Law Reform Commission of Canada
Commission de réforme du droit du Canada

procurement and transfer of human tissues and organs

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Principal Consultant

Derek J. Jones, J.D.

Bioethical Consultant

Barry Hoffmaster, Ph.D.

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

Editor's Note

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

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

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Acknowledgements

We are indebted to all those individuals with whom we consulted during the preparation of this working paper. Members of our standing advisory panels, comprising representatives of the judiciary, the practising bar (both Crown and defence), law teachers and the police, regularly advise us on our work in development. We are truly grateful to them and hereby acknowledge their considerable influence on our work.

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

Members of the Group include:

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The views expressed in this working paper are those of the Commission, and do not necessarily reflect those of Parliament, the Department of Justice or any of the individual consultants.

Introduction

Modern medicine has again begun challenging the law to rethink its views on the legal status of the human body in matters involving life and death. Ten years ago, the Law Reform Commission of Canada joined several public analysts in recommending new criteria for the determination of death.[1] Newer tools of medicine, such as mechanical respirators and circulators, had come to obscure the meaning and utility of the traditional heart-lung cessation criteria for death.

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

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

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

1. Law Reform Commission of Canada [hereinafter LRC], *Criteria for the Determination of Death*, Report 15 (Ottawa: Supply and Services Canada, 1981).

of kin. The pressures exerted by scarcity prompt calls for reforms — reforms which might include measures that challenge the values and assumptions of the existing system.

So new questions are emerging. What legal reforms, if any, should be instituted to alleviate perceived tissue scarcity? Should the brain-death criteria be amended for babies who are born without most of the upper brain and usually die within seventy-two hours after birth, to facilitate organ procurement from them? Is the selling of bodily parts or substances an acceptable means of increasing the supply of blood, tissues and organs? Or, to discourage acts of medical and economic desperation and to preserve fundamental values, should some sales of bodily parts or substances be made criminal offences? Indeed, in response to increasing concerns about international trafficking in organs, the World Health Organization has urged the international community to take measures to prevent and discourage such transactions.[2] That organization has identified organ transplantation as a biomedical development that challenges the moral and legal integrity of the individual.[3]

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

The first controversy arose a century and a half ago. In the autumn of 1843, some two decades after McGill University established the first medical school in Canada, the Medical Board of Montreal petitioned the Legislative Assembly of the Province of Canada to pass an Anatomy Act. The petition was submitted after nightly episodes in which the securing, by medical school students, of dead bodies from Montreal graveyards had provoked public outcry and calls for solutions to such "gross indecencies."[4] A scarcity of human specimens had prompted medical students, and even anatomy professors, in other Canadian locales to resort to such measures for years.[5]

Accordingly, the petitioners sought an Anatomy Act to establish a regulated, legal system for supplying cadaver bodies for dissection and anatomical study in the medical schools. The absence of an existing system, they argued, hampered medical education and the practice of the healing arts, to the public detriment.[6] A regulated system of supply

2. See 1989 World Health Organization [hereinafter WHO] Resolution, *infra*, note 1047, reproduced in part in appendix A, *infra* at 202-203.

3. WHO, *Health Aspects of Human Rights: With Special Reference to Developments in Biology and Medicine* (Geneva: The Organization, 1976).

4. See D.G. Lawrence, "'Resurrection' and Legislation or Body-Snatching in Relation to the Anatomy Act in the Province of Quebec" (1958) 32:5 Bull. Hist. Med. 408 at 411.

5. See Worthington, *infra*, note 809.

6. See Debates, *infra*, note 803 at 464-67.

would rid the community of grave-robbing, body-selling and like black market abuses. Opponents countered that a more appropriate source would be the bodies of criminals, that the proposed legislation would legalize a "traffic in corpses," and make public property of cadavers.[7] The debate resulted in passage of *An Act to regulate and facilitate the study of Anatomy*, in December 1843.[8] The Act adopted the principle that unclaimed bodies, publicly exposed or in such public institutions as hospitals, should be made available as anatomic subjects for the medical schools.

The bodily sales and bodily property language of over a century ago has been resurrected in a more modern controversy. It highlights issues surrounding the legal protection of patients and bodily integrity in a biotechnological age. In a recent case in the United States, a leukemia patient sued his doctor and a university hospital, claiming that without his knowledge or consent his pancreas cells were used to develop a therapeutically valuable "cell line."[9] The cell line has been used to make new drugs capable of controlling cancer, and is of such commercial value that the cell line has been patented. The patient claims a breach of consent, the taking of bodily property and a rightful share of the money generated by the patent.

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

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

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

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7. *Ibid.*

8. S. Prov. C. 1843, c. 5 [hereinafter *Anatomy Act*]. See chap. 3, section III.B(1), below.

9. See *Moore* (1990), *infra*, note 426.

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

It is within these broader contexts that the Commission has undertaken this Working Paper. We have done so mindful of the important work done in the area by the federal-provincial-territorial transplant working groups[10] and provincial task forces[11] in the mid-1980s, the more recent law reform initiatives by the provinces and by the Uniform Law Conference of Canada,[12] as well as the pronouncements of international organizations and foreign jurisdictions.[13] Our work is intended to draw on and complement these contributions.

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

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

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

CHAPTER ONE

Modern Therapeutic Demand and Supply

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

I. Medical Demand

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

A. Anatomical Demand

A knowledge of human anatomy is responsible for much of our understanding of illness and the treatment of disease. The word "anatomy" derives from Greek root words meaning "to cut up or dissect"; hence, human anatomy classically refers to studying the structure and function of the body through dissection.[14]

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

14. See Doris Burda Wilson and Wilfred J. Wilson, *Human Anatomy*, 2d ed. (New York: Oxford University Press, 1983) at 3.

Europe.[15] The charters of some universities[16] founded in the Renaissance even incorporated provisions authorizing the use of cadavers for medical instruction at a time when superstition and some religious sentiment[17] opposed, if not condemned, post-mortem involvement with the human body. Practical necessity also helped modify attitudes, as perhaps illustrated by the need to determine the cause of death by dissecting the bodies of victims of the Black Plague that swept late medieval Europe.[18] The sixteenth-century publication of Andreas Vesalius' *De Humani Corporis Fabrica*, the "treatise on which modern anatomy has been founded,"[19] helped standardize and establish dissection as a basic course in university medical schools. That work prompted the then Holy Roman Emperor, Charles V, to place the question of anatomical study before a theological council. The council ruled favourably and "thereby gave final assurance of the uninterrupted use of human dissection in advancing anatomy and pathology."[20] Thus, by the nineteenth century, medical students were even required to have dissected the human body before graduation.[21]

Today, human anatomy remains integral to the medical educational curricula of the twenty-two medical schools in Canada. It is a basic requirement for students of medicine, nursing, physiotherapy, dentistry and occupational therapy. Part of the simple logic behind this medical school requirement has long been that if the structure and function of the human body are not learned in the anatomy or dissecting laboratory, they will be learned by "mangling the living" in the practice of medicine.[22] In other words, a knowledge of human tissues, organs and major body systems is deemed critical to understanding, preventing and treating illness.

Acquiring such knowledge has long required human bodies as anatomical specimens, as the debate surrounding passage of the Canadian *Anatomy Act* of 1843 demonstrates. The research needs of modern medical schools have added to the demand. Today, over 600 cadaver anatomy specimens are needed annually for medical school education and teaching.[23] International pioneering work in progress on an electronic cadaver — computer-based, interactive, simulated dissection — may help to meet future anatomical demand.[24]

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15. See T.V.N. Persaud, *Early History of Human Anatomy* (Springfield, Ill.: Charles Thomas, 1984) at 77-88. See generally Arthur M. Lassek, *Human Dissection: Its Drama and Struggle* (Springfield, Ill.: Charles Thomas, 1958).

16. See Sonoma Cooper, "The Medical School of Montpellier in the Fourteenth Century" (1930) 2 (N.S.) Annals Med. Hist. 164 at 178 (describing The Medical School of Montpellier Statutes of 1340).

17. See Jack Kevorkian, *The Story of Dissection* (New York: Philosophical Library, 1959) at 39-41. But see James J. Walsh, "The Popes and the History of Anatomy" (1904) Med. Libr. and Hist. J. 10.

18. Kevorkian, *supra*, note 17 at 189.

19. James Moores Ball, *The Sack-'Em-Up Men: An Account of the Rise and Fall of the Modern Resurrectionists* (London: Oliver and Boyd, 1928) at 40.

20. Kevorkian, *supra*, note 17 at 50.

21. See chap. 3, section III.B(1), below.

22. See U.K., *Report from the Select Committee on Anatomy* (London, 1829) at 13 [hereinafter *Select Committee*].

23. Based on an informal 1989 LRC survey of provincial coroners and medical school anatomy chairpersons. Demand for most of the specimens comes from some dozen medical schools in Quebec and Ontario.

24. See Lawrence K. Altman, "Computers Create Electronic 'Cadavers' for Anatomy Lessons" *New York Times* (6 September 1988) C3.

B. Transplantation Demand

Routine tissue transplants are twentieth-century phenomena which have evolved from the simple to the complex. For decades, blood, cornea, bone marrow and skin transplants have been routine treatment for select medical conditions. Some complexity has also been mastered. Over the last fifteen years, organ transplants have played an increasing role in the treatment of disease. Indeed, as Canadian society nears the fourth decade of vital organ transplant technology, transplantation is now considered the treatment of choice for selected patients with end-stage kidney, heart or liver failure.[25] Before such developments, patients afflicted with the conditions that transplants now treat were condemned to disability, prolonged illness, reliance on artificial organs or death.

The following examination of major tissue transplant technologies portrays societal demand for bodily tissue as a partial result of the evolution of particular transplant procedures in medical treatment. The details of each transplant story may prove dramatic because certain transplants, especially organs, sometimes involve life and death. But in each story, important parts of a generality are portrayed, because human tissue transplants tend to be governed by shared principles and challenges.

Successful transplants depend, for example, on an intricate understanding of the tissue involved, skilled transplant personnel and facilities, an accurate matching of the donor and recipient tissues, the perfection of transplant procedures, maximized tissue preservation methods, effective patient selection and the management of tissue rejection. As such, the surmounting of a basic technical impediment may benefit a range of tissue transplant patients. The point is illustrated by the revolutionary impact which the drug cyclosporine had on reducing tissue rejection and dramatically boosting success rates for liver and heart transplantations in the 1980s.[26] Early results indicate that similar new drugs may further advance success rates in the 1990s.[27]

As technical impediments are overcome, the judgment as to whether a transplant procedure is considered experimental or routine therapy is guided by such medical factors as survival rates, the pros and cons of alternative treatments and the general consensus on and diffusion of the technology. As transplant procedures move from the experimental to the routine, demand for a procedure may increase. Thus, a 1984 Canadian tissue procurement conference concluded that "[t]oday, the significant factor limiting the number of transplants done is the available supply of organs and tissues."[28] That conclusion echoes the unanimous findings of federal and provincial task forces and commentators

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25. David Grant et al., "Experience of a Canadian Multi-Organ Transplant Service" (1986) 135:3 C.M.A.J. 197.

26. See generally "Proceedings of the Second International Congress on Cyclosporine: Therapeutic Use in Transplantation" (1988) 20:3 (Supp. 3) Transplant. Proc.

27. See Thomas E. Starzl et al., "Kidney Transplantation under FK 506" (1990) 264:1 JAMA 63.

28. Health and Welfare Canada [hereinafter HWC], *Ways and Means to Enhance Human Organ and Tissue Procurement and Exchange in Canada* (Ottawa: Supply and Services Canada, 1985) at 1.

that have examined the issue.[29] Five years later, the statement remains accurate. The statistics in table 1 outline the number of procedures performed and numbers of people on transplant waiting lists as some indicia of general demand and supply in Canada. The procedures performed and numbers on waiting lists are highest for two of the older tissue transplant procedures, corneal and kidney transplantation. The details behind these and other tissue transplants provide insights into the demand for and supply of human tissue.

(1) Blood Products and Vessels

Blood is a tissue that consists of a variety of cells suspended in a fluid medium called plasma.[30] Modern knowledge of the circulatory system emerged in the seventeenth century, and unsuccessful blood transfusions were attempted at about the same time.[31] The lack of success likely resulted from recipients receiving incompatible blood, which may cause minor to severe reactions.[32] It was not until the discovery of the four major blood groups (A, B, AB and O) in 1901, and the later refinement of blood-matching procedures, that successful blood transfusions were routinely performed.[33] Blood was one of the first tissues to be successfully transferred between human beings for treatment.

Further understanding of the properties of blood and the development of preservation methods made blood banking a possibility in the decade before World War II.[34] During World War II, the Canadian Red Cross Society assumed the major responsibility for the collection and distribution of blood. After the war, Canada designated that organization as the entity charged with collecting and distributing blood and blood products nationally.[35]

Today, blood transfusion is considered the "foundation of modern medicine" and has been "regarded as the first successful organ transplant."[36] The Canadian Red Cross Society operates seventeen centres across Canada through which it collects, screens and

29. Compare "Report of the Working Group on Vital Organ Transplant Centres to the Deputy Ministers of Health" (September 1985) [unpublished] at 17-19 [hereinafter FEDS]; U.S. Department of Health and Human Services, Public Health Service, Task Force on Organ Transplantation, *Organ Transplantation: Issues and Recommendations* (Washington, D.C.: U.S. Government Printing Office, 1986) at 27 (need for organs far exceeds supply) [hereinafter USTF]. See Task Force on Organ Donation, *Organ Donation in the Eighties: The Minister's Task Force on Kidney Donation* (Toronto: The Task Force, 1985) [hereinafter ONT]. See also Roger W. Evans et al., "Donor Availability as the Primary Determinant of the Future of Heart Transplantation" (1986) 255:14 JAMA 1892.

30. Paul R. Wheater, H. George Burkitt and G. Daniels, *Functional Histology*, 2d ed. (Edinburgh: Churchill Livingstone, 1987) at 36.

31. See William Harvey, *On the Motion of the Heart and Blood in Animals*, 1628 (reprint Chicago: Gateway, 1962).

32. See Gilbert M. Clark, ed., *Legal Issues in Transfusion Medicine* (Arlington, VA: American Association of Blood Banks, 1986) at 191.

33. Harvey G. Klein, "Transfusion Medicine: The Revolution of a New Discipline" (1987) 258:15 JAMA 2108.

34. *Ibid.*

35. Report of the Steering Committee to the Canadian Blood Committee, *Study on Plasma Fractionation in Canada* (Ottawa: The Committee, 1988) at 13 [hereinafter CBC].

36. *Ibid.*

TABLE 1. Select Canadian "Tissue" Transplant Statistics*

Tissue or Organ	Maximum Preservation Time	Recipient Survival Rates	Centres	Number of Procedures Performed per Year						Waiting List					Cost per Case○
				1989	1988	1987	1986	1985	1981	12/89	12/88	12/87	12/86	12/85	
Milk	(a) 1–2 days (b) 6 months frozen	—	19○	—	—	—	—	—	—	—	—	—	—	—	—
Blood	(a) 35 days□ (b) 10 years frozen●	—	17●	—	—	—	—	—	—	—	—	—	—	—	—
Bone Marrow	10+ years frozen♦	—	9	—	167	144	127	129	60	—	—	—	—	—	$80,000
Corneas	3–4 days	—	10	2,412	2,236	1,956	1,897	981	—	1,301	1,288	922	1,234	1,059	—
Kidneys	(a) 24–72 hours$^{\alpha}$ (b) 72 hours in w/UW solution$^{\beta}$	93–97% (1 year) 82–91% (5 years)	25	858	902	826	871	737	482	1,338	1,168	1,192	939	1,027	$50,000
Lungs	—	53.7% (1 year)	6	11 S 8 D	8 S 8 D	6 S 6 D	1 S 1 D	2 S	0	13 S 8 D	11 S 13 D	5 S 2 D	5 S 3 D	2 S	—
Livers	(a) 9 hours$^{\alpha}$ (b) 24–34 hours in w/UW solutions$^{\beta}$	70% (1 year) 60% (5 years)	10	120 A 34 C	97 A 35 C	82 A	66 A	36 A	1 A	48 A 10 C	28 A 4 C	12 A 11 C	15 A U C	34 A U C	$84,000
Hearts	4–8 hours	80% (1 year) 70% (5 years)	11	158	185	131	123	42	1	80	52	51	50	36	$83,000

Legend: A = adult; C = child; D = double; S = single; U = unavailable.

*Unless otherwise noted, the sources for these statistics are: Canadian Organ Replacement Register, *1988 Report* and *1989 Report* (Don Mills, Ont.: Hospital Medical Records Institute, 1990 and 1991) and Health and Welfare Canada.

○Patrick Sullivan, "Report Raises Questions about Cost of Organ Transplantation" (1988) 139:5 C.M.A.J. 433.

○See Canadian Pediatric Society, Nutrition Committee, "Statement on Human Milk Banking" (1985) 132:7 C.M.A.J. 750.

