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COMMISSION DE RÉFORME DU DROIT

REPORT

ON

THE HUMAN TISSUE ACT

March 31, 1986

Report #66

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PART I

INTRODUCTION

A. THE REFERENCE

The subject of this Report is the regulation of human tissue procurement in Manitoba. That is, we examine what rules should govern the removal and use of human tissue for therapeutic, educational or research purposes. This includes the use of organs and body parts for transplants as well as for medical research and education. We do not examine the regulation of all types of human tissue in this Report. In particular, our study does not extend to the removal and use of tissue for embryo transplants or for artificial insemination. Nor does it cover the removal and use of fetal tissue. For reasons detailed later in this Part, we are of the view that these matters raise important issues and values distinct from those involved in a general inquiry of human tissue regulation. They require discrete treatment.

Our inquiry into the regulation of human tissue procurement arose as a result of a reference from the Attorney-General of Manitoba which we received in April, 1984. In his reference, the Attorney-General requested that we inquire into and report on the need to reform *The Human Tissue Act*, C.C.S.M. c. H180, of Manitoba. It is this legislation which presently regulates the removal and use of human tissue in this province. From the outset, we were aware of the critical need to consult with the medical and legal professions as well as the public at large. In February, 1985, a Working Paper containing our preliminary conclusions and proposals was widely circulated so that we might have the benefit of public response prior to issuing this final Report to the Attorney-General. Recipients of the Working Paper included various organ donor organizations and medical associations across Canada as well as all hospital administrators in Manitoba. Physicians and lawyers in Manitoba were also notified of the availability of the Working Paper through the bulletins of their professional associations. We also issued a press release so that the public could be informed of our preliminary conclusions through the local media. About a dozen briefs were received, for which we are very grateful. We have carefully considered the valuable comments from these respondents.

B. A FACTUAL OVERVIEW

As previously stated, the use of human tissue for therapeutic, educational or research purposes includes the use of organs and body parts for transplants as well as for medical research and education. We summarize here the specific benefits for which human tissue is used, giving particular attention to Manitoba's contribution in this field. This summary is provided so that those who like ourselves are not directly involved with this aspect of the health care system can form some appreciation of the benefits and risks associated with the removal and use of human tissue for the purposes previously specified.

Most of the attention on the need for human tissue has focused upon its use for transplants rather than its use in the fields of research and education. This is understandable as the former may be seen to represent a more direct means of aiding human life than the latter, and the degree of urgency attending the need for tissue for these diverse purposes may be viewed as differing significantly. However, human tissue is required for all of these stated purposes; it would be wrong for lawmakers to concentrate exclusively upon its use in transplants.

Virtually every part of the human body can be used for therapeutic, research or educational purposes. With respect to transplants in particular, Scott reports in his text that some twenty-five different kinds of tissue were being transplanted as of 1981: these included ear tissue (tympanic membranes, fascia and ossicles), a variety of glands (pancreas, pituitary, thyroid, parathyroid and adrenal), blood vessels, tendons, cartilage, muscles, testicles, ovaries, fallopian tubes, nerves, skin, fat, bone marrow and blood.¹ Canadian health care professionals transplant vital tissue like the heart, kidney, lung, liver and pancreas gland. Post-mortem donors of these must have sustained brain death with intact circulation.² With respect to

¹Russell Scott, *The Body As Property* (1981) 19.

²Although this is the medical procedure generally followed in Canada for the transplant of vital organs, it has been reported that, in England, kidney transplants are now being performed with non-heart beating donors using the
(Footnote continued to page 3)

non-vital tissue, the transplant of tissue such as the cornea, joints, pituitary gland extractions and skin is also regularly performed in this country, to differing degrees. Although most transplants involve the use of cadaveric tissue, in some instances, tissue is removed from living donors. In practice, living donors are used for kidney transplants as well as for the transplant of regenerative tissue such as blood, semen, bone marrow and skin.

We now turn to examine in greater detail the need for and the benefits arising from the following types of human tissue:

1. Kidney. By far the most widespread transplant capability of vital tissue in Canada relates to kidneys: some 24 centres across Canada perform renal transplants.³ Over 660 renal transplants were performed in Canada in 1984; at the same time, over 1000 people were on the waiting list for a transplant.⁴ Recently, it was reported that that number has jumped to 2500.⁵ Here in Manitoba, 49 transplants were performed in 1985;⁶ at the time of writing this Report, 96 patients were on the waiting list.⁷ The waiting period in Manitoba for those patients with a low antibody level ranges from

(Footnote continued from page 2)
"Portsmouth non-snatch technique". The 1-year graft survival rate using such donors is 76%. See M. Slapak "New Ideas and Techniques for Vital Organ Procurement and Exchange" (1985), XVII Transplant. Proc. 88, at 90.

³Kidney Foundation of Canada, *Canadian Renal Failure Register, 1984 Report*, at 102.

⁴*Id.*, at 104 and 109.

⁵*The Globe and Mail*, January 8, 1986, at A2.

⁶Of these, 8 involved the transplant of a kidney from a living donor. Dr. J.R. Jeffery, Director, Transplant Program, Health Sciences Centre, Winnipeg, Manitoba. This figure is almost double that for 1984 when 25 transplants were performed. *Supra* n. 3.

⁷Ms. Del Johnston, Transplant Co-ordinator, Health Sciences Centre, Winnipeg, Manitoba, March 17, 1986.

6 months to 1 year, depending upon their ABO-blood typing.⁸ Those patients with a high antibody level must wait as long as 5 years.⁹

With scientific advances, particularly in the field of immunology, renal transplants are no longer regarded as experimental. The statistics for graft survival rate support this viewpoint. The national success rate of graft survival for cadaveric donor recipients after 1 and 2 years are 73% and 68% respectively.¹⁰ In Manitoba, which has one of the highest success rates in Canada, the graft survival rates for cadaveric donor recipients after 1 and 5 years are 82.7% and 72% respectively.¹¹ The success rates involving living donor recipients are higher: in Manitoba, the 1 year and 5 year graft survival rates are 93% and 85% respectively.¹²

2. Heart. In Canada, heart transplants are performed in London, Ottawa, Montreal and Edmonton. The Health Sciences Centre in Winnipeg expects to perform its first heart transplant by the end of this year.¹³ There is obviously a tremendous need for this tissue: the Ottawa Civic Hospital recently estimated that 2/3 of those patients who require a heart transplant die before a heart can be located.¹⁴ It is expected that this need will dramatically

⁸*Ibid.*

⁹*Supra* n. 7.

¹⁰*Supra* n. 3.

¹¹*Supra* n. 7.

¹²*Supra* n. 7. Nationally, statistics for 1984 indicate that living donor recipients have a 1 year graft survival of 93.5% and a 3 year rate of 87%.
Supra n. 3.

¹³*Winnipeg Free Press*, November 26, 1985, at 1.

¹⁴The Canadian Broadcasting Corporation - Television, *The Journal, The Heart Frontier*, March 12, 1986.

increase once the majority of Canadian physicians consider heart transplants to be non-experimental.¹⁵

3. Other vital organs. Heart-lung, lung, liver and pancreas gland transplants are also performed in Canada, primarily in Toronto and London. These transplants are, however, still irregularly performed. For example, as of about 1 year ago, it was reported that only 3 pancreas operations had been performed in Canada.¹⁶

4. Corneas. The transplantation of corneas is routinely undertaken successfully across Canada to restore sight to thousands of people.¹⁷ The cornea must be removed within approximately 6 hours after death and can be maintained for 24 hours before transplantation must take place. Thus, although there are a number of eye banks in this country, their purpose is largely grading, documentation and re-direction of corneas rather than maintenance and preservation of deposited tissue.

In Manitoba, 76 cornea transplants were performed in 1985 with a 90-95% success rate.¹⁸ The waiting period has been reduced to

¹⁵Dr. Calvin Stiller, head of the Multi-Organ Transplant Program at London University Hospital, has stated that the majority of Canadians who need a heart or liver transplant are not being referred because the majority of physicians still consider these transplants to be experimental. He stated that once referrals do increase, the 100 hearts and 75 livers currently needed in Canada each year will climb to 2000 and 1000 respectively. *Winnipeg Free Press*, July 19, 1985, at 5.

¹⁶*The Globe and Mail*, February 19, 1985, at 15.

¹⁷Surgeons now achieve better than 90% success rate for cornea transplants. C.R. Graham, Jr. "Eye Banking: A Growth Story" (1985), XVII Transplant. Proc. 105, at 106.

¹⁸ Mrs. Joan Roberts, Co-ordinator, Lions Eye Bank for Manitoba and Northwest Ontario.

approximately 1 year due to a 40% increase in donation in 1985.¹⁹ The Lions Eye Bank for Manitoba and Northwest Ontario immediate aim is to reduce the waiting period to three months.

5. Pituitary gland. This tissue is of particular importance in Manitoba. Glands are sent from hospitals across Canada to the University of Manitoba where they are processed and distributed. Extract from the pituitary gland is used as a growth hormone to treat dwarfism in children. Some 800 Canadian children have been treated since the programme was introduced in the early 1960's.²⁰ It should be noted that the hormone is also extremely valuable in the general diagnosis and treatment of endocrine disease, including the important programme of routine thyroid screening of newborns for the detection and treatment of mental retardation.

6. Skin. Although skin banking or storage is not widely undertaken in this country, viable skin from cadaveric donors is used by hospital burn units as an alternative material to cover burn wounds when sufficient autografts (removal of skin from one site on a patient's body for grafting onto another site on the body) are not available.²¹ Cadaveric skin will not normally "take" to a patient and it is not meant as a tissue substitute. However, it does serve as a protective mechanical and physiological barrier to allow time for tissue to grow on the patient which can then be permanently grafted. Under the best storage conditions, skin may be preserved

¹⁹*Ibid.*.. The exact increase in eye donations in 1985 was 42.2%.

²⁰*Winnipeg Free Press*, May 4, 1985, at 8. The Canadian Medical Research Council suspended the use of the hormone in June, 1985 because 3 American children who had been treated with the hormone died from Creutzfeldt-Jacob disease. The Council is continuing to fund the programme, however, as research into the hormone continues.

²¹In Canada, The Plastic Surgery Unit of Vancouver General Hospital has an established skin bank and a bank is being developed in Halifax. Dr. J. Stewart McMillan, Chief Coroner, Province of Saskatchewan, "The Process of Tissue Procurement in Canada" (unpublished paper, n.d.), at 10..

for several months²² and can be stored through refrigeration for up to three weeks.²³

Skin grafts from living donors are occasionally conducted in Manitoba, where a patient has sustained extensive burn wounds. Only in the extremely rare case of grafting between identical twins will such grafts survive permanently. Normally skin tissue is used as a biologic dressing. Numerous synthetic skin substitutes are now being used and evaluated but it is not certain yet whether they offer a better biological dressing than viable skin.²⁴

7. Bone. Bone banking has been done in Canada for a number of years. Any bone with potential medical application can be removed from a cadaveric donor and preserved through freezing for up to several years.²⁵ Bone grafts support a wide variety of orthopaedic procedures including the use of whole, or large pieces of bone in treatment of large benign tumors, and treatment of major fractures, which, without grafting, would require amputation.²⁶ Facilities exist in this province for the retrieval and preservation of bones.

Aside from the use of tissue for therapeutic purposes, tissue can be used for research and education. The whole body is also required for anatomical examination. Physicians in Manitoba find it difficult to conduct research, or instruct medical students on specific organs or causes of death

²²*Ibid.*

²³ Dr. G.A. Robertson, Director of Burn Unit, Health Sciences Centre, Winnipeg, February 13, 1986.

²⁴In addition, cultured epidermal transplants are being used in the United States. This is a revolutionary skin transplant technique whereby accelerated growth of a patient's skin can create large sheets of skin, sufficient to cover the entire body. The full potential of this technique is as yet undetermined. C. Baxter, S. Aggarwal, K.R. Diller, "Cryopreservation of Skin: A Review" (1985), XVII Transplant. Proc. 112.

²⁵G.E. Friedlaender, "Bone Banking and Clinical Applications" (1985), XVII Transplant. Proc. 99, at 101.

²⁶*Ibid.*

because of the limited supply of human tissue and of the whole body.²⁷

C. A SUMMARY OF THE PRINCIPAL ISSUES EXAMINED IN THIS REPORT

A comprehensive inquiry into the regulation of human tissue procurement requires that both cadaveric and *inter vivos* ("between the living") procurement be examined. One of the principal questions relative to both living and dead donors is: "when, and under whose authority, can tissue be removed?" Although this question must be asked with respect to the removal of tissue from both living and dead donors, the factual and legal distinctions which pertain to each type of donation requires that there be a separate response for each.

The factual differences between cadaveric and *inter vivos* donation are perhaps obvious. There are basically three. The first pertains to the type of tissue that can be removed. With cadaveric donation, all human tissue can be potentially used, as well as the whole body for anatomical examination. With the *inter vivos* category, donation must be confined to regenerative tissue and a kidney. The second difference relates to the status of the "donors" when tissue is procured: with *inter vivos* donation, one is dealing with vital persons whereas with the cadaveric category, tissue is procured from cadavers. This has an important consequence with respect to which persons should be legally designated to allow tissue procurement. Generally, with *inter vivos* donation, the answer will be only the donors themselves but with cadaveric tissue a broader range of persons may need to be designated if tissue is to be procured at all. The third and final factual distinction pertains to the degree of risk assumed by donors: cadaveric donors assume none while living donors may assume a risk involving life or health. This places living donors in a category similar to human subjects in medical research, and, more broadly, to those persons subject to non-therapeutic operations or procedures.

There are also important legal variations between cadaveric and *inter vivos* donation which are partially due to these factual distinctions. First, there is legislation governing cadaveric donation in Manitoba.

²⁷ Dr. Peter H. Markesteyn, Chief Medical Examiner of Manitoba, July, 1984.

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Conversely, there is no legislation governing *inter vivos* donation nor does the common law provide any clear governing principles. Secondly, the lawmaker must respond to different needs with respect to cadaveric and *inter vivos* donation. In regard to the former category, the lawmaker's task should be the promotion or encouragement of donation whereas, with the *inter vivos* category, the task should be merely to authorize donation through enabling and prohibitive clauses. This second legal distinction is important and requires elaboration.

The lawmaker's objective of promoting or encouraging cadaveric donation means that it will be insufficient merely to ask the question, "when, and under whose authority, can tissue be removed?", for this category of tissue. A lawmaker must also undertake a review of the whole organization of the tissue procurement process to achieve this objective. This entails a review of the range of mechanisms available to identify willing donors (donor cards, central registries, obligatory indications of wish) and extends to an examination of the proper role and involvement of hospitals and the medical profession in the donation process. These large-scale concerns governing the organ procurement process are at least as important as the authorization issue in finding solutions towards increasing cadaveric tissue supply. With the *inter vivos* category, as the objective is merely to authorize the removal and use of tissue, it is generally sufficient for lawmakers to confine themselves to the authorization issue. This authorization issue might be coined the "micro-legal" question whereas those issues arising from the overview of the cadaveric tissue procurement process might be dubbed the "macro-legal" questions.

The principal statute governing the authority to procure cadaveric tissue in Manitoba is *The Human Tissue Act*, the subject of our reference. This statute formally establishes a system of tissue procurement known as 'strong contracting-in'. Under this system, tissue can generally be removed and used for therapeutic, educational or research purposes after death where (1) the deceased has during his/her lifetime given a direction to that effect; or (2) in the absence of (1), the next of kin has given a direction where death has occurred or is imminent. When this legal system was established in Manitoba in 1968,²⁸ the primary concern of legislators was to ensure the

²⁸*The Human Tissue Act*, S.M. 1968, c. 31.

legality of tissue donation. That is, the principal aspect of the statute was to respond to the physician's concerns that a direction given by the deceased or the next of kin was sufficient authority to procure tissue for transplant or certain other purposes. The legal authority issue having long ago been settled, the question for lawmakers today is quite different. With scientific advances (and particularly in the field of immunology), there is a shortage of organs, especially for transplants. The immediate question now becomes whether this legislation which "legalized" organ donation in 1968 is causing the demand for tissue to exceed supply perpetually. It is in this context that we examine the present legal system of organ donation in Manitoba of 'strong contracting-in' in this Report and compare that system to others governing organ procurement. Particularly notable in this regard is the system operating in several European countries which empowers the community to remove needed cadaveric tissue unless an objection has been raised by the deceased during his/her lifetime or by the next of kin. This system is known as 'weak contracting-out'. Its implementation has been recommended by several medico-legal scholars in North America.

This is the "micro-legal" issue in cadaveric donation. Our specific conclusions and recommendations for reform on this issue are contained in Part II of this Report and listed in Part V. Suffice it to say here that, in general, we have recommended in our Report that the strong contracting-in system in Manitoba be retained. Consequently, only minor changes are recommended on the "micro-legal" scale. The major reforms for cadaveric donation are on the "macro-legal" scale. A principal recommendation in this regard is that hospitals and offices in which post-mortem examinations are conducted adopt a policy of "routine request". This policy would require that the nearest relative of a patient, who is a suitable candidate for tissue donation, be requested to consent at the time of death to donation where the patient is not known to have consented to or objected to the post-mortem donation of his/her tissue. This recommendation is similar to one recently put forward for consideration in Ontario²⁹ and was inspired by Dr. Arthur Caplan of the Hastings Center, New York, one of the leading advocates of the "required request" school of thought. The details concerning this recommendation are set forth towards the end of Part II.

²⁹Ontario Ministry of Health, *Organ Donation in the Eighties: The Minister's Task force on Kidney Donation* (1985), at 55.

The principal issues governing *inter vivos* donation are set forth in Part III of this Report. As previously mentioned, these issues are confined to the "micro-legal" scale, and are concerned with whether or not the law should allow living persons to donate tissue and, if so, under what conditions and circumstances. Generally, we took the view that the most appropriate way to respond to this question was to categorize these donors into four groupings - adults, "mature" minors, "immature" minors and the mentally disordered - and to devise policies ranging from one of essentially "laissez-faire" for adults to prohibition for the mentally disordered. The details concerning these recommendations are set forth towards the end of Part III. Basically, these recommendations reflect our philosophy, as earlier expressed, that the law should merely authorize and not encourage *inter vivos* donation. This conforms to the medical view which anticipates that the need for *inter vivos* donation will diminish as both the supply and the long-term success rate of cadaveric tissue transplants continue to improve.

There are two further Parts to our Report. In Part IV, we consider those remaining issues which apply equally to cadaveric and *inter vivos* procurement. These issues include the sale of organs, the disclosure of information, the general liability of physicians with respect to the procurement of tissue, and quasi-criminal matters pertaining to prohibitions and penalties under the proposed legislation. In the final Part of our Report, we list all of our Recommendations. We also set forth a proposed Act (with commentary) which was prepared internally by the Commission's legal staff. We offer a note of caution that, as we do not have any formal training in legislative drafting, technical improvement may be possible. However, we think that it gets across the thrust of our recommendations and, in this respect, we recommend it for adoption.

D. SPECIAL SUBJECTS NOT INCLUDED IN THIS REPORT

There are three types of tissue which we have decided should be excluded from our inquiry into the reform of *The Human Tissue Act*. The first was referred to at the outset of this Report: it pertains to the removal and use of tissue for embryo transplants or for artificial insemination. Specifically we have decided that neither ova nor spermatozoa (the male fertilizing element contained in semen) should be included in the

proposed legislation. The subject of genetic engineering raises issues which have far greater ramifications than the removal and use of human tissue generally. It would be wrong to treat it as a minor aspect of an inquiry into the reform of *The Human Tissue Act*.

Similarly, we have considered whether the regulation of embryonic and fetal tissue should properly form part of *The Human Tissue Act*. For several reasons, we have determined that its inclusion would be unsuitable. First, the kind of regulation which might be considered would have broader purposes than the use and removal of such tissue. It would extend to a general examination of medical research and treatment involving the embryo and fetus. Moreover, the area is legally complex. Aside from examining a fetus at various stages and developments, i.e. a fetus *in utero*, *ex utero*, a pre-viable fetus, etc., it would require some determination of when fetal death occurs. Given the complexity of the area, it would be preferable to conduct a broadly-based, in-depth examination of the legal status of the embryo and fetus from both a civil and criminal law perspective. We are aware that the Law Reform Commission of Canada has undertaken a two-year study along these very lines.

We have also decided that blood and blood constituents should be excluded from the ambit of *The Human Tissue Act*. The donation of blood and blood transfusions have been routine for decades in this province. We have concluded that there is no need for direct legislation in this field. This view was also reinforced by the local Canadian Red Cross Society which has made no request for legislation after a specific inquiry from us on this very issue.

E. UNIFORMITY OF LEGISLATION

One final concern should be addressed before proceeding to the next Part of our Report. It is the general policy of this Commission to recommend the implementation of uniform statutes in Manitoba where their use is appropriate for this province. However, the *Uniform Human Tissue Gift Act* was last revised in 1971 and it does not contain some of the better features of human tissue legislative reform, particularly with respect to *inter vivos* donation. While there is much to be said for achieving uniformity, we concluded that the *Uniform Act* should not be followed where a better alternative could be identified.

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PART II

CADAVERIC TISSUE

A. BACKGROUND TO RECOMMENDATIONS

1. Legislation Governing Cadaveric Tissue

(a) Historical development

The common law concerning the donation of cadavers and cadaveric tissue was both obscure and unsatisfactory. The person who was charged with the legal obligation to bury the body of the deceased (be it the executor,¹ surviving spouse,² or next of kin³) was not legally bound to carry out any previously expressed wishes of the deceased regarding the disposal of his/her remains.⁴ As well, it was uncertain whether those persons themselves had the authority to donate the cadaver or to authorize the removal of tissue from the body for transplant or research purposes.⁵

¹*Hunter v. Hunter*, [1930] 4 D.L.R. 255 (Ont. H.C.).

²*Edmonds v. Armstrong Funeral Home Ltd.*, [1931] 1 D.L.R. 676 (Alta. S.C., A.D.).

³*Miner v. Canadian Pacific Railroad* (1910), 15 W.L.R. 161 (Alta. S.C., T.D.).

⁴See *Williams v. Williams* (1882), 20 Ch. D. 659. See also W.F. Bowker, "Experimentation on Humans and Gifts of Tissue: Articles 20-23 of the Civil Code" (1973), 19 McGill L.J. 161 at 186.

⁵See P.D.G. Skegg, "Authorization of the Removal of Cadaveric Transplant Material at Common Law" (1978), 18 Med. Sci. Law 90 at 91. Here the author suggests that prior to any statutory provision for authorization, the person charged with the duty to dispose of the corpse *may* have been able to authorize removal of transplant material. However, it is recognized that such a conclusion is not free from doubt. See also The Law Reform Commission of
(Footnote continued to page 14)

The Anatomy Act was the first statute passed in Manitoba to clarify these common law rules.⁶ The original legislation authorized the University to obtain unclaimed or unwanted cadavers for purposes of anatomical study.⁷ Later amendments permitted persons to consent to the use of their bodies after death for such study.⁸ However, even today that consent must also be approved (either before or after the donor's death) by any person entitled to claim the body.⁹

Although the passage of *The Anatomy Act* helped to clarify the common law, it was limited in its scope. In particular, it merely authorized the retention of a cadaver for anatomical examination, following which any remains were to be interred. The statute did not provide for the donation of tissue. Statutory authority for the removal and use of tissue did not exist in Manitoba until *The Cornea Transplant Act* was passed in 1961.¹⁰ The

(Footnote continued from page 13)

Australia, *Human Tissue Transplants* (Report No. 7, 1977) at 26, where it is concluded that there exists no apparent authority at common law which would enable a person lawfully in possession of a body, or anyone else, to authorize removal of tissue from the body for transplant or therapeutic purposes.

⁶*The Anatomy Act*, S.M. 1947, c. 3.

⁷*The Anatomy Act*, S.M. 1947, c. 3, ss. 5(1) and 6(4).

⁸*An Act to amend the Anatomy Act*, S.M. 1959, c. 5, s. 5.

⁹ *The Anatomy Act*. C.C.S.M. c. A80, s. 6(6).

¹⁰*The Cornea Transplant Act*, S.M. 1961, c. 9. Although the Act allowed a person to make a direction for the donation of his/her eyes, the direction had to be coupled with the authorization of a person entitled to claim the body (where death occurred outside a hospital) or with the consent of the administrative head of the hospital (where death occurred within a hospital). This Act was patterned after the *Uniform Cornea Transplant Act* which was approved by the Uniform Law Conference of Canada in 1959. See Conference of Commissioners on Uniformity of Legislation in Canada, *Proceedings of the*
(Footnote continued to page 15)

increasing success of transplantation of other parts of the body, aside from the cornea, soon revealed that this legislation was too limited. The Legislature responded in 1968 by passing *The Human Tissue Act* which provided for the removal and use of human tissue generally.¹¹ This Act was patterned from the original *Uniform Human Tissue Gift Act* which had been adopted by the Uniform Law Conference of Canada.

(b) Present legislation

Since 1968, *The Human Tissue Act* has been the primary statute regulating the removal and use of cadaveric tissue. Apart from *The Human Tissue Act*, there are three statutes which affect the treatment and use of dead bodies. They are: *The Anatomy Act*, C.C.S.M. c. A80, *The Fatality Inquiries Act*, C.C.S.M. c. F52, and *The Vital Statistics Act*, C.C.S.M. c. V60. We think it would be appropriate to summarize these along with *The Human Tissue Act* so that their interrelationship will become apparent. The four statutes are accordingly detailed below.

(i) The Anatomy Act

This statute continues to govern the donation of the whole body for anatomical examination in Manitoba. That is, when persons wish to donate their whole body after death, as opposed to their body tissue, their donation is governed by this statute, rather than *The Human Tissue Act*. Their body is then used for essentially anatomical examination. The term "anatomical examination" refers to the examination by dissection of a body for the purposes of teaching or studying, or researching into morphology.¹²

The donation system for the whole body is distinct from that formally established under *The Human Tissue Act* for human tissue. That is,

(Footnote continued from page 14)
Forty-first Annual Meeting (August, 1959) at 22. This Uniform Act was later replaced by the *Uniform Human Tissue Act*.

¹¹*The Human Tissue Act*, S.M. 1968, c. 31.

¹²This definition is extracted from *The Anatomy Act* of England. See *The Anatomy Act 1984*, c. 14, s. 1(1).

a direction given by a person under *The Human Tissue Act* is sufficient legal authority to procure tissue after death for the purpose(s) set forth in the direction. No authorization by the next of kin is required. This is not so under *The Anatomy Act*. A direction under that Act must be approved and countersigned by a person who is entitled to claim the body.¹³ This type of donation system is known as 'weak contracting-in'. It is called 'contracting-in' because like *The Human Tissue Act*, it looks to volunteers to donate through an explicit direction. The adjective "weak" is added because the wishes of the deceased are not absolute but defeasible. That is, the person entitled to claim the body has the legal right to defeat the donation by not countersigning the direction.

The person entitled to claim the body may also donate the deceased's body for anatomical examination without any prior direction by the deceased to that effect during his/her lifetime.¹⁴

Aside from the donation of the whole body, *The Anatomy Act* governs the use and treatment of unclaimed or unwanted bodies. The Act provides that a body which has not been claimed for a period of 48 hours following death comes under the control of the Inspector of Anatomy appointed under the Act. After a further 24 hours, the Inspector must, if it is required, deliver the body to the University of Manitoba "for the purpose of anatomical or other scientific instruction or requirements".¹⁵

Most of the remaining provisions of the Act deal with the care of the body once it comes under the control of the Inspector and the University, either through donation or lack of a claim. Of these, there are two provisions which should be highlighted. The first is the requirement that the

¹³This countersignature may be given either before or after the donor's death. See subsection 6(6) of *The Anatomy Act*. As to the category of persons entitled to claim the body, this includes those persons identified within the term "preferred claimant" in clause 2(e) of the Act as well as a "relative or bona fide friend". See subsection 6(1) of the Act.

