear. The use of new reproductive technologies illustrates some aspects of this issue because it raises questions about why such treatment is needed in the first place and whether infertility could be prevented. What should be the relative roles of prevention and acute care (that is, medical treatment) with regard to infertility?

Preventing harm is inherent in the ethic of care. In addition, if prevention is demonstrated to be more effective in terms of health outcomes and cost than treating a problem after it has occurred, it is obviously the more desirable option as well as the more ethical approach. The issue is complex, however, because the line between prevention and treatment may be hard to establish. For example, some aspects of the current practices of physicians and dentists relate to prevention, even though their services are usually considered to be in the treatment sphere. Without systematic evaluation against established standards or criteria, it is impossible to know whether prevention programs are achieving the preventive effects intended. As we have seen, many treatments and medical services are also unevaluated and of unproven value in terms of producing health. These situations make it very difficult to judge whether the current distribution of health care resources between medical care and preventive approaches

makes most sense. However, this does not mean we should take no action for change — in fact, it is crucial that we do act, as we discuss in Part Two.

One apparent roadblock to greater emphasis on illness prevention and health promotion is the shortage of reliable data about the effectiveness of prevention and promotion strategies. We agree that evaluations of effectiveness should be an integral part of prevention strategies to provide a basis for policy and program adjustments and resource allocation decisions. At the same time, we note that many medical treatments and drug therapies have been introduced and funded without being demonstrated effective through appropriate evaluation and assessment. A double standard appears to be at work, with a greater burden of proof being required for prevention than for medical treatment: preventive efforts have often been required to demonstrate their effectiveness *before* they are supported, while medical treatments have been introduced and paid for through the health care system without good evidence of effectiveness.

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The debate about the appropriate roles for prevention and acute care has important implications for new reproductive technologies. The lessons learned from the general debate have been instructive in our deliberations regarding the appropriate roles for prevention and acute care in relation to infertility and how resources should be apportioned between them. How can we determine, for example, the relative cost-effectiveness of efforts to reduce exposure to risk factors for infertility — such as sexually transmitted diseases, smoking, and aging/delayed childbearing — and efforts to treat infertility once it has occurred? We return to these questions in Part Two, where we discuss infertility, its prevalence, and associated risk factors.

The Role of the Patient: Informed Choice

The third emerging issue in health care involves the concept of informed choice. Today's health care users want comprehensive information and greater involvement in both individual and collective decisions about health and medical care. Information is one essential component of informed decision making; the other involves the skills and opportunities needed to weigh information and make judgements in light of identified values and priorities. Fully informed choice offers potential benefits for both individuals and the health care system.

Physicians are required to obtain the informed consent of competent patients before providing any treatment offered in the health care system. There is a growing perception, however, that the current informed consent standard is insufficient, particularly in the context of new reproductive technologies. A new concept — informed choice — is emerging not as an alternative to informed consent (which will remain a requirement of the law and medical profession guidelines), but as an essential supplement and complement to it.

> Are the women who turn to the NRTs told from the outset about the real success rates of the various reproductive technologies? ...
>
> Women should know what price they will have to pay, not only in financial terms for the procedure itself, but in terms of risks to their physical and mental health and in terms of availability and time.
>
> *Brief to the Commission from the New Brunswick Advisory Council on the Status of Women, October 19, 1990.*

People have a legal right to decide what is done to their bodies; it is a denial of the inviolability of the person for someone to be touched without consent. The current informed consent standard, developed by the courts in response to litigation over the years, clarifies what information physicians must disclose to patients and acquire from them to avoid violating patients' legal rights. The standard requires that doctors obtain patients' consent by providing sufficient information about the treatment to ensure that patients know what they are agreeing to before beginning treatment. The informed consent standard thus arose in response to the question of what physicians must do to respect the physical and psychological integrity of their patients. Many people inside and outside the medical profession now believe that this approach is too narrow, given the complexity of medical problems and the range of ways to resolve them, and given growing recognition of the importance of involving people in decisions about their own health.

The concept of "informed choice" represents this broader approach. Physicians are still under a legal obligation to respect the patient's inviolability and autonomy and thus to obtain informed consent to treatment. But informed choice involves in addition the presentation of other available options, including non-medical ones, and support for patients in making choices from among these options.

The approach represented by informed choice is based in part on growing recognition that patients tend, quite understandably, to be more concerned about risks than clinicians are. When fully informed about the potential risks surrounding various approaches to treating prostate cancer, for example, men have been found to prefer less invasive treatments, particularly given great uncertainty about the benefits of more aggressive approaches. In other words, when patients have precisely the same information as clinicians about the probable results of treatment, their

choices differ considerably from those clinicians might make, because patients weigh the information differently and are generally more averse to risk. Instructions in the form of living wills and advance medical directives are other examples of how patients may be less open than physicians to intervention.

Researchers have concluded that the amount of invasive medical technology now being provided may actually exceed the amount patients would choose to have if they were fully informed and left to decide according to their own priorities and preferences. These findings may well be applicable more widely throughout the health care system and could have cost advantages for the system, but, just as important, this approach means that treatment would be offered in ways that are more consistent with patients' values and priorities.

> Our experience with physicians is that the training is more focussed on informed consent as opposed to informed choice, and there's an important distinction there.
>
> Informed consent is very much a legal concept ... It involves a physician having ascertained the course of treatment that he/she would like to administer and then getting the person to understand it sufficiently that the physician can feel as if the patient is going along with it. [On the other hand,] informed choice, as we practise it in our clinic, is outlining to the consumer the various options, with their upsides and the downsides. That's the education component, following which the support necessary to allow them to make the choice is provided.
>
> *Theme Conference on the Impact of New Reproductive Technologies on Women's Reproductive Health and Well-Being, Transcript, Vancouver, British Columbia, July 31, 1990.*

As we discuss in greater detail with respect to specific technologies, informed choice means providing relevant and understandable information about the options and the possible implications of various decisions. It means supporting individual decision making by helping people identify what is important to them and how various decisions would coincide with their priorities, given their values and circumstances. Informed choice also entails allowing as much time as possible for discussion and reflection. The concept does not mean that doctors are abdicating responsibility for recommending certain treatments or courses of action; nor is the physician always required to give the patient every piece of information available. But the concept of informed choice does entail providing information and support to enable people to reach decisions, building on the relationship of confidence and trust between the patient and the physician to create a sense of partnership in treatment decisions. The advent of medical procedures using highly complex technological procedures can make confidence and trust more difficult to maintain, but it does not eliminate the need to exercise them.

The call for informed choice is tied closely to other issues of importance to the Commission that we introduced in Chapter 2, such as the principle of autonomy, individual empowerment, and the need for accountability of people providing services or making decisions about the health care system to those who use it. We examine the implications of informed choice in the context of new reproductive technologies throughout Part Two of our report.