□Canadian Red Cross Society [hereinafter CRCS], *Clinical Guide to Transfusion: Products and Practices*, 2d ed. (Ottawa: The Society, 1987) at 29-30.

●See CRCS, *Blood Services Statistical Report 1988-89* (Ottawa: The Society, 1989) at 12, 18.

♦Personal communication with the Canadian Bone Marrow Transplant Group.

$^{\alpha}$HWC, "Symposium: Organ Transplantation in Canada Today" (1987) 20:1 Annals RCPSC 57 at 58.

$^{\beta}$See Satoru Todo et al., "Extended Preservation of Human Liver Grafts with UW Solution" (1989) 261:5 JAMA 711; Folkert O. Belzer and James H. Southard, "Principles of Solid Organ Preservation by Cold Storage" (1988) 45:4 Transplant. 673 at 675.

distributes roughly one million units of blood annually.[37] Donated blood is generally separated into red blood cells (45 per cent) and plasma (55 per cent). Red blood cells and plasma may then be further processed into the blood product derivatives that help provide lifelines into the modern hospital. Accident victims and patients undergoing major surgery, for example, require blood replenishment to prevent life-threatening shock. Similarly, severe burn victims and hemophiliacs, who lack the normal clotting factors that stop bleeding, routinely depend on plasma derivatives for treatment.

Such therapeutic needs create a demand for blood products. Since 1981 the federal, provincial and territorial governments have worked through the Canadian Blood Committee to develop a national blood policy. The national principles on which the Committee had operated for years were recently revised to emphasize voluntarism, gratuity or non-payment, national self-sufficiency, blood product safety, adequacy and security of supply, a national versus a regional blood system, cost-effectiveness and cost-efficiency.[38] Despite occasional acute local blood shortages and a chronic shortage of plasma for fractionation, the Canadian blood system is regarded in the international community as a voluntary system which generally satisfies Canada's national blood product needs.[39]

Beyond the demand for blood products themselves, modern medical needs have helped to create a demand for the conduits through which blood flows in the human body. For example, processed human umbilical cords are implanted as veins in the surgical repair of severely injured limbs.[40]

(2) Bone Marrow Transplants

Bone marrow is the soft tissue found in the inner cavity of bones. It helps to produce red blood cells, which carry oxygen, white blood cells, which attack foreign and infectious substances, and platelets, which prevent bleeding. Bone marrow transplants have been used to treat diseases such as severe aplastic anemia and leukemia for some twenty-five years.[41]

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37. See CRCS, *Blood Services Statistical Report 1988-89* (Ottawa: The Society, 1989) at 6-8, 10.

38. Effective 1991, a newly created non-profit corporate entity, called the Canadian Blood Agency, will carry forward the mission, mandate and revised principles of the CBC. In essence, the revised principles expand on and clarify the original four principles of voluntarism, gratuity, self-sufficiency and non-profit, with the exception that the latter is replaced with cost-effectiveness/cost-efficiency — a principle which may allow for limited for-profit mechanisms to help satisfy the supply and self-sufficiency principles of the national blood system. See *Annual Report of the Canadian Blood Committee to the Provincial-Territorial Conference of Ministers of Health* (1989). See also CBC, *supra*, note 35 at 19-22. Compare World Health Organization and League of Red Cross Societies, "Final Recommendations of the Meeting on the Utilization and Supply of Human Blood and Blood Products (1975)" in Piet J. Hagen, *Blood: Gift or Merchandise* (New York: Alan R. Liss, 1982) 200.

39. See U.S. Congress, Office of Technology Assessment [hereinafter OTA], *Blood Policy & Technology* (Washington, D.C.: OTA, 1985) at 177. See also text accompanying notes 202-206, below.

40. See James H. Thomas et al., "Vascular Graft Selection" (1988) 68:4 Surg. Clin. North Am. 865; Jens H. Eickhoff et al., "Four Years' Results of a Prospective, Randomized Clinical Trial Comparing Polytetrafluoroethylene and Modified Human Umbilical Vein for Below-Knee Femoropopliteal Bypass" (1987) 6:5 J. Vasc. Surg. 506.

41. Noël A. Buskard, "Bone Marrow Transplantation: 25 Years of Progress" (1988) 21:7 Annals RCPSC 487. See also Noël A. Buskard, "Future Directions of Bone Marrow Transplantation" (1987) 137:4 C.M.A.J. 277.

With long-term survival rates of roughly 50 per cent, bone marrow transplantation is considered the treatment choice for severe aplastic anemia, for example.[42] Aplastic anemia is a blood disorder characterized by a persistently subnormal level of red blood cells. In untreated cases, 80 per cent of its victims are dead within six months after diagnosis; blood transfusions and other forms of therapy yield long-term survival rates of only about 20 per cent.[43] Similarly, bone marrow transplantation offers patients afflicted with leukemia, a cancer of the white blood cells, a better chance of long-term survival than does conventional treatment of the disease by chemotherapy.[44] Indeed, recent reports indicate that 50 to 80 per cent of acute leukemia patients who receive early bone marrow transplants have had prolonged disease-free survival.[45] The treatments appear to be cost-effective as well.[46]

A want of suitably matched donors limits the number of bone marrow transplant treatments currently performed at nine Canadian bone marrow transplant centres.[47] Many candidates for bone marrow transplant depend on donors who are related to them, such as siblings, because such donors tend to be more tissue-compatible, and this reduces the likelihood of rejection. A French and American team recently reported the successful use of frozen umbilical-cord blood from a newborn infant for transplant two weeks later into her five-year-old brother, who was afflicted with a disorder normally treated by bone marrow transplant.[48] As these alternative and customary technologies continue to develop, "[a]pproximately two-thirds of patients who may be eligible for an allogeneic (from an unrelated or related donor) bone marrow transplant do not receive one because of the lack of a compatible donor."[49] If those patients could be matched, the estimated 200 bone marrow transplants annually performed in Canada might double or triple.[50] Accordingly, the Canadian Red Cross recently established a national registry to increase the bone marrow transplant donor pool of unrelated Canadians.[51]

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42. Lawrence D. Grouse and Roxanne K. Young, "Bone Marrow Transplantation: A Lifesaving Applied Art" (1983) 249:18 JAMA 2528 at 2529.

43. Robert Dinsmore and Richard J. O'Reilly, "Bone Marrow Transplantation: Current Status" (1982) 12 Pathobiology Annual 213 at 214.

44. Michael Barnett, Allen Eaves and Gordon Phillips, "An Overview of Bone Marrow Transplantation for Chronic Myeloid Leukemia" (1990) 143:3 C.M.A.J. 187 at 188-89. See also Buskard (1988), *supra*, note 41 at 488.

45. See Gail Rock et al., "Registry of Unrelated Bone Marrow Donors" (1987) 137:3 C.M.A.J. 294 at 295.

46. See FEDS, *supra*, note 29 at 53. See also OTA, *The Cost Effectiveness of Bone Marrow Transplant Therapy and Its Policy Implications* (Washington, D.C.: U.S. Government Printing Office, 1981).

47. For projections on the number of centres 1985-90, see FEDS, *supra*, note 29 at 100.

48. Eliane Gluckman et al., "Hematopoietic Reconstitution in a Patient with Fanconi's Anemia by Means of Umbilical-Cord Blood from an HLA-Identical Sibling" (1989) 321:17 N. Engl. J. Med. 1174. See also Jean-Yves Nau, "Les cordons de la vie" *Le Monde* (6 December 1989) 19.

49. Buskard (1988), *supra*, note 41 at 491.

50. See CRCS and Canadian Co-operative Bone Marrow Transplant Study Group, *Proposal to Develop and Maintain a Canadian Registry of Voluntary Donors of Bone Marrow* (Ottawa: The Society, 1988).

51. See Noël A. Buskard, "A Register of Life: The First Year of the Unrelated Bone Marrow Donor Registry" (1989) 141:6 C.M.A.J. 600. See also text accompanying note 187, below.

Increased use of autologous bone marrow transplants (ABMT) may complement efforts to meet the demand for bone marrow transplants. ABMT involves procuring the patient's own bone marrow and preserving or freezing[52] it for later reinfusion into the patient after intensive chemotherapy.[53] While ABMT generally avoids incompatibilities and disease transmission between the donor and the recipient, there is concern that use of the patient's own bone marrow risks reintroducing the patient's disease.[54] Nonetheless, recent reports of successful ABMTs world-wide suggest that the procedure may be more widely used in the future.[55]

(3) Cornea Transplants

The cornea is the outer transparent window covering the eye. Cornea transplants, or keratoplasty, seek to replace corneas so severely scarred or clouded by disease or accident that impaired vision or blindness results. Experimental transplants undertaken in the nineteenth century led to the first successful corneal transplantation in Europe in 1906.[56] Still, "[t]he modern era of keratoplasty began in the 1950s with the advent of improved surgical techniques and fine sutures, ... improved eye-banking methods, and the use of anti-inflammatory drugs to control graft rejection."[57]

Today, corneal grafting is the most frequently performed surgical tissue transplant in North America with a success rate of 90 per cent.[58] A total of 2,412 cornea transplants were performed in Canada in 1989.[59] Yet demand for the procedure exceeds the available supply of tissue. In 1989, 1,301 patients remained on active waiting lists for cornea transplants at the more than ten centres that performed the operation in Canada during that year.[60]

(4) Kidney Transplants

The first successful kidney transplant, between identical twins in Boston in 1954, ushered in the age of vital organ transplantation.[61] The procedure was first replicated in

52. Bone marrow may be frozen for up to 13 years. U.S. Department of Health and Human Services, Public Health Service, National Center for Health Services Research and Health Care Technology Assessment, *Reassessment of Autologous Bone Marrow Transplantation* (Washington, D.C.: U.S. Government Printing Office, 1988) at 2.

53. See *ibid.* at 1.

54. *Ibid.* at 12.

55. See *ibid.* at 3-12.

56. Council on Scientific Affairs, American Medical Association, "Report of the Organ Transplant Panel: Corneal Transplantation" (1988) 259:5 JAMA 719.

57. *Ibid.*

58. *Ibid.* at 719, 721.

59. Communication with HWC, and communication with the Canadian Ophthalmological Society Committee on Eye Banks, Subcommittee on Administrative Co-ordinators.

60. *Ibid.*

61. See Joseph E. Murray and J. Hartwell Harrison, "Surgical Management of Fifty Patients with Kidney Transplants Including Eighteen Pairs of Twins" (1963) 105 Am. J. Sur. 205.

Canada at a Montreal hospital in 1958.[62] Improved surgical techniques and drugs to fight organ rejection eventually enabled Montreal surgeons to transplant kidneys between non-related persons in 1963.[63]

As the oldest solid organ transplant procedure, kidney transplant today defines the prototype of vital organ transplantation. It is the most frequently performed vital organ transplant procedure both in Canada and in the world. Canadian surgeons performed approximately three times as many kidney transplants in 1989 as heart and liver transplants.[64] Some 90 per cent of kidney recipients survive one year, depending on the source of the organ and the tissue rejection therapy used.[65] For those patients who may be candidates for both transplantation and the artificial kidney, the comparable survival rates, lower cost and better quality of life attributed to kidney transplants have generally made it the treatment of choice for irreversible kidney failure.[66] As with cornea transplants, demand for the procedure greatly exceeds supply. The shortage of donated kidneys meant that 1,338 patients awaited kidney transplants in twenty-five centres across Canada at the end of 1989.[67]

(5) Heart Transplants

In 1967, South African surgeon Christian Barnard drew international attention by performing the first human heart transplant. The patient survived eighteen days.[68] Over the next fifteen months the number of heart transplants world-wide soared; surgeons performed the first Canadian heart transplant — the eighteenth in the world — at the Montreal Heart Institute in 1968.[69] Poor survival rates, however, soon dampened initial enthusiasm. By the mid-1970s, few centres in the world continued to perform what was generally considered an experimental procedure.

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62. Mae Cox, *Human Transplants in Canada* (Edmonton: Human Parts Banks of Canada, 1978) at 17.

63. *Ibid.* at 18.

64. See table 1, *supra* at 9.

65. *Ibid.* Compare FEDS, *supra*, note 29 at 23; P.A. Keown and C.R. Stiller, "Kidney Transplantation" (1986) 66:3 Surg. Clin. North Am. 517 at 534; and U.S. Department of Health and Human Services, *Report on the Scientific and Clinical Status of Organ Transplantation* (Washington, D.C.: U.S. Government Printing Office, 1988) at 16.

66. Compare Roger W. Evans et al., "The Quality of Life of Patients with End-Stage Renal Disease" (1985) 312:9 N. Engl. J. Med. 553 and Roberta G. Simmons, Linda Abress and Carol Anderson, "Rehabilitation after Kidney Transplantation" in G. James Cerilli, ed., *Organ Transplantation and Replacement* (Philadelphia: J.B. Lippincott, 1988) 481 at 488.

67. Canadian Organ Replacement Register [hereinafter CORR], *1989 Report* (Don Mills, Ont.: Hospital Medical Records Institute, 1991) at 103, 111.

68. "Cardiac Transplantation" (1967) 4 Brit. Med. J. 757. For critical discussion of the informed-consent dialogue in this first transplant, see Jay Katz, *The Silent World of Doctor and Patient* (New York: Free Press, 1984).

69. Cox, *supra*, note 62 at 46-47.

In the 1980s, refined and standardized surgical techniques, improved patient selection and clinical management and anti-rejection drugs combined to boost survival rates. The use of the anti-rejection drug, cyclosporine, for example, increased immediate survival rates by 10 to 15 per cent.[70] Today, "[e]ighty percent of all heart transplant recipients now survive at least one year, and 50 per cent will survive 5 years."[71] The improved survival rates have helped move heart transplants from being regarded as experimental procedures towards acceptance as effective therapy for end-stage heart disease.[72]

The advances in heart transplantation have also led to broader diffusion of and demand for the technology. The number of transplants has increased threefold since some fifty were performed in 1985.[73] By the end of 1989, eighty patients were reported on waiting lists for heart transplants at eight Canadian centres.[74]

(6) Liver Transplants

In 1963, Dr. Thomas Starzl attempted the first human liver transplant in Denver, Colorado.[75] The first Canadian procedure was performed in Calgary eleven years later.[76] The transplants are designed to replace livers damaged by such conditions as genetic disorders, cancer and cirrhosis.[77] Unfortunately, fewer than 30 per cent of the early liver transplant patients survived a year, the low survival rate being due to rejection, uncontrolled bleeding, infections and technical complications.[78]

Medical advances again overcame initially poor results, however. Patient management and surgical techniques improved. The advent of the anti-rejection drug cyclosporine in the early 1980s helped double and triple one- and five-year survival rates.[79] Today, depending on the specific condition being treated by the liver transplant, "[s]urvival rates are ... 70% or more."[80] As with heart and kidney transplants, improved success rates

70. USTF, *supra*, note 29 at 18 n. 4.

71. Evans et al., *supra*, note 29 at 1892.

72. Compare FEDS, *supra*, note 29 at 19 and U.S. Department of Health and Human Services, *supra*, note 65 at 23.

73. See CORR, *supra*, note 67 at 148.

74. As of December 1989. Communication with HWC, *supra*, note 59.

75. Thomas E. Starzl et al., "Evolution of Liver Transplantation" (1982) 2:5 Hepatology 614.

76. Cox, *supra*, note 62 at 47.

77. Thomas E. Starzl et al., "Liver Transplantation" (1989) 321:15 N. Engl. J. Med. 1014 at 1015.

78. William J. Wall, "Liver Transplantation: Current Concepts" (1988) 139:1 C.M.A.J. 21.

79. See Robert D. Gordon et al., "Indications for Liver Transplantation in the Cyclosporine Era" (1986) 66:3 Surg. Clinics North Am. 541 at 542-43.

80. Wall, *supra*, note 78 at 21. See also U.S. Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research, *Health Technology Assessment Reports, 1990: Assessment of Liver Transplantation* (Rockville, Md.: U.S. Department of Health and Human Services, 1990) [hereinafter *Liver Assessment*].

have increased the diffusion of and demand for the technology. Nearly twice as many adult liver transplants were performed in Canada in 1988 than were performed three years earlier.[81] By the end of 1989, forty-eight adults awaited donated livers at transplantation centres in Canada.[82]

Pediatric liver transplants are an even more recent development. Most children who are liver transplant candidates suffer from a birth defect known as biliary atresia, which is the blockage or underdevelopment of the bile duct. The bile duct transports bile from the liver to the small intestine. Duct blockage may cause jaundice or eventually lead to cirrhosis and death. While conventional surgery helps some children, "over half . . . will die within the first two to three years of life."[83] Because no Canadian centre performed liver transplants on children before 1985, pediatricians were obliged to make referrals to centres in the United States. By contrast, in 1989, Canadian surgeons performed thirty-four pediatric liver transplants; ten children remained on active waiting lists at the end of that year.[84] It remains to be seen whether a new experimental procedure may one day ease the demand for cadaveric livers for children. The new procedure involves transplanting part of the liver from a living adult donor into a child recipient, whereafter the adult donor's liver regenerates within a month and the child's new partial liver develops as the child grows.[85]

(7) Other Vital Organ Transplants

The demand for and performance of pancreatic, intestinal, lung, and heart-lung transplants are relatively modest, in part, because these newer procedures remain largely experimental.[86] For example, a Toronto team performed the first successful single and double lung transplant in the world only in 1983 and 1986 respectively.[87] Ontario surgeons performed the first successful small bowel transplant in 1989.[88] If such transplant procedures advance beyond experimental stages into established treatment modalities, the demand for them is likely to expand.[89]

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81. 97 v. 36. See table 1, *supra* at 9.

