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REPRODUCTIVE TECHNOLOGIES: ROYAL COMMISSION FINAL REPORT

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In November 1993, the Royal Commission on New Reproductive Technologies released its final report, *Proceed with Care*. It was the culmination of an inquiry, initiated in October 1989, into "current and potential medical and scientific developments related to new reproductive technologies" to consider their "social, ethical, health, research, legal and economic implications." Comprising 1,275 pages in two volumes and containing 293 recommendations, the report is divided into four parts.

PART ONE: REPRODUCTIVE TECHNOLOGIES AND CANADIAN SOCIETY

The ethical framework of the Commissioners' deliberations gave priority to families and communities, to building relationships and preventing conflict. The eight principles used to assess the application of a technology were: individual autonomy, equality, respect for human life and dignity, protection of the vulnerable, non-commercialization of reproduction, appropriate use of resources, accountability, and achieving balance between individual and collective interests.

Through several national surveys, more than 15,000 Canadians participated in personal interviews, focus groups, phone interviews, or questionnaires. The results revealed serious concerns about the technologies, including their potential threat to health, the ethical dilemmas they create, and their adverse impact on particular groups such as women, children, families, and the disabled.

The Commission insisted that all evidence about the technologies must be carefully evaluated and all decisions about their use must be based on a comprehensive assessment of their safety, effectiveness and cost, as well as their ethical, legal, and social implications. Where evidence of their intended benefits was lacking, procedures, treatments or medications should be provided only as part of carefully controlled research, not as standard medical practice.

The Commissioners recommended that two actions be taken immediately by Parliament. These were: changing the *Criminal Code* to prohibit certain practices related to the use of reproductive technologies, and establishing a new regulatory body, the National Reproductive Technologies Commission.

PART TWO: CONDITIONS, TECHNOLOGIES, AND PRACTICES

A. Prevalence, Risk Factors and Prevention of Infertility

While acknowledging the sociological and psychological dimensions of infertility, the report addresses infertility principally as a medical condition with physiological causes.

Infertility was defined as the absence of pregnancy for couples who had been married or cohabiting for at least a full year or two full years and who had not used contraception during that period. With this definition, random sampling showed that after one year 8.5% (or about 300,000 couples) of the Canadian population, and after two years 7% (or about 250,000 couples) were infertile.

The impact of various risk factors on fertility was investigated in cases of failure to carry a pregnancy to term and to give birth to a healthy

child as well as in cases of inability to conceive. Risk factors examined included: sexually transmitted diseases (accounting for an estimated 20% of infertility cases), smoking, delaying childbearing, harmful agents in the workplace and the environment, alcohol use, eating disorders, excessive exercise, stress, and medical intervention. The Commissioners recommended immediate establishment of a country-wide program of sexual health education for young people, training of health care professionals, and funding for programs and research.

B. Methods of Assisted Human Reproduction

Fertility drugs, the most common method of treating infertility, are synthesized hormones developed to regulate the reproductive system. The two most common drugs used to induce ovulation - clomiphene and human menopausal gonadotropin (hMG) - were not fully evaluated before their introduction; when used, both have side effects, ranging from mild to life-threatening.

An observed increase in multiple births in Canada was attributed to use of fertility drugs and prompted questions about their health risks for pregnant women, developing fetuses, and children, as well as about the costs of health care and other societal implications. The recommendations on fertility drugs included calls for well-designed clinical trials, changes in the drug approval system, the development of guidelines for practitioners prescribing the drugs, and enhanced monitoring and reporting.

In assisted insemination (AI), the oldest known technique for treating infertility, sperm from the husband or from a donor is introduced into the woman's body to fertilize the egg. In 1991, about 3,400 women used services at the 24 assisted insemination programs across Canada but no data were available on the AI offered by family practitioners and obstetricians. Estimates suggest that between 1,500 and 6,000 children are born through donor insemination each year. Questions on assisted insemination focused on its effectiveness and risks, the advantages and disadvantages of disclosure, commercialization, access to treatment, and the safety of collected semen.

In vitro fertilization (IVF), the most publicized infertility treatment, was carried out on several thousand women in 1991 but resulted in fewer than 400 infants. Developed originally to treat fallopian tube blockage, this fertilization of the egg outside the body has come to be used for many other infertility diagnoses but without proof of its effectiveness in such cases. Once the eggs are removed from the uterus, they may be used for research or gamete manipulation to improve fertilization, transfered back to the body followed by or accompanied by the sperm, donated to a recipient, or fertilized in a culture medium. Commissioners agreed any use of IVF except for blocked fallopian tubes should be considered research only and argued that a similar evidence-based approach should be the model for all health care.