> While the women described many health professionals as caring, attentive, and sometimes highly compassionate, they also described a medical system that they perceived as fragmented and uncoordinated, and that isolated clients. Whatever a women's background and circumstances, she perceived a need for support and advocacy to deal with some aspects of the medical system ... The settings and nuances of care made them feel vulnerable. This was equally true of the nurses in the study who talked about needing considerable emotional resources to deal with the medical system as clients.
>
> *S. Tudiver, "Manitoba Voices: A Qualitative Study of Women's Experiences with Technology in Pregnancy," in Research Volumes of the Commission, 1993.*

Privacy and Confidentiality

Privacy — the right to control information about oneself — is a fundamental value in our society, and one the Commission respects. The practice of medicine and the use of medical technologies generate large amounts of personal information in physicians' records, provincial health insurance plan records, and the records of clinics, hospitals, and other facilities. We want to ensure that our recommendations do not add to the list of intrusions into people's private lives. Therefore, we have made recommendations throughout our examination of individual technologies to ensure that privacy is respected in the collection and use of information regarding the use of reproductive technologies, which can generate intensely private information about the people involved. The loss of privacy is a risk associated with the technologies if personal information relating to their use is not safeguarded.

Individual patients clearly have an interest in ensuring that information about themselves remains confidential. People who make use of services such as assisted insemination or *in vitro* fertilization may not want that information disclosed to anyone. At the same time, others may have an interest in obtaining access to the information for various reasons. For example, researchers and policy makers could use information on the results of *in vitro* fertilization and other treatments as the basis for record linkage studies to determine long-term health effects and for decisions on health policy and public health protection. An individual born as a result of egg or sperm donation may want to learn the identity of the gamete

donor or donors. Employers or insurers may want information about an individual's health history or genetic make-up.

The Commission recognizes the inherent tension between an individual patient's interest in privacy and the interests of other individuals and society as a whole in making information available for specified purposes. The challenge, therefore, is to ensure that information is collected, used, and disclosed only in appropriate circumstances and under clearly defined conditions.

> I think there are two rights involved here: the right to confidentiality that was guaranteed at some point in the contract, and the right of the child to know his genetic origins. [Translation]
>
> *A. Klotz, private citizen, Public Hearings Transcripts, Montreal, Quebec, November 21, 1990.*

One important distinction in this regard is the difference between information that reveals the identity of a specific individual and coded information, which does not reveal an individual's identity. Coded medical data may contain information on an individual's diagnosis, treatment, and the results of treatment, as well as information about some personal characteristics (for example, age, sex, income, and general geographic location), but none of this information would permit the specific identity of the patient to be known — the data are identified only by code number, not by the patient's name. Although the data include personal information, it is known as *non-identifying* information.

Non-identifying information is the type used most often for research and policy making. For these purposes, the specific identity of people receiving treatment is not of concern; what matters is analysis of the aggregate results of many cases, which permits researchers to draw conclusions and policy makers to make informed decisions. By contrast, employers and insurers, as well as children born as a result of gamete donations, may be interested in *identifying* information — that is, named information that is linked to a specific individual.

The Commission considered how society's interest in using the information in medical records for research into patterns of illness or disability and the outcomes of treatment can be served while also satisfying people's legitimate interest in keeping information about themselves private. Research results are needed so that the use of harmful procedures or

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drugs can be stopped and improvements in medical treatment can be made. Citizens rely on governments to protect their safety, but governments can do this only if sufficient relevant knowledge can be accumulated to guide policy. Access to information about the nature and results of treatment is thus an integral part of evidence-based medicine; it is one of the essential components permitting safe care and the responsible use of health care resources.

This is of particular interest in the field of new reproductive technologies because many of the drugs, devices, and procedures used in assisted conception have yet to be assessed for effectiveness or to determine the nature and scope of the potential risks associated with them. Many of our recommendations concerning these technologies will depend on the results of such assessments being made available to policy makers and technology users alike.

New technological developments raise a host of questions. What measures exist (or need to exist) to protect disclosure of information about an individual's health or genetic make-up derived from prenatal testing to organizations or government agencies that may have a commercial or political interest in it? What protections exist (or should exist) regarding the collection, use, or disclosure of information (including samples of genetic material) relating to new reproductive technologies? Are there in fact any circumstances in which life insurance companies or employers should be permitted to gain access to information without the individual's explicit consent?

No single law regulates or protects privacy and confidentiality. Canadian law in this area is extensive and complex; rights and obligations have evolved from a complex web of international law and codes, constitutional documents, federal and provincial laws, court decisions, and professional guidelines, codes of conduct, and codes of ethics. The conflict between sometimes disparate laws adds to the complexity. At the international level, Canada has ratified human rights agreements that assert the right to protection against arbitrary interference with privacy. Canada has also adhered to international data protection principles covering both the public and the private sector in the collection, use, and disclosure of personal information. However, adherence to these latter guidelines is not mandatory.

Domestically, the courts have interpreted the *Canadian Charter of Rights and Freedoms* as protecting certain privacy rights. The federal government and three provinces have enacted general privacy legislation regulating the collection, use, and disclosure of personal information by government institutions. As well, specific pieces of legislation, such as the *Income Tax Act* and the *Statistics Act*, have incorporated privacy protections with regard to information collected in administering them. In addition, numerous laws and court decisions establish obligations of confidentiality, as do professional codes of conduct and ethics.

When it comes to individual medical records, it is the law that personal information collected by health care facilities and practitioners is confidential. Confidentiality is the duty owed by one person not to disclose information given by or about another. These laws imposing obligations of confidentiality contain exceptions: for example, the law in most provinces requires health professionals to report certain communicable diseases or cases of suspected child abuse, even if this means disclosing confidential information. This recognizes that the interests of the individual must be balanced with the interests of others. However, any increase in the number of exceptions to obligations of confidentiality — such as mandatory reporting requirements imposed on physicians — erodes privacy, and thus there is a need to demonstrate a legitimate public or social need before access is given without the individual's permission.

When it comes to individual medical records, it is the law that personal information collected by health care facilities and practitioners is confidential. New ways of protecting privacy will need to be put in place to deal with these new situations.

Increasingly, new ways of protecting privacy are called for because of new developments. Technology has permitted new forms of surveillance, such as cameras on street corners and in stores and telecommunications monitoring devices. Biotechnology has made possible testing for genetic traits and testing for the use of illegal drugs. New ways of protecting privacy will need to be put in place to deal with these new situations. In this report we are concerned mainly with how the legal and philosophical principles embodied in privacy law can be respected in the practices of facilities and practitioners offering new reproductive technologies, at the same time allowing record linkage studies and other research techniques in support of evidence-based medicine and public policy and resource allocation decisions.

New Reproductive Technologies and the Health Care System

The issues facing the health care system generally — growing expectations of patients and providers, rising costs, the internal and external limits of health care, the appropriate roles for prevention and acute care, the need for more systematic quality control, increasing demands for information and participation in decision making — are all demonstrated in the field of new reproductive technologies. By the same token, much of what the Commission has learned about new reproductive technologies has broader lessons for the health care system. Because the technologies evoke highly sensitive issues and have profound personal and social implications,

the field requires the highest possible professional standards, combining excellent medical practice with concern for the potential psychological, social, ethical, legal, and financial impact of the technologies. If we can find a way to achieve a high performance standard in new reproductive technologies, this field could provide a model for high-quality, evidence-based medical practice in general.