82. Communication with HWC, *supra*, note 59.

83. Diana Swift, "Scaled-Down Adult Livers Offer Transplant Hope to Newborns" *The Medical Post* (25 April 1989) 11.

84. Communication with HWC, *supra*, note 59.

85. See Russell W. Strong et al., "Successful Liver Transplantation from a Living Donor to Her Son" (1990) 322:21 N. Engl. J. Med. 1505; Gina Kolata, "Surgeons Complete Historic Transplant" *New York Times* (28 November 1989) C10.

86. See U.S. Department of Health and Human Services, *supra*, note 65 at 9.

87. See "CF Patient's Double Lung Transplant a First" (1988) 55:6 Ontario Med. Rev. 49; and R.F. Grossman et al., "Results of Single-Lung Transplantation for Bilateral Pulmonary Fibrosis" (1990) 322:11 N. Engl. J. Med. 727.

88. Cameron Johnston, "Canadian Surgeons Lay Claim to World's First Successful Bowel Transplant" (1989) 141:2 C.M.A.J. 156.

89. See FEDS, *supra*, note 29 at 36-38.

C. Biotechnological Demand

The onset of the biotechnological age has created new uses, demand and treatments of, and new conflicts[90] over, the human body. An American report recently identified over 100 therapeutic products under development by the biotechnology industry, "many, but not all" of which are derived from human cells or tissue.[91] Biotechnological advances hold the promise of enabling scientists to derive safe, generous quantities of pituitary and pancreatic extract, other hormones and blood-clotting factors from human tissues that for millennia had relatively little therapeutic value.

A contraction of "biological technology," the word biotechnology came into use following quantum developments in the science of manipulating cells and genetic material in the mid-1970s.[92] Cell fusion, cell culture and recombinant DNA (rDNA) are three major technologies that have proven instrumental to biotechnological applications in medicine. Recombinant technology involves the genetic engineering of deoxyribonucleic acid (DNA), the basic storage molecule for genetic information in the cell; DNA contains programmed instructions that effectively define cell components and how they are to be made.[93] In gene cloning, the recombinant DNA process, portions of DNA from one cell are isolated and transferred into another, so that the recipient cell may produce and express the genetic make-up of the original cell as it grows.[94]

Cell fusion and cell culture technologies also aim at manipulated cell growth. Cell fusion technology, which involves the fusion of cells from different species, may yield immortal hybrid cells called hybridomas.[95] To secure large numbers of genetically different cells that may be fused, biotechnologists have refined the age-old process of cell culture technology — that is, deliberately culturing living cells as has been traditionally done in cheese and yogurt making. The modern application lies in cultivating tissue-derived cells into an indefinitely replicating growth known as a cell line.[96]

While translating these technologies into therapeutic products may be a formidable undertaking, some companies have successfully moved the fruits of biotechnological research from the laboratory into the hospital. Already, genetically engineered hepatitis B vaccines, insulin and the anti-cancer agent interferon have been licensed by federal authorities in Canada.[97] Vaccines derived from rDNA for polio and sexually transmitted

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90. See chap. 3, below.

91. OTA, *New Developments in Biotechnology: Ownership of Human Tissues and Cells*, paper prepared by Gladys B. White et al. (Washington, D.C.: U.S. Government Printing Office, 1987) at 56-59 [hereinafter White].

92. A. Crafts-Lighty, *Information Sources in Biotechnology* (New York: Nature Press, 1983) at 1.

93. White, *supra*, note 91 at 41.

94. Beak Consultants, *Regulatory Policy Options for Canadian Biotechnology* (Mississauga, Ont.: Beak Consultants, 1987) at 1.1.

95. White, *supra*, note 91 at 5.

96. *Ibid.* at 33.

97. Communication with Drugs Directorate, HWC. See also OTA, *Commercial Biotechnology: An International Analysis* (Washington, D.C.: OTA, 1984) c. 5 at 119.

diseases are being developed.[98] DNA- and cell-fusion-derived growth factors have been in use in clinical trials as new bone marrow transplant technologies.[99] Recombinant Factor VIII for hemophiliacs is expected to receive federal licensure in 1991-92.

Indeed, the development of one particular genetically engineered product, human growth hormone, illustrates the impact biotechnology may have on medicine and law. Hormones are produced in such small quantities in the human body that extracting them from human organs either requires mass quantities of the tissues or is simply not feasible.[100] The extraction of insulin from human cadaveric pancreatic cells, for example, has generally not been undertaken because the concentrations of hormones are so small. Diabetes patients have thus traditionally relied on insulin extracted from the pancreases of pigs or sheep, which has occasionally had undesirable health effects on human beings.[101]

In contrast, human growth hormone has traditionally been obtained from human pituitary cells. It is used to treat dwarfism, which results from the underproduction of pituitary gland hormones. For years, Canada has relied on a national program involving the procurement of cadaver pituitaries, their pulverization and the extraction and purification of growth hormone, to treat hundreds of children.[102] An obviously important factor in the supply of therapeutic growth hormone in such circumstances is the "availability of human pituitaries."[103] Hence, several provinces have enacted presumed-consent laws to facilitate the procurement of pituitary glands from cadavers for the program.[104]

Recently, the national program underwent a basic change. Between 1985 and 1987, most Canadian pediatricians switched from cadaver-derived to rDNA-derived human growth hormone as a result of two events: first, a concern in the international medical community that recent deaths of human growth hormone patients might be attributable to their having received cadaver-derived, infected human growth hormone; secondly, the start of clinical trials to test the efficacy of recombinant human growth hormone in Canada.[105] The confluence of these events prompted Canadian authorities and physicians to accelerate

98. See *Commercial Biotechnology*, *supra*, note 97 at 143-44.

99. Beak Consultants, *supra*, note 94 at 3.12. See also Harold M. Schmeck, "Cell Growth Factors Emerge as Potent Therapies" *New York Times* (28 March 1989) C1.

100. See Ronald W. Ellis, "Vaccines, Diagnostic Proteins and Hormones" in H.-J. Rehm and G. Reed, eds, *Biotechnology*, vol. 7B (New York: VCH Publishers, 1989) 167 at 170-71.

101. See Beak Consultants, *supra*, note 94 at 3.12.

102. See "20-Year MRC Growth Hormone Trial Draws to Successful Conclusion" (1988) 17:2 MRC Newsletter 7.

103. Charles McLean et al., "The Extraction, Purification and Synthesis of Anterior Pituitary Hormones for Therapeutic and Diagnostic Use" in Colin Beardwell and Gary L. Robertson, eds, *The Pituitary* (London: Butterworths, 1981) 238 at 239.

104. See page 133, below.

105. See MRC Newsletter, *supra*, note 102. See also P. Brown, "Human Growth Hormone Therapy and Creutzfeldt-Jakob Disease: A Drama in Three Acts" (1988) 81:1 Pediatrics 85. The availability of recombinant HGH has apparently occasioned new ethical and economic concerns. See John Lantos, Mark Siegler and Leona Cuttler, "Ethical Issues in Growth Hormone Therapy" (1989) 261:7 JAMA 1020.

clinical trials which resulted in the licensing of recombinant human growth hormone in 1986. Today, Canada relies on recombinant human growth hormone for treatment purposes. These developments likely erode the need for presumed-consent legislation for the procurement of cadaver pituitaries.

II. Therapeutic Supply Sources

Although human beings provide most of the tissues and bodily parts needed in tissue transplant treatments, animals, artificial and synthetic products and tissue banks also serve as sources.

A. Animals

Animals currently play three critical roles in tissue transplant treatment. First, society has long relied on them as laboratory models for developing and refining experimental and surgical procedures for later application to human beings. For instance, human liver transplants were predicated on decades of work in animal laboratories.[106] Secondly, some patients depend on animal-derived hormones for medical treatment. The diabetic's use of insulin extracted from animal pancreases is the classic example. Thirdly, the use of catgut as absorbable sutures, pig heart valves in heart valve replacement surgery[107] and pig skin and bovine amnion as biological dressings[108] for burn victims illustrates that animal tissues serve as temporary and permanent grafts.

Whether animals should serve as a direct source for human organ transplants depends on medical research and related ethical and legal issues. These concerns were demonstrated in 1984, when a California surgeon attempted a cross-species transplant involving infant "Baby Fae." The idea of xenografts apparently dates from prehistoric times; they were initially practised in the 1900s using rabbit, pig and sheep kidneys.[109] The development of kidney transplants in the early 1960s helped resurrect the idea in the form of vital organ transplants from primates.[110] The Baby Fae case marked the first transplant of a baboon's heart into an infant who suffered from a rare heart defect that usually claims life within a month after birth.[111] Baby Fae survived twenty days before her body rejected the foreign tissue.[112]

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106. See, *e.g.*, Starzl et al., *supra*, note 75 at 614-15.

107. See Peter Bloomfield et al., "Twelve-Year Comparison of a Bjork-Shiley Mechanical Heart Valve with Porcine Bioprostheses" (1991) 324:9 N. Engl. J. Med. 573.

108. See Arnold Luterman and P. William Curreri, "Skin Transplantation" in Cerilli, *supra*, note 66 at 630. See also A.S. Brown and L.R. Barot, "Biologic Dressings and Skin Substitutes" (1986) 13:1 Clinics in Plastic Surgery 69.

109. Council on Scientific Affairs, American Medical Association, "Xenografts: Review of the Literature and Current Status" (1985) 254:23 JAMA 3353.

110. *Ibid.*

111. L.L. Bailey et al., "Baboon-to-Human Cardiac Xenotransplantation in a Neonate" (1985) 254:23 JAMA 3321.

112. *Ibid.*

The case provoked considerable controversy over several issues, namely:

- whether the institution had complied with federal laws governing such research;[113]
- whether there existed a reasonable hope of benefit for Baby Fae, or whether she simply served as a research instrumentality for science;[114]
- whether her parents were able to give informed consent, in view of evidence that the prospects for survival may have been overstated while the availability of human hearts may have been understated;[115]
- whether xenografts violate natural law or the respect that is due another species, by reducing animals to pure instruments of human welfare;[116] and
- whether societal resources should be allocated to such exotic medical experimentation even "where no reasonable alternative therapy exists."[117]

Approval of such a case in a Canadian university would depend on the deliberations and research protocols of the institutional research ethics board.[118] The Baby Fae case demonstrates that medical research of this nature is fraught with ethical and legal concerns. While those concerns likely justify rigorous review and some prohibitions, a permanent ban may foreclose the possibility of therapeutic xenografts for Canadians.

B. Human Beings

Human beings constitute the main source of transplantable tissue. The specific tissue sources may be categorized into excretions or by-products such as sweat, urine or afterbirth; regenerative substances and tissues such as skin, milk, blood or bone marrow; non-regenerative organs, for example, the heart, kidney or liver; and whole bodies or corpses.[119] Hair and teeth may overlap or not easily fit into defined categories. Still, the

113. See 45 C.F.R. s. 46.

114. Robert M. Veatch, "The Ethics of Xenografts" (1986) 18:3 (Supp. 2) Transplant. Proc. 93.

115. See U.S. Department of Health and Human Services, National Institute of Health, *Report of the National Institute of Health Site Visit* (Washington, D.C.: U.S. Government Printing Office, 1986) at 5-6. See also George J. Annas, "Baby Fae: The 'Anything Goes' School of Human Experimentation" (1985) 15:1 Hast. Cent. Rep. 15 at 16.

116. Veatch, *supra*, note 114 at 94. See also Strachan Donnelley and Williard Gaylin, "Case Studies: The Heart of the Matter" (1989) 19:1 Hast. Cent. Rep. 26. For discussion of crimes against animals, see LRC, *Recodifying Criminal Law: Revised and Enlarged Edition of Report 30*, Report 31 (Ottawa: The Commission, 1987) at 97.

117. Arthur L. Caplan, "Ethical Issues Raised by Research Involving Xenografts" (1985) 254:23 JAMA 3339 at 3342.

118. See Medical Research Council of Canada, *Guidelines on Research Involving Human Subjects* (Ottawa: Supply and Services Canada, 1987) at 19 [hereinafter MRC]. For human experimentation case law, see *infra*, note 376.

119. See Michèle Harichaux, "Le Corps Objet" in Raphaël Draï and Michèle Harichaux, eds, *Bioéthique et Droit* (Paris: P.U.F., 1988) 130 at 132-36.

categories can prove significant. For example, the donation of regenerative tissue, usually by living donors, generally involves minimal physical invasiveness and medical risk.[120]

By contrast, most non-regenerative tissues and organs come from deceased adult donors — that is, cadavers. Kidney transplants from living donors are the notable exception. Living kidney donors constituted some 15 per cent of the donor pool in Canada in 1989.[121] Infants and children may also be organ donors, although their capacity to consent to live donations and their particular vulnerability raise special legal and ethical concerns.[122]

C. Artificial and Synthetic Sources

Artificial and synthetic replacements of human bodily parts have long been used to treat illness and injury. Artificial limbs were developed centuries ago to replace arms and legs, often severed in combat. False teeth were used as early as 700 B.C.; their modern form emerged in the eighteenth or nineteenth century, to replace teeth transplants from living donors and the occasional trade in teeth from battlefield corpses.[123] Today, artificial tissue replacement technologies range from synthetic blood vessels to mechanical heart valves, to rDNA insulin, the genetically engineered hormone from the human pancreas. Synthetic lenses, artificial eyes and electronic hearing-aids have become common. By contrast, artificial devices to replace the human lung, heart, liver or pancreas are recent, more complicated phenomena.[124] Indeed, few safe and effective artificial organs have been licensed under federal law in Canada. The limited success of the artificial heart exemplifies the rule. The widespread use of the artificial kidney illustrates the exception.

(1) The Artificial Kidney

The artificial kidney, or renal dialysis, is the only artificial organ that has moved beyond experimental to routine therapy for irreversible organ failure. Following decades of research, experimentation and refinement, long-term dialysis was introduced into clinical practice in the 1960s.[125] Today, dialysis provides safe, effective treatment for many of

120. But see *Cox* v. *Saskatoon*, [1942] 1 W.W.R. 717 (Sask. C.A.) (awarding blood donor damages for transfusion infection).

121. 138 of 902. See CORR, *supra*, note 67. The 15-per-cent figure is consistent with previous years and parallels a 20-per-cent figure in the U.S. See *Canadian Renal Failure Register: 1986 Report* (Ottawa: Kidney Foundation of Canada, 1987) at 119, 122 [hereinafter CRFR]; and U.S. Department of Health and Human Services, *supra*, note 65 at 14. See generally, Peter G. Blake and Carl J. Cardella, "Kidney Donation by Living Unrelated Donors" (1989) 141:8 C.M.A.J. 773.

122. See chaps 2 and 3, below.

123. Jeanne Thomas, "Fangs for the Memories: False Teeth Have Come a Long Way over Century" *The Medical Post* (11 April 1989) 71.

124. See Harold M. Schmeck, *The Semi-Artificial Man* (New York: Walker, 1965).

125. See William Drukker, "Hemodialysis: A Historical Review" in William Drukker, Frank M. Parsons and John F. Maher, eds, *Replacement of Renal Function by Dialysis*, 2d ed. (Boston: Martinus Nijhoff, 1983) 3 at 28.

the conditions that cause irreversible kidney failure. In 1989, some 5,600 patients received dialysis at dozens of centres across Canada.[126]

Dialysis treatment typically requires three weekly visits of between three and four hours each to a dialysis centre. Because chronic dialysis patients must follow a strict regime of treatment and diet, the life-saving technology does impose quality-of-life restrictions. Owing to age and other medical factors,[127] some 40 per cent of the patients in Canada who received dialysis in 1986 were not candidates for kidney transplantation.[128]

Because the artificial kidney is the only non-experimental artificial vital organ, it plays a unique role after transplant failure. The minority of kidney transplant recipients whose transplantation fails has, in theory, two live-saving options: retransplantation and the artificial kidney. Recipients of other vital organs face a statistically greater chance of transplant failure.[129] In the event of failure, they have no safe and effective artificial organ to which they can return while awaiting another transplant.