¹⁴The donation is effected by that person signing a waiver of his/her right to claim the body. See subsection 6(4) of the Act.

¹⁵*The Anatomy Act*, s. 7(1).

University keep and preserve the body intact for at least 28 days following receipt. This essentially establishes a grace period of about one month following death during which time any person entitled to claim the body may still exercise that right upon payment of any expenses incurred with respect to the body.¹⁶ The second provision is quasi-criminal in nature and relates to the commercial trafficking of dead bodies. The Act provides in this regard that:

No person shall sell, buy, or traffic in, the bodies of dead persons, or otherwise acquire them except as authorized by this Act.¹⁷

A maximum fine of \$100 is established for a violation of this provision.¹⁸

(ii) The Human Tissue Act

As stated at the outset of this summary, this is the primary statute regulating the removal and use of cadaveric tissue. The legislation authorizes a person to obtain the possession of a body for the removal and use of tissue in accordance with a direction which has been given pursuant to the Act. The statute really sets forth three categories of persons who may give a direction. The first consists of the donors themselves. That is, the Act provides that any person who is 18 years or older may consent to the removal and use after death of any tissue or specified tissue. The second category is the nearest relative of the deceased. The Act establishes a gradational list for this category - beginning with the spouse of the deceased, if any, - and follows this with an adult child, a parent and, finally, an adult sibling. The third category of person who may give a direction under the Act consists of the "person lawfully in possession of the body" as well as the Inspector of Anatomy appointed under the *The Anatomy Act*.

A very important characteristic of these three categories is the point at which each becomes operative. That is, each of these three categories has been listed above in the priority they are given under the

¹⁶*The Anatomy Act*, s. 11 and s. 12(1).

¹⁷*The Anatomy Act*, s. 15(1).

¹⁸*The Anatomy Act*, s. 26.

legislation. Those granted supreme position under the legislation are the donors themselves. Accordingly, it is only where persons have not consented during their lifetimes to the removal and use of tissue that the Act authorizes their nearest relatives to make a direction. Similarly, it is only where there are no relatives within the second category that the third and final category of persons may give a direction.

The fact that donors themselves have priority over the second and third categories means that the donation system is one of 'strong contracting-in'. This term 'contracting-in' was referred to in our summary of *The Anatomy Act*. What the phrase effectively means is that, like the donation system under *The Anatomy Act*, that under *The Human Tissue Act* is based upon voluntarism, i.e. express donation or authorization. The adjective "strong" is added because the wishes of the deceased are to be given absolute weight. That is, neither the nearest relative (category 2) nor the person in possession/Inspector of Anatomy (category 3) is legally authorized to defeat the wishes of the deceased where (s)he has consented to the removal and use after death of any tissue or particular tissue. In this respect, the system is distinctive to that established under *The Anatomy Act* where it will be recalled, the wishes of the deceased are defeasible.

The foregoing summarizes the rudiments of the donation system established under *The Human Tissue Act*. The legislation refines these basic concepts in several respects but primarily three:

(a) Form of direction. The legislation specifies that the donor may give his direction, in writing at any time; or (2) orally in the presence of at least two witnesses during the donor's last illness. The Act does not require that the direction, whether oral or written, take any particular form. In the case of a written direction, an organ donor card issued by any one of the major agencies involved in promoting organ donation or the provisions located on the reverse side of a Manitoba driver's licence, signed by the donor, would suffice. A direction might also be included in the donor's will.¹⁹

¹⁹However, as noted by G. Dworkin, "The Law Relating to Organ Transplantation in England" (1970), 33 *Med. Law Rev.* 353, at 366, "... a direction in a will without more would in most cases be useless, since wills
(Footnote continued to page 19)

(b) Qualifications to the removal of tissue. Thus far in our summary of this legislation, it has been assumed that the removal and use of tissue occurs whenever a direction has been given by any person within category 1, 2, or 3 (in that order) in accordance with the Act. However, although this is the usual pattern, it does not always follow that tissue will be removed in accordance with a direction. The Act establishes three general situations where tissue cannot be removed notwithstanding that a direction has been given. The first is simply where there is no need for the tissue for the purposes set out in the direction (s. 4(1)). The second arises where the physician has reason to believe that an inquiry or investigation²⁰ may be required under *The Fatality Inquiries Act* and has not obtained the consent of the medical examiner to proceed. The third qualification relates to the wishes of the deceased and the nearest relative and reinforces the 'strong contracting-in' philosophy reflected in the Act. It means that where a direction is made by a donor (category 1), the physician cannot act upon the direction if (s)he has reason to believe that the donor subsequently withdrew it. Where a direction is given by the nearest relative (category 2) or person lawfully in possession of the body/Inspector of Anatomy (category 3), it means that the physician cannot act upon it if (1) (s)he has reason to believe that the deceased would, if living, have objected thereto; or (2) (s)he has actual knowledge that

(Footnote continued from page 18)

are normally looked at sometime after death, and usually this would be too late for the deceased's organs to be of medical use. The need for speedy communication is paramount and where a person does include a therapeutic bequest in his will it is considered advisable for the donor's doctor and his close relatives to be informed, and also for the request to be recorded separately."

²⁰The wording of *The Human Tissue Act* here is clumsy. The term "inquiry or investigation" is used in subsection 3(3) but in subsection 2(2) this term is replaced with the word "inquest". This discrepancy is referred to later in this Part where we recommend that "inquest" in subsection 2(2) be replaced with the term "inquiry or investigation". A similar amendment to paragraph 1(a) is made in the proposed Act, set forth later in Part V of this Report.

another member of the same class of persons as the person who gave the direction objects thereto (s. 3(3)).²¹ This third qualification further limits the authority of the nearest relative to direct the removal and use of the deceased's tissue. That is, the nearest relative's direction is inconsequential if the deceased has given a direction under the Act (i.e. 'strong contracting-in' system). Also, the direction is ineffective if the deceased, if living, would have objected to the direction or if another member of the same class of family voices an objection to the physician.

(c) The pituitary gland. Since 1979,²² *The Human Tissue Act* has provided for an exception to the 'strong contracting-in' system insofar as the removal of the pituitary gland is concerned. The Act authorizes a person who is performing a post-mortem examination to remove this gland notwithstanding that there has been no direction given under the Act. The Act specifies that any pituitary gland extracted pursuant to this authority is to be used "in the treatment of persons having a growth hormone deficiency" (s. 6(1)). The authority to remove the gland is subject to two qualifications. That is, the authority does not exist where there is reason to believe either that (1) the deceased, if living, would have objected to its removal; or (2) the nearest relative would have objected to its removal. It is notable that this authority only applies where a post-mortem examination of the body is undertaken.²³ The circumstances where such an examination is legally required are governed by *The Fatality Inquiries Act*, the statute we now turn to examine.

²¹A member of the same class refers to the gradational list of relatives set forth in category 2 and, in particular, refers to the classes of adult child, parent, and adult sibling.

²²*An Act to Amend The Human Tissue Act*, S.M. 1979. c. 20, s. 1.

²³The reference to the post-mortem examination in subsection 6(1) of the Act is not limited to an official autopsy conducted under *The Fatality Inquiries Act*. In this respect, our legislation differs from that of Alberta, Saskatchewan, Ontario and Nova Scotia.

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(iii) The Fatality Inquiries Act

This statute provides for official autopsies or post-mortem examinations to be performed where a person has died under circumstances which are sudden, violent or unexplained.²⁴ The Act also provides for autopsies to be performed in the event an inquest is required to be performed pursuant to another statute.²⁵ The Act does not require an official autopsy to be performed in every such circumstance. What it does mandate is that a medical examiner (appointed by the Lieutenant Governor in Council under the Act) inquire as to the cause and manner of death (s. 6(1)). If, as a result of that inquiry, (s)he concludes that an autopsy is necessary, an official autopsy will then occur. When an official autopsy is undertaken by a medical examiner, neither the previous wishes of the deceased nor those of the nearest relative can override this legal requirement. The legislation reflects the view that it is in the community's best interest to ensure that deaths occur naturally and that this interest should precede that of the deceased's family where they express contrary wishes.

The Fatality Inquiries Act interrelates with both *The Anatomy Act* and *The Human Tissue Act*. We stated previously under our discussion of the latter statute, that one of the qualifications to the removal of tissue was where the physician had reason to believe that an inquiry under *The Fatality Inquiries Act* may be required and had not obtained the consent of the medical examiner to proceed. This reflects again the general precedence given to the requirements of an investigation under *The Fatality Inquiries Act*. Specifically in this case, the community's right to an investigation precedes the right of the deceased or his/her family to donate human tissue. *The Fatality Inquiries Act* also interrelates with *The Human Tissue Act* in

²⁴Subsection 6(1) of the Act sets forth all of the circumstances where the medical examiner is required to commence an inquiry.

²⁵For example, subsection 24(7) of *The Workers Compensation Act*, C.C.S.M. c. W200 empowers the Workers Compensation Board to order an autopsy where it deems it necessary. An insurer may, in certain circumstances, also require an autopsy to be performed as a condition precedent to the recovery of insurance monies. See *The Insurance Act*, C.C.S.M. c. I40, s. 211, statutory condition 9(b).

that, as stated previously under our discussion of the latter statute, a person conducting a post-mortem examination may remove the pituitary gland subject to certain qualifications referred to earlier.

An investigation under *The Fatality Inquiries Act* also takes precedence over the right of the University to conduct an anatomical examination of a body under *The Anatomy Act*. Section 8 of *The Anatomy Act* sets forth four provisions, the thrust of which are to ensure that the University will not perform a post-mortem examination unless authorized by a medical examiner appointed under *The Fatality Inquiries Act*.

(iv) *The Vital Statistics Act*

One of the purposes of this Act is to provide for the registration of deaths and the issuance of burial permits in Manitoba. The Act interrelates with *The Fatality Inquiries Act* in that the district registrar appointed under *The Vital Statistics Act* must not issue a burial permit where it appears that an inquiry should have been undertaken by a medical examiner under *The Fatality Inquiries Act* but, in fact, was not (s. 14(6)).

A very important provision in *The Vital Statistics Act* is the legal definition of death which appears in section 2 of the Act. This section implements the Commission's recommendations in a previous Report.²⁶ The text of the section is as follows:

For all purposes within the legislative competence of the Legislature of Manitoba the death of a person takes place at the time at which irreversible cessation of all that person's brain function occurs.

This legal definition of death formally sanctions the right of physicians to remove tissue from post-mortem donors who have sustained brain death with intact circulation. As stated earlier in this Part of our Report, this is required for the transplant of vital organs such as the heart, liver and kidneys. In this respect, *The Vital Statistics Act* directly affects the supply of tissue donated for transplant purposes pursuant to *The Human Tissue*

²⁶The Manitoba Law Reform Commission, *Report on A Statutory Definition of Death* (Report #16, 1974).

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Act. It is an integral part of that network of provincial legislation governing death itself as well as the use and care of the bodies of deceased persons.

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Having summarized the legislation governing the use and care of bodies and of tissue of post-mortem donors, it is now appropriate to consider how well this legislation responds to the needs of those requiring tissue for therapeutic, educational and research purposes.

2. The Supply of Cadaveric Tissue

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Earlier in this Part of our Report, we referred to the shortage of cadaveric tissue, particularly for (but not limited to) transplants. Nationally, there is a shortage of several types of tissue including kidneys, corneas, lungs, hearts and livers. In Manitoba, where kidney and cornea transplants are regularly performed, we have previously referred to the waiting period for these transplants. The fact that heart transplants will soon be performed in Manitoba will also create a local need for this tissue.

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What are the reasons for the supply/demand problem? Are Manitobans not signing donor cards? Are relatives refusing to authorize the removal of tissue where the deceased has not signed a donor card? Before exploring the solutions to overcome the supply/demand problem, it is necessary to identify where the system of organ procurement known as 'strong contracting-in' has proven to be inadequate.

(a) Donation pursuant to the Deceased's Earlier Direction

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Donation pursuant to the deceased's own direction in his/her lifetime has not been a very successful means of procuring cadaveric tissue. From the information which is available, there appear to be three basic reasons for its limited success.

- Human Tissue
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- (i) Few people sign donor cards;
 - (ii) Hospitals and health care professionals are not always aware when a person has signed a donor card; and
 - (iii) Relatives of a deceased are, in practice, given the authority to countermand the wishes of a person who has signed a donor card.

Each of these three reasons identified for the limited success of tissue donation pursuant to the deceased's own direction is expanded upon below.

(i) Few people sign donor cards

There are no statistics available with respect to the number of Manitobans who have signed donor cards. However, the results of a 1983 Gallup Poll indicate that, with respect to the prairie provinces, only 23% of those questioned had signed an organ donor card.²⁷ This survey is in line with those conducted in other regions of Canada.²⁸

At first blush, these figures would seem to indicate a general unwillingness to donate. However, other statistics do not support this inference. The same survey which found that 23% of those questioned in the prairie provinces had actually signed donor cards also reported that almost triple that number (60%) either had signed or would be willing to sign a donor card for the purpose of directing a post-mortem gift of vital organs for a transplant.²⁹ This figure is in line with those conducted in other regions of Canada³⁰ and with surveys conducted in the United States, Australia and Great Britain.³¹

Taking the survey conducted on the prairie provinces specifically, why is it that 37% responded that they would be willing to donate their organs for transplant purposes but in fact had not yet signed a donor card? Lack of opportunity could not account for this discrepancy. Every Manitoban who drives has the chance to make a direction under *The Human Tissue Act* by completing the provision on the reverse side of the driver's licence. Moreover, non-drivers may, on request, obtain donation cards from various

²⁷Ontario Ministry of Health *Organ Donation in the Eighties: The Minister's Task Force on Kidney Donation* (1985), at 130, hereinafter cited as "Ontario Report".

²⁸Ontario Report, at 130.

²⁹Ontario Report, at 130.

³⁰Ontario Report, at 130.

³¹Russell Scott, *The Body as Property* (1981) 89.

donation organizations free of charge. Accordingly, documentation is widely available for anyone wishing to make a direction. The explanation must lie elsewhere.

It has been suggested that the discrepancy can be reconciled in that "it is too psychologically tempting to give an altruistic answer to a faceless pollster, so that the signing of a donor card, which is a much more significant event, is a truer indication of a person's real desires".³² A survey conducted in Ontario partially supports this statement by pointing to certain fears and ambivalences shared by those who had not actually signed donor cards.³³ On the other hand, it could be pointed out that less than 20% of all deceased persons leave wills.³⁴ This suggests "that the failure to take affirmative steps to implement the desire to donate has more to do with the general inertia that surrounds decisions related to one's death, not that the desire is not genuine."³⁵

(ii) Hospitals and health care professionals are not always aware when a person has signed a donor card

There is no system for donors to register their direction for the removal of tissue after death. This would facilitate hospital awareness of donors. Moreover, the majority of donors are accident victims. In these circumstances the potential donor is often unconscious. A health care professional may have neither the time nor the authority to search the

³²Barry Hoffmaster, "Freedom to Choose and Freedom to Lose: The Procurement of Cadaver Organs for Transplantation" (1985), XVII *Transplant. Proc.* 24, at 29.

³³From those who had not signed donor cards, several reasons were offered. These included concerns regarding the hastiness of organ removal and disfigurement of the body. See the *Ontario Report*, at 216-220. These reasons and, particularly, that regarding the hastiness of organ removal suggest the need for more educational programmes to alleviate these general fears. This need is addressed later in this Part of our Report.

³⁴*supra* n. 32, at 29.

³⁵*supra* n. 32, at 29.

possessions of the individual; the personal effects are therefore usually locked away or turned over to the family. Where the potential donor has been in an accident, the wallet or purse, which would normally contain the donor card or driver's licence, is often destroyed or lost at the scene of the accident. If it is an accident in which the police have become involved, the police may keep the victim's personal effects, and the hospital staff would have no access to them. The absence of a practical and effective means of identifying those who have provided for the post-mortem donation of their organs would appear to be a serious impediment in the process of organ procurement.

(iii) Relatives of a deceased are, in practice, given the authority to countermand the wishes of a person who has signed a donor card

Earlier in this Part of our Report, we described the system of donation established under *The Human Tissue Act*. We characterized it as a 'strong contracting-in' system. This means that neither the nearest relative (category 2) nor the person lawfully in possession of the body /Inspector of Anatomy (category 3) are vested with the legal authority to countermand the wishes of the deceased, where the deceased has, in his/her lifetime, given a direction under the Act. In practice, however, health care professionals normally seek authorization from relatives even when they are aware that the deceased has given a direction. This means that relatives are practically vested with the authority to negate the deceased's wishes.

One of the concerns expressed by these professionals is the possibility of adverse publicity or the prospect of legal proceedings if tissue were removed pursuant to the deceased's direction but contrary to the wishes of the nearest relative. The legislation, however, clearly provides that the direction of the donor constitutes full authority. Moreover, it stipulates that the authority of the nearest relative only arises where a deceased has not given a direction. Accordingly, the concern of health care professionals and hospitals with respect to their exposure to legal liability does not appear to be soundly based.

Two further rationales for this practice have been suggested. The first involves a general solicitude for the feelings of those just bereaved.

The second points to an ambivalence towards organ donation on the part of some health care professionals. That is, health care professionals who are ambivalent about tissue donation "give themselves a chance to resolve this ambivalence by creating an opportunity for relatives to negate the deceased's donation".³⁶

The fact that the nearest relative is given this countermanding authority in Manitoba has been criticized by some respondents to our Working Paper who express concern that their wish to donate will not be respected by their families. Later in this Part, the Commission addresses this concern, as well as those previously enumerated in this section which have created barriers to the tissue procurement system based upon the donor's direction.

(b) Donation where no direction by deceased

As stated previously, the removal and use of cadaveric tissue in Manitoba is almost always undertaken pursuant to the direction of the nearest relative of the deceased even where the deceased has made an earlier direction. The success of this second type of direction is dependent upon many factors but primarily two:

- (i) the willingness of the nearest relative to authorize the removal of tissue; and
- (ii) the ability and interest of health care professionals to be involved in the organ donation process.

These factors are developed further in the following paragraphs.

(i) The willingness of the nearest relative to authorize the removal of tissue

From the information which we have available for Manitoba, it would seem that over 70% (72.5%) of all relatives who are asked agree to authorize

³⁶Margaret A. Somerville, "'Procurement' vs. 'Donation' - Access to Tissues and Organs for Transplantation: Should Contracting Out Legislation Be Adopted?" (1985), XVII Transplant. Proc. 53, at 62.

the removal of tissue from the deceased.³⁷ This figure is almost identical to percentages in other jurisdictions.³⁸ It is also a very accurate reflection, not only because it is based on local statistics, but also because it is based on actuality rather than pure conjecture. The fact that over 70% of all relatives who are asked agree to authorize organ donation would suggest that familial attitude is not a major barrier to organ procurement.

(ii) The ability and interest of health care professionals to be involved in the organ donation process

This Commission does not have the financial and human resources to undertake extensive empirical research on the ability and interest of Manitoba health care professionals to be involved in the organ donation process. However, the Ontario Minister's Task Force on Kidney Donation has produced in its final Report, amongst other matters, several findings and conclusions concerning this subject. While these relate specifically to kidney donation in Ontario, we believe that many of their comments are relevant to the organ donation process which exists in this province. Some of the findings and conclusions of the Task Force are summarized below in accordance with the following three headings we have devised:

(a) Hospital policy and direction. More than one-half of the hospitals surveyed did not have a written organ donation policy (54%). As a result, there was confusion by both doctors and nurses as to procedures involved with a potential organ donor. Almost three-quarters (72%) did not have an individual or team responsible for co-ordinating the donation process in the hospital.³⁹

³⁷Ms. Del Johnstone, Kidney Transplant Co-ordinator, Health Sciences Centre regarding requests for kidney donation in 1985. Out of 29 requests made in 1985, the Centre was refused 8 times. Mrs. Joan Roberts, Co-ordinator, Lions Eye Bank, indicated that a similar percentage of authorizations occur with respect to requests for cornea transplants.

³⁸See for example, the Gallup Poll conducted in the United States for the National Kidney Foundation where almost three-quarters (72%) of those aware of organ transplants said that they would very likely give permission to have the kidney of a loved one donated after that person's death. See *Ontario Report*, at 128.

³⁹These statistics are taken from the report of the Donation Process Subcommittee of the Task Force. See *Ontario Report*, at 91 *et seq.*

(b) Education and expertise. About one-half of the doctors and nurses surveyed felt inhibited in initiating the organ donation process by 'bothering' a grieving family for consent. There was also some misunderstanding amongst health care professionals as to the type of patient who is suitable for consideration as a potential donor. Accordingly, between 45% and 80% of patients who would be suitable were not being identified as potential donors or, if identified, were not being converted into actual donors. Of those patients who were identified, further barriers existed. Large segments of the medical community were both unfamiliar and uncomfortable with the procedures for certification of brain death. Moreover, many hospitals lacked both clear guidelines and trained personnel necessary to maintain a brain-dead donor in stable condition until arrangements could be made for organ removal. Questions of legal responsibility were also seen as a barrier to the initiation of the donation process.⁴⁰

(c) Resources. Organ procurement can be extremely time consuming and disruptive, particularly for ICU staff. About three-quarters of the doctors and nurses who were surveyed cited time demands as a barrier to participating in the organ procurement process. Money is another concern. Lack of adequate remuneration for participating in the donation process and financial burdens to the hospital budget appeared to inhibit involvement.⁴¹ Considerable transportation costs may be expended in moving a donor to a transplant centre or dispatching an organ retrieval team to the hospital where the donor is located.⁴² The maintenance of a potential donor involves considerable expense and yet no mechanism exists for reimbursing the hospital for this expense.⁴³

B. THE RECOMMENDATIONS FOR REFORM

1. Alternatives to the present legal system of tissue procurement

The fact that the need for cadaveric tissue is not being met in this province compels us to raise certain fundamental questions concerning

⁴⁰Ontario Report, at 91 *et seq.*

⁴¹Ontario Report, at 91 *et seq.*

⁴²These findings are from the Donor Transplantation Subcommittee of the Task Force. See *Ontario Report*, at 137 *et seq.*

⁴³These findings are from the Organ Retrieval and Distribution Subcommittee of the Task Force. See *Ontario Report*, at 143 *et seq.*

the existing legislation. That is, is that legislation one of the principal causes of the shortage of cadaveric tissue in Manitoba? Could another legal system of organ procurement increase the supply? Or, is the choice of system largely an irrelevant consideration in finding solutions towards increasing the supply of cadaveric tissue?

Regardless of what legal system is identified as the most appropriate for organ procurement, that system must meet at least three objectives. First, it must be generally acceptable to hospitals and health care professionals. This does not mean that they should have absolute control over what system is implemented. But it does mean that they should feel reasonably comfortable with the system so that they can function well under its governing principles. Second, the legal system must be acceptable to the public at large. Third, there must be a reasonable measure of certainty with respect to its compliance with the *Canadian Charter of Rights and Freedoms*.

What alternatives are available to the existing legal system? It will be recalled that formally that system is one of 'strong contracting-in' but that health care professionals have implemented a 'weak contracting-in' system. There are two other systems of organ donation which are possible replacements to that of contracting-in. The first system is that of compulsory organ donation. It understandably attracts little support. The second is known as presumed consent; it is the more important of the two and deserves serious consideration by any law reformer. We now turn to examine each of these systems in greater detail.

(a) Compulsory tissue removal

This legal system would allow cadaveric tissue to be removed and used in all cases where it would be useful regardless of any objection by the deceased or his/her nearest relative. There is no doubt that such an approach would increase the supply of tissue. However,

[i]t is very clear that a compulsory organ removal statute would interfere with very intensely personal interests of both the

dying patient and the next of kin. Such a statute would make a dramatic break from long standing tradition with respect to the burial of human bodies.⁴⁴

It is also worthy of note that "[n]owhere, so far as can be ascertained, has a government yet legislated to take a dead body in the face of objection by the deceased; an objection always prevails".⁴⁵ Moreover, we do not believe that this system would meet any one of the three objectives of organ procurement legislation we identified at the outset of this discussion. That is, we do not think it would be acceptable to either the health care professionals or the public at large in Manitoba.⁴⁶ Nor do we think that it would comply with the *Canadian Charter of Rights and Freedoms*: it would likely constitute a breach of clause 2(a) - which pertains to freedom of religion - as well as a breach of section 7 - which generally establishes the right to life, liberty and security of the person. Notwithstanding the good which can be realized from tissue removal, it is unlikely that an organ donation system built exclusively on absolutes could be demonstrably justified under section 1 of the *Charter*.

For these reasons, we recommend that compulsory tissue removal be rejected as a viable alternative system for Manitoba.

(b) Presumed consent

(i) A general legislative scheme

Presumed consent or 'contracting-out' legislation has enjoyed increasing support as an alternative to the system of 'contracting-in' or encouraged voluntarism which exists in Manitoba. In its stronger form, 'contracting-out' would grant medical personnel the authority to remove usable tissues from a deceased person *unless* the deceased had during his/her

⁴⁴Steven I. Weissman, "Why the Uniform Anatomical Gift Act Has Failed" (1977), Tr. & Est. 264, at 267.

⁴⁵*supra* n. 31, at 95-96.

⁴⁶This view is reinforced by the fact that not one of the respondents to our Working Paper favoured a compulsory organ removal.

lifetime objected to their removal. The wishes of the relatives would be irrelevant. A weaker version of this approach would recognize the wishes of the family, who could object to organ removal in the absence of known consent or objection by the deceased.

It has been stated that the essential difference between a 'contracting-in' and a 'contracting-out' system is in who has the burden of action.⁴⁷ That is, under the former it is the volunteer whereas under the latter it is the objector. This distinction, however, may need to be confined to tissue procurement pursuant to the donor's wishes. Often 'weak contracting-out' legislation requires that the deceased's family be notified prior to the removal of tissue so that they may have an opportunity to negate the proposed removal. When this requirement exists, there is little practical difference between a 'contracting-in' and a 'contracting-out' system if the deceased has been silent during life about his/her wishes regarding tissue removal.⁴⁸

Presumed consent legislation has been adopted by at least fourteen European countries.⁴⁹ Several of those nations, including Austria, Denmark, Poland, Switzerland and France, authorize physicians to remove organs without imposing a corresponding obligation to approach families to provide them with

⁴⁷Paul Ramsey, *The Patient as Person, Explorations in Medical Ethics* (1970) 210.

⁴⁸This statement was confirmed by Prof. Carl Groth, M.D., Professor of Surgery, Huddinge Hospital, Stockholm, Sweden (December 1984). Swedish legislation requires that reasonable efforts be made to inform relatives prior to organ removal.

⁴⁹These are: Austria, Czechoslovakia, Denmark, Finland, France, Greece, Hungary, Italy, Norway, Poland, Spain, Sweden, Switzerland and West Germany. See A. Cantaluppi, A. Scalamogna and C. Ponticelli, "Legal Aspects of Organ Procurement in Different Countries" (1984), XVI *Transplant. Proc.* 102, at 103. See also Kenneth Mck. Norrie, "Human Tissue Transplants: Legal Liability in Different Jurisdictions" (1985), 34 *Int'l & Comp. L.Q.* 442, at 460.

