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PROCUREMENT AND TRANSFER OF HUMAN TISSUES AND ORGANS

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Commission

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* At the time this working paper was approved, Mr. Justice Linden was still Commission President, Judge Rivet was a Commissioner, Dr. Trevor-Deutsch was Project Co-ordinator and Madam Justice Picard and Professor Frémont had not yet joined the Commission.
Editor's Note

Note that the research in this working paper is generally current to July 1990, when the Commission adopted the recommendations set forth in chapter 5. The document has since received updating with some 1991 material.

In keeping with the proposal advanced in *Equality for All: Report of the Parliamentary Committee on Equality Rights*, we have conscientiously endeavoured to draft this working paper in gender-neutral language. In doing so, we have adhered to the standards and policies set forth in *Toward Equality: The Response to the Report of the Parliamentary Committee on Equality Rights* pertaining to the drafting of laws, since the Commission's mandate is to make proposals for modernizing Canada's federal laws.

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The very nature of the issues posed by revolutions in medicine and the biomedical technologies over the last quarter-century obliges the Commission to turn to diverse segments of society for assistance in its deliberations and analyses. Thus, in 1989, we expanded and formalized our consultative process on medico-legal issues. We established a multidisciplinary consultative committee to the Commission, the Advisory Group of Experts on Health Law. This document has had the benefit of their generous review and advice.

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Introduction

Modern medicine has again begun challenging the law to rethink its views on the legal status of the human body in matters involving life and death. Ten years ago, the Law Reform Commission of Canada joined several public analysts in recommending new criteria for the determination of death. Newer tools of medicine, such as mechanical respirators and circulators, had come to obscure the meaning and utility of the traditional heart-lung cessation criteria for death.

If a hospitalized patient could continue indefinitely on mechanical support, with no responsiveness and no brain functions, would the patient legally be dead or alive? The answer has become clearer, because the proposed brain-death criteria have become a customary standard for both modern medicine and law. Such legal reform reduces uncertainty and confusion. The certainty gives families and medical professionals a contemporary standard for responding to particular life-death scenarios. Transplanting organs from a recently deceased donor involves maintaining the dead body on artificial life support so that the donor’s organs may be preserved until a recipient is ready. The clarity afforded by the new standard for death, then, has also facilitated organ procurement and transplantation.

In the decade since the Law Reform Commission’s proposal, transplant and tissue replacement technology have come of age. Medical developments have revolutionized the therapeutic potential of transplanting human organs, tissues and cellular and genetic entities. New drugs and better established procedures have increased transplant recipients’ survival rates; they have also helped move liver and heart transplants towards the standard medical treatment that kidney transplants have attained for years in Canadian society.

The quest of high-technology medicine to conquer disease and to extend life, however, has not been without its challenges. Surgeons speak of critical organ shortages. Waiting lists for eyes, kidneys and livers are the rule in transplant centres across the country. Waiting lists, professional frustration and the loss of lives that might have been saved, portray personal and societal dramas. Such results of apparent scarcity exert pressure on the existing organ procurement system, which is based on principles of autonomy, voluntarism, protecting bodily integrity and according respect to the dead and their next
of kin. The pressures exerted by scarcity prompt calls for reforms — reforms which might include measures that challenge the values and assumptions of the existing system.

So new questions are emerging. What legal reforms, if any, should be instituted to alleviate perceived tissue scarcity? Should the brain-death criteria be amended for babies who are born without most of the upper brain and usually die within seventy-two hours after birth, to facilitate organ procurement from them? Is the selling of bodily parts or substances an acceptable means of increasing the supply of blood, tissues and organs? Or, to discourage acts of medical and economic desperation and to preserve fundamental values, should some sales of bodily parts or substances be made illegal? Indeed, in response to increasing concerns about international trafficking in organs, the World Health Organization has urged the international community to take measures to prevent and discourage such transactions. That organization has identified organ transplantation as a biomedical development that challenges the moral and legal integrity of the individual.

If the answers to questions such as those posed above are not as clear as Canadian society would wish, they nevertheless appear likely to be scrutinized and debated with increasing frequency as medicine evolves ever new means of using the body for therapeutic purposes. The questions themselves are not without historical precedent, however. Two historical controversies suggest that the medical-legal issues presented by the apparent disequilibrium between the medical demand and societal supply of human tissue and bodily substances are not unique to the transplantation age.

The first controversy arose a century and a half ago. In the autumn of 1843, some two decades after McGill University established the first medical school in Canada, the Medical Board of Montreal petitioned the Legislative Assembly of the Province of Canada to pass an Anatomy Act. The petition was submitted after nightly episodes in which the searing, by medical school students, of dead bodies from Montreal graveyards had provoked public outcry and calls for solutions to such “gross indecencies.” A scarcity of human specimens had prompted medical students, and even anatomy professors, to other Canadian locales to resort to such measures for years.

Accordingly, the petitioner sought an Anatomy Act to establish a regulated, legal system for supplying cadaver bodies for dissection and anatomical study in the medical schools. The absence of an existing system, they argued, hampered medical education and the practice of the healing arts, to the public detriment. A regulated system of supply would rid the community of grave-robbing, body-selling and like black market abuses. Opponents countered that a more appropriate source would be the bodies of criminals, that the proposed legislation would legalize a “traffic in corpses,” and make public property of cadavers. The debate resulted in passage of An Act to regulate and facilitate the study of Anatomy in December 1843. The Act adopted the principle that unclaimed bodies, publicly exposed or in such public institutions as hospitals, should be made available as anatomic subjects for the medical schools.