The increasing recognition that a significant proportion of medical care either makes very little difference to health status or has never been evaluated could prompt the beginning of a new approach to health care. New reproductive technologies offer ideal conditions in which to begin such an approach — it is a well-defined field with an identifiable set of practitioners and in Canada operates within a single-payer health care system. It must be emphasized that new reproductive technologies are applied — and can only be applied — within the broader health care system. It is the health care system that makes available trained personnel and the necessary facilities and equipment; it is through the health care system that many of the preparatory and follow-up services surrounding use of the technologies will have to be provided; and it is through the publicly funded health care system that a measure of quality control and accountability can be established to safeguard the health and safety of Canadians and ensure the wise use of collective resources.

New reproductive technologies offer ideal conditions in which to begin a new approach to health care — it is a well-defined field with an identifiable set of practitioners and in Canada operates within a single-payer health care system.

Infertility and new reproductive technologies are also fields that demonstrate the importance of involving systems other than health care — including social services, education, and legal systems — in addressing health-related problems. Our recommendations about new reproductive technologies therefore will also be relevant as a model for other similarly complex health-related problems.

The debate about new reproductive technologies has raised questions concerning what services should be considered medically necessary, who should have access, and who should pay the costs. These discussions, in turn, have helped open up the broader public debate about the future of health care in our country. There are significant difficulties inherent in attempts to reorient the health care system, as our discussion of its external and internal limits makes clear. The system is under constant pressure to find a sensible balance between ready and equitable access and cost containment. It will likely always be difficult to determine which situations and conditions should be considered medical problems. But this does not negate the need or responsibility to tackle the issue. In fact, the future of Canada's health care system depends on it.

Despite the current pressures on Canada's health care system, its great strengths should not be overlooked. The United States does not have a publicly funded system — and 37 million people have no health insurance.[1] Perhaps an equal number are underinsured and face financial catastrophe if they have a serious illness or accident. Many more are at a wholly unpredictable risk of having their coverage reduced or withdrawn, depending on the financial health of their employers. Moreover, a mixed public and private system also has inherent structural problems that result in inequities for people seeking treatment and in distortion of publicly supported health care priorities (see Chapter 20).

What Commissioners learned during our consultations and research reinforced our strong support for the values of social equity and access that are embodied in our health care system. In addition, what we observed in other countries confirmed our belief in the importance of maintaining the integrity of a publicly funded health care system. It is clear, however, that the health care system can maintain its integrity only if both its capacities and its limitations are clearly defined and respected.

Fortunately, because Canada has the appropriate structures in place — including a single-payer health care system and responsible professional organizations with a history of country-wide co-operation and collaboration — we have the opportunity in this country to organize this area of medical practice in a way that would enable new reproductive technologies to serve as a model for other areas of medical care. Openness on the part of the professionals involved, health ministries, and other interested parties will be required to apply the lessons about evidence-based practice to new reproductive technologies. We have an unusual opportunity to achieve this; it would be regrettable if we did not seize it.

Fortunately, because Canada has the appropriate structures in place — including a single-payer health care system and responsible professional organizations with a history of country-wide cooperation and collaboration — we have the opportunity in this country to organize this area of medical practice in a way that would enable new reproductive technologies to serve as a model for other areas of medical care. We have an unusual opportunity to achieve this; it would be regrettable if we did not seize it.

We are not alone in reaching these conclusions about Canada's health care system — they reflect the assessment of a growing number of people within and outside the system. By almost any measure, that assessment is a positive one — the development of our universal single-payer system is a success story about which Canadians are justifiably proud. At the same time, health care is at a crossroads and presents Canadians with crucial questions about the future of a system we all value highly. Unless we find ways to deal with current pressures on the system in a way that

maximizes the health of citizens, we run the risk of overloading it to the point of breakdown.

The crux of these choices lies in the balance between what Canadians are willing to put into the system and what we want to get out of it — questions, in other words, about resources and results. Until now, directions in health care have been determined largely by the efforts of many groups, both within and outside the system, struggling to push or pull it toward serving one interest or another. Allowing this situation to continue risks straining the system to the point where its survival is threatened. In our view, the survival of the health care system depends on sufficient numbers of Canadians agreeing on the need to preserve the collective benefits of a universal health care system, agreeing on what we want from the health care system, and agreeing, through our governments, to take the steps necessary to achieve those results.

This is the context in which the Commission's study of new reproductive technologies took place. As we have seen in this chapter, investing more resources in acute care and medical treatment does not necessarily contribute to improved health. Moreover, because the system has a virtually unlimited capacity to absorb resources, that investment could go on expanding indefinitely. The case of new reproductive technologies provides a good example; part of the debate about new reproductive technologies turns on whether and to what extent the health care system can respond to all demands for the new technologies and related services.

Unless we decide soon to adopt a new direction in managing the health care system, such debates will continue to buffet the system, and it will inevitably be eroded. If we continue along the current path, once the existence of a new medical technology becomes known, the demand by physicians and consumers for it will prove irresistible, and once again an already overburdened system will expand to meet their demands. At some point society is bound to react by simply refusing to invest any more. At that point decision makers would seize upon extra billing, user charges, and similar ways to obtain additional resources — the only possible responses if we continue to focus solely on the resources we put into the system. If that occurs, the system will inevitably be changed to introduce other payers, thus altering it in ways most Canadians would find totally unacceptable, as well as causing it to be

If we continue along the current path, once the existence of a new medical technology becomes known, the demand by physicians and consumers for it will prove irresistible, and once again an already overburdened system will expand to meet their demands ... The result would be a two-tiered system, with access to services determined by ability to pay — a system that would cost the country's economy far more than the current system, even if some of the cost was not borne by the public purse.

more costly and inefficient. The result would be a two-tiered system, with access to services determined by ability to pay — a system that would cost the country's economy far more than the current system, even if some of the cost was not borne by the public purse.

Before that happens, we have another choice. We can choose to focus instead on *results* — on what we get out of the system in which we have invested so heavily. By results we mean not only doing things right but also doing the right things. It means evaluating the results of treatment and agreeing not to provide those that are ineffective. But it also means agreeing collectively on which of the effective treatments we as a society are willing to provide within the health care system.

This is not the easiest choice, but it is the right choice. It will require a concerted response and a concerted commitment to change. In the view of Commissioners, we should begin the process of change with a comprehensive, coordinated response to new reproductive technologies along the lines we recommend in the remainder of this report. Change will involve difficult decisions about the external and internal limits of the system — which services should be part of the system's mandate and which should not, and what conditions should govern the provision of services. It will also require fundamental shifts in system orientation, bringing into the health care mainstream concepts and practices that are given lip service but are now operating on its margins: evidence-based medicine, technology assessment, prevention, and health promotion.