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an effective opportunity to object.⁵⁰ In other countries where presumed consent prevails - Finland, Greece, Italy, Norway, Spain and Sweden - physicians approach the families to be certain that they have no objection.⁵¹ In the United States, it has been suggested that, if presumed consent legislation were implemented, notification to the family would likely be an essential constitutional requirement of procedural due process.⁵² A strong argument could also be made in Canada, having regard to sections 2 and 7 of the *Canadian Charter of Rights and Freedoms*.

Before proceeding to discuss the pros and cons of presumed consent legislation, we wish to point out that we have chosen to limit our discussion on this subject in two respects. First, because we are of the view that it would be unacceptable to ignore completely the wishes and beliefs of the deceased's close family in circumstances where the deceased had not made his/her wishes respecting organ donation known, our discussion is restricted to a consideration of only the 'weak contracting-out' approach. Second, like most who consider presumed consent legislation, we do so only in the context of tissue removal for therapeutic or transplant purposes, rather than for medical research or education. The former may be seen to represent a more direct means of aiding human life than the latter, and the degree of urgency attending the need for organs for these diverse purposes may be viewed as differing significantly.

What then are the arguments in favour of 'weak contracting-out' legislation for transplant purposes? There are several. First, it is argued that, as opinion polls indicate that most persons are willing to donate their organs, a presumed consent system would give statutory effect to this willingness to donate. Second, it is contended that 'contracting-out' legislation would recognize the primacy of our ethical commitment to the preservation of human life. Related to this notion is really the main rationale for presumed consent legislation. That is, advocates of this system state that it would effectively increase the supply of cadaveric tissue. A

⁵⁰Cantaluppi, *id.*, at 102.

⁵¹Cantaluppi, *supra* n. 49, at 102.

⁵²Alfred M. Sadler, Jr., Blair L. Sadler, "A Community of Givers, Not Takers" (1984), 15(4) *Hastings Cent. Rep.* 6, at 8.

further argument which is sometimes raised is that presumed consent would minimize the impact of organ removal on both the hospital staff and the bereaved family. This last argument, however, would not apply to presumed consent legislation which would require the hospital to notify the deceased's family prior to the removal of the deceased's organs. As previously stated, it is strongly arguable that this notification would need to be a requirement of the legislation for it to be constitutionally valid.

The arguments that have been raised in favour of presumed consent legislation, and the support that it has received both by commentators and legislatures in many parts of the world, without doubt give this option some credibility and appeal. We accordingly have given it serious thought and consideration. However, we find questionable several of the arguments upon which advocates of presumed consent rely. More importantly, we are not satisfied that a system of presumed consent would in fact increase the supply of available organs.

First, we are not convinced that the opinion polls which indicate that a majority of persons when polled express a willingness to donate their organs provide a basis for adopting a system of presumed consent in this province. As mentioned previously in this Part of our Report, these polls may not accurately reflect the number of people who would *actually* consent to donation, if asked. Furthermore, even if it were to be demonstrated that most citizens are willing voluntarily to make a gift of their organs, this would not imply that a majority of persons would favour the introduction of a legislative presumption of consent. First, we note that only one of the respondents to our Working Paper supported presumed consent legislation. We are also aware of two studies in which public attitude to such legislation was tested. The first of these involved a public opinion poll conducted in Alberta in September, 1983 by the Alberta Human Tissue Procurement Task Force. Although only 37 people responded, the Task Force found that

[c]learly [the consent issue] remains a contentious area and it is probably safe to assume that the majority of Albertans would not be in favour of mandatory donation or even of implied consent to donation in the absence of express refusal.⁵³

⁵³Alberta Human Tissue Procurement Task Force, *Annual Report 1983/84*, at 18.

In the second study, it was similarly concluded that there is opposition to presumed consent legislation and that it is not viewed by the public as an acceptable alternative in Canada.⁵⁴

We referred earlier to the constitutional argument which would require that the nearest relative of the deceased be notified prior to the removal and use of the deceased's tissue. It is also strongly arguable that presumed consent legislation would necessitate the development of an accurate and accessible means for persons to record during their lifetime an objection to post-mortem donation. Otherwise, without these measures, a presumed consent system would mirror (albeit under a different name) a system of compulsory organ removal. However, if we were to attempt to develop an effective means for allowing the donor or his/her nearest relative to object to donation, we would merely find ourselves confronted with the flipside of the problems which we now encounter under our 'contracting-in' scheme. Rather than trying to ascertain at the time of death whether the deceased had earlier consented to donation, health care professionals would be faced with the task of determining whether (s)he had objected. Rather than approaching the bereaved family for consent to donation, the physician would consult with the relatives to discover if they had an objection. As previously mentioned, a 'weak contracting-out' system coupled with the right of notification would result practically in a system not at all dissimilar from one of 'contracting-in'.

Finally, the available empirical data do not show that the organ donation rate has been significantly increased in those countries which have adopted the presumed consent approach.⁵⁵ This may be due to the fact that, although there is no legal requirement of notification in many countries, physicians are apparently still following the practice of requesting donation.⁵⁶

⁵⁴Ontario Minister's Task Force on Kidney Donation, *Preliminary Report of the Donation Process Subcommittee* (December, 1984), at 9, 11.

⁵⁵*Ontario Report*, at 40; Arthur L. Caplan, "Organ Procurement: It's Not in The Cards", (1984), 24(5) *Hastings Cent. Rep.* 9.

⁵⁶Caplan, *id.*, at 11, describing the system of organ procurement in France.

All of these considerations have led us to conclude that a general scheme of presumed consent should not be introduced in Manitoba at this time. We believe that until efforts to increase the effectiveness of our present legislation are exhausted, the adoption of an alternate legislative scheme (the desirability, workability and effectiveness of which are at best uncertain) would not be justified.

(ii) Autopsies

Although we have concluded that a *general* scheme of presumed consent should not be introduced at this time, we have yet to consider whether legislation should allow for tissue to be removed during the course of a post-mortem examination except where there is reason to believe that the deceased, if living, would have objected or that a designated family member objects. It will be recalled from earlier in this Part, that *The Human Tissue Act* allows the pituitary gland to be removed in these circumstances "for use in the treatment of persons having a growth hormone deficiency".⁵⁷ This section is similar to legislation found in several other provinces.

The pituitary is a pea-sized gland located at the back of the skull. Used (amongst other matters) for producing a hormone extract that combats dwarfism in children, this tiny gland has immense therapeutic value. During a normal autopsy, the pituitary gland is removed and examined. It cannot thereafter be put back in its original place because of the damage done

⁵⁷*The Human Tissue Act*, C.C.S.M. c. H180, s. 6; *The Human Tissue Amendment Act*, S.N. 1981, c. 41, s. 1; *An Act to Amend the Human Tissue Gift Act*, S.P.E.I. 1980, c. 27, s. 1; *An Act to Amend the Fatality Inquiries Act*, S.N.S. 1982, c. 25, s. 3; *Coroners Act*, R.S.O. 1980, c. 93, s. 29; *The Coroners Amendment Act, 1980*, S.S. 1979-80, c. 57, s. 5; *Fatality Inquiries Act*, R.S.A. 1980, c. F-6, s. 27. In Alberta, Saskatchewan, Ontario and Nova Scotia, the provision is limited to *official* post-mortem examinations. Alberta, unlike the other provinces, authorizes the use of the pituitary gland retained under these circumstances for medical education and scientific research, in addition to therapeutic purposes. See also *An Act to Amend the Human Tissue Act*, S.N.B. 1984, c. 25 wherein it is required that reasonable steps be taken to ascertain whether the designated family member objects prior to such removal of the pituitary gland for therapeutic purposes.

to its connecting tissue by removal. Because it is so small, it would more than likely be treated as waste after the examination and discarded, or else placed in a body cavity along with other severed parts.⁵⁸ The great need for the pituitary for therapeutic purposes and the fact that it is routinely removed during an autopsy without leaving external trace have led to the adoption of this special statutory provision respecting the retention of the pituitary gland. It has been said:

. . . it would surely be absurd if this tiny severed gland, obtained after a gross interference with the physical integrity of a dead body, could not lawfully be used for curing sickness but must instead be destroyed or sewn up in some other part of the body. The new laws are both practical and humane. . . . The laws are activated only after the [person performing the autopsy] has produced tissue in usable form. It would be a human and economic waste to forbid this use and to compel destruction of the tissue.⁵⁹

The pituitary is not the only tissue that remains useful for therapeutic purposes even if removed some time after the deceased's heart has stopped beating. Corneas, bones, joints, inner ear parts and skin may be of therapeutic value if removed during a post-mortem examination. It has been suggested that the supply of these body parts could be increased by allowing for their removal and retention on a basis similar to that at present employed for the pituitary gland. The argument in favour of expanding the 'pituitary gland exception' to include other human tissue lies primarily in the fact that the performance of an autopsy in itself seriously interferes with the physical integrity of a dead body.

. . . [It is] the gruesome truth that a properly conducted full autopsy will involve the draining away of all blood and body fluids, and the removal of all organs, glands and the brain. Once the cause of death is ascertained, the body will then be restored to a normal appearance, so far as possible, and handed over to relatives for interment. Frequently, severed parts are carefully placed in a body cavity such as the abdominal cavity, and all incisions are stitched

⁵⁸*Supra* n. 31, at 93.

⁵⁹*Supra* n. 31, at 93-94.

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Once the body has been so extensively interfered with, why should tissue which would be useful in aiding the sick not be retained where there is no known objection by the deceased or his/her family?

Opponents of this position argue that an autopsy may be a necessary evil, but that one should not compound the affront to bodily integrity by dealing further with the remains in the absence of consent once the procedures for determining the cause of death have been completed: two wrongs do not make a right.

The only Canadian province to have adopted presumed consent legislation in relation to tissue other than the pituitary gland is Saskatchewan. A recent amendment to their *Coroners Act*⁶¹ authorizes the extraction of the deceased's corneoscleral button during an official autopsy where it is expected to be suitable for use for an immediate transplant. This may only be done where the person performing the autopsy has no reason to believe that the deceased expressed an objection to the extraction or that the deceased's close family or personal representative objects. It is our understanding that this recent legislative amendment has met with no negative response from the public or the media.

While we believe that there is some merit in the suggestion that the presumed consent approach be extended to cover the retention during an autopsy of useful tissue in addition to the pituitary gland, we are not prepared to recommend such legislative change in Manitoba at this time. In part, we rely on the reasons for which we rejected the adoption of a general scheme of presumed consent. Most importantly, we believe that the supply of human tissue can be significantly increased without the introduction of such legislation. With regard specifically to increasing the amount of tissue donated where a post-mortem examination is performed, a system of 'routine request', such as that adopted by the office of the Chief Medical Examiner in

⁶⁰*Supra* n. 31, at 92.

⁶¹*The Coroners Amendment Act, 1984, S.S. 1983-84, c. 32.*

Alberta, presents a promising option.⁶²

Our recommendations regarding presumed consent are as follows:

RECOMMENDATION 1

That, subject to Recommendation 2, the requirement of consent to remove human tissue after death for therapeutic, educational and research purposes be retained.

RECOMMENDATION 2

That the presumed consent provisions in s. 6 of The Human Tissue Act not be extended to permit the removal and retention of tissue other than the pituitary gland.

Having discussed the alternatives to the present legal system of tissue procurement, we turn now to consider the whole organization of the tissue procurement process to determine what changes can be recommended to encourage or promote cadaveric donation. Some of these changes involve legal reform; others are merely administrative. We begin with an examination of the donation process which is established to encourage each person to make a post-mortem donation of his/her tissue. We then turn to consider the donation process pursuant to which a person's nearest relative is authorized to direct tissue procurement.

2. Further Recommendations for Reform

(a) Donation pursuant to the deceased's direction

(i) Education

A system of voluntary organ donation requires a public that is aware of the progress that has been made in the fields of organ transplantation and medical research, and aware of the desperate need for organs and tissues for these purposes. As well, it is important that organ donation be viewed by

⁶²This and other legislative and non-legislative options will be examined later in this Part of the Report.

members of the public as an acceptable and commonplace matter for consideration, not unlike providing for the disposition of one's property after death. Information respecting the procedures involved in the organ donation process is required, so that people are aware of how to record their wishes to donate body parts, and to allay any fears or misconceptions which may exist in relation to organ donation. Also, constant reminders and encouragement for members of the public to take the requisite steps to donate their tissue for use after death must be given.

A study prepared for the Ontario Task Force gives some helpful advice regarding both the need for and the type of publicity which would be particularly beneficial. In particular, it was suggested that:

1. There is a need for constant, ongoing publicity that would make organ donation a routine, natural thing to do;
2. The public wants to hear about actual cases and success stories;
3. The public is not adequately made aware of the needs for organs;
4. More attention must be drawn to the driver's licence attachment respecting organ donation.⁶³

Those involved in existing transplant and research programmes have attempted to educate the public about organ donation through the distribution of literature and donor cards, and by making public appearances. However, they have not had sufficient resources to develop the type of large-scale publicity campaign that is required. Public funding and initiative with respect to public awareness programmes, as well as funding of private organizations which are involved in public education relating to organ donation, are required.

We are of the view that public awareness and education forms an integral part of our voluntary organ donation process. We recommend:

⁶³*Ontario Report*, at 228 *et seq.*

RECOMMENDATION 3

That an ongoing educational programme be implemented, aimed at increasing public awareness of organ transplantation and medical research, informing the public about the donation process, and encouraging the public to record and make known their wishes to donate organs.

There is one specific concern which we should like to address regarding public attitude towards donation. One of the specific findings of the study prepared for the Ontario Task Force was that, of those who had not signed donor cards, a major reason expressed was the fear that organs would be hastily removed.⁶⁴ Many non-donors worried that they might not really be dead when tissue was removed. This, of course, is not the case. As previously mentioned in this Part of our Report, *The Vital Statistics Act* provides for a legal definition of brain death.⁶⁵ Moreover, the College of Physicians and Surgeons of Manitoba has identified the criteria for brain death, and has stipulated that

. . . determination of death should be made by the attending physician and by a consultant familiar with the diagnosis and treatment of coma. The decision should not be made by a member of an organ transplant team.⁶⁶

Nevertheless, public anxiety created by the fear that organs may be removed prematurely obviously has an adverse effect on the public's willingness to donate tissue for transplant purposes. We think that it is important to allay that anxiety by statutorily ensuring that the life of a potential donor is adequately protected. We note in this regard that the *Uniform Human Tissue Gift Act*⁶⁷ contains a provision which would achieve

⁶⁴*Ontario Report*, at 216.

⁶⁵*Supra* at 22.

⁶⁶The College of Physicians and Surgeons of Manitoba, "Brain Death Protocol", January 26, 1983.

⁶⁷Conference of Commissioners on Uniformity of Legislation in Canada, *Proceedings of the Forty-seventh Annual Meeting* (August, 1965) at 31. In
(Footnote continued to page 42)

this effect. It essentially provides that when a transplant requires the post-mortem donor to have sustained brain death with intact circulation,⁶⁸ the determination of death shall be determined by two physicians. It further stipulates that neither physician can have any association with the proposed recipient which might influence his/her judgment, nor can they later participate in the transplant procedures. We recommend a similar provision be added to Manitoba's *Human Tissue Act*. Our recommendation, in detail, is as follows:

RECOMMENDATION 4

That The Human Tissue Act provide that where a successful transplant requires the donor to have sustained brain death with intact circulation, the determination of death be made by two physicians who

- (i) do not have any association with the proposed transplant recipient which might influence their judgment; and*
- (ii) do not later participate in the transplant procedures.*

It was noted earlier in this Part of our Report that signed organ donor cards do not provide the most important means of donor identification. We are of the view, however, that they serve an important purpose, and we encourage their continued use and distribution. Donor cards prompt awareness and consideration of organ donation and may serve to stimulate useful discussion. Their educational value should not be underestimated.

(Footnote continued from page 41)

1970 the Uniform Law Conference of Canada amended the Act and again in 1971 further amendments were made, including a change of title to the *Uniform Human Tissue Gift Act*. See Conference of Commissioners on Uniformity of Legislation in Canada, *Proceedings of the Fifty-second Annual Meeting* (August, 1970) at 36 and *Proceedings of the Fifty-third Annual Meeting* (August, 1971) at 76, hereinafter referred to as the *Uniform Act*.

⁶⁸As previously stated in Part I of this Report, this requirement exists with respect to the transplant of vital organs like the heart, liver and kidneys. This need does not extend to the transplant of non-perfusible tissue such as corneas or bone.

The provision on the back of the driver's licence is probably the most accessible donor form. However, we have some concerns regarding this form. First, we note that it is included on the back of the licence simply as a courtesy of the Registrar of Motor Vehicles; there is no legislative requirement for the donation form to be included in the licence.⁶⁹ We think that the Legislature should ensure the continued existence of the donor card. We recommend:

RECOMMENDATION 5

That section 27 of The Highway Traffic Act be amended to provide that the form to consent to the donation of cadaveric tissue under The Human Tissue Act be part of the particulars of the licence.

The form on the back of the driver's licence provides for consent under *The Human Tissue Act* for the donation of "my body" or "the following specified parts of my body". However, as previously detailed, *The Human Tissue Act* only regulates the removal and use of tissue. The donation of whole bodies for anatomical examination is governed by *The Anatomy Act*. It has been brought to our attention that uncertainty exists as to whether persons who indicate on their drivers' licences their wish to donate their "body" are authorizing the use of any part of their body under *The Human Tissue Act* or authorizing the donation of their whole body to the University under *The Anatomy Act*.⁷⁰ The present donation provisions found on the back of the Manitoba driver's licences are ambiguous and inconsistent with the existing legislation. Changes are undoubtedly required.

The ambiguity regarding the donation form could be easily resolved by clearly differentiating between the donation of any needed organs or parts of the body and the donation of the whole body for anatomical examination. However, we think that the confusion regarding the donation begs a much

⁶⁹Subsection 27(2) of *The Highway Traffic Act*, C.C.S.M. c. H60, provides for the particulars of the licence form. Reference to the donor form is absent.

⁷⁰Dr. Peter H. Markesteyn, Chief Medical Examiner for Manitoba, January, 1985; Ms. Del Johnston, Transplant Co-ordinator, Health Sciences Centre, Winnipeg, January, 1985.

broader question. That is, should there be two separate statutes i.e. *The Anatomy Act* and *The Human Tissue Act*, governing the donation of the whole body, on the one hand, and body tissue, on the other?

Our concern regarding the fact that cadaveric donation is divided between two statutes is more than just one of form. We noted previously that the donation system under *The Anatomy Act* is one of 'weak contracting-in'.⁷¹ It appears to us that there is a need to rationalize these two disparate systems. We have a further concern with the donation system under *The Anatomy Act*. That is, there is no statutory protection in favour of a person who does not wish to have his/her body donated for anatomical examination. Under *The Human Tissue Act*, it will be recalled that there is a qualification to the removal of tissue pursuant to the direction of the nearest relative; tissue cannot be removed pursuant to that direction where there is reason to believe that the deceased, if living, would have objected. No similar qualification is provided for where the claimant wishes to donate the deceased's whole body under *The Anatomy Act*. We are of the view that the wishes of the deceased should be absolute. The claimant should not be able to defeat the wishes of a deceased where (s)he wishes to donate. Nor should the claimant be able to donate the deceased's body where (s)he has reason to believe the deceased, if living, would have objected. If the donation of the whole body was provided for under *The Human Tissue Act*, these objectives would be met. Moreover, the consolidation would simplify general donor cards. It would also make Manitoba's law in this area uniform with most other North American jurisdictions.⁷² Accordingly, we recommend:

RECOMMENDATION 6

That the scope of The Human Tissue Act be broadened to provide for the donation of the whole body for anatomical examination in addition

⁷¹While it is true that the donation system under *The Human Tissue Act* is, in practice, one of 'weak contracting-in', later in this Part of our Report we recommend that those directly involved in the donation process administer that process in conformity with the legislation.

⁷²Both the *Uniform Human Tissue Gift Act* (1971) and the *American Uniform Anatomical Gift Act* (1968) deal with donation of the whole body and the donation of body tissue.

to the donation of human tissue for therapeutic, educational and research purposes.

There is one further matter of substance which we should like to address before we turn to examine the proper form of the driver's licence. This pertains to the minimum legal age of a donor. *The Human Tissue Act* stipulates that one must be 18 years of age or over to complete a donor card. We were led to re-examine this question of age when we were wrestling with the subject of which age groups should be able to consent to an *inter vivos* donation of tissue. As detailed later in Part III of this Report, we concluded that there are many minors who are quite capable of understanding the nature and effect of the removal of tissue. On this principal basis, we concluded that age should not be an absolute qualifier but that, instead, the right to donate should lie where a person is found to have sufficient capacity of understanding.

The law of *inter vivos* donation can be a law of specific application while the law governing cadaveric donation must be of general application. Accordingly, age is the right criterion to be used for cadaveric donation. But should it be 18 years when 16 year olds may be quite capable of understanding the ramifications of a direction? If the law allows 16 year olds to donate their living tissue, would it not be inconsistent to preclude them from signing donor cards allowing their tissue or their whole body to be used after death?

It is difficult to draw the line at any particular point: persons mature at various rates such that some 14 year olds would fully understand the meaning of a direction while others at 16 years would not. There is no "right" answer. After due consideration, we recommend:

RECOMMENDATION 7

That The Human Tissue Act be amended to allow a minor who has attained 16 years of age to make a direction for the use and removal of tissue or donation of the whole body where a parent of the minor also consents in writing to the direction.

(ii) Driver's licence

Finally, we have considered the organ donation form on the back of the driver's licence. To resolve the ambiguities presently surrounding that form and to incorporate the changes we have proposed regarding donation under *The Human Tissue Act*, we recommend:

RECOMMENDATION 8:

That the organ donation form on the Manitoba driver's licence be amended to be similar to the following:

IF YOU WISH TO DONATE YOUR BODY OR PART OF YOUR BODY FOR USE FOR HUMANITARIAN PURPOSES AFTER DEATH, PLEASE COMPLETE THE FORM BELOW.

CONSENT UNDER THE HUMAN TISSUE ACT, C.C.S.M. c. H180

I, _____
CONSENT TO THE USE, AFTER MY DEATH OF; (Check Appropriate Box)

- a) ANY NEEDED ORGANS OR PARTS OF MY BODY; or
 THE FOLLOWING SPECIFIED PARTS OF MY BODY,
NAMELY:

FOR (Strike Out Purposes Not In Accordance With Your Wishes)

TRANSPLANT AND OTHER THERAPEUTIC PURPOSES/
MEDICAL EDUCATION PURPOSES/
SCIENTIFIC RESEARCH PURPOSES.

OR

- b) MY WHOLE BODY FOR PURPOSES OF ANATOMICAL EXAMINATION.

CO-SIGNATURE OF PARENT WHERE
DONOR UNDER 18 YEARS OF AGE

SIGNATURE

We are also of the view that an information brochure should be sent out with driver's licence renewal applications. This would constitute one aspect of the ongoing educational programme referred to in Recommendation 3. As well, it would serve to assist persons in making an informed decision when filling out the organ donation form attached to the licence. We therefore further recommend:

RECOMMENDATION 9

That a pamphlet be distributed with the application for renewal of a driver's licence, including information respecting such matters as

- the need for human tissue and the whole body;*
- the tissue for which there is a particular demand;*
- the procedure for the declaration of death (see Recommendation 4);*
- the various options presented on the donor form;*
- the importance of informing close family members of one's wish to make a post-mortem donation.*

(iii) A central registry?

It has been suggested that the supply of available human tissue would increase in Manitoba if there were established a central computerized register of willing donors. Such a system could record whether a person had consented to the donation of tissue or the donation of the whole body and possibly provide a medical profile to facilitate their post-mortem use. The register could then be consulted following the deaths of suitable donors to determine if they had previously recorded their consent. If so, removal could begin immediately; if not, the consent of the nearest relative would be required.

The Commission has considered whether a donor registry system should be recommended in Manitoba. It is our view that a registry of donors should *not* be established at this time. Our reasons for not favouring its establishment are set forth below.

Our first concern pertains to the effectiveness of such a register. To be truly effective, the register would have to function 24 hours a day, every day, and provide up-to-date information to ensure its continuing accuracy:

Practically, a registry is fraught with major problems. The first and most important concerns the temporary nature of next-of-kin relationships. Through marriage, divorce, and death, family relationships change. Each change requires a fresh entry for the registry. Second, under this system modifying the scope of the gift is cumbersome: each time an individual wishes to change the gift, he or she must report back to the registry. Third, the creation and maintenance of such a registry will be costly. Finally, a registry forces physicians to go through an additional mechanism, which may not be up-to-date, rather than rely on a donor card or deal directly with the family.⁷³

Even if it were possible to establish a truly effective registry, we question whether it would increase the supply of human tissue. Indeed, it is arguable that the establishment of a registry might, in fact, *reduce* the supply of human tissue. It will be recalled that surveys have shown that a majority of persons who express a willingness to donate their tissue have not, in fact, signed donor cards.⁷⁴ Although this suggests that many of those who would not record their consent in a registry would nevertheless be willing to have their tissue donated, their family might think otherwise. That is, they might think that the deceased's failure to record consent in the 'official' register was tantamount to the deceased's rejection of the idea of donation. This could falsely influence their decision against donating the deceased's tissue. For these reasons, we recommend:

RECOMMENDATION 10

That a donor registry not be established in Manitoba at this time.

We are fortified in this view by the fact that a similar position

⁷³*Supra* n. 52, at 8.

⁷⁴*Supra* at 24-25 of this Report and accompanying authorities.

was reached by the Law Reform Commission of Australia⁷⁵ and the Minister's Task Force on Kidney Donation.⁷⁶

(iv) Obligatory indication of wish?

Another mechanism which we have considered is whether the public should be obliged to indicate their wish regarding donation on some government form. This could be a driver's licence or M.H.S.C. registration card. Essentially it would require each person to answer a question on donation phrased similar to the form on the reverse side of the driver's licence. A person would be required to answer either affirmatively or negatively. So as to protect a person's privacy, a third box could be added to be checked by those who would prefer not to answer any question regarding donation.

There has been no empirical research undertaken in Manitoba to determine what percentage of the public would answer affirmatively. However, statistics available in other jurisdictions would suggest that an obligatory recording could reduce the supply of potential donors up to 30% of the present amount.⁷⁷ Because we are not certain that an obligatory recording would effectively increase the supply of tissue, we recommend:

RECOMMENDATION 11

That a mechanism of donor identification, known as obligatory indication of wish, not be established in Manitoba at this time.

(v) Conduct of health care professionals

Previously in this Part of our Report, we referred to the fact that the practice of health care professionals is to request donation from the nearest relative even when they are apprised of the fact that the deceased had made an earlier direction. This in effect gives the nearest relative the authority to countermand the wishes of the deceased. This practice does not

⁷⁵The Law Reform Commission of Australia, *supra* n. 5, at 95.

⁷⁶Ontario Report, at 101.

⁷⁷Ontario Report, at 41-42.

conform with *The Human Tissue Act* which treats the wishes of the deceased as absolute and not defeasible.

It is understandable that health care professionals would wish to be solicitous of the feelings of the recently bereaved. However, "it needs to be kept in mind that such an approach is to respect the feelings of the relatives more than the wishes of the deceased, which may not be justified".⁷⁸ This practice has been criticized by some of the respondents to our Working Paper who express concern that their written direction will not be carried out because they cannot convince their family to agree with their decision.