(2) The Artificial Heart

Therapeutic use of the artificial heart is less advanced. Some heart assistance devices such as implantable pacemakers and synthetic and mechanical heart valves were developed in the 1960s and are now routinely used in treatment.[130] However, the implantable artificial heart remains an experimental medical device[131] which thus affords patients neither the safety nor the quality of life that kidney dialysis does. Artificial heart patients run the risk of blood clots, infections and a diminished quality of life.[132]

At the few Canadian hospitals using the artificial heart, the device has served as a "temporary bridge" to heart transplantation. Such use gained currency following attempts to implant a permanent, artificial heart in five patients in the United States in the early 1980s.[133] Implantation did permit some patients to be mobile and resume normal routines during their 10 to 620 days of extended life.[134] But their quality of life was compromised

126. CORR, *supra*, note 67 at 5,155.

127. OTA, *Life-sustaining Technologies and the Elderly* (Washington, D.C.: OTA, 1987) at 249.

128. CRFR, *supra*, note 121 at 119, 131-32 (1,506 of 3,484 registered dialysis patients, 43%, medically unsuitable candidates for transplant).

129. See table 1, *supra* at 9.

130. See Wilfred Lynch, *Implants: Reconstructing the Human Body* (New York: Van Nostrand Reinhold, 1982) at 53, 75.

131. As an experimental medical device, its use is governed by federal research guidelines and federal medical devices law. See MRC, *supra*, note 118 at 19. See also chap. 3, below.

132. See Steven H. Miles et al., "The Total Artificial Heart: An Ethics Perspective on Current Clinical Research and Deployment" (1988) 94:2 Chest 409.

133. See Gideon Gil, "The Artificial Heart Juggernaut" (1989) 19:2 Hast. Cent. Rep. 24.

134. William C. DeVries, "The Permanent Artificial Heart" (1988) 259:6 JAMA 849.

by massive strokes, chronic infection and chronic hospitalization.[135] The device continues to provoke wide ethical debate.[136]

(3) Genetically Engineered Cells, Tissues and Drugs

Genetically engineered insulin, anti-cancer agents, human growth hormone, and blood-clotting factors have already been described; moreover, biosynthetic skin, veins, glands and valves are at different stages of development and use.[137] Ongoing research on rDNA cell growth factors further suggests how these new tissue replacement technologies may help to ease the demand for scarce therapeutic tissues. Genetically engineered cell growth factors replicate and propagate growth-promoting substances that are produced naturally in the human body. They are expected to be used in treatment ranging from attacking cancer cells to aiding bone marrow transplants.[138]

Clinical trials have recently examined the use of growth factors to stimulate red blood cell production to treat anemia, which is a deficiency in red blood cells. Kidney dialysis and transplant patients often require repeated blood transfusions to treat the anemic side-effects of kidney failure. Scientists have found that the increase in red blood cells from taking the genetically engineered hormone, erythropoietin, tends to reduce the frequency of transfusions, and thus the patient's quality of life is enhanced.[139] Canadian and United States federal drug authorities approved erythropoietin as safe and effective for such treatments in 1989-90.[140]

D. Tissue Banking and Preservation

When removed from the body, tissue is deprived of blood and the essential nutrients and oxygen that blood carries. Normally, such deprivation results in damage or death to

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135. *Ibid.*

136. See Miles et al., *supra*, note 132. Compare George J. Annas, "Death and the Magic Machine: Informed Consent to the Artificial Heart" (1987) 9 W. New Engl. L. Rev. 89; and U.S. Department of Health and Human Services, The Working Group on Mechanical Circulatory Support of The National Heart, Lung, and Blood Institute, *Artificial Heart and Assist Devices: Directions, Needs, Costs, Societal and Ethical Issues* (Washington, D.C.: National Institute of Health, 1985).

137. See Bloomfield et al., *supra*, note 107; text accompanying notes 97 to 105, *supra*; *infra*, note 206; and chap. 3, table 2, *infra* at 121. See also E. Bell and M. Rosenberg, "The Commercial Use of Cultivated Human Cells" (1990) 22:3 Transplant. Proc. 971; Lawrence M. Fisher, "3 Companies Speed Artificial Skin" *New York Times* (12 September 1990) D1; and "Biomatériaux: l'avenir de l'homme-prothèse" *Le Monde* (5 September 1990) 25.

138. See Michael B. Sporn and Anita B. Roberts, *Peptide Growth Factors and Their Receptors* (New York: Springer-Verlag, 1990).

139. See Joseph W. Eschbach et al., "Treatment of the Anemia of Progressive Renal Failure with Recombinant Human Erythropoietin" (1989) 321:3 N. Engl. J. Med. 158.

140. See Rhonda L. Rundle, "Biotech Battlefront: Amgen, Cleared to Sell Kidney Patient Drug, Still Faces Big Hurdles" *Wall Street Journal* (2 June 1989) A1. For discussion of U.S. biotech company patent disputes over EPO see also *Amgen Inc.* v. *Chugai Pharmaceutical Co.*, *infra*, note 776.

the tissue. In tissue preservation, an attempt is made to suspend this degenerative process. Through medical science, tissue can be frozen and chemically preserved for treatment and research purposes.[141]

As with transplant technology, medical scientists began mastering the therapeutic storage of simple tissues before developing preservation methods for kidneys and other complex tissues and vital organs. Tissue banking is largely a post-World-War-II development which began with the routine storage of blood in the 1940s.[142] Developments since then have lead to the routine storage of regenerative bodily substances such as blood, sperm, skin, bone marrow, cells and milk from living donors, and non-regenerative tissues such as heart valves, veins, tendons, nerves, bones and corneal tissue from cadavers.[143] Currently, tissue banks "range in size and complexity from comprehensive centres . . . to small local operations providing one type of tissue for one physician, and under that physician's own responsibility."[144]

Unfortunately, even today tissue banks do not exist for livers, kidneys and hearts. Under current transplantation practice, those vital organs require virtually continuous perfusion with blood to prevent deterioration. Using traditional preservation solutions, surgeons generally have only hours — at the most, days — between removal of the organ from the donor and its implantation into the recipient.[145] A recently approved new chemical preservative, the UW solution, may double or triple the time surgeons have to get a donated organ to a transplant recipient.[146] Still, the contrast with the more generous time constraints of tissue procurement, the narrow period in which transplant surgeons must work and the non-regenerativeness of vital organs combine to accentuate the necessity of rapidly and properly matching and transplanting organs that become available.

Milk Banks: Human milk was one of the first bodily substances to be banked for therapeutic use. The first Canadian milk bank was established during the 1920s at the Winnipeg Children's Hospital.[147] By the mid-1980s, some twenty banks were in existence.[148] They provide human milk to infants who are unable to obtain a sufficient supply from their own mothers.[149] While women in some countries are paid to donate

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141. See R. Razaboni and W.W. Shaw, "Preservation of Tissue for Transplantation and Replantation" (1983) 10:1 Clinics in Plastic Surgery 211 at 212-13.

142. See text accompanying notes 33-35, *supra*.

143. See *Report of the Alberta Human Tissue Procurement Task Force* (Edmonton, Alta: The Task Force, 1985) at 24.

144. *Ibid.* For legal responses to such developments, compare *An Act to amend the Public Health Protection Act*, S.Q. 1990, c. 55 and a recent Belgian Crown Order, *infra*, note 958.

145. See table 1, *supra* at 9.

146. See *ibid.* See also Satoru Todo et al., "Extended Preservation of Human Liver Grafts with UW Solution" (1989) 261:5 JAMA 711; Folkert O. Belzer and James H. Southard, "Principles of Solid Organ Preservation by Cold Storage" (1988) 45:4 Transplant. 673 at 675.

147. Gilbert Sharpe, *The Law & Medicine in Canada*, 2d ed. (Toronto: Butterworths, 1987) at 330.

148. See Canadian Pediatric Society, Nutrition Committee, "Statement on Human Milk Banking" (1985) 132:7 C.M.A.J. 750.

149. R.S. Sauvé et al., "Mothers' Milk Bank: Microbiologic Aspects" (1984) 75 Can. J. Public Health 133.

milk at supermarkets that serve as distribution centres, the Canadian practice has been to encourage mothers to donate gratuitously to hospital-based milk banks.[150] Donated human milk may be refrigerated twenty-four to forty-eight hours or frozen for up to six months.[151]

Blood Banks: Blood-banking technology has become more sophisticated and its use routine since its origins in the 1940s.[152] The length of storage before therapeutic use depends on the blood product. Whole blood may be refrigerated some thirty-five days, frozen plasma may be stored for three to twelve months, and frozen red blood cells may be stored for up to ten years.[153] With 900 blood banks estimated to exist in Canada, blood banking is the most common and most frequently used tissue-banking practice.[154]

Eye Banks: The first Canadian eye bank was established at the University of Toronto in 1955.[155] Today, ten eye banks provide services across Canada. Donated corneas are obtained from deceased donors and stored in a refrigerated tissue solution for up to three or four days.[156] Some banks freeze and store viable corneas, which they later thaw for transplantation. The three- to four-day refrigeration method used by most Canadian eye banks, however, means that they function as centres for the collection, grading and distribution of fresh corneas.[157] From April 1988 to March 1989 Canadian eye banks procured, stored or distributed over 5,000 donor eyes. Some 600 eyes were either placed in long-term storage or processed and stored for use as live contact lenses, 1,800 were used for research and teaching and 2,300 were transplanted.[158]

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150. Compare the results of a 1981 survey identifying one Canadian bank as paying donors, with the Finnish practice of paying donors $20/litre. See Calgary Mothers' Milk Bank, *Mothers' Milk Bank Manual* (Calgary, Alta: Calgary Mothers' Milk Bank, 1984) at 5 and Martti A. Siimes and Niilo Hallman, "A Perspective on Human Milk Banking 1978" (1979) 94:1 J. Pediatr. 173. Personal communication with Professor Siimes revealed that the 1977 figure of $13/litre has been increased to $20/litre.

151. HWC, *Infection Control Guidelines for Perinatal Care* (Ottawa: HWC, 1988) at 11-12; HWC, *Family-Centred Maternity and Newborn Care: National Guidelines* (Ottawa: Supply and Services Canada, 1987) para. 7.11 at 72. While milk banks are generally regulated by professional guidelines in Canada, other jurisdictions have enacted legislation and regulations to govern their practices and procedures. See, *e.g.*, N.Y. Pub. Health Law, ss 2505, 4360 (McKinney, 1991 Supp.), and French milk banks regulations, *infra*, note 934.

152. See section I.B(1), above.

153. See CBC, *supra*, note 35 at 34, citing CRSC, *Clinical Guide to Transfusion: Products and Practices*, 2d ed. (Ottawa: The Society, 1987) at 29.

154. One bank per 17 CRCS transfusion centres, plus one bank per 882 hospitals that received CRCS-distributed blood products in 1988-89. See *Blood Services Statistical Report 1988-89*, *supra*, note 37 at 58.

155. See Anne Wolf, "The Eye Bank of Canada, 1951 to 1988" [unpublished] at 1.

156. See Council on Scientific Affairs, *supra*, note 56 at 720.

157. See Manitoba Law Reform Commission, *Report on the Human Tissue Act*, Report 66 (Winnipeg: The Commission, 1986) at 5 [hereinafter MLRC]; Cox, *supra*, note 62 at 10.

158. Of 2,342 transplanted corneas, 301 involved fresh corneas usually used within 24 hours, 1,994 had been refrigerated for transplant within one to four days and 47 transplants involved corneas frozen before March 1988. Eye Bank of British Columbia, "Canadian Eye Bank Statistics, April 1st 1988 to March 31st 1989" [unpublished].

Sperm Banks: Donated human sperm may be frozen and banked for years before being thawed for use in infertility treatment. The first successful pregnancies resulting from frozen sperm were reported in the 1950s.[159] Artificial insemination in Canada began in the late 1960s.[160] A survey of eighteen Canadian artificial insemination centres, conducted in the early 1980s, elicited eleven responses: three reported regularly using frozen semen while eight relied on fresh semen.[161] Today, artificial insemination is "widely practiced using both fresh and frozen semen."[162] While the use of frozen semen has been more prevalent in some foreign jurisdictions,[163] recent concerns about the risks of HIV infection have led to calls in Canada for the mandatory and exclusive use of frozen semen to enable a more accurate screening of donors.[164] The increased practice of freezing other reproductive tissues is also becoming a component of modern infertility treatment.[165]

Cell and DNA Banks: Extended refrigeration and the long-term freezing of viable human cells have facilitated the development of cell and DNA banking, as an aid in the diagnosis of diseases. Frozen human cells may remain viable for as long as twenty years.[166] Such long-term storage of cells facilitates research and enables diagnostic comparisons to be made, for example, between cells suspected of having genetic abnormality and stored cells known to have genetic abnormality. This work is carried out by such entities as the Repository for Mutant Human Cell Strains at the Montreal Children's Hospital.

DNA banking also plays a role in the diagnosis of genetic disease. A DNA bank "is a facility that stores DNA for future analysis."[167] DNA may be extracted from the cells of preserved blood, fresh or frozen tissues or viable cells, and may then be stored indefinitely in micro-vials for later use in diagnosis. In a national screening program for Huntington's disease, recently undertaken at fourteen Canadian centres, to test whether patients carry the Huntington's disease gene, a DNA sample extracted from preserved tissue of a deceased

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159. See R.G. Bunge, W.C. Keettel and J.K. Sherman, "Clinical Use of Frozen Semen: Report of Four Cases" (1954) 5 Fertil. Steril. 520.

160. See Jacques E. Rioux and C.D.F. Ackman, "Artificial Insemination and Sperm Banks: The Canadian Experience" in Georges David and Wendel S. Price, eds, *Human Artificial Insemination and Semen Preservation* (New York: Plenum Press, 1980) 31.

161. HWC, *Report of the Advisory Committee on the Storage and Utilization of Human Sperm* (Ottawa: HWC, 1981) at x, 72.

162. HWC, Federal Centre for AIDS, *Guidelines for Prevention of HIV Infection in Organ and Tissue Transplantation* (October 1989) 15S4 (Supp.) Canada Diseases Wkly Rpt at 17 [hereinafter FCA].

163. See Derek J. Jones, "Artificial Procreation, Societal Reconceptions: Legal Insight from France" (1988) 36 Am. J. Comp. L. 525.

164. See FCA, *supra*, note 162 at 4 (use of fresh semen not recommended). See also The Canadian Fertility and Andrology Society, *Guidelines for Therapeutic Donor Insemination* (Montreal: The Society, 1988) at 3.

165. See LRC, *Medically Assisted Procreation*, Working Paper 65 (Ottawa: The Commission, 1992) and American Medical Association, "Board of Trustees Report: Frozen Pre-Embryos" (1990) 263:18 JAMA 2484. For a discussion of litigation over frozen embryos, see *infra*, note 415.

166. Linda Madisen et al., "DNA Banking: The Effects of Storage of Blood and Isolated DNA on the Integrity of DNA" (1987) 27 Am. J. Med. Genet. 379 at 388.

167. Ad Hoc Committee on DNA Technology, American Society of Human Genetics, "DNA Banking and DNA Analysis: Points to Consider" (1988) 42:5 Am. J. Human Genet. 781 [hereinafter ASHG].

relative of the patient may be required if preserved blood has not been stored.[168] In those screening trials, the need for preserved tissue has sometimes been met by the Canadian Brain Tissue Bank in Toronto. For years that Bank has been storing donated brain tissue for research purposes.[169] More recently, it has provided, to genetic analysts, brain tissue of deceased relatives from which the analysts then extract DNA and test it for Huntington's disease. If the genes for other degenerative brain conditions such as Alzheimer's disease are identified, the Bank might play a similar and perhaps expanded role.[170]

Bone Banks: Canada has some sixty bone banks,[171] which are capable of storing frozen bone indefinitely.[172] Bone is used largely in reconstructive surgery, such as in the treatment of tumours or fractures,[173] after it is procured from living and cadaver donors. Living donors may donate bone for removal during such surgery as total hip or total knee replacement.[174] Cadaver bones, typically the long bones of the leg and arms, may be procured independent of, or in conjunction with, organ procurement.[175]

As these tissue-banking technologies have evolved, so too have their medical and societal functions.[176] The ability to preserve a spectrum of human tissue and bodily substances has generated a common cluster of issues for tissue banks: What are the medical and non-medical criteria for donor and recipient participation?[177] What are the requirements and consequences of donor and recipient informed consent?[178] What are the

168. See Madisen et al., *supra*, note 166 at 380. See also Lawrence Surtees, "Doctors Using New Gene Probes in Huntington's Disease Program" *The [Toronto] Globe and Mail* (29 August 1988) A14; Kathleen Nolan and Sara Swenson, "New Tools, New Dilemmas: Genetic Frontiers" (1988) 18:5 Hast. Cent. Rep. 40. See generally, Note, "Legal Implications of the G-8 Huntington's Disease Genetic Marker" (1988-89) 39 Case W. Res. L. Rev. 273.

169. For British practices, see Diana Brahams, "Brain Banks" (1990) 335:8684 Lancet 282.

170. See Harold M. Schmeck, "Gene-Mappers Identify Dozens of Trouble Spots" *New York Times* (20 June 1989) C1 at C6 (gene-mappers seek to identify chromosomes or genes related to Alzheimer's disease, Down's syndrome, dwarfism, epilepsy).