The choices that are necessary must be based on more than scientific data, however. Although they must be informed by the evidence, they must also involve thorough and principled analysis of the ethical, social, and other implications of various courses of action. This is what the Commission has attempted to do with respect to new reproductive technologies. After wide consultation, evaluation of the evidence, and ethical analysis, we have made recommendations about which technologies can be considered effective and that Canadians should be willing, collectively, to pay for. Governments will have to decide whether they agree.

Despite the difficulty of embarking on change of this magnitude, and even though the shift may take years to complete, focussing on results will produce indisputable benefits: better medicine, better resource management, and preservation of a system Canadians consider essential to our way of life. Making this choice now will ensure that our children and grandchildren continue to enjoy the standard of health care and the overall health status we have come to expect. It is the choice that will allow us to maintain the advantages of a system Canadians prize so highly: quality care and equitable access for all Canadians, regardless of income.

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Achieving Responsible Regulation of New Reproductive Technologies

We developed the ethical framework and evidence-based approach, described in the two preceding chapters, as tools to illuminate and orient our review of the elements of our mandate. This permitted us to assess reproductive technologies, make judgements about them, and develop recommendations. Our conclusion, based on this ethical and evidence-based review, is that decisive, timely, and comprehensive national action is required with respect to the regulation of new reproductive technologies. In light of this belief, and in conformity with the federal government's constitutional responsibilities and the expectations of Canadians, Commissioners strongly recommend several major federal initiatives in the field of new reproductive technologies to provide the national framework that we believe is urgently required. The broad outlines of this national framework are sketched in this chapter; how they will apply in detail with respect to the individual technologies enumerated in our mandate is discussed in greater depth throughout Part Two of our report.

Before proceeding with this discussion, we consider it important to emphasize that although the national framework (for which Commissioners heard calls time and again in testimony and submissions) is necessary, it is not sufficient. Strong provincial and professional leadership in specific areas referred to throughout Part Two of our report is also essential. Indeed, the success of the broad national approach we recommend will also depend on provincial and professional action and involvement in a wide

Our conclusion, based on this ethical and evidence-based review, is that decisive, timely, and comprehensive national action is required with respect to the regulation of new reproductive technologies.

range of new reproductive technology-related issues in the years to come. Concerted action and cooperation by the provinces, the professions, and other key participants in the context of the proposed national framework are the only way to ensure ethical and accountable use of new reproductive technologies in Canada — for now and for the future.

Federal Legislation: Establishing Boundaries and Setting Limits

As the discussion throughout our report makes clear, certain aspects of the research, development, and use of new reproductive technologies have particular social significance and raise particularly pressing issues for Canadians as individuals and as a society. Our analysis of the extensive data and research gathered during the course of our mandate leads us to conclude that public concerns about the need for effective social control of the use of these technologies are justified.

Consistent with the federal government's responsibility to legislate for the peace, order, and good government of Canada in matters of national interest, including in relation to the national health and welfare of Canadians, and in light of Parliament's extensive powers to protect public health, public security, and the public interest by means of the criminal law, we conclude that certain technologies and practices should be subject to the most stringent form of control available: outright prohibition under threat of criminal prosecution under the Canadian *Criminal Code*. This form of control will, in effect, establish clear boundaries around new reproductive technologies, excluding those practices that are, because of their unsafe or unethical character, considered unacceptable under any circumstances. In particular, the Commission recommends that the Parliament of Canada legislate to ensure that

- for-profit activities in connection with the creation, exchange, and use of human reproductive materials, including sperm, eggs, zygotes, embryos, fetuses, and fetal tissue, are prohibited (see Chapters 19, 20, 22, and 31);
- advertising for, making payment for, or acting as an intermediary in order to derive financial or commercial benefit from preconception arrangements, are prohibited (see Chapter 23);
- research involving human zygotes or embryos directed toward development of ectogenesis, cloning, the creation of human/animal hybrids, and the maturing and fertilization of eggs from fetuses is prohibited (see Chapter 22); and

- unwanted medical treatment and other interferences, or threatened interferences, with the physical autonomy of pregnant women are prohibited (see Chapter 30).

In our view, these legislative prohibitions fall squarely within the federal government's constitutional mandate to protect public health, public security, and the public interest, and to promote constitutional values of human dignity and equality. These measures would place clear limits on practices that Canadians consider unacceptable and would help to ensure that the future evolution of new reproductive technologies reflects the public interest.

The criminal law approach, while essential for establishing boundaries with respect to some uses of new reproductive technologies, provides less flexibility than is desirable for continuing regulation and management of other, more acceptable, aspects of the technologies. A second kind of response is therefore required in addition to these criminal law measures, to ensure that the technologies and practices deemed acceptable, provided they are subject to appropriate limits, receive the continuing monitoring and the public debate required by their profound implications.

These other areas require a more dynamic and responsive approach, one capable of adapting to new medical and scientific knowledge, responding to the results of technology assessment, and accommodating changes in Canada's social fabric. They also require an approach that can assure Canadians that appropriate attention is being paid to broader issues as well — including the protection and advancement of the public interest, the individual and collective interests of women, and the well-being of parents and children in the formation of families.

> The lack of a federal regulatory or informational presence in NRTs is all the more serious because of the paucity of provincial/territorial and professional standards guiding research and monitoring ... Thus, Canada needs a national body to review and approve research proposals, set ethical standards, set national standards of informed consent for NRT research and therapy, standardize data collection on NRTs, and monitor access and service provision.
>
> *Brief to the Commission from the Canadian Advisory Council on the Status of Women, March 1991.*

In the next section we outline our proposals for implementing the regulation of the technologies and practices we consider acceptable — provided they are assessed and delivered in an appropriate way — and to ensuring their continuing congruence with Canadians' values and priorities.

Calls for a National Reproductive Technologies Commission

Throughout our public hearings and in the many briefs we received, one of the clearest themes that emerged was the need for a national body to establish standards and to oversee activities and developments in the field of new reproductive technologies within the overall boundaries set by federal legislation. Near unanimous concern was expressed that without such national standards and control, the current patchwork of standards and services would persist. As one group appearing before the Commission expressed it, "it is simply unacceptable for us to think of such matters that are so fundamental to the very essence of life differing greatly across the country" (*Women's Rights Committee of the Nova Scotia New Democrats, Public Hearings Transcripts, Halifax, Nova Scotia, October 17, 1990*).

The call for an independent national body came not only from national, regional, and local women's groups, but from groups representing legal, health care, religious, and scientific bodies. As the Charter of Rights Coalition Manitoba stated in their testimony before the Commission:

> A national council on reproductive technologies [should have] a mandate to assess the medical and ethical implications of ongoing research on reproductive technologies and the appropriateness of new technologies; foster links among researchers, decision-makers and consumers of reproductive technologies; instigate public education and discussion on reproductive technologies in all areas of the country and encompassing all groups; administer a research budget ...; [and] have the authority to develop regulations under [federal] legislation about each emerging technology. (*B. Suek, Charter of Rights Coalition Manitoba, Public Hearings Transcripts, Winnipeg, Manitoba, October 23, 1990.*)

Those appearing before the Commission proposed several functions for the national body, including setting and enforcing national standards and guidelines, standardizing data collection and analysis, licensing clinics and practitioners, monitoring research and services, and providing information and advice to governments regarding policy, legislation, and regulation.