C. Prenatal Diagnosis Techniques and Genetics

Prenatal diagnosis for genetic diseases and anomalies is done through routine screening tests during pregnancy; examples are: ultrasound, maternal serum alpha-fetoprotein (MSAFP), amniocentesis, chorionic villus sampling (CVS) and targeted ultrasound to identify fetal anomalies. Newer technologies, such as DNA analysis of fetal cells in a pregnant woman's blood, pre-implantation diagnosis, and magnetic resonance imaging, are under development. A Commission survey of genetics centres found that approximately 5% of diagnostic tests showed the fetus to have a serious congenital anomaly or genetic disease; in such cases about 80% of pregnancies were terminated.

General recommendations focused on the need for supportive counselling, informed consent, protection of privacy and confidentiality, and reasonable access to the technologies. The Commission found evidence of effectiveness and low risk in the standard applications of all common diagnostic PND technologies. Funding for large multicentre trials of newly developing technologies was recommended.

Presymptomatic testing is currently provided for a few late-onset disorders such as Huntington disease and adult polycystic kidney disease, where, if either parent has the disorder, each child has a 50% chance of inheriting the gene. The Commission argued for the restriction of this testing to genetic centres. Prenatal testing for genetic predisposition toward multifactorial disorders, such as certain cancers, cardiovascular disease and mental illness, is not currently being done in Canada and the Commission recommended against its introduction. Gene therapy and genetic alteration in the reproductive context are experimental and as such were seen to require close monitoring and controls.

The three distinct techniques employed in sex selection for non-medical reasons are sperm treatment followed by assisted insemination, sex-selective zygote transfer, and prenatal detection of fetal sex to enable sex-selective abortion. Except where medically indicated (for example, in cases of diseases linked to the X chromosome), the Commission recommended that the techniques not be available for use.

D. Research Involving Human Zygotes, Embryos and Fetal Tissue

It was recommended that egg and embryo donation and embryo research made possible through IVF be permitted only under particular conditions. Women who have experienced menopause at the usual age would not be candidates for donated eggs or zygotes. Designated donation of human eggs and embryos and payment for donation would not be permitted. Research involving genetic alteration of zygotes or embryos would be prohibited.

The serious social and ethical implications of transplanting fetal tissue obtained from elective abortions to correct diseases such as Parkinson, Alzheimer and diabetes were addressed. Other uses of fetal tissue from both spontaneous and elective abortions include: basic medical research on normal and abnormal fetal development; viral diagnostics; pathology testing; the development and testing of new pharmaceutical products; and medical education. It was recommended that fetal death must be established before tissue is taken and that any tissue must be used only to increase understanding of human functioning or disease.

PART THREE: RECOMMENDATIONS

The first category of federal recommendations called for *Criminal Code* prohibitions on selling human eggs, sperm, zygotes, or fetal tissue; advertising for, paying for, or acting as an intermediary for preconception (surrogacy) arrangements; using embryos in research related to cloning, creating animal/human hybrids, fertilizing eggs from female fetuses for implantation; and unwanted medical treatment or other interference with the physical autonomy of pregnant women.

The second category focused on the creation of the National Reproductive Technologies Commission (NRTC) to oversee licensing and to monitor reproductive technologies and practices. The NRTC would have five areas of regulatory responsibility: sperm collection, storage and distribution with assisted insemination services; assisted conception services, including egg retrieval and use; prenatal diagnosis; human zygote research; and the provision of human fetal tissue for research or other specified purposes. A sixth area would be responsible for compilation and evaluation of data on causes of infertility, promotion of national and international research, and options for preventing or reducing infertility.

More active roles were recommended for certain federal departments. Health would initiate and coordinate campaigns for the prevention of infertility and its Drugs Directorate would improve its system of drug approval and post-marketing surveillance. The Medical Research Council would give higher priority to basic and applied research on sexual and reproductive health concerns. Human Resources would address issues related to delayed childbearing and occupational health, while Environment would have a role in controlling environmental threats to reproductive health.

PART FOUR, ANNEX, GLOSSARY, AND APPENDICES

This part of the report includes: the dissenting opinions of one Commissioner on six areas of the report, suggesting greater caution in the application of some technologies; a glossary of technical terms; and six appendices of general information on the Commission's work.

CONCLUSION

The report of the Royal Commission on New Reproductive Technologies represents a major step toward regulating the proliferation of scientific and medical applications in the area. The report is limited, however, in that it fails to challenge the current organization of the science and medicine underlying the technologies; thus some doubt arises with respect to the Commission's decisions about the evaluation of these technologies and the resulting evidence in support of their use.