171. Compare Gordon Russell, Richard Hu and Jim Raso, "Bone Banking in Canada: A Review" (1989) 32:4 Can. J. Surg. 231 and FCA, *supra*, note 162 at 17.

172. Nikki Jackson Jacobs, "Establishing a Surgical Bone Bank" in Kenneth Fawcett and Alice R. Barr, eds, *Tissue Banking* (Arlington, VI: American Association of Blood Banks, 1987) 67.

173. See *ibid.* See also Allan E. Gross, "The Use of Allografts in Orthopedic Surgery" (1989) 6 Transplantation/Implantation Today 44.

174. Jacobs, *supra*, note 172.

175. See William W. Tomford and Henri J. Mankin, "Cadaver Bone Procurement" in Fawcett and Barr, *supra*, note 172, 97.

176. See generally T.F. Kirn, "Tissue Banking in Midst of Revolution of Expansion as More Uses Are Found for Various Transplants" (1987) 258:3 JAMA 302.

177. See Ken Pole, "Red Cross Challenged over Blood Donor Policy" *The Medical Post* (20 June 1989) 12 (CRCS-directed blood donor policy challenged). For discussion of litigation over rights to participate in sperm bank services, see Jones, *supra*, note 163.

178. Does consent establish rights over the control and transfer of tissue? See Bartha M. Knoppers and Claude M. Laberge, "DNA Sampling and Informed Consent" (1989) 140:9 C.M.A.J. 1023 at 1027. See also *infra*, note 184.

contours of any duty to maintain confidential medical records?[179] Should banking procedures be regulated by professional standards or legislation?[180] To what extent should a bank be liable for furnishing diseased tissue?[181]

Thus, if new tissue-banking practices tend to create new functions, they may also create new issues. Autologous, "self-directed" tissue banking is an example. In contrast to traditional donors, who may give anatomical gifts to society at large through a tissue bank, autologous or self-directed donors of blood, bone marrow, DNA and reproductive matter might more accurately be called "depositors," for they bank their tissue for later use in treating their own or a family member's medical conditions.[182]

The recent Canadian practice of banking one's blood at a Red Cross centre or at a commercial, autologous blood bank exemplifies the trend.[183] Such deposit practices tend to modify the relationship between the tissue bank and the tissue depositor, particularly regarding control or ownership of the deposited material.[184] Finally, it should be noted that, beyond serving as repositories to assist medical treatment and research, tissue banks also assist commercial undertakings, for example, by storing patented human cell lines and human biologics.[185]

III. Co-ordinating Supply and Demand

To co-ordinate supply and demand, tissue exchange networks have developed from the local to the international level. Some efforts are structured within a cohesive national system. For example, the seventeen Canadian Red Cross transfusion centres largely serve regional blood collection and distribution needs within the framework of the national blood services, common principles and uniform procedures.[186] The system results from forty years of experience and evolution.

Tissue donor registries and organ exchange networks are more recent. Donor registries centralize the names and medical data of potential organ donors to facilitate the rapid matching of tissue types between a transplant patient and a potential donor. To expand

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179. See generally Lorne Elkin Rozovsky and Fay Adrienne Rozovsky, eds, *The Canadian Law of Patient Records* (Toronto: Butterworths, 1984). See also chap. 3, below.

180. See *supra*, note 151.

181. See *infra*, notes 501-503.

182. See ASHG, *supra*, note 167 at 782.

183. See Anne Gilmore, "Red Cross Gets Go-Ahead for Autologous Blood Service" (1988) 138:2 C.M.A.J. 157. See also *Blood Services Statistical Report 1988-89*, *supra*, note 37 at 11 (autologous collection at 17 CRCS centres); National Blood Resource Education Program Expert Panel, "The Use of Autologous Blood" (1990) 263:3 JAMA 414.

184. See ASHG, *supra*, note 167 at 782 ("Banked DNA is the property of the depositor unless otherwise stipulated"). See also chap. 3, below.

185. See American Type Culture Collection, *Catalogue of Cell Lines and Hybridomas*, 5th ed. (Rockville, Md: American Type Culture Collection, 1985) at vi.

186. See text accompanying notes 34-39, above.

the existing bone marrow transplant pool between unrelated donors and recipients, for example, the Canadian Red Cross Society recently established a national registry of 100,000 bone marrow transplant donors, who would provide compatible tissue to Canadian bone marrow transplant centres.[187] The Canadian Red Cross estimates that the registry will benefit an additional 400 bone marrow transplant patients annually.[188]

Organ exchange networks build on these information-exchanging principles. Nine provincial organ retrieval programs operate in Canada.[189] The first such network was established as a collaborative effort between four transplant centres in Toronto in 1976. By 1978, the Metro Organ Retrieval and Exchange (MORE) program functioned province-wide. It maintains a twenty-four-hour organ retrieval team, offers advice to referring hospitals and arranges for the transfer of donors to transplant centres.[190] Similar organ retrieval programs are now in operation in British Columbia, Manitoba, Saskatchewan, Alberta, the Maritimes and Quebec.[191]

Retrieval programs and transplant centres play critical roles in the organ donation process. The process begins by identifying potential donors. The typical donor has suffered irreversible brain injury, often from a car accident. Not surprisingly, then, most potential donors originate from the intensive care units of major hospitals.[192] Once a potential donor is identified, it is determined whether he or she has indicated a willingness to donate (for example, by driver's licence). If not, the potential donor's next of kin, who is authorized by law to consent or decline,[193] may be approached to discuss the possibility.

Following the certified brain death of the donor, which may require some twenty-four hours,[194] the next of kin signs the necessary consent forms. The donor is thereafter mechanically maintained and given continuous intensive clinical and biochemical monitoring, to preserve the organs for transplantation.[195] Monitoring may include administering antibiotics to fight infection, checking blood pressure and body temperature,

187. See *supra*, notes 50 and 51. Compare the U.S. registry involving 50 blood banks and 17 bone marrow transplant centres. Jane E. Brody, "New Registry Is Raising Hope for Those in Need of Bone Marrow" *New York Times* (12 January 1988) C1.

188. *Ibid.*

189. Anne Gilmore, "Procuring Donor Organs: Firm but Friendly Encouragement Required" (1986) 134:8 C.M.A.J. 932 at 937.

190. ONT, *supra*, note 29 at 114.

191. See Federal-Provincial Advisory Committee on Institutional and Medical Services, Subcommittee on Institutional Programs, *Organ and Tissue Donation Services in Hospitals: Guidelines for Establishing Standards for Special Services in Hospitals* (Ottawa: Supply and Services Canada, 1987) at 42-45.

192. ONT, *supra*, note 29 at 103. Joseph M. Darby et al., "Approach to Management of the Heartbeating 'Brain Dead' Organ Donor" (1989) 261:15 JAMA 2222 (98%).

193. See chap. 3, below.

194. See Canadian Congress on Neurological Sciences, "A CMA Position: Guidelines for the Diagnosis of Brain Death" (1987) 136:2 C.M.A.J. 200A. See also Canadian Congress Committee on Brain Death, "Death and Brain Death: A New Formulation for Canadian Medicine" (1988) 138:5 C.M.A.J. 405.

195. See ONT, *supra*, note 29 at 93.

rotating the body to prevent skin ulcers, registering hourly urine output and even resuscitating the minority of brain-dead, mechanically maintained donors who undergo heart failure during the maintenance phase.[196] The matching of blood and tissue types also precedes the actual surgical procedure. Donor tissue and blood must be rigorously screened to detect transmissible diseases.[197]

When a possible match is confirmed, one of three procurement options will be pursued. For some of the more established procurement and transplant procedures, such as kidney transplants, a medical team at the donor hospital may simply excise the kidney and ship it. Alternatively, the donor may be transported to the recipient hospital,[198] or a procurement team may drive or fly to the donor hospital. In the latter case, the organ is surgically removed, packed in ice and quickly returned by the procurement team to the recipient hospital. Surgical implantation of the organ may then begin. Some thirty-two hours are needed to co-ordinate the retrieval and transplantation of an organ such as a kidney: multiple organ retrieval from a single donor requires another ten hours.[199] Co-ordinating the supply of and demand for tissue sometimes necessitates international transfers.[200]

IV. Emerging Supply-and-Demand Dilemmas

The apparent shortfalls between the supply of and demand for tissue accentuate dilemmas confronting societies with advanced tissue transplant technologies. The dilemmas are illustrated by debates over tissue sales, consent requirements, bodily property and allocating scarce organs.

A. Scarcity, Payments and Biocommerce

To what extent should society prohibit or regulate the sale of human bodily parts and tissues? Some Canadian analysts have suggested regulated sales as a solution to organ shortages.[201] If sales are to be prohibited or regulated, how should they be defined? Are all payments that accompany tissue transfers "sales" money? What of tissues imported for Canadian patients from foreign jurisdictions where donors of semen, blood products, milk, bone marrow, placentas and kidneys receive payment in association with anatomical donations?

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196. See Darby et al., *supra*, note 192 at 2225-26.

197. See FCA, *supra*, note 162 (despite HIV transmission in other countries, no documented cases of HIV transmission in Canadian kidney, liver, heart, heart/lung, cornea, skin, bone, bone marrow, transplants; one reported case of HIV transmission associated with surrogate motherhood) at 1-2; U.S. Centers for Disease Control, "Semen Banking, Organ and Tissue Transplantation, and HIV Antibody Testing" (1988) 259:9 JAMA 1301. For case law regarding negligent screening of transplant tissues, see *infra*, note 501.

198. See A. Grenvik et al., "Multiple Organ Procurement by Interhospital Transfer of Heartbeating Cadavers" (1984) 16:1 Transplant. Proc. 251.

199. Gilmore, *supra*, note 189 at 936.

200. See the discussion of international transfers in chap. 4, below.

201. See, *e.g.*, G. Sharpe, "Commerce in Tissue and Organs" (1985) 17:6 (Supp. 4) Transplant. Proc. 33 at 38.

Canadian reliance on products that derive from commercially processed, imported fractionated plasma illustrates some of the practical realities that structure current public policy on sales. The collection of the plasma component of donated blood is instrumental in modern medical treatment. Fractionated plasma helps derive Factor VIII, a clotting agent used to treat some 2,800 hemophiliacs in Canada.[202] Unfortunately, world-wide need for Factor VIII has greatly exceeded its availability.[203] In Canada, most plasma that is collected by the Canadian Red Cross Society is fractionated into Factor VIII and fifteen other fractionated products by a laboratory in the United States; additional Factor VII plasma by-products are purchased on the international market,[204] which is largely supplied by a commercial plasmapheresis industry in the United States. The American industry, which supplies much of the world market, so relies on paid plasma donations that "[m]ore than half the world's supply of fractionable plasma is obtained by plasmapheresis of paid donors."[205] The development of recombinant Factor VIII may alter national and international plasma markets.[206]

The current Canadian and world shortage of fractionated plasma, however, suggests that the sale and purchase of scarce human biological products may sometimes prove necessary. Dramatic shortfalls between supply and demand tend to create an economic value for scarce biological substances. That such value may translate into open or black market prices magnifies the fundamental question of whether society wishes to adopt an ethic of gift or commercial exchange for some or all tissues and substances. If the ethical aversion to biocommerce remains, how should the law express the aversion in the face of heightened economic value of scarce human tissues and increasingly routine monetary exchanges in their transfer? These considerations will be examined more closely in subsequent chapters.

B. Bodily Integrity and Consent

Modern medical needs and tissue procurement practices also raise several issues concerning consent, the possession and ownership of human tissues and the ethics and legalities of maintaining brain-dead individuals for tissue donation and other medical purposes. The resolution of many of these issues implicates the bodily and moral integrity of living and deceased donors as well as the emotional and religious interests of their families.

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202. Communication with the Canadian Hemophilia Society.

203. Anthony F.H. Britten, "Worldwide Supply of Blood and Blood Products" (1987) 11:1 World J. Surg. 82.

204. CBC, *supra*, note 35 at 72.

205. Britten, *supra*, note 203 at 84.

206. See Simon Jones, "Genetically Engineered Synthetic Factor B Gives Hemophiliacs New Hope" *The Medical Post* (15 November 1988) 11; and Richard Schwartz et al., "Human Recombinant DNA-Derived Antihemophilic Factor (Factor VIII) in the Treatment of Hemophilia A" (1990) 323:26 N. Engl. J. Med. 1801.

(1) Express or Presumed Consent

The informed-consent principle generally holds that health providers may invade a patient's person after securing the patient's consent.[207] The principle applies to transplant recipients and living donors. However, some question the extent to which informed consent should apply to the undeclared, potential donor: namely the deceased hospital patient who has indicated no preference to donate or not while alive.

Should society require the next of kin's consent in such instances? Critics argue that consent poses undue procedural burdens on the organ procurement process, thereby reducing the number of available organs.[208] Instead, it is suggested that society presume consent to the use of the body for medical science, unless there is evidence to the contrary. Whether societal needs for vital organs justify the adoption of presumed consent is a question that merits scrutiny, because it would amend the traditional Canadian approach and because the practice has been adopted in several foreign jurisdictions.

Presumed-consent considerations extend beyond strict tissue scarcity, however. Some have suggested that society should also presume next of kin consent to the hospital use of brain-dead, artificially maintained "cadaver-patients" for medical research, experimentation and the hands-on training of medical school students.[209] Are such proposals ethically and legally defensible? The competing principles of presumed consent and express consent, as well as the interest and values at stake compel a fuller exploration of the issue.

Subsequent chapters will also explore some new and old consent questions. The issues surrounding consent to organ transplantation in minors or incompetents are not novel.[210] The current controversy surrounding consent to anencephalic newborn tissue donation, however, raises newer ethical and legal questions on the definition of death. These, too, will be explored in subsequent chapters.

(2) Bodily Property and Possessory Interests

What does the age-old legal principle that there is "no property in a corpse" mean in the context of increasing therapeutic and biotechnological use, exchange and storage of bodily substances from living and deceased donors?[211] Novel legal conflicts involving the control and ownership of bodily substances have recently arisen in foreign jurisdictions.[212] Some have involved substances deposited in tissue banks. Others have arisen between the sources of human cells and tissues and those persons who procure and use them for biotechnological, therapeutic purposes.[213] Do the human "contributing" sources

207. See chap. 3, below.

208. See, *e.g.*, Thomas E. Starzl, "Implied Consent for Cadaveric Organ Donation" (1984) 251:12 JAMA 1592.

209. See chap. 3, below.

210. *Ibid.*

211. *Ibid.*

212. *Ibid.*

213. *Ibid.*

have legal interests or rights in the profitable therapeutic fruits of biotechnology? If these developments invite society to rethink its valuing of and legal regard for human tissue, certain conflicts biotechnology has occasioned also challenge us to examine the benefits and limits of attaching property notions to the human body. Some of these questions will be explored.

C. Allocating Scarce Medical Resources

Finally, we feel compelled to draw attention to critical questions that lie beyond the scope of the immediate inquiry. The increasing tension between the conquest of disease and the costs of high technology medicine poses daunting choices in the rationing or societal triage of scarce medical resources.[214] Does Canada's commitment to providing "reasonable access" to medically necessary hospital services[215] entitle patients to organ replacement technology? The scope of any such entitlement is not clear. In British litigation to compel the Ministry of Health to fulfil its "duty to provide comprehensive health services" Lord Denning declared the following:

> As Lord Justice Oliver said in the course of argument, it cannot be supposed that the Secretary of State has to provide all the kidney machines which are asked for, or for all the new developments, such as heart transplants, in every case where people would benefit from them.[216]

Indeed, the extensive monetary and medical resources required for high technology organ transplants have persuaded some analysts[217] to favour allocating resources to health care areas judged to be more needy. Some jurisdictions agree. The state of Oregon, for example, has acted on its obligation to provide reasonable and "medically necessary care"[218] in an era of scarce resources by funding only kidney and corneal transplants in

214. See P. Morgan and L. Cohen, "The Ottawa Heart Institute: It's Good, but Can We Afford It?" (1990) 142:6 C.M.A.J. 616; Calvin R. Stiller, "High-Tech Medicine and the Control of Health Care Costs" (1989) 140:8 C.M.A.J. 905. See generally, U.S. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research [hereinafter President's Commission], *Securing Access to Health Care* (Washington, D.C.: The Commission, 1983).

215. See discussion of the *Canada Health Act*, chap. 3, section III.A(4), below.

216. *R.* v. *Secretary of State for Social Services* (18 March 1980), (C.A.) [unreported, available on Lexis] discussed in Diana Brahams, "Enforcing a Duty to Care for Patients in the NHS" (1984) 2:8413 Lancet 1224.

217. Compare "Report of the Massachusetts Task Force on Organ Transplantation" (1985) 13:1 Law Med. Health Care 8 and Thomas D. Overcast and Roger W. Evans, "Technology Assessment, Public Policy and Transplantation: Restrained Appraisal of the Massachusetts Task Force Approach" (1985) 13:3 Law Med. Health Care 106. See also H.T. Engelhardt, "Shattuck Lecture — Allocating Scarce Medical Resources and the Availability of Organ Transplantation" (1984) 311:1 N. Engl. J. Med. 66.