It is our recommendation that hospitals and health care professionals in Manitoba should take full advantage of the provisions of the legislation. When it comes to their attention that the deceased made an earlier direction, the family should be simply informed of the deceased's decision only as a matter of formality. This is the practice in four American states - California, Colorado, Florida and Wyoming⁷⁹ - and we recommend its implementation in this province. Our recommendation reads as follows:

RECOMMENDATION 12

That hospitals in this province follow the policy of organ donation presently established by the Legislature in The Human Tissue Act: this means that where the deceased gave an earlier direction concerning donation, the hospital should inform the family of the deceased's express wishes but not give them the opportunity to countermand that direction.

⁷⁸*supra* n. 36, at 61.

⁷⁹Thomas D. Overcast, et. al., "Problems in the Identification of Potential Organ Donors" (1984), 251 (12) J.A.M.A. 1559, at 1562.

(b) Donation where no direction by deceased

(i) The willingness of the nearest relative to authorize the removal of tissue

As previously stated in this Part of the Report⁸⁰ the information we have available suggests that familial attitude is not a major barrier to organ procurement. There are, however, some reforms which we think would improve the process of donation where there has been no earlier direction given by the deceased. These changes are mostly of a legal nature. They are summarized below:

(a) A 'strong contracting-in' system: Our present legislation does not expressly prohibit the nearest relative from giving consent to organ donation where (s)he has reason to believe that the person who died or whose death is imminent would have objected thereto. The *Uniform Human Tissue Gift Act* does contain such a prohibition. As we are of the view that the wishes of the deceased should always be paramount, for clarity we recommend the implementation of a similar provision. Our recommendation is as follows:

RECOMMENDATION 13

That The Human Tissue Act be amended expressly to prohibit the nearest relative from making a direction under the Act if (s)he has reason to believe that the person who died or whose death is imminent would have objected thereto.

(b) Availability of the nearest relative: The legislation establishes a gradational list, beginning with the spouse, and continuing with an adult child, a parent and, finally, an adult sibling. Presently, the legislation is drafted so that it is only possible to move down the prioritized list where no such person exists in a previous category. For example, consent can only be given by an adult child if the deceased had no spouse. If there is a spouse, even if the spouse is unavailable, organ donation cannot be authorized by any family member from the subsequent categories. On the other hand, the *Uniform Human Tissue Gift Act* allows one to move down the list where the family member is "not readily available".⁸¹ We are of the view

⁸⁰*Supra* at 27-28 of this Report and accompanying authorities.

⁸¹The *Uniform Act*, s. 5(1).

that a similar provision is desirable. We recommend:

RECOMMENDATION 14

That The Human Tissue Act be amended so that if the nearest relative is not available, the hospital be authorized to confer with the next nearest relative identified in the legislation.

At present, the Act provides that no person shall act upon a direction given by the nearest relative if (s)he has actual knowledge that another member of the same class of persons as the relative who gave the direction objects thereto. In light of Recommendation 14, this provision requires minor amendment to prohibit action where there is actual knowledge that a member of the same class as the person who gave consent objects or where there is actual knowledge that a member of a prior class (who was not available) objects thereto. We therefore recommend:

RECOMMENDATION 15

That the Act be amended to ensure that no person act upon the direction a relative if (s)he has actual knowledge that a person, who is of the same or closer relationship to the deceased person than the relative who gave the direction, objects thereto.

(c) Those to be included in the prioritized list: As stated previously, the Act presently sets forth a gradational list of 5 groups of persons who may give a direction where the deceased has left none. These are: (1) spouse; (2) an adult child; (3) a parent; (4) an adult sibling; (5) the person lawfully in possession of the body or the Inspector of Anatomy appointed under *The Anatomy Act*.

We recommend that there be two changes made to this list. First, we think that the definition of spouse should be broadened to include a common law spouse. Secondly, we think that the definition of parent should be expanded to include a guardian appointed under *The Child and Family Services Act*.⁸² Both of these changes conform to the views of the majority of the respondents to our Working Paper.⁸³ Our recommendation regarding these

⁸²*The Child and Family Services Act* S.M. 1985, c. 8.

⁸³We also considered whether a separated spouse should be excluded from the definition of a spouse. We concluded that it would be difficult for health care professionals to administer such a law. Moreover, now that the federal law allows persons to apply for a divorce after a 1 year separation it is probable that the definition would already exclude those who are no longer emotionally attached to deceased persons.

changes is as follows:

RECOMMENDATION 16

That the definition of nearest relative under the Act be expanded to allow

- (a) a common law spouse of the deceased; and*
- (b) a guardian of the deceased appointed under The Child and Family Services Act*

the right to authorize the donation of the whole body or the donation of human tissue.

(d) Form of direction: At present, our Act does not provide for the form of consent given by family members. In Saskatchewan,⁸⁴ for example, provision is made for written, oral or mechanically-recorded consent. We believe such clarity is desirable and therefore recommend:

RECOMMENDATION 17

That it be provided that a direction given by the nearest relative under The Human Tissue Act must be

- in a writing signed by the nearest relative;*
- orally by the nearest relative in the presence of at least two witnesses;*
- by the telegraphic, recorded telephonic, or other recorded message of the nearest relative; or*
- by a telephonic message received and heard by two persons from the nearest relative where the two persons subsequently record in writing the nature and contents of the direction.*

(e) Consent of medical examiner: It will be recalled from our earlier discussion of the legislation, that a person cannot remove tissue pursuant to a direction under *The Human Tissue Act* where (s)he has reason to believe that an inquiry or investigation may be required under *The Fatality Inquiries Act* and has not obtained the consent of the medical examiner to

⁸⁴*The Human Tissue Gift Act, R.S.S. 1978, c. H-15, s. 6(1).*

proceed. In fact, the drafting of the Act is imperfect in that the qualification to the removal of tissue pursuant to the deceased's direction arises where "an inquest" is likely. Conversely, the qualification pursuant to the direction of the *nearest relative* arises where "an inquiry or investigation" is likely. The latter phrase is broader than the former. We see no reason for this discrepancy and recommend:

RECOMMENDATION 18

That the Act be amended to ensure that no person shall remove tissue pursuant to the direction of the deceased where that person has reason to believe that an inquiry or investigation may be required to be held respecting the cause and manner of death except with the consent of a medical examiner or chief medical examiner appointed under The Fatality Inquiries Act.

- (ii) The ability and interest of health care professionals to be involved in the organ donation process

We previously summarized the findings of the Ontario Task Force with respect to the interest and involvement of health care professionals in the tissue procurement system.⁸⁵ One key factor which emerges from the study and from others is that the major obstacle to organ procurement is the failure of health care professionals to ask family members about organ donation. One of the solutions which has been suggested to increase the supply is quite remarkable in its simplicity: ASK. More specifically, a policy has been recommended by the Task Force and by others in North America which would require health care professionals to request of family members organ donation where a potential organ donor is identified.

The policy could be extended beyond the involvement of health care professionals in hospitals to the office of the Chief Medical Examiner in Manitoba, and, indeed, whenever a post-mortem examination is conducted. It will be recalled from our overview in Part I that it is quite possible to transplant successfully non-perfusable tissue, such as the corneas, skin and bone, hours after death has occurred. Indeed, we are aware of one office of

⁸⁵*Supra* 28 *et seq.* of this Report.

the Chief Medical Examiner which adopted this policy on a provisional basis in Edmonton, Alberta in August, 1984 with respect to eye donation.⁸⁶ We find the results of the Alberta programme very encouraging. The programme provides a good example of the success which can be achieved through the adoption of a policy of routinely requesting donation from family members.⁸⁷

⁸⁶Dr. John Butt, Chief Medical Examiner, Province of Alberta, January, 1985. Prior to this, the office had practised a passive approach to organ donation: tissues were retained during the performance of an autopsy for purposes of donation only when it was brought to the attention of the medical examiner that the deceased or his family wished to donate body parts (except, of course, with respect to the removal of the pituitary gland pursuant to the *The Fatality Inquiries Act*, R.S.A. 1980, c. F-6, s. 27).

The intention to commence the practice of routinely requesting consent to eye donation was first announced through the media so that the public would be aware of the new procedure.

Bodies which arrive at the medical examiner's office for post-mortem examination are assessed for suitability for eye donation. The critical factors are (1) age (between the age of 4 to 60 years); time of death (known to be within preceding six hours); and (c) absence of certain medical conditions contra-indicating eye donation. If the deceased is determined to be suitable as an eye donor, a member of the investigative staff contacts the deceased's family. Eye donation is discussed in a tactful and positive manner, and the family is given the opportunity to make an educated and informed consent. Where the request is made in person, a consent form is signed; if over the telephone, the conversation is recorded.

We have been advised that approximately 10 percent of the deceased persons upon whom official autopsies are performed are assessed to be suitable eye donors, and in approximately 45 percent of these cases, consent for eye donation is given by the families. Statistics forwarded to us indicate that, as of the end of January, 1985, twenty pairs of eyes had been obtained under this programme.

It is our understanding that the staff involved in making the requests had initially anticipated some discomfort in approaching the families at such a difficult time. However, the experience has proved to be positive; families are not repulsed by being asked to consider eye donation, and no criticism has been voiced by the families or the media. As of a year ago, plans were underway for extending the programme to Calgary, Alberta.

⁸⁷Dr. Peter H. Markesteyn, Chief Medical Examiner for Manitoba, January 1985, has expressed to us his strong support of the Alberta approach. Unfortunately, the staffing in Manitoba is not sufficient to allow for the adoption of a routine request programme in this province at this time. However, whenever possible, the office of the medical examiner does notify a representative from the Eye Bank if a suitable donor is identified. Personnel from the Eye Bank may then contact the deceased's family to seek consent for eye donation. We offer our support and encouragement for the continuation of this practice.

A policy of requesting family members for tissue donation has been legislated in the state of New York. As of January 1 of this year, hospital administrators are required to request the families of patients, who are suitable candidates to make organ donations, to consent at the time of death to an anatomical gift. Exceptions to the request requirement would be permitted when the hospital has (1) actual notice of either contrary intention by the deceased or of opposition by a family member; or (2) reason to believe that an anatomical gift is contrary to the deceased's religious beliefs.⁸⁸ Legislative officials responsible for the implementation of this legislation credit Dr. Arthur T. Caplan, associate director of the Hastings Center, New York for providing its inspiration.⁸⁹

Dr. Caplan is one of the chief proponents of a "required request" policy for health care professionals. His reasons for favouring this policy are set forth below:

A policy of "required request" directly addresses the major obstacles in procuring cadaver organs for transplantation. Such a policy requires that hospital personnel routinely consider the need for transplantable tissues. It ensures that the burden of decisions concerning donation is equitably allocated among all families whose relatives might serve as organ donors. A policy of routine required request standardizes the process of routine inquiring about organ donation in such a way that it lessens the psychological burden on both health professionals and family members at a time of great stress and emotional upheaval. Moreover, it removes the option not to inquire, which is often chosen under the present system because of fears concerning legal and financial consequences. Finally, a policy of required request preserves the right of individuals to refuse consent, since voluntary choice remains the ethical foundation on which organ donation rests.⁹⁰

⁸⁸State of New York, Senate Bill Number 4925-C, entitled *An Act to amend the public health law, in relation to anatomical gifts; consents*, approved by the Governor: August 2, 1985.

⁸⁹*The New York Times*, August 14, 1985, p. A1.

⁹⁰Arthur L. Caplan, "Ethical and Policy Issues in the Procurement of Cadaver Organs for Transplantation" (1984), 311 (15) *New Eng. J. Med.* 981, at 983.

We are of the view that the adoption of a policy of routinely requesting consent from potential donors' families is fundamental in achieving the goal of increasing the supply of donated human tissue. The appropriate person to seek consent in a hospital (e.g. attending physician, ICU nurse, hospital chaplain) or in a medical examiner's office (e.g. investigative officer), could be determined by the individual hospital or office. We recommend:

RECOMMENDATION 19

That a policy of routine request be considered for adoption by hospitals and by offices in which post-mortem examinations are conducted, to be followed whenever a suitable candidate for tissue donation is identified and the prospective donor is not known to have consented to or objected to the post-mortem donation of his/her tissue.

We believe that those directly involved in the health care system are better able than ourselves to specify the manner in which a routine request policy could be administered. However, we put forward for consideration a proposal of the Ontario Task Force on Kidney Donation regarding implementation of the policy in hospitals. The proposal is called "recorded consideration". It would require every physician (or designate) to record on the hospital chart that consideration was given to request the nearest relative for organ donation. The physician (or designate) would record the outcome of the request or, where a request was not made, the reasons therefore. It would leave some discretion with health care professionals in the hospital to assess whether a request would be appropriate, having regard to all of the circumstances of each case, including (but not limited to) the cause of imminent death, the religious beliefs of the deceased or family, and prior opposition expressed by the deceased or family. Concurrently, it would require written reasons where that professional determined that a request for donation was inappropriate.

We believe that there are other measures which could be adopted by hospitals and health care professionals to reduce the number of obstacles to organ procurement. These are set forth below in our final recommendation on this subject. We recommend:

RECOMMENDATION 20

That consideration be given by members of the medical profession, the nursing profession, hospital administrators, hospital and medical associations, organ procurement agencies and government agencies involved with hospital administration and the provision of medical services to the following suggestions

(a) regarding hospital policy and direction:

- Every hospital should establish or adopt
 - an Organ Donation Committee (which is not an ad hoc committee) to implement policies and guidelines respecting the initiation and execution of the organ donation process: lay representation should be included on this Committee;
 - an individual or team responsible for co-ordinating organ donation within the hospital;
 - guidelines and criteria for the identification of suitable organ donors;
 - guidelines for the diagnosis of brain death;
 - guidelines for organ retrieval and donor maintenance;
 - guidelines for effective methods of organ storage.
- The above policies and guidelines should be developed by the hospital Organ Donation Committee in conjunction with provincial hospital and medical associations, and The Manitoba Organ Procurement Committee. Appropriate modifications may be required for small hospitals and hospitals with no Intensive Care Unit.
- The establishment of guidelines and criteria for organ donation within a hospital should be made a necessary requirement for hospital accreditation.

(b) regarding education and expertise:

- A specialized team should be available to travel to hospitals to declare brain death when required.
- An organ retrieval team should be available to travel to hospitals when required.
- A 24-hour telephone advice service should be provided for hospitals seeking information or assistance respecting the organ donation process.

- A transportation system for the rapid and efficient transport of donors, retrieval teams and organs should be developed.
- Hospital personnel who participated in procuring an organ for transplantation should be given recognition for their efforts and provided with feedback as to the outcome of the organ transplant.
- A provincial body responsible for co-ordinating organ retrieval and distribution within the province, and co-ordinating activities with other jurisdictions, should be funded and supported.
- Medical schools, nursing schools and professional associations should provide educational programmes
 - to make physicians and nurses aware of organ transplantation and medical research, the critical shortage of organs, and the important role of medical staff in the organ donation process;
 - to encourage a positive attitude in medical professionals toward organ donation;
 - to educate medical professionals in the identification of suitable organ donors and the procedures involved in the declaration of brain death;
 - to instill within physicians a sense of ethical obligation and professional responsibility to consider organ donation at the time of death of one of their patients.

(c) regarding resources:

- Physicians should receive remuneration for time spent identifying potential organ donors, declaring brain death, obtaining consent to donation and maintaining organ donors.
- Hospitals should be reimbursed for expenses involved in donor maintenance and transportation.
- Families of organ donors should be reimbursed for any costs incurred by them in relation to the donation process.
- Regional hospitals capable of donor support should be clearly identified.

This concludes our recommendations dealing solely with the procurement of cadaveric tissue. In the next Part of our Report, we consider what legislation would be appropriate to regulate the donation of *inter vivos* ("between the living") donation.

PART III

INTER VIVOS TISSUE

A. INTRODUCTION

As we indicated in Part I, there is no legislation in Manitoba governing *inter vivos* donation of tissue. The present *Human Tissue Act* deals only with cadaveric tissue. The common law of *inter vivos* donation is limited: Canadian courts have never directly addressed this issue. However, as was discussed previously, donation of both regenerative and non-regenerative tissue does take place in Canada. In this province, *inter vivos* renal transplants and skin grafts are performed and represent important supplements to those transplants using cadaveric sources. The question for the lawmaker becomes whether the law should generally allow *inter vivos* donations, and if so, subject to what conditions and circumstances.

In answering the threshold question of whether the law should permit *inter vivos* donations, we are of the view that primary consideration should be given to the practical need for tissue procurement from living donors. Also relevant in this regard is the higher success rate of tissue transplants from living donors. Having said that, however, we are of the opinion that the law should define clearly the circumstances and conditions under which *inter vivos* donation should be allowed to continue. Legal regulation is required to lend both certainty and protection to those directly involved: donors and health care professionals. In determining the specific rules which should govern this area, we wish to point out that we do not believe that it is the task of lawmakers to promote or encourage *inter vivos* donation. The extent of its relevance should be left to the discretion of the professionals who are involved on a day-to-day basis with the medical exigencies and developments in this area.

Having concluded that legal regulation of *inter vivos* donation is preferable to absolute prohibition, we turn now to consider what conditions and circumstances should circumscribe the donation process. In order to answer this question properly, it is essential to appreciate the risks attendant with the removal of living tissue. Three types of tissue will be considered: kidneys, bone marrow and skin.

1. Kidney. The graft success rate from living donors was referred to in Part I of this Report.

There are mainly two risks to *inter vivos* donors. The first is the immediate risk associated with the surgical procedure. The second is the long-term risk of living with only one kidney.

Estimates of the surgical risk vary. In one study of 1000 kidney donors, 17% had surgical complications; 2.5% of which were major.¹ Another review of renal donors identified complications in 4.7% of the cases studied.² The threat of death or permanent disability from donation has been estimated at .1%³, although reportedly, the worldwide mortality rate is unknown.⁴

In terms of the long-term medical effects of kidney donation, one study found no substantial physiological effects from living with one kidney.⁵ Indeed, this risk has been described as the same risk that a 25 to 35-year old person takes in driving 8,000 miles a year; life insurance companies accept kidney donors as a normal risk.⁶ Despite this evidence, however, concern still remains over the future health of donors with solitary kidneys.⁷

The immediate and long-term psychological effects of kidney donation have also been investigated. Fear of operations and losing part of one's body, as well as hostility toward the recipient, are some of the possible psychological side-effects involved. However, increased self-esteem, avoidance of guilt and satisfaction from family gratitude have also been identified in *inter vivos* tissue donors.⁸

¹D.E.R. Sutherland, "Living Related Donors Should Be Used Whenever Possible" (1985), XVII Transplant. Proc. 1503, at 1508.

²Ontario Ministry of Health, *Organ Donation in the Eighties: The Minister's Task Force on Kidney Donation* (1985), at 201.

³J. Dukeminier Jr., "Supplying organs for Transplantation" (1970), 68 Mich. L. Rev. 811 at 850, n. 154.

⁴*Supra* n. 1, at 1507.

⁵*Supra* n. 1, at 1509. Researchers analyzed a number of factors including hypertension and creatinine clearance levels in donors.

⁶*Supra* n. 3, at 850, n. 154.

⁷Kidney Foundation of Canada, *Canadian Renal Failure Register, 1984 Report*, at 99.

⁸D.H. Baron, M. Botsford and G.F. Cole, "Live Organ Tissue Transplants from Minor Donors in Massachusetts" (1975), 55 Bos. U.L. Rev. 159 at 164, n. 20.

2. Bone marrow donations. Bone marrow transplants are most frequently performed in cases of aplastic anemia and leukemia. It has been found that with transplants from identical histocompatible donors, a long-term remission rate of 40-80% can be expected. For many patients, no other effective treatment exists;⁹ the mortality rate without transplant is high.

The main risk of bone marrow donation is said to be associated with the requirement for a general or spinal anaesthetic.¹⁰ However, the donation process is also painful and as described below, involves other risks:

. . . the donor is subjected to as many as 200 aspirations of the pelvic bone with a needle specially designed to remove bone marrow. Approximately one pint is removed from an adult and considerably less from a child. The marrow regenerates in a matter of weeks. However, there is a slight possibility of bone fracture, bone infection, or rupture of an artery with loss of limb. In addition, there is a possibility of skin scarring.¹¹

3. Skin grafting. The graft cutting procedure involves removing a layer of skin, usually from the thigh of a donor, who has been administered a general anaesthetic. The process is said to be extremely painful and healing of the donor site is analogous to the healing of deep abrasions or second degree burns. The site will heal in one to several weeks, depending on the thickness of the graft but scarring at the site is inevitable.¹²

From the foregoing, it can be seen that there are immediate surgical risks attendant with each of the three types of *inter vivos* donations described; the main one in each case is associated with the administration of a general anaesthetic. The long-term risks of skin and bone marrow donations are slight as these tissues have the capacity to regenerate. Although some studies have found no major long-term adverse effects of kidney donation, these findings are inconclusive. Thus, the potential risk of living with one kidney remains an important factor for consideration.

⁹National Institutes of Health (U.S.), Technology Assessment Meeting Statement, *Donor Registries for Bone Marrow Transplantation* (May, 1985), at 2 and 14.

¹⁰M.D. Levine, et al, "The Medical Ethics of Bone Marrow Transplantation in Childhood" (1975), 86:1 J. of Pediatr. 145 at 145-46.

¹¹*Supra* n. 8, at 164, n. 20.

¹²R. Rudolph, J.C. Fisher, J.L. Ninnemann, *Skin Grafting* (1984), 131-3.

Aside from the medical risks associated with *inter vivos* tissue donation, it is important to remember that pain and suffering accompany *inter vivos* tissue donation, particularly skin and bone marrow donations. Thus, although these tissues have a regenerative quality, it is difficult to weigh the long-term medical risks of non-regenerative tissue donation against the immediate physical hardship of the donation of regenerative tissue: it cannot be said that donation of one type of tissue involves a higher degree of combined risk and hardship than another. However, we do believe that the concept of permanent versus temporary loss is an important factor distinguishing the donation of a kidney from the donation of skin or bone marrow. We think that recognition should be given to this distinction in determining who should be able to donate tissue and under what circumstances and conditions.

It is important to appreciate the fact that *inter vivos* donation is a non-therapeutic procedure for the donor: no physical benefit accompanies donation. However, the legal principles which govern therapeutic medical procedures are relevant to non-therapeutic procedures, particularly with respect to the requirement of consent. The common law provides, as a general principle, that therapeutic medical treatment may only be undertaken with the valid consent of the patient. To constitute a valid consent, the patient must have the requisite capacity, information and freedom to render consent. Capacity in this respect relates to the ability of the patient to appreciate fully the nature and consequences of the proposed medical treatment. Incapacity may arise by reason of age or mental disorder, so-called "unsound mind". In this way, the law recognizes essentially three distinct groups based upon capacity to consent: adults, minors and the mentally disordered. For the purposes of our discussion we shall similarly categorize donors of *inter vivos* tissue.

In the remainder of this Part of our Report, we examine these three categories of living donors separately. Our analysis begins with a summary of the relevant law. We then turn to consider options for reform and assess their relative merits. Each section concludes with our recommendations for reform.

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B. ADULT DONORS

1. The Present Law

(a) Therapeutic medical procedures

As briefly discussed previously, medical treatment may only be undertaken where three conditions have been met: a patient has the requisite capacity, information and freedom to give consent. First, in terms of capacity, adults are presumed to have the capacity to choose to agree or disagree to proposed therapeutic medical procedures. This freedom of choice is based upon the fundamental principle that persons who are of the age of majority have personal autonomy and, as a corollary to this, are accountable for their decisions. The presumption of an adult's capacity to consent, in the medical context, may be rebutted where (s)he is under the influence of drugs or alcohol, in an emergency situation or otherwise unable to freely exercise his/her will.

With respect to the second requirement for valid consent - adequate information - the Supreme Court of Canada, in the case of *Hopp v. Lepp*¹³ has stated that a physician,

. . . should answer any specific questions posed by the patient as to the risks involved and should, without being questioned, disclose to him the nature of the proposed operation, its gravity, any material risks and any special or unusual risks attendant upon the performance of the operation.¹⁴

¹³(1980), 112 D.L.R. (3d) 67.

¹⁴*Id.*, at 81.

Finally, the patient must give his/her consent *voluntarily*. This means that the patient must be free from coercion, deceit or fraudulent misrepresentation. In the case of *Reibl v. Hughes*,¹⁵ the Supreme Court of Canada stated that, where there has been "misrepresentation or fraud to secure consent",¹⁶ an action in battery may lie against the medical practitioner.

The practitioner who administers treatment in the absence of valid consent may be liable in battery and negligence. Generally, battery is appropriate where there has been no consent at all or where surgery or treatment has been performed or given beyond that to which there was consent. On the other hand, an action in negligence arises where the adequacy of consent is in question due to the failure to inform the patient fully.

The application of these general principles of consent will now be examined in the context of *inter vivos* donations.

(b) *Inter vivos* donation

In Canada, it may be questionable whether *inter vivos* donation is lawful, even if the prospective donor is an adult. Section 45 of the *Criminal Code* authorizes surgery only for the "benefit" of an individual where it is "reasonable to perform the operation". Also, it is arguable that a surgeon who removes tissue for donation purposes could be charged under s. 228(a) of the *Code* which deals with "maiming". It would appear, however, that

. . . the question of criminality in such cases [adult donors] appears realistically to be moot. There are, after all, statutes approving live donations in several provinces. The procedure has

¹⁵(1980), 14 C.C.L.T. 1.

¹⁶*Id.*, at 14.

become an accepted medical practice and evidently a socially acceptable one as well.¹⁷

As there is no legislation which permits *inter vivos* tissue donation in Manitoba and no Canadian decisions on point, the legal positions of both physicians and donors are unclear. However, given that donations do take place in Manitoba, it must be assumed that, in practice, the principles which govern therapeutic procedures are being applied in relation to *inter vivos* donations. That is, removal of tissue from a competent adult is undertaken where the patient renders consent to the procedure. However, there has been some suggestion that, as *inter vivos* donation is non-therapeutic, additional safeguards to the common law are required. In any event, it is evident that legislation is needed in this area to clarify the legal positions of the surgeon and donor and, perhaps, to offer protection to the donor which has not otherwise been provided. We turn now to consider some of the legislative proposals concerning adult tissue donation as well as the principles behind these proposals.

2. Options for Reform

There is a wide spectrum of opinion as to how the law should deal with *inter vivos* donation of tissue by adults. At the liberal end of this spectrum is the view that *inter vivos* donations should be treated like any other medical procedure, according to the common law requirements. Namely, donations should be allowed if an adult, who is competent and adequately informed, voluntarily consents to the donation of tissue. At the other, more restrictive end of the spectrum, is the view that *inter vivos* donations should not be permitted under any circumstances. Proponents of this view point to the problems of obtaining valid consent to such procedures and the need to protect donors from their own philanthropy. Between these two extremes fall proposals which allow for adult donations subject to certain

¹⁷G. Sharpe and G. Sawyer, *Doctors and the Law* (1978) 224.

socially

safeguards. The first proposal discussed here adopts the aforementioned liberal approach.

(a) The Uniform Human Tissue Gift Act¹⁸

Part I of this Act, which deals with *inter vivos* donations, applies the common law principles which govern therapeutic medical procedure to such donations. To date, eight provinces and one of the territories have adopted this Part of the *Uniform Act*.¹⁹ Subsection 3(1) provides that,

Any person who has attained the age of majority, is mentally competent to consent, and is able to make a free and informed decision may in writing signed by him consent to the removal forthwith from his body of the tissue specified in the consent and its implantation in the body of another living person.