We examined the extensive evidence on how new reproductive technologies are currently being researched, developed, and applied in Canada, we listened to Canadians talking

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We have concluded that an independent national body, charged with overseeing and controlling the development and application of research, technologies, and practices in this field, is urgently required. In our view, this is the only way to ensure that the appropriate mix of resources, skills, and experience is brought to bear on reproductive technologies in all their dimensions: ethical, social, legal, scientific, and medical.

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about how they expect their governments to respond to these issues, and we considered the possible ways of achieving our goal of ensuring that only ethical, effective, and accountable use is made of reproductive technologies. We have concluded that an independent national body, charged with overseeing and controlling the development and application of research, technologies, and practices in this field, is urgently required. In our view, this is the only way to ensure that the appropriate mix of resources, skills, and experience is brought to bear on reproductive technologies in all their dimensions: ethical, social, legal, scientific, and medical.

The Need for a National Regulatory Commission

Throughout Part Two of our report we recommend numerous measures and safeguards that we have concluded are necessary to ensure that only technologies and services that are ethically acceptable and effective at tolerable levels of risk are offered and that they are offered in appropriate ways. Several requirements are common to all the areas the Commission examined: the need for adequate and reliable information to guide policy and practice; the need for standards and guidelines for the organization and provision of services; the need for effective means to ensure compliance; and the need for accountability.

Efforts with respect to specific technologies have been made to meet some of these needs. However, we found that levels of self-regulation and accountability vary enormously from one area of practice to another. It is clearly important, in contemplating coherent regulatory intervention with respect to new reproductive technologies, to build upon previous efforts and to enlist the skills and cooperation of relevant professionals and communities of expertise and experience. Because it is so fundamental to the future of our society and to us as individuals, however, primary responsibility for regulating research and technology relating to human reproduction cannot be left entirely to self-regulating professional and other bodies, but must be assumed by government.

> A government body should be established with responsibility for approving proposals to apply new knowledge and procedures in new reproductive technologies in clinical practice. This body should also have the authority to accredit infertility centres and the people in them. [Translation]
>
> *G. Bleau, Centre de recherche en reproduction humaine de l'Université de Montréal, Public Hearings Transcripts, Montreal, Quebec, November 22, 1990.*

At the same time, we believe that existing legislation, government structures, and self-regulation mechanisms are not adequate to meet the demands of regulating this complex and rapidly evolving area of technology. This is because, for the most part, their mandates are too narrow and too focussed on one isolated facet of the technologies — be it the health services delivery, the medical, the scientific, or the research aspect — to provide the comprehensive overview and integrated approach we see as essential.

> A regulatory body must be formally established to set and enforce standards, principles and regulations under which NRT research is carried out ...
>
> We believe the body must not be composed merely of scientists, doctors or academic ethicists, but must be representative of the community as a whole.
>
> *N. Riche, Executive Vice-President, Canadian Labour Congress, Public Hearings Transcripts, Toronto, Ontario, October 31, 1990.*

Thus, we conclude that a new, federally funded, independent body should be established by Parliament to assume comprehensive regulatory responsibility in this area. As we have already argued, such regulatory responsibility is consistent with Parliament's power and responsibility to intervene in the interests of national health and welfare pursuant to the federal peace, order, and good government, criminal law, trade and commerce, and related federal powers. In light of these considerations, the Royal Commission on New Reproductive Technologies recommends that

1. The federal government establish an independent National Reproductive Technologies Commission charged with the primary responsibility of ensuring that new reproductive technologies are developed and applied in the national public interest.

Creation of a National Commission to provide national regulatory oversight and control in the field of new reproductive technologies is needed on several grounds. The rapid pace at which reproductive technologies and practices are being introduced and disseminated dictates an immediate regulatory response. A National Commission could be established and put into operation within a relatively short time frame. This is a crucial consideration. In Commissioners' assessment, the time that would be required to enhance current mechanisms or develop new mechanisms for interprovincial regulatory and policy harmonization, and to adapt them to the complex area of new reproductive technologies, goes far beyond what is acceptable, given the urgency of action to deal with these issues while

there is still time to contain and control current practices and future developments.

A National Commission would permit the creation and implementation of coherent, comprehensive, and effective nation-wide standards and monitoring devices. This is in contrast to what could realistically be achieved through piecemeal federal reform on a department-by-department basis, through individual responses by each province and territory, or through non-governmental or self-regulatory initiatives.

Just as this Royal Commission did in its work, a National Commission could apply an ethical framework in decision making and ensure that the interests of all concerned groups and individuals are considered in setting policy and standards and assuring adherence to them in practice. This is in contrast to the relatively narrow range of interests that has been involved in the past in decision making in this area. Because of the multiple dimensions of reproductive technologies, a mechanism is needed to ensure that the strengths, skills, experience, and values of all interested systems and communities are integrated and taken into account in decisions about the technologies. A body such as the one we recommend, with a comprehensive mandate and inclusive membership, would provide such a mechanism.

> [A] national organism for implementing reforms ... might be charged with such responsibilities as establishing national IVF reporting standards and a national registry, advising government, encouraging studies on the long-term medical and psychological effects, [and] overseeing the licensing of clinics [and] gametes and embryo banks ... [W]e believe that both the consuming public and health service providers have particular reasons for supporting national government standards.
>
> Consumers seem likely to welcome initiatives that enhance public safety and that simplify and make accurate the technical information they need to make informed health decisions.
>
> *G. Létourneau, President, Law Reform Commission of Canada, Public Hearings Transcripts, Montreal, Quebec, November 21, 1990.*

Like this Royal Commission, a National Commission would be highly visible and would generate significant levels of public awareness about the technologies and their application, as well as other developments in the field of reproductive health and research. Appropriately structured, the National Commission would provide an important avenue for airing and evaluating public concerns about specific issues and practices. As an independent body, established at arm's length from existing institutions and reporting directly to Parliament, a National Commission would enable the public to have confidence that the control and monitoring of new reproductive technologies was not subject to manipulation from political, commercial, scientific, bureaucratic, or other interests and that the

technologies were being regulated in the interests of Canadians in all their diversity, not only for the present but for future generations as well.

As a single and identifiable source of regulatory authority, a National Commission could provide maximum opportunities for public input and participation and could be held to a high standard of public accountability. A National Commission of the type we envisage would respond to the need for public participation, visibility, and accountability identified by intervenors throughout our mandate.

By establishing policies and standards for reproductive technologies and services provided in Canada, a National Commission could minimize interprovincial disparities in services and standards, promote equal treatment across the country, and reduce duplication of effort, thereby making more responsible use of available resources. In particular, a National Commission could ensure greater standardization of practices relating to patient referrals, counselling, consent, treatment, reporting, and evaluation, among other matters, through its licensing and monitoring functions. By harmonizing the existing patchwork of standards and practices and ensuring consistency and equity in how individuals across the country are dealt with, the National Commission would respond to one of the major concerns expressed by those who appeared before the Commission.