The bodily sales and bodily property language of over a century ago has been resurrected in a more modern controversy. It highlights issues surrounding the legal protection of patients; and bodily integrity in a biotechnological age. In a recent case in the United States, a leukemia patient sued his doctor and a university hospital, claiming that without his knowledge or consent his pancreas cells were used to develop a therapeutically valuable “cell line.” The cell line has been used to make new drugs capable of controlling cancer, and is of such commercial value that the cell line has been patented. The patient claims a breach of consent, the taking of bodily property and a rightful share of the money generated by the patent.

No such cases have been reported in Canada. Nevertheless, the case illustrates the potential for disputes between the sources of human cells and tissues and those persons who acquire and use them. It suggests the unprecedented economic and commercial value that particular bodily substances and materials may attain, by virtue of new medical biotechnologies and the legal protection given to the commercial fruits of the technologies. The case would also seem to symbolize an important transitional era through which law and society have begun to journey. The era is characterized by a societal search to define the content of the legal regimes likely to govern tissue transfers and tissue replacement technologies into the twenty-first century.

It is the broader contexts of these tissue transfer and transplant issues that provoke the general question of whether the law is keeping pace with the modern medical demands for the human body. The 1843 debates on the Anatomy Act parallel concerns expressed today in debates over alternatives for increasing the supply of cadaver organs. Analysts again ask whether the law is hindering or properly regulating the supply of human tissues and bodily substances. Since the tissues in demand today are sought for therapeutic transplantation or transfusion into the human body, safety concerns have also arisen. If legal reforms are in order, what rights, duties and balance of interests should be affirmed or changed?

In search of answers to such questions, we have examined the medical and legal aspects of procuring and transferring natural human tissues and bodily substances, relative to emerging tissue replacement technologies. Initial research made clear that answers to some of the difficult questions posed by modern developments likely depend on the ethical

5. See Worthington, infra, note 809.
7. Ibid.
9. See Moore (1990), infra, note 426.
implications of an increasing medical reductionism of the human body. If the facility by which medicine reduces the human body to its biological components for therapeutic benefit is boggling, it is partially so because it also touches basic social values and views on the uses of living and dead bodies. Medical science will continue to develop increasingly sophisticated means of converting formerly useless bodily parts and substances into modern therapeutic agents. This tendency and its full societal implications have persuaded us that critical to understanding the legal and medical view of the human body is an understanding of our evolving ethical outlook. Hence, from a historic perspective, the inquiry into these subject-matters traces the evolution of law on the human body, and its ethical underpinnings, as society has moved from the anatomical age of the nineteenth century into the transplantation and biotechnological ages of the twentieth century.

It is within these broader contexts that the Commission has undertaken this Working Paper. We have done so mindful of the important work done in the area by the federal-provincial-territorial transplant working groups and provincial task forces in the mid-1980s, the more recent law reform initiatives by the provinces and by the Uniform Law Conference of Canada, as well as the pronouncements of international organizations and foreign jurisdictions. Our work is intended to draw on and complement these contributions.

The following, then, is our initial analysis and views on major legal issues presented by human tissue procurement and transfer law in Canadian society. Chapter 1 discusses the medical need for and the supply of human tissue and bodily substances; emerging legal and ethical dilemmas provoked by demand and supply disequilibria are examined there as well. Chapter 2 is an analysis of the underlying ethical considerations of tissue procurement. Chapter 3 examines existing law on the human body through the lens of common, civil and criminal law. It looks at historical and current tissue procurement legislation and considers the human rights implications. Chapter 4 examines the leading legal approaches to tissue transfer issues in foreign jurisdictions, as well as legal issues presented by the international transfer of human therapeutic tissue and tissue replacement technology. Chapter 5 outlines arguments for and against major law reform options, proposes general principles and summarizes our recommendations.

Because fetal tissue and human gametes and embryos evoke special concerns, they generally are not treated in the present analysis. Nor are the critical questions concerning the allocation of scarce medical resources generally within the scope of the immediate inquiry. The focus here is on procurement and transfer issues.

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10. See infra, note 29.
11. See infra, notes 29 and 143.
12. See pages 130-136, below.
13. See chap. 4, below.

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CHAPTER ONE

Modern Therapeutic Demand and Supply

The demand for and supply of human tissue and bodily substance result from several factors, including evolving medical needs and practice. This chapter examines the anatomical, medical and biotechnological demands as they relate to supplies from living and deceased donors, synthetic and artificial sources and tissue banks. The overview reveals vibrant tensions between evolving therapeutic needs and the accelerating ingenuity of medicine to remake the human body with tissue replacement technology. Leading non-medical determinants of supply and demand are identified, and ethical-legal questions that warrant closer examination in subsequent chapters are highlighted here. This chapter concludes by summarizing the major determinants in the supply-and-demand dynamic.

I. Medical Demand

Modern therapeutic demand for the human body reflects the need for and use of human tissue, bodily parts and bodily substances in medical education, research and treatment. The demand expresses the convergence of the anatomical, transplantation and biotechnological ages in current medical practice.

A. Anatomical Demand

A knowledge of human anatomy is responsible for much of our understanding of illness and the treatment of disease. The word "anatomy" derives from Greek root words meaning "to cut up or dissect"; hence, human anatomy classically refers to studying the structure and function of the body through dissection.

While dissection and anatomical studies are more than 4,000 years old, modern anatomy owes its origins to the rise of eminent faculties of medicine in thirteenth-century