As "tissue" is defined in the *Uniform Act* as essentially non-regenerative in nature, the scope of the Act is effectively limited to renal donations. In addition, such donations are allowed for transplant purposes only. The only difference to the common law provided by section 3 is the requirement of

¹⁸Conference of Commissioners on Uniformity of Legislation in Canada, *Proceedings of the Fifty-second Annual Meeting* (August, 1970) at 36 and *Proceedings of the Fifty-third Annual Meeting* (August, 1971) at 76, hereinafter referred to as the *Uniform Act*.

¹⁹New Brunswick and Manitoba are the only provinces which have not adopted legislation in line with the *Uniform Act*. It should be noted that the Newfoundland *Human Tissue Act, 1971*, S.N. No. 66, s. 6, includes an additional provision that a physician may remove tissue as provided in s. 3(1) only if it is reasonable to do so, having regard to the state of health of the person referred to at the time the removal is made and to all the circumstances of the case.

written consent. Arguably, this change is a minimal one, as most hospitals routinely require written consent to all surgical procedures and in some provinces this is a statutory requirement.²⁰

The main criticism of Part I of the *Uniform Act* is that it fails to deal with regenerative tissue, donation of which is presumably left to the uncertainties of the common law. One possible explanation for this omission is that the drafters thought that donation of regenerative tissue did not pose as great a risk, and therefore, was not as contentious an issue as donation of non-regenerative tissue. However, given the attendant pain and risks of bone marrow or skin graft donation procedures, we are of the view that comprehensive human tissue legislation should include provisions governing both non-regenerative and regenerative tissue donation.

(b) The *Draft Health Care Services Consent Act*

Under the auspices of the Ontario Ministries of Health, Community & Social Services and the Attorney-General, the Interdisciplinary Committee on Medical Consent investigated the issue of patient consent to health care services. In December 1979, the Committee submitted their recommendations along with a draft bill incorporating these recommendations.²¹ With respect to *inter vivos* donations the *Draft Act* provides that:

17(1) . . . any person may give consent to the removal of tissue, including skin and bone marrow, from his body, for the purpose of implantation in another living human body or for the purpose of medical education or scientific research.

²⁰See, e.g.: *Hospital Management Regulation*, under the *Public Hospitals Act*; R.R.O. 1980, Reg. 865, s. 50.

²¹Ontario Interministerial Committee on Medical Consent, *Options on Medical Consent - Part 2* (1979) and the *Draft Health Care Services Consent Act* - hereinafter referred to as the *Draft Act*.

This section is limited to persons who are mentally competent, as donations by incompetent donors are dealt with separately. It is important to note that the Act deals with tissue donation in a more comprehensive manner than does the *Uniform Act*, as it provides for donation of both regenerative and non-regenerative tissue. However, it does not provide any safeguards to the common law principles respecting consent. To date, Ontario has not passed the *Draft Act*.

(c) The Australian Transplantation and Anatomy Ordinance²²

In June 1977, the Australian Law Reform Commission reported on the subject of human tissue transplants. Included in the Report was a draft Ordinance which has since been substantially adopted by a number of the Australian states and territories.²³ The draft Ordinance provides that both non-regenerative tissue and regenerative tissue may be donated if the following four conditions are present:

- (1) the donor is legally adult (over 18 years of age);
- (2) the donor is of sound mind;
- (3) the donor's consent is based on independent medical advice; and
- (4) the donor's consent is in writing.

²²Australia Law Reform Commission, *Human Tissue Transplants*, (Report No. 7, 1977), with the draft Transplantation and Anatomy Ordinance hereinafter referred to as the "Draft Ordinance".

²³The *Transplantation & Anatomy Ordinance 1978*, Australian Capital Territory, No. 44 of 1978; *The Human Tissue Transplant Act 1979*, Northern Territory, *The Transplantation and Anatomy Act 1979*, Queensland, No. 74 of 1979, as am. by No. 21 of 1984 and No. 90 of 1984; *The Transplantation and Anatomy Bill 1983*, South Australia; *The Human Tissue Act 1982*, Victoria.

There is also a provision which expressly gives donors the power to revoke their consent anytime before tissue is removed. Further, there is a "cooling off" period of 24 hours after consent is given, before the removal of non-regenerative tissue can take place.²⁴

It should be noted that a distinction is also drawn between non-regenerative and regenerative tissue in terms of the purposes for which they may be donated. Non-regenerative tissue (kidney) may only be removed for transplants while regenerative tissue may be removed for "other therapeutic, scientific or medical purposes". We believe this distinction between the purposes for which non-regenerative and regenerative tissue may be removed is a legitimate one. Later in this Part, we recommend it be one of the principles adopted by our Legislature for the removal of tissue from living adult donors.

(d) The Quebec Civil Code

In 1971, Quebec introduced three new articles to its *Civil Code* to deal with experimentation, transplants from cadavers and *inter vivos* transplants.²⁵ Article 20 deals with the latter topic and provides, in part that,

A person of full age may consent in writing to disposal *inter vivos* of a part of his body or submit to an experiment provided that the risk assumed is not disproportionate to the benefit anticipated.

The problem we see with this provision is in the interpretation of the substantive condition "not disproportionate to the benefit anticipated". Is *the test an objective or a subjective one, or a combination of both? The*

²⁴Draft Ordinance, ss. 9, 10.

²⁵*Civil Code*, Art. 20, as am. by S.Q. 1971, c. 84, s. 3.

meaning of the term "benefit" is also unclear. Given that donation is not physically beneficial to the donor, benefit may refer to a psychological, social, or even spiritual benefit to the donor, or it may refer to the anticipated benefits to the recipient.

Although the Code appears to provide more protection to the potential donor than does the common law, we think that this provision is too broadly drafted for its implementation to be accepted in this common law jurisdiction. More specific legislative direction is desirable for both physicians and donors, particularly in light of the health risks associated with *inter vivos* donations.

3. Recommendations for Reform

(a) The purposes for which tissue donation should be authorized

One of the issues which must be addressed is the *purpose* for which tissue donation should be allowed. Two distinct approaches to this question arise from our review of the options for reform. The first approach is that taken by the Ontario *Draft Act*. This legislation authorizes both non-regenerative and regenerative tissue to be donated by an adult for the purposes of a transplant, medical education or scientific research. Quebec's provision is equally as broad. The second, more restrictive approach is that found in the Australian draft Ordinance. This provides that non-regenerative tissue may be donated for transplant purposes only, while regenerative tissue may be donated for transplant purposes as well as for "other therapeutic, scientific or medical purposes".

We are of the opinion that the second approach is preferable. This coincides with our view that there is a conceptual distinction between regenerative and non-regenerative tissue. As kidney donation involves permanent removal of an organ, it should be confined to circumstances where transplant is contemplated. For regenerative tissue, legally competent adults should be authorized to donate tissue for other therapeutic, scientific or medical purposes. We recommend:

RECOMMENDATION 21

That legislation authorize adult living donors to donate

- (a) specified non-regenerative tissue for the purpose of a transplant; and
- (b) specified regenerative tissue for therapeutic, scientific or medical purposes

subject to the procedures set forth in Recommendation 2 of this Report.

(b) The procedures governing adult donation

The *Uniform Act* and the *Ontario Draft Act* both incorporate the notion that, in relation to donation, adults should be free to deal with their bodies as they wish, subject only to the normal requirements of consent. As the potential adult donor relies on his/her own maturity and experience in reaching a decision, additional safeguards are not seen as necessary. This approach upholds the philosophy that a donor should have the right to donate tissue, even in circumstances which may appear to be against his/her best interests. The operative premise is the supremacy of personal autonomy.

Critics of this approach argue that it is more difficult to secure valid consent to a non-therapeutic donation than to a therapeutic procedure: the potential donor may be highly susceptible to pressures from family, physicians and the potential recipient. Indeed, they argue that it is questionable whether a person can ever render an informed and voluntary decision to donate tissue, particularly to a family member.

At least one study supports this view. In that study, none of the thirty kidney donors studied weighed alternatives and reached the decision to donate in a rational manner. Twenty-three of the donors made the decision "irrationally", "in a split second", without resort to the usual "decision-making process". For another five of the donors, donation was the inevitable result of a long process of screening and testing which eliminated

all other candidates. These donors did not reflect on the question of whether to donate, but simply followed through with the donation as a matter of course. In all cases, the "decision" to donate was made before the sessions with the transplant doctors in which relevant information was put before these individuals and they were finally asked to decide.²⁶

Critics of the "laissez-faire" approach also argue that the determination of whether the potential donor has validly consented to donation is left to the physician who is involved in the transplantation process and who is faced with a conflict which may colour his/her judgment. That conflict is between the physician's responsibility to save, or greatly improve, the quality of the life of the potential recipient by securing the necessary donation, and his/her duty to ensure that the potential donor is adequately protected from abuse.²⁷ As this problem does not arise in the therapeutic context, it is suggested that the patient in this non-therapeutic situation may require additional safeguards to those afforded by the common law.

The Quebec and Australian approaches to this problem provide some additional substantive procedural protections. These include a "risk factor" and the requirement that independent medical advice be secured prior to donation. Other procedural suggestions have included compulsory psychiatric

²⁶C.H. Fellner and J.R. Marshall, "Kidney Donors - The Myth of Informed Consent" (1970), 126 *Amer. J. Psychiat.* 1245 at 1247.

²⁷C. Sugiyama, "Inter vivos Transplantation and the *Human Tissue Gift Act*, S.O. 1971 c. 83" (1976), 34 *U.T. Fac. L. Rev.* 124 at 136, n. 90. And see, *supra* n. 2, at 209 where 42% of donors and potential donors studied perceived *no risks* prior to donation, reflecting the lack of information provided by health care professionals.

evaluation of all potential donors,²⁸ review by a compulsory screening committee composed of members of the medical and legal communities²⁹ and the provision of a higher standard for consent in donation cases, comparable to that required in human experimentation.³⁰

We have considered the range of substantive and procedural protections which may be established to govern *inter vivos* donation. In principle, we are of the view that the "laissez-faire" tradition associated with therapeutic procedures should generally apply to the donation of tissue. However, we believe that the determination of whether a potential donor has rendered a valid consent to the removal of specified tissue should be made by an "independent" physician who is not associated with either the transplant procedures or the potential recipient. It will be recalled from Part II of this Report that a similar safeguard was recommended for the determination of brain death in cadaveric donation. The law should ensure that there is no "reasonable apprehension of bias", to borrow a phrase from the field of administrative law.

We are also of the view that to ensure compliance with the common law requirements of consent, donors should provide their consent in writing, in the presence of an independent physician. That physician should, in turn, certify *in writing* that (s)he is satisfied that each condition of valid consent (capacity, information and voluntariness) has been met. Accordingly, we recommend:

²⁸D.M. Bernstein and R.G. Simmons, "The Adolescent Kidney Donor: The Right to Give" (1974), 131 *Amer. J. Psychiat.* 1338 at 1342.

²⁹*Supra* n. 27 at 136, n. 89.

³⁰*Supra* n. 27, at 136, n. 90 - *Halushka v. University of Saskatchewan* (1965), 53 D.L.R. (2d) 436 (Sask. C.A.).

RECOMMENDATION 22

That the legislation provide that the donation of specified non-regenerative and regenerative tissue by an adult be authorized where a physician, who has had no association with a proposed recipient of tissue that might influence his/her judgment, certifies in writing that

- (a) the consent in writing of the person, the terms of which consent are set out in the certificate, was given in his/her presence;
- (b) (s)he explained to the proposed donor, before the consent was given, the nature and effect of the removal and use of the specified tissue; and
- (c) (s)he is satisfied that the proposed donor has attained the age of 18 years, understands the nature and effect of the removal and use of the specified tissue, and that the consent has been freely given.

C. MINOR DONORS

1. The Present Law

(a) Therapeutic medical procedures

In Manitoba, any competent person 18 years of age or over may give valid consent to therapeutic medical treatment and care. Any person under this age is not competent to consent to medical treatment and his/her parent or guardian is vested with the authority to give consent on his/her behalf. This authority is based on the common law principle that the parent or guardian is responsible for the physical and mental health and well-being of the child.³¹ Only in circumstances where the parent fails to fulfil these duties may a court, exercising its *parens patriae* jurisdiction, step in to protect the child.³²

³¹See, *Hepton v. Maat*, [1957] S.C.R. 606. See also: *The Child and Family Services Act*, S.M. 1985 c. 8, s. 17(b)(iii).

³²See also, s. 197(1) of the Canadian *Criminal Code* which provides that a parent/guardian is under a legal duty to provide necessities of life to a child under 16 years of age. This includes the duty to provide medical necessities, *R. v. Brooks* (1902), 5 C.C.C. 372 (B.C.S.C.) and *R. v. Tutton and Tutton* (1985), 14 W.C.B. 10 (Ont. C.A.).

However, the common law recognizes two exceptions to the principle that a minor may not consent to medical treatment. These exceptions are known as the "mature minor" and the "emancipated minor" rules. Minors who fall within these categories have the capacity to consent to therapeutic medical treatment.

A mature minor is one who is able to appreciate fully the nature and consequences of a proposed medical procedure. This minor is usually close to the age of majority and has the maturity and intelligence to provide valid consent. The mature minor rule was applied in the case of *Johnston v. Wellesley Hospital*.³³ The plaintiff brought an action in negligence against a dermatologist for the administration of acne scar treatments which were undertaken with the consent of the plaintiff when he was nineteen-years old. In finding that there had been sufficient authorization for the treatments, the Court stated that a minor could be:

. . . obviously intelligent and as fully capable of understanding the possible consequences of medical or surgical procedure as an adult I can find nothing in any of the old reported cases, except where infants of tender age or young children were involved, where the Courts have found that a person under 21 years of age was legally incapable of consenting to medical treatment.³⁴

The second category is the emancipated minor. These are minors who have a lifestyle that is so independent of their parents that they have assumed responsibility for their own lives. A married minor or one who is financially independent and living away from home are the principal examples of minors included within this category.³⁵

These exceptions fill in a conceptual "gap" between a child of tender years or "immature minor" and an adult, where it seems logical that a minor

³³(1970), 17 D.L.R. (3d) 139 (Ont. H.C.). The age of majority in Ontario at that time was 21 years.

³⁴*Id.*, at 144.

³⁵E. Picard, *Liability of Doctors & Hospitals* (1984) 56. And see, *Booth v. Toronto General Hospital* (1910), 17 O.W.R. 118 (K.B.).

should be able to consent to therapeutic medical treatment. However, medical practitioners have been hesitant to accept the consent of a patient under the age of majority in light of the possible consequences should their assessment of the maturity or the independence of the patient be incorrect.³⁶ In response to this problem, a number of provinces, of which Manitoba is not one, have lowered the legal age required to consent to beneficial medical care.³⁷ Some of the other provinces have looked into this question but, as yet, have not followed suit.³⁸

These common law and statutory developments in relation to therapeutic medical treatment of minors are instructive when considering non-therapeutic treatment of minors. The mature and emancipated minor rules demonstrate that the courts do not regard age as the only factor to be considered in determining whether a minor may consent to medical treatment. In addition, the provincial legislation in this area indicates that some jurisdictions believe that, as a matter of public policy, minors should be able to consent to therapeutic treatment. How far the judiciary and the state have gone in extending these developments to the administration of non-therapeutic medical procedures on minors, specifically *inter vivos* donations, is the subject of the next section.

³⁶*Id.*, at 55 referring to Boldt, "The Provision of Birth Control Services to Unwed Minors, A National Survey of Physician Attitudes and Practices" (1982), 73 Can. J. Pub. Health 392.

³⁷*Medical Consent of Minors Act*, S.N.B. 1976, c. M-6.1 - age sixteen; *Public Health Protection Act*, L.R.Q. 1977, c. P-35, s. 42 - age fourteen unless extended treatment is necessary; *Hospital Management Regulation* under the *Public Hospitals Act*; R.R.O. 1980, Reg. 865, s. 50 - age sixteen where treatment is undertaken in hospital; *Infants Act*, R.S.B.C. 1979, c. 196, s. 16 - age sixteen.

³⁸Law Reform Commission of Saskatchewan, *Proposals for a Consent of Minors to Health Care Act* (1980). Alberta Institute of Law Research and Reform, *Consent of Minors to Health Care* (Report No. 19, 1975). See also: Conference of Commissioners on Uniformity of Legislation in Canada, *Proceedings of the Fifty-Seventh Annual Meeting*, (August, 1975) at 30.

(b) Inter vivos donation

From the foregoing discussion of consent to therapeutic medical treatment, two questions arise with respect to the involvement of minors in *inter vivos* donation procedures. First, is parental consent sufficient authority for a donation? Second, are there any circumstances where a minor alone may validly consent to a donation?

Although there are no Canadian cases which deal with *inter vivos* transplants, there is a body of American jurisprudence which is instructive in showing how the legal system has grappled with these issues. The American courts have used three basic tests in determining whether to authorize *inter vivos* donations by minors.

(i) Best interests test

The issue of *inter vivos* kidney donation by minors was first dealt with in three cases from the Massachusetts Supreme Court, each involving a set of identical twins.³⁹ In each of these cases, the Court used a two-pronged approach in its consideration of whether it should authorize the operation. First, it questioned the potential donor (two were aged 14 and one was aged 19) to determine if he was of sufficient intelligence to understand the nature and consequences of the proposed operation. Next, the Court assessed what impact would result to the healthy twin if the operation did not take place and his brother died.⁴⁰

In each case, the Court authorized the operation on the basis that the donor understood the nature and consequences of the operation and that the operation was necessary for the continued good health and well-being of the healthy twin as well as the ill one. The Court found that the death of the donee would be so traumatic to the donor that it would be in the best

³⁹*Masden v. Harrison*, Eq. No. 68651, (Mass., June 12, 1957); *Huskey v. Harrison*, Eq. No. 68666, (Mass., Aug. 30, 1957); *Foster v. Harrison*, Eq. No. 68674, (Mass., Nov. 20, 1957).

⁴⁰W.J. Curran, "A Problem of Consent: Kidney Transplantation in Minors" (1959), 34 N.Y.U.L. Rev. 891, at 893-94.

interests of the donor to try to save his brother. In determining the best interests of the donor, the Court relied on its finding that psychological benefits would accompany donation. These benefits were the donor's feeling that he had done something to save his brother's life and the "grave-emotional impact" that would result if donation were not undertaken and the brother died.⁴¹

A number of commentators have criticized the interpretation of the best interests test used in these and subsequent decisions where *inter vivos* donations from minors have been authorized.⁴² The effort to find a psychological benefit has been characterized as, "an unpalatable charade of a parade of psychiatric experts finding a 'benefit' in what is patently non-beneficial to the donor."⁴³ In addition the quality of psychiatric testimony has also been criticized as,

. . . consciously providing the court with the necessary words to satisfy the psychological benefit finding required as a condition to granting the requested relief. The sense of contrivance is strongest when the donor, as in some recent cases, is too young to have developed the kind of deep ties with his sibling that the testimony suggests.⁴⁴

⁴¹*Id.*, at 893.

⁴²C.H. Baron, M. Botsford, G.F. Cole, "Live Organ & Tissue Transplants from Minor Donors in Massachusetts" (1975), 55 B.U.L.R. 159 at 169. The authors note that "[t]he Massachusetts court appears to have followed the best interests approach in almost all cases." And at n. 15, p. 161, they list some 19 additional cases from Massachusetts (involving kidney and bone marrow) between 1957 and 1970. See also, Earl F. Rose, "Medicolegal Problems Associated with Organ and Tissue Transplantations" (1984), 31 Med. Trial Tech. Q. 99 at 104, which notes that since the 1957 cases, ". . . 22 additional court orders granting permission for minor donors have been given in Massachusetts, and there have been no refusals involving kidney, bone marrow and skin transplants. Connecticut, Georgia, Maryland, Illinois, Kentucky & Virginia have followed the Massachusetts precedents."

⁴³G.S. Sharpe, "The Minor Transplant Donor" (1975), 7 Ottawa L. Rev. 85 at 98.

⁴⁴Baron, *supra* n. 42 at 171, and n. 63, where the authors note the cases
(Footnote continued to page 80)

Given the artificiality of the psychological benefit approach, a number of suggestions have been made to explain the true underlying rationale for the decisions in the three landmark cases from Massachusetts. First, it has been argued that the court simply applied the mature minor rule as each of the donors was able to appreciate the nature and consequences of the proposed procedure.⁴⁵ Some courts have used this approach to authorize donation.⁴⁶ However, this interpretation does not explain why the Massachusetts court went out of its way to find a benefit to the donor. A second interpretation is that the finding of benefit, albeit psychological, transformed the otherwise non-therapeutic procedure into a therapeutic one. Once a finding of benefit was made by the court, it did not have to provide further authorization, as parental consent to the donation was now sufficient legal authority.⁴⁷

The final interpretation of these decisions, and in our opinion the most satisfactory, is expressed by one commentator as follows:

The court neither dismissed the action on the ground that no effective consent could be rendered nor authorized it on the ground that consent of either the parents or the 14-year-old donor could be treated as effective. Instead, it heard evidence and decided for itself whether, under the circumstances, the operation should be permitted to go forward.⁴⁸

In effect, it is arguable that judicial authorization was sought in these cases to determine "the lawfulness of the procedure", so as to protect

(Footnote continued from page 79)
of: *Camitta v. Alcorn*, Eq. No. 74-23 (Mass., Feb. 14, 1974) - four-year old donor; *Camitta v. Schillinger*, Eq. No. 74-18 (Mass., Jan. 31, 1974) - five- and eight-year old prospective donors; recipient less than one-year old.

⁴⁵Baron, *supra* n. 42, at 169.

⁴⁶*Infra*, at 82.

⁴⁷Baron, *supra* n. 42, at 171.

⁴⁸Baron, *supra* n. 42 at 161.

the physicians and hospital involved in performing the transplant from future legal action.⁴⁹ It is questionable whether the interests of the minor donors were really the paramount considerations. It would seem that a court would not want to stand in the way of technological advance, especially an advance that is life-saving. Therefore, it was incumbent on the Massachusetts court to find some basis for the authorization of the transplant, that basis being psychological benefit. Only a few courts have formulated alternative approaches to the question of *inter vivos* donations by minors.

(ii) Review of parental decision or the "fair and reasonable test"

In *Nathan v. Farinelli*,⁵⁰ the best interests test was rejected as being highly speculative. In this case, the court was asked to authorize the transplantation of bone marrow from a six-year old donor to her ten-year old brother, who was suffering from aplastic anemia. The court stated that the best approach,

. . . is to consider that the primary right and responsibility for deciding the delicate question of whether bone marrow should be taken from Tony and transplanted in William is that of the parents with reference to both children.⁵¹

Judicial review of the parents' decision was necessary as they faced a conflict in determining what was in the best interests of both their children. The Court found that the parents had properly weighed the costs and benefits of the transplant to each child and had reached a "fair and reasonable" decision in concluding that the transplant should occur.⁵²

This judgment has been praised as being a "forthright approach" which

⁴⁹D.H. Meyers, *The Human Body and The Law* (1970) 123.

⁵⁰Eq. No. 74-87, (Mass., July 3, 1974).

⁵¹*Id.*, at 10.

⁵²*Id.*, at 11.

correctly rejects the best interests test.⁵³ It suggests that the decision as to whether a minor should be required to donate tissue should be made by weighing the interests of the donor against those of the donee.

(iii) Minors' consent - Application of the mature minor rule

A third test is that applied by the Massachusetts Supreme Court in the case of *Rappeport v. Stott*.⁵⁴ Here the Court approved the donation of bone marrow by a seventeen-year old on the basis that he was "capable of consenting to the proposed procedure so as to prevent the creation of liability therefor."⁵⁵ The Court did not attempt to find any psychological benefit to the donor nor did it attempt to review the parents' decision.

It has been argued that if a person is incapable of consenting to a proposed non-therapeutic medical procedure by reason of age or mental handicap, then no person or authority should be allowed to render proxy consent on his/her behalf.⁵⁶ By limiting donation, as in this case, to mature or emancipated minors, valid consent is actually rendered by the donor. This is in keeping with the general principle applicable to medical treatment that treatment may only be undertaken with the valid consent of the patient.

However, the problem with this approach is that it limits the instances where a minor will be able to donate. It has been argued that,

[t]he law should not deny absolutely the life-saving potential of transplants to individuals for whom the only suitable prospective

⁵³G.J. Annas, L.H. Glantz, B.F. Katz, *Informed Consent to Human Experimentation* (1977) 85. See also, *Hart v. Brown*, 289 A. 2d 386 (Conn. Sup. Ct. 1972) where a 7-year old was allowed to donate a kidney to her identical twin. Evidence was given by a psychiatrist, clergyman, guardian *ad litem* for the donor and donee and the parents.

⁵⁴Civil No. J. 74-57 (Mass., Aug. 28, 1974).

⁵⁵*Id.*, at 3.

⁵⁶*Supra* n. 43 at 99.

donors are young minors, especially in cases in which there is an overwhelming probability that the prospective donor would consent were he old enough to give an informed and considerate decision.⁵⁷

As will be seen, these two opposing approaches are also reflected in the different legislation which has been proposed or adopted in various jurisdictions.

(iv) Summary of the American common law

To return to the questions raised at the beginning of this section, according to the American decisions, is parental consent sufficient authorization for *inter vivos* donation by a minor? Are there any circumstances where a minor alone may validly consent to *inter vivos* donation? Although the American courts have provided no clear and consistent analysis by which to answer these questions, a number of broad principles are discernible from the case law.

1. It is evident that parental consent to *inter vivos* donations of regenerative and some non-regenerative tissue is insufficient authority to protect a hospital and its physicians from liability for a non-consensual operation. Generally, court authorization is sought where a kidney or bone marrow transplant is contemplated.

2. The exception to the first principle is in the case of a mature minor. (By analogy, it is arguable that the exception should also include an emancipated minor.) Where a minor is close to the age of majority and is able to appreciate fully the nature and consequences of the non-therapeutic procedure, his/her consent may be sufficient authorization.

3. The best interests test has often been applied in determining whether *inter vivos* donation by minors should be allowed. Critics point to the artificiality of a "psychological benefit" and how application of this test, in practice, has undermined the substantive interests of minors.

⁵⁷Baron, *supra* n. 42, at 176.

4. Another approach which has been used by some courts is the review of parental decisions to ensure that the decision to allow a child to donate to a sibling is fair and reasonable. This involves weighing the costs and benefits to the donor and donee of the proposed procedure.

In summary, it is difficult to balance the rights and interests of a minor donor against the life or health of a potential recipient. Some commentators have noted that, in theory, the best interests of the minor should be the paramount consideration in the determination of whether *inter vivos* donation of tissue should be permitted.⁵⁸ Unfortunately, in applying the best interests test, the American courts have simply engaged in a cost-benefit analysis or have relied on questionable psychiatric evidence to find a benefit to the donor. However, it may be that with adequate safeguards, a court could find a proper balance between the interests of the potential donor and the potential recipient. The following survey of statutory authority and proposed legislation suggests some possible approaches to this question.

2. Options for Reform

(a) The Uniform Human Tissue Gift Act

The *Uniform Act* effectively prohibits *inter vivos* donation of tissue (defined as not including regenerative tissue) by minors. It provides that a transplant from one living human body to another may only be done in accordance with the Act, but not otherwise,⁵⁹ and there is no provision for donations by minors. However, if a physician removes tissue from a minor because (s)he mistakenly believes that the minor has attained the age of majority or that the minor could give a free and informed decision, the minor's consent will operate as valid authority for the physician to undertake the procedure.⁶⁰

⁵⁸Baron, *supra* n. 42, at 178.