> We ask that governments inform the public in a timely and appropriate way about the implications and consequences inherent in the use of new reproductive technologies and then to introduce laws to regulate their use. [Translation]
>
> *Brief to the Commission from the Association féminine d'éducation et d'action sociale, November 1990.*

In summary, we reject a piecemeal and incremental response to new reproductive technologies on both conceptual and practical grounds. As discussed in Chapter 1, we are of the view that the federal government has the necessary constitutional jurisdiction to establish the National Commission we recommend. We recognize that there has been a clear trend, in recent federal policy, away from the commission model as a choice of regulatory instrument, and toward an amalgamation of agency functions and an overall reduction of federal intervention and spending in the interests of cutting federal government costs. We consider, however, that the immediate and long-term cost of establishing and funding a National Commission along the model we propose represents a reasonable financial commitment, given the federal government's constitutional responsibilities in this area and the importance of the functions the National Commission will assume. Such expenditure is also more than warranted, in view of the short- and long-term savings in direct costs to the Canadian health care system, and the overall societal benefits.

We note that existing federal agencies such as the National Transportation Agency and the Canadian Radio-Television and Telecommunications Commission, among others, are performing comparable

licensing, monitoring, and advisory functions, on a vastly greater scale than we envision for the National Reproductive Technologies Commission. We are convinced by what we heard from Canadians, and by what we learned from our own investigations and study during the course of our mandate, that the expenditures that would be entailed by our recommendations are equally, if not more, justified in relation to new reproductive technologies. We believe that for the federal government to reject our recommendations for a National Reproductive Technologies Commission in the name of fiscal restraint would be not only politically irresponsible, but false economy, and that a majority of Canadians will share this assessment.

> We must establish a commission to provide factual and unbiased information for the public on new reproductive technology; to provide a network to generate communication between peoples for understanding and respect; to monitor and ensure strict adherence to codes of ethics; to establish a national policy of ethics for IVF and other related clinics; to establish licensing standards and ensure a registry or record of their success and problems.
>
> *M. McWaters, private citizen, Public Hearings Transcripts, Vancouver, British Columbia, November 27, 1990.*

In short, for all the reasons outlined above — the need for a holistic approach to a rapidly evolving technological field, the urgency of action, the need for comprehensiveness and uniformity, and the need for public visibility and accountability — Commissioners are strongly of the view that a National Reproductive Technologies Commission of the type we propose must be put in place as an immediate federal priority. We believe that the National Commission we recommend presents not only the most effective, but the only feasible response to the urgent need and justified public demand for coherent, effective, and appropriate national regulation of new reproductive technologies. The field is developing too rapidly, and the potential for harm to citizens is too great, for Canada's response to be delayed, fragmented, or tentative.

The field of new reproductive technologies is developing too rapidly, and the potential for harm to citizens is too great, for Canada's response to be delayed, fragmented, or tentative.

Functions of the National Regulatory Commission

The major functions we propose for the National Commission are licensing and monitoring; guideline and standard setting; information collection, evaluation, and dissemination; records storage; consultation,

coordination, and intergovernmental cooperation; and monitoring of future technologies and practices. We propose that the National Commission establish six sub-committees to assume these functions in specific areas of its mandate.

In particular, we recommend that the National Commission establish five permanent sub-committees with responsibility for developing standards and guidelines and for regulatory oversight in the following areas of activity and service: sperm collection, sperm storage and distribution, and the provision of assisted insemination services; assisted conception services; prenatal diagnosis; human zygote/embryo research; and the provision of fetal tissue for research.

In addition we recommend that the National Commission establish a sixth sub-committee with primary responsibility in the field of infertility prevention. This sub-committee would have as its major mandate the compilation and evaluation of data pertaining to the causes of infertility, and the regulatory, public education, and other options available for reducing its incidence or for preventing it.

> We recommend that ... the criteria and effectiveness evaluation methods used by fertility clinics be standardized, so that clinic users can exercise more informed choices about where to seek treatment. [Translation]
>
> *M. Lopez, Association Québécoise pour la Fertilité Inc., Public Hearings Transcripts, Montreal, Quebec, November 22, 1990.*

We also recommend that the National Commission be empowered to create temporary or ad hoc sub-committees, with expert participation from outside the National Commission, to report to and advise the permanent sub-committees on issues raising particular difficulties or warranting special attention.

Licensing and Monitoring

In light of the regulatory shortcomings we identify in our discussion of specific technologies later in the report, the Commission recommends that a primary focus of activity of the National Commission be the licensing and monitoring of practices and services related to new reproductive technologies. In particular, we recommend that the following five areas be subject to compulsory licensing by the National Commission through its sub-committees:

- sperm collection; sperm storage and distribution; and the provision of assisted insemination services;
- assisted conception services, including egg retrieval and use;
- prenatal diagnosis;
- research involving human zygotes; and

- the provision of human fetal tissue for research or other specified purposes.

Engaging in any of these activities or providing services that are subject to regulation without a licence, or without complying with the National Commission's licensing requirements, would constitute an offence subject to fine and/or imprisonment.

Individuals or facilities seeking to engage in the activities that we recommend be subject to licensing would be required to apply to the National Commission in a prescribed form, and to provide the Commission with all information necessary for it to assess whether the applicable standards and conditions of licence had been met. Provided they met such conditions, applicants could be eligible for licences to provide services in more than one licensing category. A facility providing assisted conception services might, for example, also seek a licence to collect or to store and distribute sperm.

> We believe that the National Commission we recommend presents not only the most effective, but the only feasible response to the urgent need and justified public demand for coherent, effective, and appropriate national regulation of new reproductive technologies.

Licence applications would be heard by a panel of at least three members of the National Commission, in an oral hearing, open to the public. In addition to submissions from the applicant, the panel could also hear submissions from interested third parties with relevant information.

Following the licence hearing, the panel would issue a written decision to grant or deny the application, subject to any relevant conditions of licence. The National Commission's decision to approve or deny a licence would be subject to appeal to the Federal Court of Canada on matters of jurisdiction. Licence holders would be subject to continuing monitoring and review through the requirement, among other conditions of licence, that they report to the National Commission on their activities annually. They would also be required to inform the Commission in the event of staff or other changes substantially affecting the conditions of licence. Licences would be subject to renewal every five years, and would be revocable by the National Commission at any time for breach of conditions of licence.

Guideline and Standard Setting

As an essential aspect of its licensing function, we propose that the National Commission be responsible for developing national guidelines and standards of practice applicable to the development and delivery of new reproductive technologies. We recommend that these standards and guidelines be developed by the permanent sub-committees on the basis of the recommendations detailed in Part Two of this report and in conjunction

with relevant professional bodies and other interested parties. The guidelines and standards developed by the sub-committees would be used to assess the merits of individual licence applications during the licence hearing process. These guidelines and standards would also apply as ongoing conditions of licence for service providers and activities subject to compulsory licensing. As outlined above, licence compliance would be subject to continuing review, and failure to respect any conditions of licence imposed would be grounds for revocation of licence, upon recommendation by the relevant sub-committee.