218. As in Canada, the obligation derives from participation in the federal medicare program. In the U.S., transplant funding litigation has arisen over whether recent federal transplant laws modify the medicare obligation to provide reasonable and necessary medical care. *Ellis* v. *Patterson*, *infra*, note 1001 at 54 (discussing U.S. transplant funding litigation).

favour of increased funding for maternal and infant health care.[219] If these public choices are best guided by open ethical deliberation, economic analysis and rigorous medical technology assessments, societal and institutional mechanisms for such analyses must be advanced. For while the Federal-Provincial Transplant Working Group concluded that kidney transplants, and to a lesser extent heart and bone marrow transplants, are cost-effective, it also suggested that technology assessment and cost-effectiveness evidence on the newer transplants remain in the early stages of evaluation.[220] The continuing emergence of such evidence will help answer an increasingly basic question: What is the optimal societal investment in primary care and high technology medicine?

Such macro-allocative decisions have clear implications for the health care consumer. Yet, if a decision is made to support or fund organ transplants, on what bases should society allocate scarce organs? Authorities have recently disputed the ethics of excluding patients afflicted with alcohol-based liver diseases from liver transplant waiting lists, for example.[221] The conflict raises the more general question, How should we designate priorities on transplant waiting lists: by medical need; a first-come first-served basis; a lottery; social standing; medical prognosis; or the ability to pay?[222] The answers clearly depend on a host of macro- and micro-allocation considerations.[223] Basic principles of fairness and efficiency, coupled with the deep public interest in tissue donation, may suggest

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219. See Jennifer Dixon and H. Gilbert Welch, "Priority Setting: Lessons from Oregon" (1991) 337:8746 Lancet 891.

220. See FEDS, *supra*, note 29 at 53. See also Evans et al., *supra*, note 66; *Liver Assessment*, *supra*, note 80; R.W. Evans, "The Economics of Heart Transplantation" (1987) 75:1 Circulation 63. For an early technology assessment of bone marrow transplants, see *Cost Effectiveness*, *supra*, note 46. See generally Institute of Medicine, *Assessing Medical Technologies* (Washington, D.C.: National Academy Press, 1985).

221. Compare Carl Cohen et al., "Alcoholics and Liver Transplantation" (1991) 265:10 JAMA 1299; Alvin H. Moss, "Should Alcoholics Compete Equally for Liver Transplantation?" (1991) 265:10 JAMA 1295; Kevin Schwartzman, "*In Vino Veritas?*: Alcoholics and Liver Transplantation" (1989) 141:12 C.M.A.J. 1262; *Allen* v. *Mansour*, 681 F. Supp. 1232 (E.D. Mich. 1986) (state liver transplant selection criteria requiring documented two years abstinence from alcohol is "arbitrary and unreasonable" exclusion); "Alcoholics to Get Low Priority for Liver Transplants, Hospital Rules" *The [Toronto] Globe and Mail* (16 March 1990) A10 (ethically acceptable to give alcoholics low priority for liver transplants).

222. See "Proceedings of a Conference on Patient Selection Criteria in Transplantation" (1989) 21:3 Transplant. Proc. See also John F. Kilner, "Age as a Basis for Allocating Lifesaving Medical Resources: An Ethical Analysis" (1988) 13:3 J. Health Pol. Pol'y L. 405; Arthur L. Caplan, "Equity in the Selection of Recipients for Cardiac Transplants" (1987) 75:1 Circulation 10; Karen J. Merrikin and Thomas D. Overcast, "Patient Selection for Heart Transplantation: When Is a Discriminating Choice Discrimination" (1985) 10:1 J. Health Pol. Pol'y L. 7; Maxwell J. Mehlman, "Rationing Expensive Lifesaving Medical Treatments" [1985] Wis. L. Rev. 239; James F. Blumstein, "Rationing Medical Resources: A Constitutional, Legal, and Policy Analysis" (1981) 59 Tex. L. Rev. 1345; Thomas Halper, *The Misfortunes of Others: End-Stage Renal Disease in the United Kingdom* (New York: Cambridge University Press, 1989); Henri J. Aaron and William B. Schwartz, *The Painful Prescription: Rationing Hospital Care* (Washington, D.C.: Brookings Institution, 1984); Jean de Kervasdoue, John Kimberly and Victor Rodwin, *The End of an Illusion: The Future of Health Policy in Western Industrialized Nations* (Berkeley: University of California Press, 1984); Guido Calabresi and Philip Bobbitt, *Tragic Choices* (New York: Norton, 1978); Note, "Due Process in the Allocation of Scarce Life-Saving Medical Resources" (1975) 84 Yale L.J. 1734; Note, "Scarce Medical Resources" (1969) 69 Colum. L. Rev. 620.

223. See J.B. Dossetor, "Ethical Issues in Organ Allocation" (1988) 20:1 Transplant. Proc. 1053. See generally Deborah Mathieu, ed., *Organ Substitution Technology: Ethical, Legal, and Public Policy Issues* (Boulder, Colo.: Westview, 1988).

that medical practitioners who receive donated human tissues hold these precious resources in public trust and have a societal duty to allocate them equitably and efficiently.[224] Indeed, because the issues implicate fundamental values and pressing questions of distributive justice, they merit the immediate attention of government, professional groups, and the public.

V. Determinants of Supply and Demand

The foregoing overview suggests that the supply and the demand for human tissues and scarce biological substances are evolving and dynamic. The state of transplant technology, the sophistication of tissue procurement networks, legal rights and duties and the moral propriety of particular medical procedures — all may influence supply and demand disequilibria.

Improvements in the state of the art of tissue replacement technology appear to be the initial driving force in the dynamic. Such advances are illustrated by the impact of cyclosporine on organ transplant outcomes and by the development of genetically engineered human growth hormone to replace cadaver pituitary human growth hormone.

Tissue supply and demand depend on non-medical factors as well. Debates over the Baby Fae case, the artificial heart and consent requirements demonstrate that tissue transplants take place in an evolving ethical and legal infrastructure. Moreover, administrative factors may influence tissue supply and demand, as is evidenced by the seventeen Canadian Red Cross blood donor centres, the nine regional organ procurement networks and developing international tissue exchange networks.

Finally, public and professional attitudes exert a telling influence on supply and demand, especially with regard to organ transplantation. Few people take comfort in the practical aspects of confronting death. The chronic discrepancy between the low number of completed tissue donation cards and public poll surveys indicating high support of tissue donation suggests ambivalence about the actual organ donation process.[225]

The ambivalence stems from several factors, including the individual's not having considered the practicalities of organ donation, death anxiety, fear and distrust on the

224. See USTF, *supra*, note 29 at 80 (donated organs a national resource).

225. See Jan A. Walker et al., "Parental Attitudes toward Pediatric Organ Donation: A Survey" (1990) 142:12 C.M.A.J. 1383 at 1384 (80% surveyed families willing to donate); P.K. Basu, K.M. Hazariwala and M.L. Chipman, "Public Attitudes toward Donation of Body Parts, Particularly the Eye" (1989) 24:5 Can. J. Ophthalmol. 216 (roughly half of the respondents willing to donate had signed donor cards); M. Robinette, "Organ Donation: Factors Contributing to the Imbalance between Demand and Supply" in David R. Grant and William J. Wall, eds, *First Canadian Symposium on Multi-Organ Transplantation: April 28 and 29, 1988* (London, Ont.: University of Western Ontario, Scitex, 1989) 69; Barbara E. Nolan and Nicholas P. Spanos, "Psychosocial Variables Associated with Willingness to Donate Organs" (1989) 141:1 C.M.A.J. 27.

determination of death.[226] The public ambivalence typically results in a recurrent "undeclared donor scenario" in Canadian hospitals — that is, a scenario in which a recently deceased hospital patient, who meets the medical criteria for organ donation, has not made known his or her intentions on donation. The tragedy that has befallen the family of the potential donor understandably tends to make family members unlikely to consider or initiate the donation of their own accord. Should anything be done to further donation in such circumstances? Should a trained medical-bereavement team delicately and supportively take the initiative, since studies suggest that most families actually support being approached as part of their bereavement process?[227] Or, should we spare family members talk on these matters by routinely procuring organs on the presumption that such procurement is justified to save lives and grief and that the deceased would likely support the humanitarian gesture?

Even medical professionals are not immune from ambivalence in resolving the undeclared-donor scenario. Over the last five years, Canadian analysts have repeatedly characterized national organ scarcity as the consequence of medical community reluctance to approach the grieving family of a recently deceased, undeclared, potential donor. In 1985, a federal-provincial transplant task force described professional reluctance as "one of the most significant barriers" to increasing organ donation.[228] That same year, provincial task forces in Ontario and Alberta concluded that such reluctance erects major, significant barriers to donation.[229] These conclusions were echoed more recently in a Canadian transplant surgeon's observations that "[a]lthough barriers exist at each step of the donation process, the major ones occur within the health care system primarily because of a reluctance of the medical community to approach families of potential donors for consent."[230]

Clearly, the tragic side of the life-from-death reality of current Canadian organ procurement and donation practice weeps ambivalence. The ambivalence is a major contributing factor with regard to the current scarcity of available organs.[231] Only 10 to 20 per cent

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226. Nolan and Spanos, *supra*, note 225 at 27. In a recent U.S. survey, "the two most common reasons given for not permitting organ donation were (1) they might do something to me before I am really dead; (2) doctors might hasten my death." Judith Areen, "A Scarcity of Organs" (1988) 38 J. Legal Educ. 555 at 562, discussing report of U.S. Task Force on Organ Transplantation.

227. See Helen Levine Batten and Jeffrey M. Prottas, "Kind Strangers: The Families of Organ Donors" (1987) 6:2 Health Aff. 35. See also chap. 4, below.

228. FEDS, *supra*, note 29 at 95.

229. ONT, *supra*, note 29 at 97 (identifying failure to identify suitable donor and failure to initiate donation process as medical barriers to procurement); *Report of the Alberta Human Tissue Procurement Task Force*, *supra*, note 143 at 18 ("The most significant barrier to obtaining organs and tissue for transplantation is thought to lie within the medical profession itself. For whatever reason, medical staff appear reluctant to counsel organ donation."). See also *Review of Organ and Tissue Donation and Transplantation in Saskatchewan* (Regina, Sask.: Ministry of Health, 1987) at 62, 65.

230. Robinette, *supra*, note 225 at 72.

231. See generally Jeffrey M. Prottas and Helen Levine Batten, "Health Professionals and Hospital Administrators in Organ Procurement: Attitudes, Reservations and Their Resolutions" (1988) 78:6 Am. J. Pub. Health 642. See also ONT, *supra*, note 29 at 97.

of potential organ donors currently become actual donors.[232] Yet, the federal-provincial transplant task force has concluded that a sufficient supply of organs is "potentially available" if the organs can be procured.[233] What means, if any, then, should society invoke to cultivate attitudes and practices favourable to donation to help overcome the organ donation shortfall? Massive public education and professional training? Increased incentives? Modest coercion? May the law contribute to resolving the undeclared donor scenario, as has been suggested in other countries? To answer such questions requires an examination of the ethical and legal infrastructure in which tissue procurement and transplantation take place.

232. Robinette, *supra*, note 225 at 69 (10%); ONT, *supra*, note 29 (10%); Darby et al., *supra*, note 192 at 2222 (15%-20%).

233. FEDS, *supra*, note 29 at 95.

CHAPTER TWO

The Ethics of Tissue Procurement

If medicine fashions the tools for remaking the human body, ethics helps fashion the moral contours for their use. Tissue replacement technologies offer newer means for acting on the long-cherished ethical value of saving life. Society understandably welcomes these advances. Saving life is not alone, however, amongst core societal values. How we structure the tissue procurement process — how we go about saving life — might prove important, if only because these techniques, machines and technologies provoke moral choice, to be made in light of new practices, ways of living and ways of thinking about life, death, the human body and physical and spiritual existence. For all their novelty, these highest of technologies still do little to quell our enduring need to live in harmony with and comprehend the moral import of the very tools we create.[234] Ethics addresses this constant dimension of humanity, by allowing us to see how some of the tools, practices and eventual policies touch diverse and sometimes competing human values.

As such, moral inquiry into tissue procurement policy involves the basic tasks of applied bioethics: (1) identifying underlying values; (2) weighing values that conflict or compete; and (3) choosing a course or policy that implements priorities assigned to competing values.[235]

The values of autonomy, non-maleficence and beneficence figure prominently in current biomedical and transplant ethics.[236] Autonomy enables individuals to direct their lives according to their own interests and goals. To secure consent before procuring a person's organs for transplantation is to respect the person's autonomy. Non-maleficence requires that one not harm others, while beneficence encourages one to benefit others.

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234. See Laurence H. Tribe, "Technology Assessment and the Fourth Discontinuity: The Limits of Instrumental Rationality" (1973) 46 S. Cal. L. Rev. 617 ("There remains, it is said, a fourth great discontinuity — that between man and his machines — which must be bridged if man is to live in harmony with his tools, and hence with himself").

235. See Terrence F. Ackerman, "What Bioethics Should Be" (1980) 5:3 J. Med. Phil. 260, 261.

236. See Tom L. Beauchamp and James F. Childress, *Principles of Biomedical Ethics*, 3d ed. (New York: Oxford University Press, 1989). Justice, another prominent bioethical principle, aims at a fair distribution of social benefits and burdens. Because the focus of the immediate inquiry centres on procurement, the pressing challenges of allocating scarce tissue and medical resources are not generally explored here. Compare James F. Childress, "Some Moral Connections between Organ Procurement and Organ Distribution" (1987) 3 J. Contemp. Health L. Pol'y 85.

Consulting the relatives of recently deceased individuals about tissue procurement may avoid harm, by not treating the body of a loved one offensively. Tissue transfers may also advance beneficence by helping to save the lives of transplant recipients.

Resolving the value conflicts in tissue procurement practices may sometimes prove more difficult than identifying them. How much importance, for example, should be assigned to saving life, if the tissue procurement process used overrides fundamental religious beliefs? The conclusion that life and health preservation prevails over other values might lead policy makers to opt for a policy of routine procurement. Yet, if respect for the wishes of surviving relatives is deemed paramount, procurement conditioned on the consent of relatives might be preferred. The choices are difficult because the values in conflict do not reduce to common denominators, despite a desire to prioritize them for ethical choice. The value orderings that are ultimately chosen need not be absolute, however. Some analysts emphasize the possibility of arriving at compromise policies that balance important and competing values in the procurement process.[237]

This framework of analysis — identifying and attempting to weigh and prioritize competing values — is used to explore the following tissue procurement questions:

— What is the moral basis of the prevailing model for organ donation, as compared with possible alternatives?

— Since transplantation depends largely upon organs recovered from the dead, how do moral considerations such as respect for persons, protecting bodily integrity and promoting human dignity apply to the treatment of dead bodies?

— What are the moral arguments for and against the sale of human tissues?

— What are the ethical implications of regarding human bodies as property?

Section I thus examines the giving and taking of cadaveric tissue and the ethical meaning of "harm" to the dead. Section II discusses the ethics of tissue procurement from living adults, children[238] and mentally disabled persons. Section III looks at moral duties to donate. The final section explores the relation between our physical bodies and notions of self, with respect to various tissue procurement practices, bodily property and human tissues sales. At least one clear conclusion emerges from the discussion: competing views of the body-self relation strongly influence, and often determine, the moral assessment of particular tissue procurement proposals and practices.

I. Deceased Donors

To help save life, how should society obtain the therapeutic human tissues of the recently deceased? Shall we procure them routinely and efficiently? Or, is a community

237. See David A. Peters, "Protecting Autonomy in Organ Procurement Procedures: Some Overlooked Issues" (1986) 64 Milbank Mem. Fund Q. 241 at 263, and David A. Peters, "Required Request: A Practical Proposal for Increasing the Supply of Cadaver Organs for Transplantation" (1985) 84 Wis. Med. J. 10 at 12.

238. For a discussion of anencephalic infants as organ "donors," see chap. 3, section II.B, below.

of givers preferable to a community of takers? The simple extremes of pure giving and taking may be slightly abstracted from social reality. But exploring them places in sharp relief the moral foundations, philosophical disputes and competing values embedded in societal tissue transfer policies, which range from pure altruism to routine procurement.

A. Altruism — Giving Is Better Than Taking

The word "donation" is virtually synonymous with human tissue transfers in Canada.[239] Donation derives from the Latin word for gift.[240] Altruism, the unselfish concern for the welfare of others,[241] is often invoked to explain motivations for the giving.