⁵⁹The *Uniform Act*, s. 2.

⁶⁰The *Uniform Act*, s. 3(2).

Much of the literature dealing with these provisions is highly critical.⁶¹ It is thought that the prohibition of donation by minors was in reaction to the American decisions,⁶² which included authorization of donations by very young children.⁶³ As Bernard Starkman points out in his discussion of these provisions,

[l]egislation by reaction may be flawed by overreaction, a failure to deal with important related issues and an absence of clear and supportable public policy positions arrived at through careful analysis of possible options. The blanket prohibition against minors' donations of non-regenerative tissue is subject to all these criticisms.⁶⁴

He argues that these provisions are biased in favour of facilitation of medical practice and protection of the physician. And notably, the legislation "was enacted in response to physicians' requests for legislative protection in performing organ transplant operations . . .".⁶⁵

This view is reinforced by the fact that the *Uniform Act* provides that consent by a minor will be valid if the person who acted upon it had no reason to believe that consent was not valid. Obviously, this approach fails to provide adequate safeguards to the "unwitting" minor donor. In fact, it is even arguable that this section releases the medical practitioner from his/her common law duty to make enquiries as to the donor's capacity to consent. It has been argued that this provision,

⁶¹See, B. Starkman, "Consent and the Human Tissue Gift Acts: A Rationale for Change" (1980), 1 *Health L. Can.* 5; C. Sugiyama, *supra* n. 27, R.B. Middleton *et. al.*, "Provincial law for giving transplant material moving toward uniformity" (1973), 108 *C.M.A.J.* 1455.

⁶²Starkman, *id.*, at 5.

⁶³*supra* n. 43 and n. 61.

⁶⁴Starkman, *supra* n. 61, at 5.

⁶⁵Starkman, *supra* n. 61, at 5.

. . . would seem to imply that doctors are entitled to presume capacity to consent unless the patient gives indications to the contrary. In view of the nature of the procedure involved ("non-beneficial"), it is arguable that the presumption should favour a *lack* of capacity⁶⁶

Even in the absence of "a reverse onus" provision it seems evident that at least some elementary safeguards should be required to ensure that the donor has capacity to consent. Again, we note that, as the *Uniform Act* does not deal with regenerative tissue, the problem of minor donations of skin grafts and bone marrow is left unresolved.

The problems with the *Uniform Act* are summed up by Starkman as follows:

The Act is an overreaction which attempts to protect minors by arbitrarily excluding them as a class from being possible donors and which then makes substantial inroads on protection for donors in an effort to shield physicians from the consequences of an absence of safeguards for their patients' protection.⁶⁷

(b) The Quebec Civil Code

Quebec's approach to the issue of *inter vivos* donations by minors is in sharp contrast to that of the Uniform Law Conference of Canada. The 1971 amendments to the *Code* made provision for *inter vivos* donations by minors. As stated earlier, Article 20 of the *Civil Code* provides that an adult may consent in writing to *inter vivos* disposal of a part of his/her body provided that the risk assumed is not disproportionate to the benefit anticipated.⁶⁸ The *Code* goes on to provide that:

A minor capable of discernment, may do likewise with the consent of the person having the parental authority and a judge of the Superior

⁶⁶*Supra* n. 27, at 135.

⁶⁷Starkman, *supra* n. 61, at 6.

⁶⁸*Civil Code* Art. 20, as am. by S.Q. 1971..

Court, provided that no serious risk to his health results therefrom.⁶⁹

This approach has been praised by critics of the *Uniform Act*. They maintain that Article 20 "better accommodates the competing interests of the medical profession and the potential transplant donor . . .".⁷⁰ In allowing donations by discerning minors, the *Code* emphasizes the ability to consent rather than age as the main factor in determining who should donate tissue. The requirement of parental and judicial approval, as well as the "risk" provision, are additional safeguards to the potential minor donor.

(c) The Australian Transplantation and Anatomy Ordinance⁷¹

As indicated earlier, this Ordinance was prepared and recommended for implementation in a report by the Australian Law Reform Commission.⁷² In the case of *inter vivos* donation of tissue by minors, the draft Ordinance deals separately with regenerative and non-regenerative tissue.

Inter vivos donation of regenerative tissue may be made by a minor (under 18 years of age) to a family member or relative if the following circumstances exist:

1. the minor understands the nature and effect of the removal of tissue and the nature of the transplantation, and agrees to the removal;
2. a parent consents, in writing, to the removal;
3. independent medical advice is given to the parent and the minor by a medical practitioner who is not part of the transplant

⁶⁹*Civil Code* Art. 20, as am. by S.Q. 1971.

⁷⁰*Supra* n. 27, at 139. It is generally acknowledged that "a minor capable of discernment" refers to a minor who is able to appreciate fully the nature and consequences of the proposed procedure.

⁷¹*Supra* n. 22.

⁷²*Supra* n. 22.

team.⁷³

As a general rule, donation of non-regenerative tissue by a minor is prohibited.⁷⁴ However, an exception to this rule exists in the following circumstances:

1. the minor and potential recipient are members of the same family;
2. there exists independent medical evidence that the potential recipient is in danger of dying if the transplant does not occur;
3. there is independent medical evidence as to the nature and effect of the removal and transplantation;
4. the parents of the minor have consented, in writing, to the removal;
5. the minor understands the nature and effect of the removal and the nature of the transplantation, and agrees to the removal;
6. an ad hoc committee of three independent persons, which includes a judge, a medical practitioner and one other person, (a social worker or psychiatrist) has considered all of the available facts and unanimously agrees that the removal is in the best interests of the minor.⁷⁵

The philosophy behind this legislation is stated as follows:

The pressure for permitting tissue donation by young persons below the general age of majority arises from the tragic circumstances in which the requirement can occur. Cases have been known in which a child may die without a successful transplant.⁷⁶

⁷³Draft Ordinance, s. 14.

⁷⁴Draft Ordinance, s. 13.

⁷⁵Draft Ordinance, s. 15.

⁷⁶*Supra* n. 22, at 49.

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However, as donation is a non-therapeutic procedure, the legislation reflects the concern that additional safeguards are necessary to protect the donor adequately. In this regard, the Act clearly differentiates between donation of regenerative and non-regenerative tissue.⁷⁷ Consent by the parents and a physician are the only requirements necessary for regenerative tissue donation by a minor. Non-regenerative tissue donation is permissible where further conditions are met: namely, where the life of a family member is in danger and a committee decides that the donation is in the best interests of the minor.

Some critics of the Australian legislation object to the idea that a minor should be allowed to donate non-regenerative tissue, even under special circumstances. It is argued that a minor should not be "forced" to participate simply because others sanction the procedure. However, even in the face of this type of criticism as well as a request from the Australian College of Pediatrics to delete the non-regenerative tissue section,⁷⁸ the philosophy of the Commission has prevailed in a number of Australian states and territories.⁷⁹

(d) The Draft Health Care Services Consent Act⁸⁰

As previously indicated, the *Draft Act* provides that any person may give consent to the removal of tissue, including skin and bone marrow, from his/her body, for the purpose of implantation into another living human body or for the purpose of medical education or scientific research.⁸¹

⁷⁷As seen earlier, the American courts and the *Uniform Act* make no such distinction.

⁷⁸P.D. Phelan, "Comment" on "Some Medico-Legal Implications of The Human Tissue Transplant Act" (1979), 2 *Med. J. Aust.* 536.

⁷⁹*Supra* n. 23.

⁸⁰*Supra* n. 21.

⁸¹*Draft Act*, s. 17(1).

This provision governs donors who are mentally competent to consent. In regard to "special procedures" such as, *inter vivos* tissue donations, anyone under the age of majority may not donate unless certain procedures are followed.⁸²

First, the health care provider must determine whether the minor is competent.⁸³ This finding is subject to review by a superior court.⁸⁴ If the patient is found to be incompetent, a parent or other approved individual must consent to the proposed procedure. The physician then must consider whether the patient meets the criteria established for the performance of the surgical procedure.⁸⁵ In the case of kidney donation, the Interministerial Committee suggests the following criteria in their recommendations:

- (1) the likelihood of the patient dying without the transplant;
- (2) the fact that other reasonable alternatives, such as dialysis and cadaver kidneys, would not be appropriate;
- (3) the minimal risk to the donor;
- (4) the fact that the donor represents the closest match, so use of this organ offers the best chance of success.⁸⁶

These criteria are not embodied in the *Draft Act* but there has been some suggestion that they would be provided in the final legislation.⁸⁷ Presumably, similar considerations could be adopted with respect to bone marrow and skin graft donations.

⁸²*Draft Act*, ss. 7, 17(2).

⁸³*Supra* n. 21, at VI.

⁸⁴*Supra* n. 21, at VII.

⁸⁵*Supra* n. 21, at XVII.

⁸⁶*Supra* n. 21, at XV-XVI.

⁸⁷Starkman, *supra* n. 61, at 7.

The determination of incompetency, the appropriate parental consent and the physician's certification that the procedure meets the necessary criteria, would then be forwarded for consideration before a special committee composed of physicians, lawyers and lay persons. An "Official Guardian" would represent the incompetent and, if a majority of the Committee approved, the tissue removal would take place.⁸⁸

3. Recommendations for Reform

As we have seen from our review of the options, there are essentially two basic approaches to legislation governing the donation of tissue from minors. The first is absolute prohibition. This approach was essentially adopted by the Uniform Law Conference of Canada. An advocate of this approach has explained his position thus:

If adults cannot be compelled to undergo self-mutilating surgery, I remain wholly unpersuaded why children should be subjected to intolerable social, family and psychological pressure, which would never arise in the absence of such a law. . . . It is my firmly held belief that this provision transcends the ethical imperatives of the medical profession and should be firmly resisted.⁸⁹

The second school of thought maintains that tissue donation should be allowed by minors, but only in special circumstances and under specific conditions. This philosophy is reflected in the Australian legislation, the Quebec *Civil Code*, the Ontario *Draft Act* and the American common law; as we have seen, each provides its own set of circumstances and conditions where minor donation will be permitted.

We prefer the second approach: that is, that minors should be authorized to donate tissue in certain instances and subject to certain conditions. We have arrived at this conclusion for two reasons. First, we do not believe that absolute prohibitions should be legislated where life is

⁸⁸*Supra* n. 21, at XVIII.

⁸⁹p. Gerber, "Some Medico-Legal Implications of the Human Tissue Transplant Act" (1979), 2 *Med. J. Aust.* 533, at 535.

being jeopardized. Second, we believe that prohibiting minors from donating means choosing *age* rather than *capacity* as the principal factor in determining legal authorization. The selection of the age of majority as the determining factor in this context has been described as,

. . . an inappropriate and unnecessary importation from the law of property into the law dealing with the integrity of the person. Its relevance may be judged from the fact that twenty-one, the former age of majority, was taken from the age requirement for knighthood, which became linked with landholding under the feudal tenurial system introduced by William I from Normandy.⁹⁰

We think that the common law notion that some minors are capable of rendering consent to therapeutic procedures should be applied to the non-therapeutic context and a minor who is capable of rendering an informed and voluntary consent to a proposed donation should not be precluded from doing so simply by reason of age.

(a) The "mature" minor

The issues now to be addressed are in what set of circumstances donation should be authorized and which conditions precedent should be established for donation to take place. Before proceeding to deal with those questions in detail, we set forth below the *possible* circumstances and conditions for consideration:

- (1) The type of tissue which may be donated:
 - (a) regenerative only;
 - (b) non-regenerative and regenerative.
- (2) The purposes for which tissue may be donated:
 - (a) transplant only;
 - (b) other therapeutic purposes;
 - (c) research and educational purposes;

⁹⁰Starkman, *supra* n. 61, at 6.

- (d) all of the above.
- (3) The safeguards provided:
- (a) procedural:
- (i) minor's consent or agreement;
 - (ii) parental consent;
 - (iii) review by and information supplied by an independent physician;
 - (iv) review by a superior court judge;
 - (v) appointment of a guardian *ad litem*.
- (b) substantive:
- (i) best interest test;
 - (ii) review of reasonableness of parents' decision;
 - (iii) "no serious risk to the health" of the minor;
 - (iv) donor and recipient members of the same immediate family.

It is our general view that where a determination has been made that a minor understands the nature and consequences of a proposed procedure, the law should treat him/her like an adult. We have used the word "like" advisedly as we think that three further conditions to those recommended for adults should be required for mature minors. These are that (1) the minor donor and the recipient be members of the same immediate family; (2) the tissue be donated for transplant purposes only; and (3) the consent of a parent be required. We have added these conditions because we think that non-therapeutic procedures in the case of minors should be confined to circumstances where familial need and support are present. To this extent, we would not extend our "laissez-faire" philosophy regarding adults *mutatis mutandis* to minors; some recognition must be given to both the legal and factual reality of adulthood. Our recommendation regarding the right of a mature minor to donate living tissue is as follows:

RECOMMENDATION 23

That where a minor is found to be capable of understanding the nature and effect of the removal and transplant of specified regenerative or non-regenerative tissue from his/her body, (s)he may consent in writing to the removal from his/her body of the specified tissue, for the purpose of the transplant of that tissue to a member of his/her immediate family.

Having established that a mature minor may donate living tissue, the question arises regarding who should make the determination as to whether any particular minor is competent to consent. We think that a minor would be sufficiently protected if an independent physician certified the minor's competency in writing. In the event that a physician was uncertain as to the minor's ability to understand the nature and consequences of the proposed removal and transplant of tissue, an application could be brought to the Court of Queen's Bench for such a determination. We think that this superior court would be the appropriate forum. Its members have the attributes of impartiality, a good grasp of procedural fairness and some background regarding capacity in the field of therapeutic medical procedures. We recommend:

RECOMMENDATION 24

That, subject to Recommendation 25, the determination of whether a minor is capable of understanding the nature and consequences of the removal and transplant of specified tissue be made by an independent physician who must certify in writing that,

- (a) the consent in writing of the minor and a parent of the minor, the terms of which consent are set out in the certificate, was given in his/her presence;*
- (b) the minor and the potential recipient are members of the same immediate family;*
- (c) (s)he explained to the minor and to the parent of the minor the nature and effect of the removal and transplant of the tissue specified in the consent; and*
- (d) (s)he is satisfied that*
 - (i) the minor understands the nature and effect of the removal and transplant of the tissue, and*
 - (ii) the consent of the minor and of the parent are freely given.*

RECOMMENDATION 25

That where a physician is not satisfied that a minor understands the nature and effect of the removal and transplant of the tissue, an application be brought before a judge of the Court of Queen's Bench for an order that the minor is competent to consent to the removal of the specified tissue.

(b) The "immature" minor

The final question for determination with respect to the *inter vivos* donation of tissue by minors is whether donation should be confined to "mature" minors only or whether there are any circumstances and conditions where an "immature" minor should be allowed to donate tissue. By the term "immature minor", we are referring to a minor who is unable to appreciate the nature and effect of a proposed removal and transplant of tissue.

It will be recalled from our discussion of the American common law, that courts have routinely permitted "immature" minors to donate tissue. The Interministerial Committee on Medical Consent makes provision for the donation of *inter vivos* tissue by "incompetent" minors. Where a minor has been found to be incompetent, parental consent as well as the approval of a special committee is required. This applies to the donation of both regenerative and non-regenerative tissues for transplant purposes.

We think that of vital practical concern is the necessity of bone marrow and kidney donation from young donors; they may be the only potential histocompatible donors, particularly where a sibling is in need. In the case of kidney donation, however, two factors mitigate the necessity for donations from "immature" donors. First, donation will not normally be life-saving but rather, will be "life-enhancing". Second, other sources, such as living adult donors as well as cadaveric donation may be available. Given these factors, we are of the opinion that immature minors should not be authorized to donate non-regenerative tissue, even with the approval of a court or committee and parental consent.

In the case of bone marrow, however, histocompatibility is crucial and transplant may be life-saving; without a transplant, death is often inevitable. Thus, in this instance, donation of tissue by a young sibling is both critical and perhaps the only option available. As well, the loss to the donor is not permanent. We are of the opinion that to prohibit these transplants would cut off an important life-saving resource. Therefore, we

are of the view that donation of regenerative tissue should be allowed but only where adequate substantial and procedural safeguards are in place. In particular, we believe such donations should occur only where: (1) the proposed donor and recipient are members of the same immediate family; (2) the proposed recipient is likely to die without the transplant in question; and (3) the risk to the life or health of this potential donor is not substantial. These three substantive criteria should be certified, in writing, by an independent physician who has explained the nature and effect of the removal and transplant of the tissue before the minor agrees and the parent provides the required written consent to the donation.

In addition, with respect to procedural requirements, we are of the view that the Court of Queen's Bench should make the determination as to whether regenerative tissue donation by an "immature" minor should be allowed. Again, the employment of the superior court for this purpose reflects our view that its members have the necessary attributes previously identified along with a strong sense of those values involving civil liberties.

We now turn to examine briefly the substantive test which the Court should apply in determining whether to authorize the donation of regenerative tissue. We are not prepared to recommend the "best interests of the child" test traditionally applied by the American courts. We have previously referred to the criticisms of this test and, in particular, to the artificiality of the finding of psychological benefit. Instead, we prefer the second approach adopted by some American courts whereby the court essentially reviews the parents' decision to determine whether it is both "fair and reasonable" having regard to all of the circumstances of the case. This allows the court, in a forthright manner, to balance the risks of donation against the interests of the proposed recipient. We recommend:

RECOMMENDATION 26

That, subject to Recommendations 27 and 28, where a minor, by reason of age, is not capable of understanding the nature and effect of the removal and transplant of tissue from his/her body, a parent of that minor may consent, in writing, to the removal of specified regenerative tissue from the body of that minor for the purpose of the transplant of that tissue to a member of the same immediate family.

RECOMMENDATION 27

That a consent under Recommendation 26 be given in the presence of a physician who shall certify in writing that,

- (a) the consent in writing of the parent, the terms of which consent are set out in the certificate, was given in his/her presence;*
- (b) the minor and the proposed recipient are members of the same immediate family;*
- (c) (s)he explained to the parent and to the minor before the consent was given the nature and effect of the removal and transplant of the tissue of the minor specified in the consent; and*
- (d) (s)he is satisfied that*
 - (i) the potential recipient is likely to die unless the tissue specified in the consent is transplanted to his/her body;*
 - (ii) the minor does not object to the removal of the tissue specified in the consent; and*
 - (iii) the risk to the life or health of the minor is not substantial.*

RECOMMENDATION 28

That a consent under Recommendation 26 be reviewed by a judge of the Court of Queen's Bench who may determine that, having regard to all the circumstances of the case, the consent of the parent is both fair and reasonable.

D. MENTALLY DISORDERED PERSONS

The subject of *inter vivos* donations by persons found to be mentally disordered involves many of the issues already discussed concerning minors. Again, there is no legislation in Manitoba which specifically deals with this issue and there are no Canadian decisions directly on point. And again, the main issue is consent. In the case of medical procedures undertaken for the benefit of the health of mentally disordered persons, the committee of the person may consent to such procedures. However, the question becomes more difficult with respect to non-therapeutic procedures such as

inter vivos donations and sterilization procedures. The main issues for consideration here are in what circumstances, if any, should *inter vivos* donations be undertaken and what safeguards are needed to ensure that the interests of the mentally disordered are not undermined by those directly involved with the donation process: the parents, the potential recipient and the health care professionals.

1. The Scope of the Classification

It is necessary to define the parameters of the mentally disordered in the context of medical treatment. Are individuals who are labelled "mentally retarded" or "mentally ill" to be assumed to be unable to consent? The Law Reform Commission of Canada recently addressed this problem in their Working Paper on the sterilization of the mentally handicapped. After reviewing various methods and criteria to define mental retardation and mental illness, the Commission concluded that no satisfactory definitions could be derived as, ". . . no universally applicable standards can be applied to the mentally handicapped since they do not constitute a cohesive, consistent, or definable group".⁹¹

To determine whether an individual is mentally competent for the purposes of medical treatment, reference must be made to each person's capacity rather than to his/her label as a "mentally disordered" person. It should not be assumed that a mentally disordered person is incapable of rendering consent even if (s)he is institutionalized or subject to a court order or interdiction.⁹² Indeed,

[l]ikewise, a person who is committed under the Criminal Code by Lieutenant-Governor's Warrant, or under The Penitentiaries Act does not lose his right to refuse or consent to treatment.⁹³

As in any instance where competency to medical treatment is at issue, the question is whether a person is able reasonably to understand the

⁹¹Law Reform Commission of Canada, *Protection of Life: Sterilization, Implications for Mentally Retarded and Mentally Ill Persons* (Working Paper No. 24, 1979), at 76.

⁹²*Id.*, at 106.

⁹³L.E. Rozovsky, *Canadian Hospital Law* 2nd ed. (1979) 43.

nature and consequences of the proposed treatment so as to be capable of rendering an informed decision. We are of the view that persons who are competent to consent to the proposed procedure should be permitted to donate, notwithstanding that they may have a mental disability or handicap.

In terms of who should make the determination of whether an individual with a mental disorder is able to understand the nature and effect of a proposed *inter vivos* donation, we are of the opinion that similar concerns as those pertaining to minors arise here. As previously discussed, in a non-therapeutic situation, a physician's objectivity may be compromised where (s)he faces the competing interests of protecting the minor donor and saving the life of the potential recipient. Thus, to protect best the interests of both donor and physician, we recommended that the determination of competency be made by an independent physician who is not associated with either the potential recipient or the transplant proceedings. Where that physician is uncertain as to whether a person who is mentally disordered is capable of understanding, the legislation should allow for an application to be brought to the Court of Queen's Bench. We recommend:

RECOMMENDATION 29

That the determination of whether a person who is mentally disordered is capable of understanding the nature and effect of the removal of specified regenerative or non-regenerative tissue be made by a physician who has had no association with the proposed recipient of tissue that might influence his/her judgment.

RECOMMENDATION 30

That where a physician is not satisfied that a mentally disordered person understands the nature and effect of the removal of tissue, an application may be brought before a judge of the Court of Queen's Bench for an order that the person is competent to consent to the removal of the specified tissue.

Where a person with a mental disorder is unable to render valid consent, the essential question arises as to whether such a person should ever be required to undergo an *inter vivos* donation procedure. This issue will be addressed in the following review of the present common law position in the United States with respect to *inter vivos* donation by mentally disordered persons. Proposals for reform from other jurisdictions will also be reviewed.

2. Inter Vivos Donation

A number of American decisions deal specifically with the issue of *inter vivos* donation of tissue by mentally disordered persons. The American decisions are instructive as they help to identify what legislative initiatives may be required in this area.

For the mentally disordered, the courts have frequently applied the best interests test discussed earlier; where a donor may derive psychological benefit from donation, the transplant will be permitted. The landmark case in this regard is *Strunk v. Strunk*⁹⁴ where 4 of 7 judges of the Kentucky Court of Appeal authorized a kidney transplant from a mentally retarded 27-year old to his brother on the basis of psychiatric evidence to the effect that the death of the donee would have an extremely traumatic effect on the donor.⁹⁵ As in the previously discussed cases dealing with donations by minors, this case turned on psychiatric proof that the operation would be of psychological benefit to the donor.

The criticisms of the best interests test, also discussed earlier, apply *mutatis mutandis* to cases dealing with incompetents. The application of this test to young children and to the mentally incompetent is expressed well by the dissenting judges in the *Strunk* case where they stated that,

[t]he majority opinion is predicated upon the finding of the circuit court that there will be psychological benefits to the ward but points out that the incompetent has the mental age of a six-year old child. It is common knowledge beyond dispute that the loss of a close relative or friend to a six-year old child is not of major impact. Opinions concerning psychological trauma are at best nebulous.⁹⁶

A few decisions, where authority to donate tissue was denied,

94445 S.W. 2d 145 (KY., 1969).

⁹⁵*Id.*, at 145.

⁹⁶*Id.*, at 150.

reflect this latter view. One of these cases was *In re Richardson*⁹⁷ where a 17-year old boy with Down's Syndrome was asked to donate a kidney to his 32-year old sister. Although the petitioner relied on the *Strunk* case as authority to proceed with the transplant, the Court found that the case was factually distinguishable relative to the finding of the best interests of the incompetent. It found no uniquely beneficial relationship between this brother and sister as there was in the *Strunk* case. In addition, Roy Richardson, unlike Jerry Strunk, was of such a low mental age (4 years) as to have no understanding of the procedure and no desire to help his sister. Thus, the court refused the petition on the basis that there was no immediate psychological benefit to the incompetent and, further, there would be no future benefit to him as his sister had never been concerned with him and probably would not be in the future.⁹⁸

On the other hand, unfortunately, courts have relied on *Strunk* in authorizing donations by mentally incompetent individuals in instances which seem more factually analogous to the *In re Richardson* case.⁹⁹ For example, in an unreported case, a 13-year old retarded and almost psychotic boy was asked to donate bone marrow to his brother who suffered from aplastic anemia. There were two other children in the family but the parents refused to allow them to donate and would only consent to donation by the retarded son. A guardian *ad litem* was appointed to represent the interests of the retarded child. There was no dispute that the child was totally unable to

⁹⁷284 So. 2d 185 (La., 1973).

⁹⁸Donation was also refused in *Lausier v. Pescinski*, 226 N.W. 2d 180 (Wis., 1975) at 182 because the death of a sibling would cause the incompetent no anguish and he would derive no psychological benefit from acting as donor.

⁹⁹See: *Little v. Little*, 576 S.W. 2d 493 (Tex., 1979) at 499, where the court authorized the donation of a kidney from a 14-year old retarded girl to her brother on the basis that the risks were minimal and that not only would she derive psychological benefit because of "lack of sadness" but she would also experience increase in "personal welfare". See also: *Howard v. Fulton-Dekalb Hospital Authority*, 42 U.S. Law Week 2322, where the court authorized donation of a kidney from a 15-year old mentally retarded girl to her mother.

understand the nature of the procedure or derive any benefit from it but the procedure was allowed.¹⁰⁰

Application of the psychological benefit test, first expounded in the three Massachusetts cases, to situations where mentally disordered persons have limited intellectual capacity, has been criticized as a judicial justification for donation when, in fact, the underlying rationale in these cases is the balancing of the social worth of two individuals. In the *Strunk* case, Mrs. Strunk's testimony illustrates this point.

Every person has some purpose in life, even those who have the misfortune of being born with very low mental capacity. It must be Jerry's [the incompetent] purpose, then, because he has been denied the mental ability to make any contribution to date, to now donate an organ of his body to save the life of the one person he loves the most. . . .¹⁰¹

The use of such utilitarian principles in the context of lifesaving donations has prompted the criticism that,

¹⁰⁰*The Children's Hospital Medical Centre et al v. Ralph F. Faber et al*, S. Jud. Ct., Suffolk County, Eq. No. 73-171 (1973). Quoted from: *supra* n. 10 at 147-148. The text from which this summary was taken did not indicate the basis for the court's decision. However, it may have been influenced by the guardian *ad litem's* report in which he "refused to deny this boy the 'right' to help his dying brother simply because others did not have easy access to his cognitive process". Also this case involved regenerative tissue.

¹⁰¹C. J. Cronan, "Spare Parts from Incompetents: A Problem of Consent" (1969), 9 J. Fam. L. 309 at 315, n. 27. It is also interesting to note:

"Indeed, during the hearings in the *Strunk* case, the Director of the Renal Division, University of Kentucky Medical Centre, testified that if something should later happen to the retarded donor's remaining kidney, based on selection criteria at the Medical Centre, the donor would not be eligible for either hemodialysis or transplantation."

Supra n. 53, at 87.