In addition to their role in the actual licensing process, the guidelines and standards developed by the sub-committees could provide important direction for providers and activities that are not subject to direct regulation by the National Commission. As discussed in Chapter 26, for example, such standards could furnish guidance for individual physicians providing services, such as prenatal ultrasound or MSAFP screening, outside licensed prenatal diagnosis facilities. Such guidelines could also provide important direction to individual practitioners in prescribing fertility drugs for women having difficulty conceiving.

Information Collection, Evaluation, and Dissemination

As a necessary complement to its licensing function, we recommend that the National Commission be responsible for tabulating, analyzing, and evaluating data about the technologies and their use collected by practitioners and facilities providing licensed services across the country. We also recommend that the National Commission work to remain abreast of new information and findings that become available internationally. Continuing analysis and evaluation of incoming data would enable the National Commission and its sub-committees to modify and adapt guidelines, such as those relating to treatments that can be offered safely and effectively, as technologies and practices evolve and as new information becomes available. Such activities by the National Commission have at least two major benefits to provincial ministries of health in their management of health care. First, they will enable more rapid gathering of sufficient data on which to base timely and reliable conclusions about the benefits and harms of technology uses in this evolving field than would be possible for any individual province working in isolation. Second, this national approach would permit efficient and effective use of public resources by reducing duplication of effort and enabling the benefits of country-wide technology assessment to be shared by all provincial health care systems.

In keeping with the objective of open and accountable regulation, we recommend that the research and analysis compiled by the National Commission and all of its sub-committees be available to interested researchers and members of the general public. We also recommend that the National Commission submit and publish an annual report to

Parliament as a means of keeping Canadians apprised of what is occurring in practice in Canada and of new directions and developments in this field. By presenting data and an analysis of what is happening in the field of new reproductive technologies in an accessible language and format, the National Commission's annual report can promote public awareness and inform public debate on issues requiring public discussion and policy consideration. In addition, the collection of information on use of the technologies will allow evaluation of longer-term outcomes in a way that has not been possible to date. By increasing the volume and accessibility of objective information about new reproductive technologies, such publication will also help Canadians make informed decisions about whether and under what circumstances to consider using these technologies.

Records Storage

The National Commission would collect and store two major categories of records and data provided by the various categories of licence holders as part of their conditions of licence. The first category would include records on donors of gametes (eggs and sperm) and zygotes, and on children born as a result of gamete or zygote donations. The second category would include data to enable the evaluation of the outcomes and longer-term implications of infertility treatments for women and for the ongoing health of children born as a result of reproductive technologies. These data would be collected in standardized formats established by the National Commission to enable country-wide comparisons and record linkage with other data bases for research purposes.

For both categories of records and data, systems would be put in place to ensure secure storage of the data and protection of confidentiality of information on individuals. As outlined in greater depth in Chapters 19 and 20, in the case of records involving gamete and zygote donations, only non-identifying information about donors would be available to parents and children, except in the event of court-ordered release of identifying information.

As discussed in Chapter 18, data would be available only in coded form (so that individuals could not be identified) and only to bona fide researchers working on research projects evaluated and approved by the National Commission.

Consultation, Coordination, and Intergovernmental Cooperation

We recommend that the National Commission provide advice to, and assist in the coordination of, governmental and non-governmental initiatives in relation to new reproductive technologies, including providing information to the Government of Canada about international developments and assuring an international presence on these issues. This would be

among the subjects the National Commission should address in its annual report to Parliament. We recommend that the National Commission promote cooperation in health and public education and other efforts in relation to new reproductive technologies, and between governments, health practitioners, researchers, and others involved in the development and application of new reproductive technologies. All are essential partners in the efforts that will be needed to protect and promote the interests of technology users and of Canadians generally.

We recommend in particular that the National Commission work closely with the provinces on issues related to access to and funding of services and technologies. Throughout our report, we have remained acutely conscious of the fundamental relationship between technology use and provincial health care funding policies. For example, the use of some services of unproven benefit has grown rapidly, in part as a result of funding decisions regarding this service under provincial health insurance plans, while other interventions of proven benefit have not been funded; we examine several such examples in Part Two of our report. Provincial health plan funding decisions thus have had a direct impact on access to and use of technologies, irrespective of the merits of such technologies in treating or overcoming reproductive problems or conditions.

> The Commission [should] strongly recommend the establishment of:
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> - a National Review Board on Medical and Bioethical Issues which would provide ongoing study and evaluation of advances in technology,
> - in order to advise the government of Canada and the provincial governments on needed legislation or regulation,
> - to assist in the development of national standards for that purpose, and
> - to provide direction with regard to research grants. Such a Board would include medical researchers, practitioners and nurses, representatives of the disciplines of law, philosophy, ethics, religion and an equal number of lay persons and should be at least fifty per cent women.
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> *Brief to the Commission from the United Church of Canada, Division of Mission in Canada, January 17, 1991.*

We are strongly aware of the substantial implications of many of our recommendations for provincial health care policies and funding choices. We recognize the need for the National Commission's decision-making processes to take into account provincial interests and to reflect provincial priorities and preoccupations. There is a clear need to work together on these issues. We address these provincial health-related issues in greater depth as they arise with respect to particular technologies

and practices in the chapters that follow. In addition, we recommend that the provinces and the National Commission establish a regular forum for the mutual exchange of information and concerns — for example, through the Conference of Deputy Ministers of Health, an existing body that has successfully promoted collaborative action on issues of national importance and mutual concern to federal and provincial/territorial governments.

Monitoring of Future Technologies and Practices

As knowledge in the field of new reproductive technologies increases, the issues facing governments and the public will continue to evolve. The decision-making structures and processes we propose for the National Commission must therefore be capable of adapting over time, to meet emerging and unanticipated needs and regulatory demands. For example, many of the concerns we heard from Canadians related to procedures that are, for the moment, projected possibilities rather than actual practice. As time passes, however, this situation may change, so that new controls and guidelines may become imperative. We have identified these areas throughout Part Two of our report and have recommended that the National Commission monitor developments closely, so that it can react in a timely way as the need arises.

Because of the rapid evolution of reproductive technologies, we recommend that the National Commission be empowered to set and modify its policies, priorities, and procedures to meet the changes in the regulatory environment that are sure to arise. At the same time, we believe that the licensing and policy-making structures we propose will permit the National Commission and its sub-committees to maintain a rigorous level of oversight across the spectrum of reproductive technologies.