Proponents typically offer three general reasons to support the gift ethic formalized in national blood policy principles and Canadian tissue transfer law.[242] These are that altruistic tissue transfers nurture community bonds and generosity, accord respect that is due the dead human body and avoid the perceived ills and risks of routine procurement policies. The first reason appeals to the kind of society that many might prefer:

> A society will be a better human community in which giving and receiving is the rule, not taking for the sake of good to come. The civilizing task of mankind is the fostering, the achievement, or the shoring up of consensual community in general, and not only in regard to the advancement of medical science and the availability of cadaver organs in efforts to save the lives of others. Civilization means living our consensual communities, not living in communities in which consent and refusal go on, just as surely as we live our bodies, not in them. The positive consent called for by Gift Acts, answering the need for gifts by encouraging real givers, meets the measure of authentic community among men. The routine taking of organs would deprive individuals of the exercise of the virtue of generosity.[243]

So conceived, donated human tissues become the material and symbolic gifts of life that bond strangers in our communities.[244]

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239. The language and vernacular of the tissue transfer process reflects moral precepts, which echo in the titles of substantive articles on the subject. See, *e.g.*, Alfred M. Sadler and Blair L. Sadler, "A Community of Givers, Not Takers" (1984) 14:5 Hast. Cent. Rep. 6. See also David Helwig, "Organ Procurement: Coercion or Informed Consent?" (1988) 139:1 C.M.A.J. 59 ("'But . . . ,' the father countered, 'I heard somebody talking about harvesting. I'm a farmer. I know what harvest means, and I don't want any part of that, where we tear the cob of corn from the stalk and don't care about the stalk. I care. That's my boy.'"). Some regard the official ideology of tissue procurement as "both too simple and too sentimental." R.C. Fox, "Organ Transplantation: Sociocultural Aspects" in Warren T. Reich, ed., *Encyclopedia of Bioethics*, vol. 3 (New York: Free Press, 1978) 1166 at 1168. For an anthropological discussion of the norms that structure the exchange of gifts, see Marcel Mauss, *The Gift: Forms and Functions of Exchange in Archaic Societies*, trans. I. Cunnison (London: Cohen & West, 1969).

240. J.B. Sykes, ed., *The Concise Oxford Dictionary*, 7th ed. (Oxford: Clarendon Press, 1982) at 285.

241. *Ibid.* at 26.

242. See chap. 3, section III.B, below.

243. Paul Ramsey, *The Patient as Person: Explorations in Medical Ethics* (New Haven: Yale University Press, 1970) at 210.

244. See Richard M. Titmuss, *The Gift Relationship: From Human Blood to Social Policy* (London: George Allen & Unwin, 1970). See also Roberta G. Simmons, Susan Klein Marine and Richard L. Simmons, *Gift of Life: The Effect of Organ Transplantation on Individual, Family and Societal Dynamics* (New Jersey: Transaction, 1987).

A second reason for favouring altruism turns on the role of the body in our understanding of what it means to be a person. Under one view, persons are seen as inseparable from their bodies. Consequently, the dignity of the human body is inseparable from the dignity of the person.[245] This nexus survives death, because the body then symbolizes the person who once lived:

> Admittedly the corpse is no longer a man. The cadaver is a kind of shroud that now masks rather than expresses the soul that once animated it. And yet — while the body retains its recognizable form, even in death, it commands a certain respect. No longer a human presence, it still reminds us of that presence which once was utterly inseparable from it.[246]

Moreover, if we associate the value of human dignity with the value of autonomy, then a tissue transfer system that respects wishes — to donate or not — that take effect after death may seem more accommodating of those values.

A third reason suggested in favour of a system of giving is that, beyond promoting altruism and accommodating such values as autonomy, it is more likely than other alternatives to constrain harmful attitudes and abusive practices. For example, some people object to routine procurement because they perceive it as more likely to foster negative attitudes that reduce both deceased and living human beings to an assembly of interchangeable spare parts.[247] The concern again centres on how procurement systems affect how we think of our physical and moral selves. To be seen as a living "spare parts pre-cadaver," or medical commodity, risks demeaning individuality and human dignity by reducing human beings to potential physical instrumentalities of well-intended biomedical science.

Another concern is that routine procurement is likely to alter the patient-provider-hospital relation. It may cast the hospital into the role of the taker-"devourer," obscure its traditional role of care giver and provider of "the healing mission"[248] and thus erode the trust upon which the healing arts so depend. Indeed, Canadian and American studies have documented the public's distrust and fear about premature organ procurement.[249] Like concerns about dying patients being perceived as containers of spare parts and concerns about disrespecting the dead, the distrust seems somewhat generic to transplantation. Ethically and legally questionable research and medical teaching interventions on mechanically maintained dead patients, for example, have occurred in different procurement systems.[250] If it cannot be shown that one system significantly decreases or increases the likelihood of such concerns arising, they may be inherent to both the donation and taking of organs.

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245. William F. May, "Attitudes toward the Newly Dead" (1973) 1:1 Hast. Cent. Stud. 3. See also William F. May, "Religious Justifications for Donating Body Parts" (1985) 15:1 Hast. Cent. Rep. 38 at 39.

246. May (1973), *supra*, note 245 at 3. See also May (1985), *supra*, note 245 at 39-40.

247. See Ramsey, *supra*, note 243 at 209 ("everyone a useful precadaver").

248. See May (1973), *supra*, note 245 at 6.

249. See James F. Childress, "Ethical Criteria for Procuring and Distributing Organs for Transplantation" (1989) 14:1 J. Health Pol. Pol'y L. 87 at 91-92. See *supra*, note 226.

250. For a discussion of recent practices, some of which have provoked criminal charges, in both express- and presumed-consent countries, see chap. 3, below. See also Willard Gaylin, "Harvesting the Dead" (1974) 249 Harper's 23 at 26 (describing bioemporiums, where the mechanically maintained dead are used for teaching, research and transplantable tissues); and Paul Taylor, "MDs Ponder What to Do with Up to 10,000 'Living Dead'" *The [Toronto] Globe and Mail* (23 August 1989) A1.

The expression of these ideals and fears indicates a basic difficulty experienced by proponents of altruism, as pressing medical needs increasingly challenge the underlying theories and daily consequences of pure altruism. In the extreme, the tension pits intangible moral, emotive concerns against the tangible, more quantifiable benefits of increased tissue supplies.

For example, while the blood donation system seems to work, only a minority of individuals actually takes steps to donate organs after death.[251] Even if a community of tissue givers is morally preferable to a community in which tissues are taken, persistent tissue scarcity nudges society to ask how strong the preference is for giving. Might not other less costly venues permit the exercise of generosity[252] and the building of a consensual community while reducing transplant waiting lists? Does the minority, who exercises generosity by donating organs, sufficiently enhance the overall moral and physical good of the community to justify not altering the procurement system?

The moral good of altruism is not easily measurable. Altruism, as envisaged, does not necessarily mean enlightened acts of free will. To use a popular phrase, it is "encouraged voluntarism." Those unwilling to contemplate death and organ donation are encouraged to do so through societal laws and practices.[253] Some consider that the intangible benefits flowing from the opportunity offered by altruism for moral enlightenment in the community are more important than transplant benefits.[254] But what are the specific intangible benefits that need to be weighed against the material benefits of more tissues for transplant? Broad altruistic appeals do not pinpoint the specific values that compete with preserving life, nor do they explain why those values are more important than routinely prolonging life.

In short, if the ideal of unfocused generosity remains elusive, can we not satisfy immediate human needs in other ways? What alternative policies for procuring cadaver organs are morally viable, if the ideal of an "authentic community" either cannot be measured and attained or exacts too high a price in terms of human lives and suffering?

B. Routine Procurement — Taking Is Better Than Giving

The tension between immediate quantifiable medical needs and the less measurable, perhaps more symbolic, attributes of altruism leads some ethicists to propose the routine procurement of tissue from the dead. For them, the choice is between "interest or life on one side and symbolism and sentiment on the other."[255] Once the competing values are couched in these terms, symbolism loses:

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251. See text accompanying note 226, above.

252. See James L. Muyskens, "An Alternative Policy for Obtaining Cadaver Organs for Transplantation" (1978) 8 Phil. Pub. Aff. 88 at 96.

253. See Ramsey, *supra*, note 243 at 210.

254. See *ibid.* at 210-11.

255. Joel Feinberg, "The Mistreatment of Dead Bodies" (1985) 15:1 Hast. Cent. Rep. 31 at 32.

> On the one side of the scale is the saving of human lives; on the other is the right of a person ... by the use of a symbolic ritual to convert his consent into a genuine 'gift'. Even in this extreme confrontation of interest with symbol, ... [proponents of the giving of organs accord] the symbol more weight. If the subject were not itself so grim I might be tempted to charge [them] with sentimentality.
>
> ... [B]alancing tests ... dictate that appeals to interest ... have greater weight and cogency than appeals to offended sentiment, and should take precedence when conflict between the two is unavoidable.[256]

The critique is that the naked sentiment evoked by a dead human body, for example, promotes emotional indulgences that either distract from true ethical deliberation or obscure pre-eminent interests. As one critic suggests, "[t]he error consists of attaching a value to a symbol, and then absorbing oneself in the sentiments evoked by the symbol at the expense of real interests, including the very interests the symbol represents."[257] Such critics concede that "social utility" may be promoted by "widespread respect for certain natural symbols," but conclude that this "real but diffuse value would be outweighed" whenever genuine interests are at stake.[258] If sentiments attach to genuine values, these values still lose in competitions with interests, apparently because the values prove too "diffuse."

In many respects, the debate about procuring organs thus reflects a more fundamental debate. On one side is the prevailing philosophical school, which regards morality as a rational enterprise with little place for non-rationality. Emotions acquire a determinate focus through images and symbols. This rationalist school worries that the link between emotion, values and symbolism is, at least, morally distracting and, at most, morally destructive of other values or interests that are thought to be pre-eminent. On the other side is a view that lived morality is embedded in the customs, traditions and beliefs of particular communities and is expressed through symbols and sentiments as well as reason.[259] This school worries that the greatest moral danger in our technological society is "devaluing feeling and not attending to or nurturing moral emotions."[260] The ethics of tissue procurement thus becomes an arena for a basic philosophical dispute over practical morality.

Having identified the depths of the dispute, what can we say of the role of emotions in morality? It does seem self-evident that correct moral choices are not simply or consistently inspired by emotion and symbolism. Rational deliberation is undoubtedly a

256. *Ibid.* at 32.

257. *Ibid.* If the "mistake" lies in detaching interests from the sentiments symbols evoke, then even naked sentiments may possess legitimate values, as registered by any interests they may ultimately reflect. The "mistake" might be rectified by identifying the interest associated with sentiment and pitting it against the "real interest" on the other side.

258. *Ibid.*

259. May (1985), *supra*, note 245 at 38 ("Academic ethicists working on the subject of organ transplants usually appeal to reason alone, uninformed by religious tradition or by the communities that, however imperfectly, embody those traditions").

260. Sydney Callahan, "The Role of Emotion in Ethical Decisionmaking" (1988) 18:3 Hast. Cent. Rep. 9 at 12.

prime ingredient. However, two reasons may raise doubt about its being the only legitimate ingredient. First, those dismissive of sentiment provide no coherent, compelling argument for categorically purging emotion from the debate and uniformly preferring interests over sentiments. Their most compelling critique aims at some of the quantifiable consequences of routine giving. The critique is conveyed through consequentialist examples that impart their own symbolic appeal. One example counterposes the non-use of a newly dead body against untold medical benefits presumed to derive from autopsies and research on cadavers.[261] Does the recently deceased patient symbolize a human being, represent untold potential research benefits or symbolize and represent both?

Secondly, in the absence of a more affirmative, coherent theory, the strict rationalist view tends to become absolutist, detached and unheeding of the potential moral insights that may be born of the rational-irrational deliberation evoked by human experience in diverse communities. If an interest basis for rejecting a tissue procurement proposal is not articulated, the emotive argument that a practice is too repugnant will not be heard to convey a moral message; nor will it outweigh the benefits presumed to arise from procurement.[262] A more tempered view about the role of emotions in moral decision making might broaden the field of acceptable ethical choice beyond the confines of strict rationalist morality.

Thus, if writers who have regard for symbols and sentiment may be criticized for overly indulging the moral force of emotion and for having difficulty measuring the moral benefits of pure altruism, they would still seem more accommodating of diverse moral values and options. The preference for altruism is not absolute. Its proponents find neither the routine giving nor the taking of cadaver organs inherently wrong,[263] but insist that giving be tried first: "[H]uman attitudes toward death (and the newly dead) are such that a system of organized giving must be granted a serious test before entertaining the alternative of routine salvaging."[264] In essence, these writers recognize a range of disparate values relevant to transplantation. They prefer a procurement policy that tries to accommodate those values. Their conclusion is comparative: "[T]o foster the organized giving of cadaver organs is preferable to the routine use of organs by hospitals."[265]

The difference between these competing schools of thought may suggest a path out of the underlying philosophical impasse. The dispute over the giving and taking of cadaver organs does arise from disagreements about what legitimate values need to be considered and how much weight should be given to inconsistent values. The disagreements, in turn, spring from deeper sources: differing views about the nature of morality and about the

261. Feinberg, *supra*, note 255 at 32. Query: Would the appeal to preventing "thousands" of unknown illnesses and deaths be as enticing if we were able to read the protocol and determine how likely or how speculative the benefits to be derived from this particular cadaveric research were?

262. See *ibid.* at 33.

263. Ramsey, *supra*, note 243 at 208.

264. May (1973), *supra*, note 245 at 4.

265. Ramsey, *supra*, note 243 at 209.

relation between persons and their bodies. Yet, both schools assign great importance to the value of preserving life and health. They dispute its precise weighting. The exchange of views suggests that the underlying philosophical bind might be relieved by deciding whether a policy of giving has received a fair test. If so, its proponents would seem willing to move towards the routine taking of cadaver organs. If not, then competing legitimate values require, in their view, that we persevere in and reform the system of giving, to improve its yield of therapeutic tissues.

C. Giving, Taking and Harming the Dead

Lingering through this discussion, but rarely openly addressed, is the question of how or whether the dead can be "harmed." Some, in an attempt to allay the moral misgivings of transplant professionals, claim that "it is impossible to inflict personal harm on a dead patient."[266] Are dead persons, in fact, harmed when doctors in training practice non-consensual interventions on their bodies, or when they are used for unauthorized research?[267] If so, what is the nature of the harm? An infringement of autonomy? A violation of human dignity? A moral wrong to the community?

One way in which the dead seem unlikely to be harmed is by the violation of their autonomy. Moral autonomy allows persons to direct their lives according to their own values and to protect themselves from what they regard as harm and exploitation. Obviously, dead persons have no lives to superintend. Strictly speaking, the functions of autonomy are no longer relevant to the cadaver, then, because the dead have no moral autonomy.[268]

Can the dead be harmed by having their interests infringed? The same logic would seem to apply. According to a dominant rationalist view, rights are attributed only to persons who have interests. Interests "must be compounded somehow out of wants and purposes, both of which in turn presuppose something like expectation, belief, and cognitive awareness."[269] In this view, then, the dead, who no longer possess these attributes, have no interests and, since rights are predicated upon interests, would also have no rights that might be violated.

According to another view, however, this conclusion cannot be drawn:

266. See Stuart J. Youngner et al., "Psychosocial and Ethical Implications of Organ Retrieval" (1985) 313:5 N. Engl. J. Med. 321 at 323.

267. See chap. 3, section II.C(3), below, and *Arnaud* v. *Odom*, *infra*, note 872.

268. Albert R. Jonsen, "Transplantation of Fetal Tissue: An Ethicist's Viewpoint" (1988) 36:3 Clinical Research 215 at 219; Russell Scott, *The Body as Property* (New York: Viking Press, 1981) at 260 ("Certainly the dead must be respected, ... but the dead body is a thing utterly different from the living body. The very idea of applying the notion of personal autonomy to a corpse is absurd; at most, personal autonomy is only artificially extended beyond death."). But see ALRC, *infra*, note 1010.

269. Joel Feinberg, "Is There a Right to Be Born?" in James Rachels, ed., *Understanding Moral Philosophy* (Encino, Calif.: Dickenson, 1976) 346 at 349.

> [D]ead persons can have rights against us, namely rights to the fulfillment of promises made to them when they were alive, and rights not to be falsely defamed to those who once knew and loved them. This admittedly paradoxical conclusion is supported by the idea that certain of a dead person's interests can be thought to survive their owner's death and constitute claims against us that persist beyond the life of the claimant. This in turn requires us to think of interests as fulfilled only by the coming into existence of that which is desired, and not simply as "satisfaction of desire" in the sense of contentment in the mind of the desirer when he believes that his desire has been fulfilled.[270]

In this analysis, certain interests survive a person's death and generate rights. These are usually restricted to "their interests in a good reputation, proper disposal of their worldly possessions, and considerate handling of their corpse."[271]

This view has intuitive appeal but suffers from certain limitations. It lacks a theoretical account of how the dead have interests. Moreover, it does not provide a specific account of how select interests survive death. Rather, there is only an appeal to the distinction between fulfilling and satisfying desires. Since interests are products of subjective states of mind, such as desires, it does make some sense to talk about our desires or interests being fulfilled after death. The knowledge that our wishes will be respected after death may well give us a fuller sense of personal autonomy. It would also seem to impart a greater sense of peace in the preparation for and contemplation of death. Thus, the utter disregard of one's[272] burial wishes, or the failure to honour one's express wishes on the post-mortem use of one's body, lend credence to the claim that people have interests that survive their deaths and that they may be harmed when the interests are violated.[273] What remains refractory is providing a coherent philosophical explanation of this intuition.