. . . comparing interpersonal utilities, weighing and comparing utilities in particular situations is slippery business and subject to bias and abuse. . . . The long-run social effects of such a precedent will be unpredictable, perhaps including the destruction of the traditional moral values upon which the cohesiveness of society depends.¹⁰²

Arguably, any test which purports to authorize a physically non-therapeutic procedure on the basis that the procedure is psychologically beneficial to the donor at least should be applied in circumstances where persons have the intellectual capacity to derive that benefit. To do otherwise is simply to use the test as a means to achieve a desired end.

3. Options for Reform

(a) The Uniform Human Tissue Gift Act,¹⁰³ the Australian Transplantation and Donation Ordinance¹⁰⁴ and the Quebec Civil Code¹⁰⁵

These proposals prohibit the donation of tissue by mentally incompetent persons under all circumstances. As previously discussed, the *Uniform Act* refers only to non-regenerative tissue while the other two statutes prohibit donation of both regenerative and non-regenerative tissue.

The reasons for these absolute prohibitions are not clear from the background materials to these statutes.¹⁰⁶ It would seem, however, that the philosophy of the legislators must have been that, in the absence of the ability to consent to a non-therapeutic donation procedure, a mentally incompetent person should not be compelled to undergo such a procedure simply because a court or other authority permits it. Even safeguards such as the

¹⁰²J.A. Robertson, "Organ Donations by Incompetents and the Substituted Judgment Doctrine" (1976), 76 Colum. L. Rev. 48 at 51-52.

¹⁰³*Supra* n. 18.

¹⁰⁴*Supra* n. 22.

¹⁰⁵*Supra* n. 25.

¹⁰⁶*Supra* n. 18, n. 22 and Civil Code Revision Office, *Report on the Recognition of Certain Rights Concernings the Human Body*, (1971).

appointment of a guardian *ad litem* are seen as inadequate protection of the interests of the mentally incompetent. Accordingly, the only effective means to avoid abuse is the implementation of an absolute prohibition.

(b) The Draft Health Care Services Consent Act¹⁰⁷

The *Draft Act* provides in section 17, that a mentally incompetent person may donate regenerative and non-regenerative tissue for transplant, education or research purposes if:

- (1) the nearest relative, the Public Trustee or a person designated by the incompetent before he became incompetent, consents to the removal of such tissue; and
- (2) a majority of the Health Procedures Protection Committee, appointed under the Act, approves of such removal.

The Interministerial Committee states in its recommendations with reference to the Ontario *Human Tissue Gift Act*, that,

. . . for incompetent persons, it does not allow that such donations may be warranted on the basis of appropriate criteria, in an analogous fashion to other special procedures.¹⁰⁸

The Committee goes on to indicate, as in the case of minors, what such criteria might be in the case of a kidney donation. Again, these criteria address the minimal risk to the donor and immense benefit to the donee. The same procedure, as described earlier in the case of minors, would also be followed in the case of mentally incompetent persons, including representation by the "Official Guardian" to protect the incompetent's interests at the hearing.¹⁰⁹

It is arguable that this legislation as it pertains to mentally incompetent individuals is simply a codification of the best interests test

¹⁰⁷*Supra* n. 21.

¹⁰⁸*Supra* n. 21, at XV.

¹⁰⁹*Supra* n. 21, at XVIII.

applied by the American courts. Again, this approach is open to the abuse of others weighing the social benefits of two individuals.

4. Recommendations

Essentially, two basic approaches to the issue of *inter vivos* donation by the mentally disordered are discernible from the legislation and decisions in this area.

The first approach is based on the view that surgical intervention, whether therapeutic or non-therapeutic, should only be undertaken if the common law requirements for such intervention are met. That is, a medical procedure may be undertaken only with the valid consent of the patient. Where the patient is not competent to consent, substituted consent should only be permitted where there is an emergency or where the procedure is life-saving or otherwise physically therapeutic to that patient. According to this standard, a mentally disordered person may donate tissue only if (s)he has the capacity to consent to the donation. Under no circumstances, even with court or committee review and a host of procedural safeguards, should a mentally disordered person be compelled to donate live tissue. Australia, Quebec and seven other provinces have adopted this approach.

The second approach subscribes to the view that *inter vivos* donation by incompetent persons should be allowed under certain circumstances. From this premise, two sub-categories of opinion emerge.

The first sub-category is made up of those who advocate application of the best interests test in determining whether, in a particular case, a mentally incompetent person should donate. Since the *Strunk* case, this approach has been applied by the American courts in cases dealing with donation by the mentally handicapped of both regenerative and non-regenerative tissue. Arguably, this is also the approach which would be adopted by the Review Committee to be appointed under the Ontario *Draft Act*.

The criteria used in application of this test are, at best, unclear. The early Massachusetts decisions in the area of minors set the

groundwork for subsequent application of the criterion of "psychological benefit" in cases such as *Strunk* and *Richardson*. The Interministerial Committee has also suggested some criteria in respect to donation of kidneys but both of these seem inadequate. If the best interests test is to be the standard used, then legislation will be necessary to overcome the problem that,

. . . the best interests test can be and has been so vaguely and loosely applied as to permit arbitrary manipulation for utilitarian ends. The test contains no criteria or standards for determining what constitutes a benefit, or the amount of benefit that must be shown in a particular case.¹¹⁰

The second sub-category of opinion, pertaining to what approach should be used in authorizing donations by incompetents, is comprised of advocates of the substituted judgment test. One advocate of this approach, J.A. Robertson, criticizes the best interests approach as being open to abuse by those who would apply utilitarian principles in reaching a decision. He states that, as the determinative factor in medical treatment of competent people is consent or choice, the same factor should operate, as nearly as possible, in treatment of the mentally incompetent. This can be accomplished by focusing on the inferred wishes of the competent person.¹¹¹

This approach is very similar to the best interests test, particularly with respect to young children or a mentally handicapped person with low mental age. In these cases, where it may be difficult to discern the donor's personal preferences, the reasonable person standard would be applied to supplement this information. The great danger of this test seems to be that decision-makers can authorize donation on the basis of imputing an altruistic character to a mentally incompetent individual simply because they perceive him/her to be happy and loving. Even more disturbing is the possibility that application of the reasonable person standard would almost always lead to authorization of donation by the incompetent to members of his/her family.

¹¹⁰*Supra* n. 102, at 56.

¹¹¹*Supra* n. 102, at 62-63.

Arguably both the best interests test and the substituted judgment test are open to abuse. By allowing *inter vivos* donation by the mentally disordered, even with safeguards in place, the decision-maker still is placed in a position where (s)he is forced to decide between the right of inviolability of a person in special need of protection and the life of a person in need of tissue. That the interests of a mentally disordered person could ever be adequately protected in such circumstances, we believe, is highly questionable. Accordingly, our final recommendation on the regulation of *inter vivos* donation is:

RECOMMENDATION 31

That where a person is not found to be capable of understanding the nature and effect of the removal of tissue otherwise than by reason of age, that person be prohibited from donating tissue for any purpose.

This concludes our recommendations dealing solely with the *inter vivos* donation of tissue. In the next Part of our Report, we consider what legislation should be recommended with respect to those issues which apply equally to cadaveric and *inter vivos* donation.

PART IV

FURTHER RECOMMENDATIONS FOR REFORM

In this penultimate part of our Report, we examine those remaining subjects which relate to both cadaveric procurement and *inter vivos* donation. These subjects comprise the commercial use of tissue and the legal exposure of physicians with respect to the removal and use of tissue for transplant and other purposes. Also considered in this Part are recommendations for reform on the issue of privacy, for both donors and recipients, and quasi-criminal concerns pertaining to the appropriate penalties for contravention of the proposed legislation. We deal with each of these areas under separate headings.

A. PRIVACY

The present *Human Tissue Act* contains no provision pertaining to the right of privacy of donors and potential recipients. We think that the inclusion of a section which regulates this topic would be beneficial to these persons.

We have examined the various options of reform and have assessed their relative merits. The *Uniform Human Tissue Gift Act* contains a section which essentially provides that, unless legally required, no information revealing the identity of possible and actual donors and recipients may be released. However, a party to a transplant operation may reveal information about himself/herself. A similar provision is found in the Australian draft Ordinance.¹ However, the Ordinance contains further exceptions to the anti-disclosure principle. One of these is where information is required "for

¹Australia Law Reform Commission, *Human Tissue Transplants*, (Report No. 7, 1977), with the draft Transplantation and Anatomy Ordinance hereinafter referred to as the "Draft Ordinance", s. 47.

the purposes of hospital administration or *bona fide* medical research".²
We think the provision of the *Uniform Act* should be implemented with the proviso that, as a further exception, disclosure may be allowed where it is required for the purposes of hospital administration or medical research. We recommend:

RECOMMENDATION 32

That, subject to Recommendation 33, the legislation provide that no person shall disclose or give to any other person any information or document whereby the identity of any person

- (a) who has given or refused to give a direction or consent;*
- (b) with respect to whom a direction or consent has been given; or*
- (c) into whose body tissue has been, is being or may be transplanted;*

may become publicly known.

RECOMMENDATION 33

That Recommendation 32 not apply to or in relation to information disclosed

- (a) in pursuance of an order of a Court or when otherwise required by law;*
- (b) for the purposes of hospital administration or bona fide medical research; or*
- (c) with the consent of the person to whom the information relates.*

B. COMMERCE IN TISSUE AND WHOLE BODIES

Some suggestion has been made that under the present system of "contracting-in" the legalization or "commerce" in cadaveric and *inter vivos* tissue would greatly enhance the supply of human tissue. With whole bodies and cadaveric tissue, the sale could be effected in a number of ways: payment

²Draft Ordinance, s. 47(2)(b).

could be tendered before actual "performance" of the contract, with price based upon an actuarial calculation of the "transplantable condition" or other use of a specific tissue.³ Alternatively, an agreed price could be paid into the vendor's estate upon his/her death or his/her relatives could sell the body or tissue after death. In terms of *inter vivos* donation, the market for these tissues, especially kidneys, would probably be strong, as there is evidence of worldwide "blackmarket" trading in human tissue.⁴

Not surprisingly, a general free market in bodies and tissue has been widely criticized. First, on a very practical level, the enforcement of contracts for sale of these commodities would involve very perplexing legal and logistic problems.⁵ Second, and more importantly, are the objections based upon moral, ethical and social grounds. As one commentator has stated: "contemporary society makes a considered judgement in a variety of contexts that not everything should be bought and sold."⁶ Examples of these include: sales which tend to subvert the public good; sales in which the presence of markets tend to defeat the purpose of the marketed institution; sales born of desperation; and sales of the basic rights of citizenship.⁷ Arguably commerce in whole bodies and tissue falls within each of these "blocked" contexts.

Commerce in human tissue would likely encourage blackmail, coercion, or duress; cause deterioration in standards of testing; increase the possibility of donors lying or concealing health defects, thus increasing the danger to recipients, as well as wrongly encourage donations from the poor.⁸

³B. Freedman, "The Ethical Continuity of Transplantation" (1985), XVII, *Transplant. Proc.* 17 at 21.

⁴Russell Scott, *The Body As Property* (1981) 181-82.

⁵*Id.*, at 182-83.

⁶*Supra* n. 3, at 21.

⁷*Supra* n. 3, at 22.

⁸*Supra* n. 1, at 86.

There is a further reason against the commercial use of whole bodies and tissue which is of

. . . greater intrinsic importance. That which cannot be sought and sold is by definition priceless. By removing human life and health from the marketplace, we affirm this principle which underlies much contemporary thinking about ethics: the intrinsic, ineliminable, ineluctable value of human life and health. This affirmation is itself a process which can and should be constantly repeated without ever exhausting its point.⁹

For the foregoing reasons, we have concluded that commerce in whole bodies and cadaveric and living tissue should be prohibited. With respect to the scope of the legislation, we note that subsection 15(1) of *The Anatomy Act* already prohibits commerce in whole bodies. We are of the view, therefore, that the prohibition of *The Human Tissue Act* can be confined to commerce in tissue. We recommend:

RECOMMENDATION 34

That the legislation prohibit the purchase or sale, for valuable consideration, of tissue for therapeutic, educational or scientific purposes.

We wish to make two comments about this recommendation. First, it should be noted that, for various reasons identified in Part I, this report does not extend to an examination of the donation of, *inter alia*, spermatozoa or blood and blood constituent. Consequently Recommendation 34 would not prohibit the continuation of a number of programmes involving the donation of tissue which rely on small honorariums. Second, Recommendation 34 does not attempt to preclude the reimbursement of reasonable expenses incurred by donors or their family or the provision of reasonable remuneration to those health care professionals who render their services in relation to the donation process. In regard to this second comment, it may be that some ambiguity exists with respect to the ambit of the prohibition. Accordingly, we recommend:

⁹*Supra* n. 3, at 23.

RECOMMENDATION 35

That the legislation implementing Recommendation 34 contain a savings clause which clarifies that the prohibition does not preclude

- (a) the provision of reasonable remuneration to a person for his/her services rendered in relation to the lawful donation of tissue; and
- (b) the reimbursement of expenses to a donor of tissue, or to his/her family, which expenses have been reasonably incurred in relation to the lawful donation of tissue.

It will be recalled that earlier, in Recommendation 20, we recommended that consideration be given to broadening the present basis for remunerating and reimbursing those persons involved, both professionally and otherwise, in the donation process.

C. PENALTIES

There is no penalty section in the present *Human Tissue Act* where tissue is removed contrary to the provisions of the Act. Without a specific penalty clause, the penalty contained in *The Summary Convictions Act*¹⁰ would apply. The maximum penalty is now fixed at a fine of \$500 or to imprisonment for a term not exceeding 3 months, or to both.¹¹

We think that the penalty for non-compliance with the Act should be higher than this. We note, for example, that the penalty recently stipulated by American federal legislation for infringement of its anti-commerce provision in organ procurement is \$50,000 or imprisonment for a term of 5 years, or to both.¹² We have considered other legislation in Manitoba which imposes penalties for contravention of provisions broadly analagous to the

¹⁰*The Summary Convictions Act*, C.C.S.M. c. S230.

¹¹*The Summary Convictions Act*, C.C.S.M. c. S230, s.4

¹²*The National Organ Transplant Act*, Public Law 98-507, October 19, 1984, s. 301.

sale of tissue. *The Child and Family Services Act*¹³ establishes a maximum fine of \$10,000 for the purported sale of a child. We think that a similar ceiling would be appropriate for contravention of *The Human Tissue Act*. We believe this amount would be appropriate particularly in light of the present commercial value of organs on the "black market". We think that the maximum term of imprisonment should be one year. We recommend:

RECOMMENDATION 36

That the legislation provide that a maximum penalty for infringement of the legislation be a fine of \$10,000 or imprisonment for a one-year term, or both.

We noted earlier that *The Anatomy Act* prohibits the sale of whole bodies. The maximum penalty stipulated for contravention of this provision, and of the Act generally, is \$100.¹⁴ We suggest that this maximum be raised to reflect the severity of the offence of trafficking in dead bodies. A penalty comparable to that we have proposed for *The Human Tissue Act* would, in our view, be appropriate.

D. CIVIL LIABILITY

The *Uniform Human Tissue Gift Act* protects any person "for any act done in good faith and without negligence in the exercise or intended exercise of any authority conferred by [the] Act".¹⁵ A similar provision exists in the Australian Ordinance¹⁶ and the American *Uniform Anatomical Gift Act*.¹⁷ Although these provisions merely codify what is likely the common law position regarding legal exposure, there is merit in making express what is implied. We recommend:

¹³S.M. 1985, c. 8, s. 84

¹⁴*The Anatomy Act*, C.C.S.M. c. A80, s. 26.

¹⁵Conference of Commissioners on Uniformity of Legislation in Canada, *Proceedings of the Fifty-second Annual Meeting* (August, 1970) at 36 and *Proceedings of the Fifty-third Annual Meeting* (August, 1971) at 76, hereinafter referred to as the *Uniform Act*, s. 9.

¹⁶Draft Ordinance, s. 43.

¹⁷*Uniform Anatomical Gift Act*, s. 7(c).

RECOMMENDATION 37

That the legislation protect a person for any act done in good faith and without negligence in the exercise or intended exercise of any authority conferred by the legislation.

This recommendation would not change the law of negligence as it applies to health care professionals. These persons would still be required to observe the normal duty of care provided by tort law.

There is one further legislative provision which we think would be beneficial. The *Uniform Human Tissue Gift Act*¹⁸ clarifies that "[a]ny dealing with a body that was lawful before [the] Act came into force shall, except as provided in [the] Act, continue to be lawful". This saving provision clarifies that other lawful actions, such as anatomical examinations of unclaimed bodies and official autopsies, would not be affected by the Act. These matters are regulated by other statutes, notably *The Anatomy Act* and *The Fatality Inquiries Act*. Reference was made to these Acts in our summary of the present legislation in Part II. Our final recommendation is:

RECOMMENDATION 38

That the legislation contain a savings clause clarifying that any dealing with the whole body or any tissue thereof that was lawful before the Act comes into force shall continue to be lawful, except as provided in the Act.

¹⁸The *Uniform Act*, s. 12.

PART V

LIST OF RECOMMENDATIONS AND THE PROPOSED *HUMAN TISSUE ACT*

A. LIST OF RECOMMENDATIONS

The recommendations of the Commission in this Report are as follows:

PART II

CADAVERIC TISSUE

1. That, subject to Recommendation 2, the requirement of consent to remove human tissue after death for therapeutic, educational and research purposes be retained. (p. 39)
2. That the presumed consent provisions in section 6 of *The Human Tissue Act* not be extended to permit the removal and retention of tissue other than the pituitary gland. (p. 39)
3. That an ongoing educational programme be implemented, aimed at increasing public awareness of organ transplantation and medical research, informing the public about the donation process, and encouraging the public to record and make known their wishes to donate organs. (p. 41)
4. That *The Human Tissue Act* provide that where a successful transplant requires the donor to have sustained brain death with intact circulation, the determination of death be made by two physicians who
 - (i) do not have any association with the proposed transplant recipient which might influence their judgment; and
 - (ii) do not later participate in the transplant procedures. (p. 42)
5. That section 27 of *The Highway Traffic Act* be amended to provide that the form to consent to the donation of cadaveric tissue under *The Human Tissue Act* be part of the particulars of the licence. (p. 43)
6. That the scope of *The Human Tissue Act* be broadened to provide for the donation of the whole body for anatomical examination in addition to the donation of human tissue for therapeutic, educational and research purposes. (pp. 44-45)
7. That *The Human Tissue Act* be amended to allow a minor who has attained 16 years of age to make a direction for the use and removal of tissue or donation of the whole body where a parent of the minor also consents in writing to the direction. (p. 45)

8. That the organ donation form on the Manitoba driver's licence be amended to be similar to the form set forth on page 46 of this Report. (p. 46)
9. That a pamphlet be distributed with the application for renewal of a driver's licence, including information respecting such matters as
 - the need for human tissue and the whole body;
 - the tissue for which there is a particular demand;
 - the procedure for the declaration of death (see Recommendation 4);
 - the various options presented on the donor form;
 - the importance of informing close family members of one's wish to make a post-mortem donation. (p. 47)
10. That a donor registry not be established in Manitoba at this time. (p. 48)
11. That a mechanism of donor identification, known as obligatory indication of wish, not be established in Manitoba at this time. (p. 49)
12. That hospitals in this province follow the policy of organ donation presently established by the Legislature in *The Human Tissue Act*: this means that where the deceased gave an earlier direction concerning donation, the hospital should inform the family of the deceased's express wishes but not give them the opportunity to countermand that direction. (p. 50)
13. That *The Human Tissue Act* be amended expressly to prohibit the nearest relative from making a direction under the Act if (s)he has reason to believe that the person who died or whose death is imminent would have objected thereto. (p. 51)
14. That *The Human Tissue Act* be amended so that if the nearest relative is not available, the hospital be authorized to confer with the next nearest relative identified in the legislation. (p. 52)
15. That the *Act* be amended to ensure that no person act upon the direction of a relative if (s)he has actual knowledge that a person, who is of the same or closer relationship to the deceased person than the relative who gave the direction, objects thereto. (p. 52)
16. That the definition of nearest relative under the *Act* be expanded to allow
 - (a) a common law spouse of the deceased; and
 - (b) a guardian of the deceased appointed under *The Child and Family Services Act*the right to authorize the donation of the whole body or the donation of human tissue. (p. 53)

17. That it be provided that a direction given by the nearest relative under *The Human Tissue Act* must be

- in a writing signed by the nearest relative;
- orally by the nearest relative in the presence of at least two witnesses;
- by the telegraphic, recorded telephonic, or other recorded message of the nearest relative; or
- by a telephonic message received and heard by two persons from the nearest relative where the two persons subsequently record in writing the nature and contents of the direction. (p. 53)

18. That the *Act* be amended to ensure that no person shall remove tissue pursuant to the direction of the deceased where that person has reason to believe that an inquiry or investigation may be required to be held respecting the cause and manner of death except with the consent of a medical examiner or chief medical examiner appointed under *The Fatality Inquiries Act*. (p. 54)

19. That a policy of routine request be considered for adoption by hospitals and by offices in which post-mortem examinations are conducted, to be followed whenever a suitable candidate for tissue donation is identified and the prospective donor is not known to have consented to or objected to the post-mortem donation of his/her tissue. (p. 57)

20. That consideration be given by members of the medical profession, the nursing profession, hospital administrators, hospital and medical associations, organ procurement agencies and government agencies involved with hospital administration and the provision of medical services to the following suggestions

(a) regarding hospital policy and direction:

- Every hospital should establish or adopt
 - an Organ Donation Committee (which is not an *ad hoc* committee) to implement policies and guidelines respecting the initiation and execution of the organ donation process: lay representation should be included on this Committee;
 - an individual or team responsible for co-ordinating organ donation within the hospital;
 - guidelines and criteria for the identification of suitable organ donors;
 - guidelines for the diagnosis of brain death;
 - guidelines for organ retrieval and donor maintenance;
 - guidelines for effective methods of organ storage.
- The above policies and guidelines should be developed by the hospital Organ Donation Committee in conjunction with provincial hospital and medical associations and The Manitoba Organ Procurement Committee. Appropriate modifications may be required for small hospitals and hospitals with no Intensive Care Unit.

- The establishment of guidelines and criteria for organ donation within a hospital should be made a necessary requirement for hospital accreditation.

(b) regarding education and expertise:

- A specialized team should be available to travel to hospitals to declare brain death when required.
- An organ retrieval team should be available to travel to hospitals when required.
- A 24-hour telephone advice service should be provided for hospitals seeking information or assistance respecting the organ donation process.
- A transportation system for the rapid and efficient transport of donors, retrieval teams and organs should be developed.
- Hospital personnel who participated in procuring an organ for transplantation should be given recognition for their efforts and provided with feedback as to the outcome of the organ transplant.
- A provincial body responsible for co-ordinating organ retrieval and distribution within the province, and co-ordinating activities with other jurisdictions, should be funded and supported.
- Medical schools, nursing schools and professional associations should provide educational programmes
 - to make physicians and nurses aware of organ transplantation and medical research, the critical shortage of organs, and the important role of medical staff in the organ donation process;
 - to encourage a positive attitude in medical professionals toward organ donation;
 - to educate medical professionals in the identification of suitable organ donors and the procedures involved in the declaration of brain death;
 - to instill within physicians a sense of ethical obligation and professional responsibility to consider organ donation at the time of death of one of their patients.

(c) regarding resources:

- Physicians should receive remuneration for time spent identifying potential organ donors, declaring brain death, obtaining consent to donation and maintaining organ donors.
- Hospitals should be reimbursed for expenses involved in donor maintenance and transportation.

- Families of organ donors should be reimbursed for any costs incurred by them in relation to the donation process.
- Regional hospitals capable of donor support should be clearly identified. (pp. 58-59)

PART III

INTER VIVOS TISSUE

21. That legislation authorize adult donors to donate
 - (a) specified non-regenerative tissue for the purpose of a transplant; and
 - (b) specified regenerative tissue for therapeutic, scientific or medical purposessubject to the procedures set forth in Recommendation 22 of this Report. (p. 72)
22. That the legislation provide that the donation of specified non-regenerative and regenerative tissue be authorized where a physician, who has had no association with a proposed recipient of tissue that might influence his/her judgment, certifies in writing that
 - (a) the proposed donor consented in writing, in his/her presence, to the donation of the tissue specified in the consent;
 - (b) (s)he explained to the proposed donor, before the consent was given, the nature and effect of the removal and use of the specified tissue;
 - (c) (s)he is satisfied that the proposed donor has attained the age of 18 years, understands the nature and effect of the removal and use of the specified tissue, and has freely consented to the removal. (p. 75)
23. That where a minor is found to be capable of understanding the nature and effect of the removal and transplant of specified regenerative or non-regenerative tissue from his/her body, (s)he may consent in writing to the removal from his/her body of the specified tissue, for the purpose of the transplant of that tissue to a member of his/her immediate family. (p. 93)
24. That, subject to Recommendation 25, the determination of whether a minor is capable of understanding the nature and consequences of the removal and transplant of specified tissue be made by an independent physician who must certify in writing that,
 - (a) the consent in writing of the minor and a parent of the minor, the terms of which consent are set out in the certificate, was given in his or her presence;
 - (b) the minor and the potential recipient are members of the same immediate family;
 - (c) he or she explained to the minor and to the parent of the minor the nature and effect of the removal and transplant of the tissue specified in the consent; and

- (d) he or she is satisfied that;
 - (i) the minor understands the nature and effect of the removal and transplant of the tissue; and
 - (ii) the consent of the minor and of the parent are freely given.
(p. 94)

- 25. That where a physician is not satisfied that a minor understands the nature and effect of the removal and transplant of the tissue, an application be brought before a judge of the Court of Queen's Bench for an order that the minor is competent to consent to the removal of the specified tissue. (p. 94)

- 26. That, subject to Recommendations 27 and 28, where a minor, by reason of age, is not capable of understanding the nature and effect of the removal and transplant of tissue from his/her body, a parent of that minor may consent, in writing, to the removal of specified regenerative tissue from the body of that minor for the purpose of the transplant of that tissue to a member of the same immediate family. (p. 96)

- 27. That a consent under Recommendation 26 be given in the presence of a physician who shall certify in writing that
 - (a) the consent in writing of the parent, the terms of which consent are set out in the certificate, was given in his or her presence;
 - (b) the minor and the proposed recipient are members of the same immediate family;
 - (c) he or she explained to the parent and to the minor before the consent was given the nature and effect of the removal and transplant of the tissue of the minor specified in the consent; and
 - (d) he or she is satisfied that
 - (i) the potential recipient is likely to die unless the tissue specified in the consent is transplanted to his/her body;
 - (ii) the minor does not object to the removal of the tissue specified in the consent; and
 - (iii) the risk to the life or health of the minor is not substantial. (p. 97)

- 28. That a consent under Recommendation 26 be reviewed by a judge of the Court of Queen's Bench who may determine that, having regard to all the circumstances of the case, the consent of the parent is both fair and reasonable. (p. 97)

- 29. That the determination of whether a person who is mentally disordered is capable of understanding the nature and effect of the removal of specified regenerative or non-regenerative tissue be made by a physician who has had no association with the proposed recipient of tissue that might influence his/her judgment. (p. 99)

- 30. That where a physician is not satisfied that a mentally disordered person understands the nature and effect of the removal of tissue, an application may be brought before a judge of the Court of Queen's Bench for an order that the person is competent to consent to the removal of the specified tissue. (p. 99)

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eely given.
31. That where a person is not found to be capable of understanding the nature and effect of the removal of tissue otherwise than by reason of age, that person be prohibited from donating tissue for any purpose. (p. 107)

PART IV

FURTHER RECOMMENDATIONS FOR REFORM

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32. That, subject to Recommendation 33, the legislation provide that no person shall disclose or give to any other person any information or document whereby the identity of any person
- (a) who has given or refused to give a direction or consent;
 - (b) with respect to whom a direction or consent has been given; or
 - (c) into whose body tissue has been, is being or may be transplanted;
- may become publicly known. (p. 109)
33. That Recommendation 32 not apply to or in relation to information disclosed
- (a) in pursuance of an order of a Court or when otherwise required by law;
 - (b) for the purposes of hospital administration or bona fide medical research; or
 - (c) with the consent of the person to whom the information relates. (p. 109)
34. That the legislation prohibit the purchase or sale, for valuable consideration, of tissue for therapeutic, educational or scientific purposes. (p. 111)
35. That the legislation implementing Recommendation 34 contain a savings clause which clarifies that the prohibition does not preclude
- (a) the provision of reasonable remuneration to a person for his/her services rendered in relation to the lawful donation of tissue; and
 - (b) the reimbursement of expenses to a donor of tissue, or to his/her family which expenses have been reasonably incurred in relation to the lawful donation of tissue. (p. 112)
36. That the legislation provide that a maximum penalty for infringement of the legislation be a fine of \$10,000 or imprisonment for a 1-year term, or both. (p. 113)
37. That the legislation protect a person for any act done in good faith and without negligence in the exercise or intended exercise of any authority conferred by the legislation. (p. 114)
38. That the legislation contain a savings clause clarifying that any dealing with the whole body or any tissue thereof that was lawful before the Act comes into force shall continue to be lawful, except as provided in the Act. (p. 114)
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B. THE PROPOSED *HUMAN TISSUE ACT*

ARRANGEMENT OF SECTIONS

SECTION

1 Definitions.

PART I - PROCUREMENT OF TISSUE AFTER DEATH

- 2 Definitions.
- 3 Direction by persons for use of body or tissue after death.
- 4 Direction by nearest relative.
- 5 Removal of pituitary gland.
- 6 Determination of death.
- 7 Where specified use fails.