Continuing interaction with those directly engaged in the research, development, and application of reproductive technologies will assist the National Commission in this objective. Equally important, the National Commission must work to promote informed public discussion and debate of new reproductive technology issues as they emerge, in Canada and elsewhere. For example, it would be open to the National Commission to develop and publish discussion papers setting out the issues and policy options in various fields, with the aim of provoking broad public discussion and promoting the development of consensus on areas in which the National Commission is considering or is intending to introduce policies or regulations. In our view, such efforts will enhance the National Commission's ability to provide sound advice to governments on domestic and international policy matters related to new reproductive technologies in a forward-looking and prescriptive way, rather than merely a reactive way. Promoting a high level of public dialogue in relation to emerging issues will also ensure greater levels of public accountability and public trust, without which effective and responsible regulation cannot occur.

Composition of the National Regulatory Commission

We recommend that the National Commission be composed of 12 members, appointed by the Governor in Council, at least 6 of whom, including the president, are appointed on a full-time basis. We recommend that National Commission members be appointed for an initial five-year term, with a possible one-, two-, or three-year renewal of their terms, to allow for the staggering of new appointments. We are of the view that this number and term of appointment will permit the development of a high level of expertise while allowing for sufficiently diverse representation of interests and a close working relationship among National Commission members.

> The selection of community representatives should not be in the hands of NRT service providers. The CACSW agrees with the World Health Organization, which advises that committees overseeing service systems for infertility should consist of a group of informed laypeople from the community, at least 50% of whom should be women. The proceedings and deliberations of these committees should be available to the public. Although the WHO directive was intended to apply only to infertility services, the CACSW believes the committees should be mandated to oversee all aspects of reproductive health services.
>
> *Brief to the Commission from the Canadian Advisory Council on the Status of Women, March 1991.*

Human reproduction and the issues surrounding it are of equal importance and interest to women and men. They both have a role in reproduction, but they bring different experiences and perspectives to these issues. Moreover, women more often undergo the treatments and other procedures related to new reproductive technologies. Commissioners want to ensure, therefore, that the perspectives of both women and men are applied to the specific sorts of decisions and advice that the National Commission will be called upon to provide. We were reminded many times by intervenors and in submissions of the particular impact of new reproductive technologies on women, and of the clear need for women to be integrally involved in deliberations about new reproductive technologies. For these reasons we believe that women should make up a substantial proportion of the National Commission's members, normally at least half. In addition, membership of the National Commission should always include persons knowledgeable about the interests and perspectives of those with disabilities, those who are infertile, and those who are members of racial minority, Aboriginal, and economically disadvantaged communities. A range of expertise should also be represented, including reproductive medicine, ethics, law, and social

sciences. In other words, Commissioners see the need for a broad mix of views in the membership of the National Commission and are confident that there are many Canadians, both women and men, who are fully qualified to take on these responsibilities and from among whom such appointments can be made.

As discussed in greater detail in the chapters that follow, we recommend that the National Commission's six permanent sub-committees include both National Commission and non-National Commission membership, and that outside (non-National Commission) members include people representing the views and interests of governments, professional bodies, consumers, and other groups with particular interest in the area of sub-committee activity in question. Like National Commission members themselves, we recommend that at least half of 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 new reproductive technologies in a way that meets the concerns of Canadian society as a whole.

> We urge the Commission to recommend the setting up of an independent body which is representative of our multi-cultural and multi-racial society. This body should be mandated with the monitoring of the developments that are taking place in the research and practice of NRTs. We further urge that as it is women whose bodies and lives are most strongly affected by reproduction, this body be made up of women. It is only through such participation that we can begin to address the present patriarchal biases being reflected in NRTs.
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> *S. Thobani, Immigrant and Visible Minority Women of British Columbia, Public Hearings Transcripts, Vancouver, British Columbia, November 26, 1990.*

Other Federal Policy and Program Initiatives

In Part Two of our report, we recommend other measures that would fall within the responsibilities of the federal departments of Health, Human Resources and Labour, the Environment, and Industry and Science, as well as the Medical Research Council of Canada (MRC). These recommendations fall into several broad categories:

- recommendations directed to infertility prevention and reproductive health promotion through steps to address sexually transmitted diseases, smoking, delayed childbearing, alcohol use, and other

aspects of sexual health education, as well as exposure to factors in the workplace and the environment that may pose risks to fertility (Chapters 10 to 15);

- recommendations directed to reform of the current process for approval and post-marketing surveillance of prescription drugs (Chapter 18);
- recommendations concerning the funding of medical research in such areas as sexual and reproductive health (Chapters 10 and 13) and human embryo research (Chapter 22);
- recommendations about the current state of the adoption system in Canada (Chapter 16); and
- recommendations about patenting in the context of reproductive technologies (Chapter 24).

Ensuring That Future Development Is in the Public Interest

Taken together, the comprehensive initiatives we propose — legislation creating boundaries around acceptable practices and establishing a National Reproductive Technologies Commission to regulate and monitor activities and developments in this field — are essential to the future welfare of individual Canadians and for Canadian society as a whole. The regulation we recommend will ensure that new reproductive technologies are dealt with in a timely, comprehensive, coherent, and effective way. It will help ensure that Canadians in all parts of the country are dealt with equally and protected equally, in conformity with the fundamental values set out in the *Canadian Charter of Rights and Freedoms* and congruent with the values and priorities of Canadians themselves.

In making these recommendations we are conscious, as we have stated, of the significant provincial interest in the field of new reproductive technologies. Over the course of our mandate, however, we were reminded repeatedly of the dangerous and inequitable situation created by the existing patchwork of laws, standards, programs, and services across Canada. During our public hearings, in oral and written briefs submitted by individuals and groups, and in public opinion surveys, inequitable interprovincial variation in levels of access to services and in the regulation and control of the technologies emerged as a major source of public dissatisfaction and concern.

As we examine specific technologies in Part Two of our report, we note that several provinces/territories have already focussed on the need for law reform to take account of developments in this field. Some have adopted legislation touching upon certain aspects of new reproductive technologies,

such as the issue of the paternity of children born through the use of donor sperm, while others are awaiting our recommendations before deciding what action to take. We recognize that coherent and effective regulation in the best interests of all Canadians is impossible without the cooperation and support of the provinces and of non-governmental organizations and individuals involved in the research, development, and delivery of new reproductive technologies and services. We believe that this need is already widely recognized and that, given the tremendous importance of these issues for individual Canadians and for Canadian society as a whole, cooperation and support will be forthcoming.

As is evident in the development of our publicly supported health care system, Canadians have been able to work together when it was important for the well-being of all that we do so — this is among the achievements that make us proud to be Canadians. We believe that governments will see that the interests of citizens and society depend on our participation together in a response to the deeply important choices before us. If we want Canadians to continue to feel that the country's institutions and public policies express common values and promote a sense of our common humanity, decency, and caring, we must overcome difficulties of jurisdiction and boundaries and take a united approach. We need to set clear limits on what can and cannot be done with new reproductive technologies, then manage the use of the technologies within these boundaries in a caring, ethical, and responsible way. It is concern for the well-being of our fellow citizens that binds us together; the approach we recommend gives concrete expression to this concern.

We need to set clear limits on what can and cannot be done with new reproductive technologies, then manage the use of the technologies within these boundaries in a caring, ethical, and responsible way.