PART II - DONATION OF TISSUE BY LIVING PERSONS

- 8 Definitions.
- 9 Consent by adult living donor.
- 10 Consent by mature minor living donor.
- 11 Consent by parent where minor is not capable of understanding by reason of age.
- 12 Prohibition of physician with respect to a certificate under Part II.
- 13 Effect of consent under Part II.

PART III - GENERAL

- 14 Civil liability.
- 15 Prohibition.
- 16 Disclosure of information.
- 17 Lawful dealings not affected, exceptions.
- 18 Sale, etc. of tissue prohibited.
- 19 Offence.
- 20 Repeal of former Act.
- 21 Commencement of Act.

THE PROPOSED HUMAN TISSUE ACT

Definitions.

1 In this Act

"adult" means a person who has attained the age of majority;

"minor" means a person who is under the age of majority;

"physician" means a legally qualified medical practitioner;

"non-regenerative tissue" means tissue other than regenerative tissue;

"regenerative tissue" means tissue that, after injury or removal, is replaced in the body of a living person by natural processes;

"tissue" includes an organ, a part of a human body, or a substance extracted from the human body or from a part of the human body but does not include

- (a) spermatozoa or ova;
- (b) embryonic or fetal tissue; or
- (c) blood or blood constituent;

"transplant" as a noun means the removal of tissue from a human body, whether living or dead, and its implantation in another living human body, and in its other forms it has corresponding meanings.

PART I

PROCUREMENT OF TISSUE AFTER DEATH

Definitions.

2 In this Part

"nearest relative" means

- (a) a spouse;
- (b) if none or if none is available, a daughter or son who is of the age of majority;
- (c) if none or if none is available, a parent;
- (d) if none or if none is available, a brother or sister who is of the age of majority; or
- (e) if none or if none is available, the person lawfully in possession of the body or the Inspector of Anatomy under The Anatomy Act;

"parent" means a biological parent or adoptive parent and includes a guardian appointed under The Child and Family Services Act;

EXPLANATORY NOTES

Both "adult" and "minor" are defined in accordance with the distinctive legal treatment given to these two age groups in both Parts I and II of this Act.

Similarly, a distinction is drawn between regenerative and non-regenerative tissue with respect to the donation of this tissue by living persons. As shall be seen later, in Part II, non-regenerative tissue may only be donated by living persons for the purpose of a transplant while regenerative tissue may be donated for broader purposes where the donor is an adult (s.9(1).) As well, only regenerative tissue can be donated by a minor who, by reason of age, is not capable of understanding the nature and effect of the removal and transplant of tissue (s.11(1)). It should be noted that the term "tissue" is also defined in Section 1.

"Tissue" excludes the three types of tissue set forth in Part I of our Report which, for various reasons there identified, we thought should be excluded from our consideration (see pp. 11-12 of this Report).

"Transplant" is a term used frequently throughout the proposed Act. It is used in Part I (s.6) for the determination of death section. It also appears in Part II to limit the purposes for which tissue may be removed from living persons.

Part I of the Act deals with the procurement of tissue after death. This appears prior to the donation of tissue by living persons (Part II) in accordance with the Commission's general philosophy that the latter should only be undertaken for transplant purposes where *inter vivos* donation is considered to have a better chance of success than a cadaver donation or where it is not medically feasible to wait for a cadaver donation. Part I implements a "contracting-in" system of tissue procurement in accordance with Recommendation 1 of the Report.

"Nearest relative" sets forth who may direct the use of the body or any tissue of a person after his or her death where, in accordance with Part I, no direction has been made by that person during his or her life. The nearest relative given pre-eminent authority is the spouse, if any. ("Spouse" is later defined in Section 2 to include a *de facto* or common law spouse.) The definition implements Recommendation 14 in that it proposes that one may descend the list where a certain person is "not available" as well as where no such relative exists.

"Parent" is defined to include a guardian appointed under *The Child and Family Services Act*, S.M. 1985, c. 8. This implements Recommendation 16.

"person lawfully in possession of the body" does not include

- (a) a medical examiner in possession of a body for the purpose of an inquiry or investigation; or
- (b) an embalmer or funeral director in possession of a body for the purpose of its burial, cremation, or other disposal;

"spouse" includes a person who, although not married to the deceased, was at the time of death of the deceased living with the deceased as that person's husband or wife on a permanent domestic basis;

"writing" includes a will and any other testamentary instrument whether or not probate has been applied for or granted and whether or not the will or other testamentary instrument is valid.

Direction by adult for use of body or tissue after death.

3(1) Any adult may direct,

- (a) in a writing signed by that adult at any time; or
- (b) orally in the presence of at least two witnesses;

that his or her whole body or any tissue thereof be used after death for therapeutic purposes, medical education or scientific research.

Direction by minor of 16 years for use of body or tissue after death.

3(2) Any minor who is sixteen years of age or older may give a direction under subsection (1) with the consent of a parent.

Direction is full authority, exceptions.

3(3) Upon the death of a person who has given a direction under this section, the direction is binding and is full authority for the use of the whole body or the removal and use of the specified tissue for the purposes specified in the direction, except that no person shall

- (a) act upon a direction given under this section if he or she has reason to believe that the person who gave it was not capable of understanding its nature and effect;
- (b) act upon a direction given under this section if he or she has reason to believe that it was subsequently withdrawn; and
- (c) act upon a direction if he or she has reason to believe that an inquiry or investigation may be required to be held respecting the cause and manner of death except with the consent of a medical examiner or chief medical examiner appointed under The Fatality Inquiries Act.

"Person lawfully in possession of the body" is an expression contained in numerous human tissue statutes. As in the present Act, no positive definition is given. It would, however, appear to include a person who is a "claimant" of the body under *The Anatomy Act*, C.C.S.M. c. A80 and a hospital where death occurs within that institution. The Act authorizes a person lawfully in possession of the body to direct the use of the body or of tissue of the body of a deceased adult where there is no one or no one available that is in a closer relationship to the deceased in accordance with the definition of "nearest relative", above.

"Spouse" is broadly defined to include a common law spouse. This implements Recommendation 16 of the Report.

Although the Act defines a "writing" to include a will prior to probate, it has been suggested that it would be preferable for a person to make a direction in a writing which is more likely to be examined immediately at the time of his or her death, such as the completion of the form on the back of a driver's licence. Advising one's doctor and close relatives of one's direction is also considered advisable.

Subsection 3(1) authorizes an adult to make a direction for the use of his or her body or of tissue thereof for any one or more of the purposes set forth in that subsection. This proposed subsection revises the present legislation in one respect: it authorizes a person to direct the use of his or her *body* after death. Under the present legislative scheme, the direction for the use of one's body after death is governed by subsection 6(5) of *The Anatomy Act*, C.C.S.M. c. A80. Unlike that legislation, the proposed Act would not require that a direction for the use of the body be countersigned by the next of kin (see s. 6(6) of that Act). This change implements Recommendation 6 of the Report.

Subsection 3(2) would revise the present legislation by allowing a minor of 16 years or older to make a direction with the consent of a parent. This change implements Recommendation 7 of the Report.

Subsection 3(3) is substantially similar to subsection 2(3) of the present Act. Clause (a), however, is new. It would ensure that a direction not be acted upon where a person responsible for the removal of tissue has reason to believe that the donor was not capable of understanding its meaning. It is expected that this provision would not be used often. It would apply, for example, where a donor was incapable by reason of a mental disorder from fully comprehending the meaning of the direction and this fact was brought to the attention of the person proposing to remove the tissue. Clause (c) is revised to implement Recommendation 18 of the Report.

Direction by nearest relative.

4(1) Where a person of any age who has not given a valid direction under section 3

- (a) dies; or
- (b) in the opinion of a physician is incapable of making a direction by reason of injury or disease and the death of that person is imminent;

the nearest relative may direct that the whole body of that person or any tissue thereof be used after death for therapeutic purposes, medical education or scientific research.

Prohibition.

4(2) The nearest relative shall not give a direction under subsection (1) if he or she has reason to believe that the person who died or whose death is imminent would have objected thereto.

Form of direction.

4(3) A direction under this section must be given

- (a) in a writing signed by the nearest relative;
- (b) orally by the nearest relative in the presence of at least two witnesses;
- (c) by the telegraphic, recorded telephonic, or other recorded message of the nearest relative; or
- (d) by a telephone message received and heard by two persons from the nearest relative where the two persons subsequently record in writing the nature and contents of the direction.

Direction is full authority, exceptions.

4(4) Upon the death of a person in respect of whom a direction is given under this section, the direction is binding and is full authority for the use of the whole body or the removal and use of the specified tissue for the purposes specified in the direction, except that no person shall

- (a) act upon the direction if he or she has actual knowledge that a person who is of the same or closer relationship to the deceased person than the nearest relative who gave the direction, objects thereto;
- (b) act upon a direction if he or she has reason to believe that an inquiry or investigation may be required to be held respecting the cause and manner of death except with the consent of a medical examiner or chief medical examiner appointed under The Fatality Inquiries Act.

Subsection 4(1) is similar to its counterpart in the present Act. However, it clarifies that the direction by the nearest relative can be made where someone of any age dies and, in this respect it conforms to the wording of the *Uniform Act*. Like section 3 of the proposed Act it extends the right of donation to that of the whole body. Like the present subsection, it implements a system of post-mortem organ procurement which is known as "strong contracting-in". Under that system the authority of a nearest relative to make a direction is confined to those cases where a person has not made a direction under section 3 during his or her lifetime. This means that the nearest relative has no authority to override the wishes of the deceased who has made such a direction. Its wording is perhaps less cumbersome than its present counterpart because the definition of "nearest relative" in section 2 eliminates the need to recite those persons who have the authority to make a direction under this subsection. The subsection is broader than its present counterpart in that it also deals with the direction of the nearest relative where death is imminent. This is presently set forth separately in subsection 3(2) of the Act.

Subsection 4(2) implements Recommendation 13 of the Report. It essentially stipulates more directly than the earlier Act that the views of the deceased regarding donation are paramount.

Subsection 4(3) is new. It clarifies the form of making a direction under subsection 4(1) and implements Recommendation 17 of the Report. The subsection is similar to the relevant Saskatchewan legislation (*The Human Tissue Gift Act*, R.R.S. 1978, c. H-15, S. 6(1).)

Subsection 4(4) is substantially similar to its counterpart in the present Act. However, clause (a) is revised to implement Recommendation 15 of the Report.

Removal of pituitary gland.

5(1) Notwithstanding that no direction has been given under this Part with respect to the use after death of the whole body or any tissue thereof, any person performing a post mortem examination of a body may, without incurring any liability therefor, remove the pituitary gland from the body and cause it to be delivered to any person or agency designated by the Inspector of Anatomy appointed under The Anatomy Act for use in the treatment of persons having a growth hormone deficiency.

Where section does not apply.

5(2) This section does not apply where the person performing the post mortem examination of the body has reason to believe

- (a) that the deceased would, if living, have objected to the removal of the pituitary gland for use in the treatment of persons having a growth hormone deficiency; or
- (b) that
 - (i) the surviving spouse of the deceased, or
 - (ii) if none, any of his/her children 18 years of age or over, or
 - (iii) if none, either of his/her parents, or
 - (iv) if none, any of his or her brothers or sisters 18 years or over, objects to the removal of the pituitary gland for use in the treatment of persons having a growth hormone deficiency.

Determination of death.

6(1) For the purposes of a post-mortem transplant, the determination of death as defined under The Vital Statistics Act shall be made by at least two physicians.

Prohibition.

6(2) No physician who has had any association with the proposed recipient that might influence his or her judgment shall take any part in the determination of the fact of death of the donor.

Idem.

6(3) No physician who took any part in the determination of the fact of death of the donor shall participate in any way in the transplant procedures.

Exceptions.

6(4) Nothing in this section in any way affects a physician in the removal of eyes, bone or skin for transplants.

Subsections 5(1) and 5(2) are similar to subsections 6(1) and (2) of the present Act. These subsections were drafted to preclude the procurement of tissue other than the pituitary gland via the presumed consent system in accordance with Recommendation 2 of the Report. In light of the ongoing medical research into the use of the pituitary gland, we recognize that reform of this section, to reflect relevant research findings, may have to be considered in the future.

Section 6 implements Recommendation 4 of the Report. It is similar to section 7 of the *Uniform Act*. Subsection 6(1) refers to the definition of death presently housed in section 2 of *The Vital Statistics Act*, C.C.S.M. c. V60. That section states that "for all purposes within the legislative competence of the Legislature of Manitoba the death of a person takes place at the time at which irreversible cessation of all that person's brain function occurs". Subsection 6(4) excludes the removal of eyes, bone or skin for transplants from the requirements of the section as these types of tissue are non-perfusable and, accordingly, need not be taken from a "brain-dead" donor.

Where specified use fails.

7(1) Where a direction given under this Part cannot for any reason be used for any of the purposes specified therein, the tissue and the body to which it belongs shall be dealt with and disposed of as if no direction had been given.

Disposal of body where direction for use of tissue.

7(2) Where

- (a) a direction has been given under this Part for the use of tissue after death for any purpose specified in the direction and tissue has been removed in accordance with this Part; and
- (b) no direction has been given under this Part for the use of the whole body for any purpose specified in the direction;

the body of the deceased person shall be returned forthwith to the person who would have had custody and control of the body if no direction had been made under this Part.

Disposal of body where direction for use of body.

7(3) Where a direction has been given under this Part for the use of the whole body after death the body of the deceased person shall be under the control of the Inspector of Anatomy appointed under The Anatomy Act and the provisions of that Act govern with respect to the custody and control of the body.

PART II

DONATION OF TISSUE BY LIVING PERSONS

Definitions.

8 In this Part,

"member of the same immediate family" means a person who is a mother, father, step-mother, step-father, sister, brother, step-sister, step-brother, to the minor living donor;

"parent" means a biological parent or adoptive parent of a child who has care and control of that child, and includes a guardian appointed under The Child and Family Services Act.

Subsection 7(1) is identical to subsection 4(1) of the present Act. Subsections 7(2) and 7(3) are new. They clarify the effect of directing the use of tissue and the use of the whole body.

Subsection 7(2) provides that where a direction is given for the use of tissue only, the body is returned to the next of kin who are then responsible for burial. Subsection 7(3) clarifies that where a direction is given for the use of the whole body, it comes into the custody of the Inspector of Anatomy and thereafter *The Anatomy Act* governs with respect to the treatment and disposition of the body.

Part II of the Act deals with the donation of tissue by living persons. This subject is not dealt with under the present Act. Manitoba is the only province aside from New Brunswick which does not have legislation governing this topic.

"Member of the same immediate family" is defined for the purpose of sections 10 and 11. Under those sections, minors may donate certain specified tissue provided that, amongst other matters, the proposed recipient is a member of the same immediate family as the minor living donor.

"Parent" is defined similarly to its definition in Part I. However, it is more restrictive in that the biological or adoptive parent must be a custodial parent.

Consent by adult living donor to removal of tissue.

9(1) Any adult may consent in writing to the removal from his or her body of

- (a) specified regenerative tissue for therapeutic purposes, medical education or scientific research; and
- (b) specified non-regenerative tissue for the purpose of the transplant of such tissue to the body of another living person.

Physician to give certificate in relation to consent.

9(2) A consent under this section must be given in the presence of a physician who shall certify in writing that

- (a) the consent in writing of the person, the terms of which consent are set out in the certificate, was given in his or her presence;
- (b) he or she explained to the person before the consent was given the nature and effect of the removal from the body of that person of the tissue specified in the consent; and
- (c) he or she is satisfied that
 - (i) the person has attained the age of 18 years;
 - (ii) the person understands the nature and effect of the removal and use of the tissue; and
 - (iii) the consent is freely given.

Where the capacity of the adult to consent is uncertain.

9(3) Where a physician is not satisfied that the adult understands the nature and effect of the removal of the tissue, an application may be brought before a judge of the Court of Queen's Bench for an order as to whether the adult is competent to consent to the removal of the specified tissue.

Consent by mature minor living donor to removal of tissue.

10(1) Any minor who is capable of understanding the nature and effect of the removal and transplant of tissue from his or her body may consent in writing to the removal from his or her body of specified regenerative or non-regenerative tissue for the purpose of the transplant of that tissue to another member of the same immediate family.

Physician to give certificate in relation to consent.

10(2) A consent under this section must be given in the presence of a physician who shall certify in writing that,

- (a) the consent in writing of the minor and a parent of the minor, the terms of which consent are set out in the certificate, was given in his or her presence;
- (b) the minor and the potential recipient are members of the same immediate family;

Section 9 sets forth the authority of an adult to donate tissue. Unlike those sections which pertain to the minor, section 9 authorizes an adult to donate regenerative tissue other than for just transplant purposes. This implements Recommendation 21 of the Report. Subsection 2 implements Recommendations 22 and 29. It requires a physician to give a certificate in relation to the consent. Later, in sections 12 and 13, it is clarified that the certificate is to be given by an "independent" physician and that a consent given in accordance with this section is sufficient authority for another physician to remove the tissue in question. Subsection 3 implements Recommendation 30. It provides that where a physician is in doubt about a person's understanding, an order can be sought from the Court of Queen's Bench.

Section 10 sets forth the authority of a "mature" minor to donate tissue. Like section 9, this section authorizes a mature minor to consent to the removal of both regenerative and non-regenerative tissue. Unlike section 9, however, regenerative tissue can only be used for transplant purposes and the transplant of both types of tissue must be for a member of the same immediate family (as defined in section 8). This implements Recommendation 23 of the Report. As explained in reference to the notes under section 9, section 12 clarifies that the certifying physician under subsection (2) must be "independent" while section 13 clarifies the effect of a consent given in accordance with this section.

Subsection 10(2) implements Recommendation 24 of the Report.

- (c) he or she explained to the minor and to the parent of the minor the nature and effect of the removal and transplant of the tissue specified in the consent; and
- (d) he or she is satisfied that;
 - (i) the minor understands the nature and effect of the removal and transplant of the tissue; and
 - (ii) the consent of the minor and of the parent are freely given.

Where the capacity of the minor to consent is uncertain.

10(3) Where a physician is not satisfied that the minor understands the nature and effect of the removal and transplant of the tissue, an application may be brought before a judge of the Court of Queen's Bench for an order that the minor is competent to consent to the removal of the specified tissue.

Conversion of procedure to application under subsec. 11(3).

10(4) Where an application is brought under subsection (3) in relation to the removal and transplant of specified regenerative tissue and the Court determines that the minor, by reason of age, is not competent to consent to the removal of that tissue, the application may be treated and disposed of as if it were an application brought under subsection 11(3) of this Act.

Consent by parent where minor is not capable of understanding by reason of age.

11(1) Where a minor, by reason of age, is not capable of understanding the nature and effect of the removal and transplant of tissue from his or her body, a parent of that minor may consent, in writing, to the removal of specified regenerative tissue from the body of that minor for the purpose of the transplant of that tissue to a member of the same immediate family.

Physician to give certificate in relation to consent.

11(2) A consent under this section must be given in the presence of a physician who shall certify in writing that

- (a) the consent in writing of the parent, the terms of which consent are set out in the certificate, was given in his or her presence;
- (b) the minor and the proposed recipient are members of the same immediate family;
- (c) he or she explained to the parent and to the minor before the consent was given the nature and effect of the removal and transplant of the tissue of the minor specified in the consent; and
- (d) he or she is satisfied that
 - (i) the potential recipient is likely to die unless the tissue specified in the consent is transplanted to his or her body;
 - (ii) the minor does not object to the removal of the tissue specified in the consent; and
 - (iii) the risk to the life and health of the minor is not substantial.

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Subsection 10(3) allows for the question of a minor's capacity to consent to be heard by a Court of Queen's Bench judge where a physician is uncertain of that capacity. This is in accordance with Recommendation 25.

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Subsection 10(4) provides for the conversion of an application brought under Subsection 10(3) to that of a review under subsection 11(3) where a judge concludes that the minor in question is incapable of giving his or her consent by reason of his or her age and the donation pertains to regenerative tissue.

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Section 11 sets forth the authority for tissue to be removed from a minor who, by reason of age, is not capable of understanding the nature and effect of the removal and transplant of tissue from his or her body. The section authorizes a parent (as defined in section 8) to consent to the removal of regenerative tissue for the purpose of its transplant to a member of the same immediate family. This implements Recommendation 26 of the Report. Unlike sections 9 and 10, a consent under this section must be reviewed by a Court of Queen's Bench judge (Recommendation 28). As with respect to these two sections, a certificate of a physician (as described in Section 12) is also required (Recommendation 27).

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Approval by Court of Queen's Bench.

11(3) A consent under this section shall be reviewed by a judge of the Court of Queen's Bench who may determine that, having regard to all the circumstances of the case, the consent of the parent is both fair and reasonable.

Prohibition.

12 No physician who has had any association with a proposed recipient of tissue that might influence his or her judgment shall give a certificate in relation to a consent under this Part.

Effect of consent under Part II.

13 A consent given in accordance with this Part is sufficient authority for a physician, other than the physician who gave the certificate, to remove the tissue specified in the consent for the purpose specified except that no physician shall remove the tissue specified in the consent where he or she has reason to believe that the consent has been revoked.

PART III

GENERAL

Civil liability.

14 No action or other proceeding for damages lies against any person for any act done in good faith and without negligence in the exercise or intended exercise of any authority conferred by this Act.

Prohibition.

15 No person shall remove tissue from the body of a person, whether living or dead, except in accordance with a direction or consent that, under this Act, is sufficient authority for the removal of the tissue by that person.

Disclosure of information.

16(1) No person shall disclose or give to any other person any information or document whereby the identity of any person,

- (a) who has given or refused to give a direction or consent;
- (b) with respect to whom a direction or consent has been given; or
- (c) into whose body tissue has been, is being or may be transplanted,

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Section 12 clarifies that the physician who certifies a consent under this Part should not have any association with the proposed recipient which might colour his or her judgment.

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Section 14 implements Recommendation 37 of the Report and is identical to section 9 of the *Uniform Act*.

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Section 15 makes certain that the process of removing tissue for organ donation under the Act is exhaustive. The section is confined to the donation of *tissue* and does not extend to the donation of the whole body because of the provisions in *The Anatomy Act* authorizing unclaimed bodies to be used for anatomical examination.

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Section 16 implements Recommendations 32 and 33 of the Report. These sections entitle the donor and proposed recipient to have some privacy with respect to information concerning the transplant to the extent they feel such privacy is desirable.

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Exceptions.

16(2) Subsection (1) does not apply to or in relation to any information or document disclosed

- (a) in pursuance of an order of a court or when otherwise required by law;
- (b) for the purposes of hospital administration or bona fide medical research; or
- (c) with the consent of the person to whom the information relates.

Lawful dealings not affected, exception.

17 Any dealing with a body or part or parts thereof that was lawful before this Act came into force shall, except as provided in this Act, continue to be lawful.

Sale, etc. of tissue prohibited.

18(1) No person shall buy, sell or otherwise deal in, directly or indirectly, for valuable consideration, any tissue for therapeutic purposes, medical education or scientific research.

Exceptions.

18(2) Nothing in this section prohibits

- (a) the provision of reasonable remuneration to a person for his or her services rendered in relation to the donation of tissue for any of the purposes specified under this Act; or
- (b) the reimbursement of expenses to a donor of tissue or to his or her family, which have been reasonably incurred in relation to the donation of tissue for any of the purposes specified under this Act.

Offence.

19 Every person who knowingly contravenes any provision in this Act is guilty of an offence and is liable on summary conviction to a fine of not more than \$10,000 or to imprisonment for a term of not more than 1 year, or to both.

*Repeal.

20 The Human Tissue Act, being Chapter H180 of the Revised Statutes, is repealed.

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Section 17 implements Recommendation 38.

Subsection 18(1) prohibits the commercial sale of organs and implements Recommendation 34 of the Report.

Subsection 18(2) clarifies that the prior subsection does not prevent a person from receiving reasonable remuneration for his or her services rendered in relation to the removal and transplant of tissue. A similar savings clause appears for donors and their families insofar as their reasonable expenses are concerned. This subsection implements Recommendation 35 of the Report.

Section 19 provides for the penalty to be imposed when a person knowingly contravenes the Act. It implements Recommendation 36 of the Report. There is no penalty section under the existing Act. The section proposes a maximum fine which is ten times greater than the *Uniform Act* (that Act suggests a ceiling of \$1,000) because of the present commercial value of organs and, in particular, kidneys.

Commencement of Act.


21 This Act comes into force on a day it receives the royal assent.

*Note to draftsman: The inclusion of the donation of the whole body in this Act will also require the repeal of subsections 6(5), 6(6) and 6(7) of *The Anatomy Act*, C.C.S.M. c. A80 and the amendment of other subsections of that Act, such as s. 8(3), which refer to these provisions. While the Commission's reference was confined to an examination of *The Human Tissue Act*, we have suggested in Part IV of this Report that the maximum fine of one hundred dollars stipulated in section 26 of *The Anatomy Act* for, *inter alia*, trafficking in dead bodies should be raised to a figure similar to that suggested in section 19 of our proposed Act.

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This is a Report pursuant to subsection 5(3) of *The Law Reform Commission Act*, signed this 31st day of March, 1986.



Clifford H.C. Edwards, Chairman



Knox B. Foster, Commissioner



Lee Gibson, Commissioner



John C. Irvine, Commissioner



Gerald O. Jewers, Commissioner

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