What of broader notions of harm that encompass potential moral wrongs such as indecent treatment of the dead or acts that violate human dignity? Morality, after all, encompasses more than the duty not to harm. It has been suggested, for instance, that it would be unjust to refuse to confer an award or bestow an honour because the person who qualified for it has died. In this view, merely fulfilling the conditions for an award entitles one to it; one need not "be able to personally claim it, to be in fact entitled to it and have a right to it."[274] Similarly, a failure to dispose of property as set forth in a will might be morally wrong because it is unjust, even if contravening the will of the decedent cannot be said to harm the decedent. General strictures of morality, notably requirements of justice, might therefore preclude certain actions with respect to the dead.[275]

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270. *Ibid.*

271. Raymond A. Belliotti, "Do Dead Human Beings Have Rights?" (1979) 60 Personalist 201 at 208. For a list of possible rights of the dead, see *ibid.* at 209.

272. See Peters (1986), *supra*, note 237 at 254.

273. See George Pitcher, "The Misfortunes of the Dead" (1984) 21:2 Am. Phil. Q. 183 ("If we allow our unfettered intuition to operate on certain examples, it becomes abundantly clear that we think the dead can indeed be wronged").

274. Belliotti, *supra*, note 271 at 206.

275. See Childress, *supra*, note 249 at 98 (People may be wronged when their wills are thwarted). Yet, wronging implies that there still are subjects of a wrong, which seems problematic when applied to the dead.

Embedded in these notions of potential moral wrongs is a premise that dead bodies deserve moral protection by virtue of their symbolic function. This view is especially prevalent in religions that demand respect for the dead body in the belief that both living and dead human beings are created in the image of God; thus, for example, "Jews and Christians respect the body of the dead as symbolic of the human person and his dignity."[276] In this view, acts disrespectful of the dead may contravene religious beliefs and constitute symbolic moral wrongs in the community sharing these beliefs, by violating concepts of human dignity that seem wedded to the body even after death. Whether such potential moral wrongs constitute harms would appear to be definitional.[277]

Of course, any such concepts of wrong or harming will be challenged, or perhaps redefined, by competing views and values. We have seen that the ethical role and emotive force of symbols in practical morality provoke deep philosophical debate. Proponents of rationalist morality warn against respecting symbols "too much."[278] The warning extends to the moral status of the recently deceased patient:

> A dead body is no longer a person. Even though corpses must be respected because they were once living persons, the obligation of respect has less force than when it is applied to living persons. In the case of intubating newly dead bodies, the respect is limited to avoiding disfigurement or ridicule of the cadaver.[279]

The high, and perhaps increasing, medical value placed on use of the human body means that any competing emotive, religious or symbolic values associated with protecting the dead must be weighed against the medical interests of the living.[280] The tendency of the medical interests to be more tangible, quantifiable and immediate may suggest that the more emotive, ethereal and symbolic values will not fare well in competition with those interests. What is needed in these conflicts is a comparative appraisal of the specific competing interests and values. If making that particularized judgment is a task not amenable to easy philosophic resolution, the judgment nevertheless remains the crux of the moral controversy over the supply of cadaver tissue.

II. Living Donors

What restrictions does morality impose upon the acquisition of organs from living persons? For competent adults, the value of respecting autonomy would seem to preclude

276. White, *supra*, note 91 at 138-39.

277. Joel Feinberg, "Sentiment and Sentimentality in Practical Ethics" (1982) 56 Proc. Addresses Am. Phil. A. 19 at 20 ("[I]ndignation can achieve red hot intensity when there is no harm produced at all, but only disrespect shown to some precious symbol, like a flag or a cross").

278. Feinberg, *supra*, note 255 at 31.

279. James P. Orlowski, George A. Kanoti and Maxwell J. Mehlman, "The Ethics of Using Newly Dead Patients for Teaching and Practising Intubation Techniques" (1988) 319:7 N. Engl. J. Med. 439 at 440 (arguing for medical use of the newly dead without consent of surviving family members).

280. Belliotti, *supra*, note 271 at 207-08.

taking without the person's consent. For incompetent individuals lacking personal autonomy, the situation is less clear. Does treating children and mentally impaired persons differently than competent adults exploit their incompetence and vulnerability, or is it morally justified?

A. Adults

Under modern bioethical theory, the functions of consent in medical treatment include the promotion of individual autonomy and the protection of the patient from harm.[281] Consent alone, however, does not ensure the moral acceptability of the medical intervention. Commonly accepted biomedical principles also suggest that the donor should gain from the sacrifice, through the prevention of foreseeable harm or the acquisition of benefit.[282] In some instances, even consent and the bare prospect of preventing harm may not ensure moral acceptability, because those conditions alone arguably countenance a living father's donation of his heart to save his son:

> [T]he self-giving of hearts may well meet the test of consent alone, if this is the necessary and a sufficient right-making feature. ... If need be, the self-giving of hearts can also meet the "prevention of detriment" test — the detriment of suffering a son's death judged to be more unbearable than one's own — or it can meet the "spiritual benefits" test.[283]

Such a donation is morally unacceptable, because it violates the bodily integrity and results in the death of the donor.[284]

Hence, a third condition, risk-benefit appraisal, is required to protect the values associated with a donor's bodily integrity.[285] Under one formulation, tissue transplants are morally justified when (1) the risk to the donor is "very much less" than the potential benefit to the recipient, or (2) "the objective benefit" to the recipient "heavily" outweighs the loss to the donor.[286] The nature of the physical risks to the donor depends largely on the tissue to be donated and the state of the art of the transplant procedure. Blood, sperm, bone marrow[287] and kidney donation involve varying degrees of risk, surgical invasiveness and irreversibility. One estimate made some twenty-five years ago compared

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281. See Beauchamp and Childress, *supra*, note 236 at 76, discussing A.M. Capron, "Informed Consent in Catastrophic Disease and Treatment" (1974) 123 U. Pa. L. Rev. 364. See also Jay Katz and Alexander Morgan Capron, *Catastrophic Diseases: Who Decides What?* (New York: Russell Sage Foundation, 1975) c. 6 at 79.

282. See Beauchamp and Childress discussing non-maleficence, *supra*, note 236 at 120.

283. Ramsey, *supra*, note 243 at 190.

284. See *ibid.* See also Beauchamp and Childress, *supra*, note 236 at 370.

285. See Beauchamp and Childress discussing beneficence, *supra*, note 236 at 194. See also Ramsey, *supra*, note 243 at 195 ("Bodily integrity must be a norm operating in the assessment of the morality of the self-giving of organs, even if it is outweighed").

286. Ramsey, *supra*, note 243 at 195.

287. See *Reassessment of Autologous Bone Marrow Transplantation*, *infra*, note 534 at 2.

the risks of kidney donation with the risks of injury or death associated with commuting sixteen miles a day,[288] and found that the "figures seem to offer the opportunity of a reasonable sacrifice."[289]

Thus, three conditions emerge for the permissibility of using organs from the living: (1) the donor must consent freely and knowledgeably; (2) there must be some reasonably expected benefit to the donor; and (3) likely benefits to the recipient must considerably outweigh likely harms to the donor. If we accept these, can any of these conditions ever be waived or overridden as, for example, with children and mentally disabled persons?

B. Children and Mentally Disabled Persons[290]

Some courts have approved tissue procurement from children and incompetent adults without strict adherence to all of the above conditions.[291] Why are they treated differently? What should happen to these ethical requirements, if the potential donor is incapacitated by reason of age or mental disability? If incompetency and vulnerability do not dictate a ban on procurement from such persons, on what moral grounds may it proceed?

A ban on using children and mentally handicapped persons as organ donors could rest on three grounds.[292] First, one may insist that the requirement of patient consent be applied to all bodily intrusions. When a person lacks the legal capacity to consent, no valid consent can be had and hence no violation of bodily integrity is justified. Secondly, a flat prohibition may be urged on the grounds that children and mentally disabled persons are sought as organ donors, as some have claimed, because "what often happens inside a family, and outside, is a balancing of social worth, whether consciously or not."[293] Thirdly, one may argue that the ethical requirement of patient benefit lies unfulfilled, because vulnerable donors receive neither physical nor putative psychological benefits from sacrificing their tissue.

These concerns parallel the major concerns in the ethics regarding the use of children and mentally disabled persons in medical research for which they receive no discernible benefits.[294] Insisting upon consent from individuals who lack the capacity to consent effectively bars non-therapeutic medical research, even if it offers protections to vulnerable

288. Ramsey, *supra*, note 243 at 177, citing J.P. Merrill, "Letters and Comments" (1964) 61 Ann. Internal Med. 356.

289. *Ibid.* at 196. The improved surgical techniques and cumulative experience of the last 25 years suggest donor risks are even less today.

290. For a discussion of anencephalic organ donors, see chap. 3, section II.B, below.

291. See *infra*, notes 300, 302. See also Scott, *supra*, note 268, c. 5 at 101.

292. Scott, *supra*, note 268 at 122.

293. *Ibid.*

294. Compare MRC, *supra*, note 118 at 28-32, and Barry Hoffmaster, "The Medical Research Council's New Guidelines on Research Involving Human Subjects: Too Much Law, Too Little Ethics" (1989) 10 Health L. Can. 146.

persons.[295] Banning such research may also condemn other vulnerable persons to continue to be afflicted with diseases that can only be conquered by further research. With organ donation, although the potential harms of a comparable prohibition may not be as extensive in society, they would, in individual cases, be just as severe.

Requiring consent from the incompetent may also be misplaced. If consent functions primarily to protect autonomy, and those lacking the legal capacity to consent by definition already lack autonomy,[296] then imposing a requirement of donor consent fails to effect its underlying rationale. This is not to deny the moral function of securing consent from mature minors or from a potential donor's relatives or guardians. Mature minors may possess the autonomy that consent helps protect. Moreover, it is obviously desirable to defend incompetent, vulnerable individuals by having someone concerned about their welfare make an independent appraisal of risks and benefits. An independent assessment or proxy consent requirement may thus protect incompetent patients from harms, check fraud and duress and encourage self-scrutiny by medical professionals.[297]

If a potential tissue donor lacks the autonomy to exercise consent, on what alternative moral grounds might tissue procurement be based? As with competent individuals, the value of beneficence suggests that donation might be justified if reasonably foreseeable benefits to the donor offset likely harms. This donor-centred perspective helps ensure that organs are not taken from individuals who cannot speak for themselves. Focusing the harm-benefit appraisal on genuine benefits also diminishes the risk that the appraisal may be used to mask biases about the incompetent individual's being of less social worth.

Can children and mentally handicapped persons legitimately be said to benefit from sacrificing organs? While strong scepticism[298] or a rebuttable presumption[299] against such procedures might help to police ulterior motives, the argument for donation to prevent net harm is still compelling in particular cases. For example, a Quebec court recently authorized a five-year-old to donate bone marrow to his brother ill with cancer.[300] In the early days of kidney transplants, Massachusetts courts authorized donations between minor twins.[301] In one of the leading cases on psychological donor benefits, a court in the United States weighed the harms and benefits involved in a mentally impaired person's donation of a kidney to his brother, and concluded that the donor's "well-being would be jeopardized

295. See LRC, *Biomedical Experimentation Involving Human Subjects*, Working Paper 61 (Ottawa: The Commission, 1989) at 40-42 (recommending federal statute to govern non-therapeutic medical research on children).

296. See MRC, *supra*, note 118 at 28 ("By definition, a legally incompetent subject is not autonomous, and cannot give a legally or ethically valid consent").

297. See Capron, *supra*, note 281.

298. See Ramsey, *supra*, note 243 at 172.

299. Rodney K. Adams, "Live Organ Donors and Informed Consent" (1987) 8 J. Legal Med. 555 at 582.

300. See *Cayouette et Mathieu*, *infra*, note 380.

301. William J. Curran, "A Problem of Consent: Kidney Transplantation in Minors" (1959) 34 N.Y.U. L. Rev. 891.

more severely by the loss of his brother than by the removal of a kidney."[302] Thus, concentrating on an expansive view of human existence in risk-benefit appraisals may yield outcomes that differ substantially from those that flow from an exclusive focus on the physical person.

To suggest, as these cases do, that psychological benefits are morally relevant,[303] however, does not say to what degree putative psychological benefits might count. Risk-benefit appraisals must be addressed in concrete situations. Disagreement about whether this can be done helps distinguish those who would permit organs to be taken from children and mentally handicapped persons from those who would not. In moral terms, the difference is that the former group takes a contextualist approach and the latter group, a principled approach. In law, it is the difference between equity and strict application of rules.[304]

Advocates of the former approach have confidence in the ability of human beings to discern what is right or best in particular idiosyncratic circumstances. Thus, some analysts regard transplant cases decided on psychological-benefit theories as "judgements ... characterized by humanity and compassion rather than blind adherence to one principle or test."[305] Others disparage psychological-benefit theories as a speculative and unreliable standard[306] dependent on situation ethics and palm-tree justice. In their view, general principles or rules need to be applied uniformly to avoid the evils of bias and subjectivity. They hold that consistency is the hallmark of both principled morality and the rule of law and must be observed even if it results in uncompassionate or unfair outcomes in some cases. With respect to taking organs, therefore, they insist that children and mentally disabled persons be treated the same as adults. Once again, a tissue transfer conflict springs partially from a fundamental philosophical dispute.

III. A Moral Duty to Donate

If ethical values, such as autonomy and non-maleficence, work negatively to shield our bodies from non-consensual, harmful interventions to obtain tissue, do they also work positively to obligate us to donate tissue? The prevailing North American model of altruism

302. *Strunk* v. *Strunk*, 445 S.W. 2d 145 at 146 (Ky 1969). But see *In re Guardianship of Pescinski*, 226 N.W. 2d 180 (Wisc. 1975) (denying authorization for incompetent adult chronic schizophrenic mental patient to donate kidney to sister), as modified by *Re Guardianship of Eberhardy*, 307 N.W. 2d 881 at 893 n. 13 (Wisc. 1981). These cases were recently discussed in *Curran* v. *Bosze*, *infra*, note 535 at 1326-29.

303. See MRC, *supra*, note 118 at 7 ("The harms that may be incurred are legion and include ... loss of dignity and self-esteem, guilt and remorse, or feelings of exploitation and degradation"). If psychological harms are morally relevant to, and may count against human subjects participation in non-therapeutic medical research, might not psychological benefits count in favour of donation?

304. See *The Nicomachean Ethics of Aristotle*, 1925, trans. Sir David Ross (reprinted London: Oxford University Press, 1966) Bk. V, c. 10.

305. Scott, *supra*, note 268 at 121.

306. See Adams, *supra*, note 299 at 579 n. 168.

and the rubrics of "gift" and "donation" are not clear on the question.[307] Those terms reflect the prohibition against paying persons who provide organs. They also imply that making tissue available for transplant is an act of charity — that doing so is morally praiseworthy but not necessarily a matter of moral obligation.[308]

Is there, in fact, a moral duty to donate tissues? Many philosophers have contemplated a general duty to do good unto others. Among them, the eighteenth-century German philosopher, Immanuel Kant, is noteworthy for his discussion of beneficence.[309] Thus, the notion of a general duty to help others has developed a respectable philosophical lineage following upon those thinkers. Indeed, theories of justice and social contract might suggest that one must be willing to give to be entitled to receive. As we shall see, however, the primary difficulty lies less in the soundness of the argument than in the practical policies apparently needed to implement a duty to donate.

Kant posits a duty to act based on the maxim that we all sometimes need the help of others:

> A ... man finds things going well for himself but sees others (whom he could help) struggling with great hardships; and he thinks: what does it matter to me? Let everybody be as happy as Heaven wills or as he can make himself; I shall take nothing from him nor even envy him; but I have no desire to contribute anything to his well-being or to his assistance when in need .... But ... it is impossible to will that such a principle should hold everywhere as a law of nature. For a will which resolved in this way would contradict itself, inasmuch as cases might often arise in which one would have need of the love and sympathy of others and in which he would deprive himself, by such a law of nature springing from his own will, of all hope of the aid he wants for himself.[310]

Three points about this argument need to be recognized. First, Kant distinguishes a duty not to harm from a duty to benefit others. The former is an undisputed, stringent moral requirement; it is the heart of law, morality and medical ethics. The extent to which morality proceeds beyond this minimum, negative duty and imposes positive duties to help others is contested. Secondly, it is unclear whether Kant intended these as noble, societal Golden Rules or as simple appeals to enlightened self-interest. Thirdly, Kant viewed any moral duty of beneficence as discretionary,[311] not absolute. A general duty of beneficence may be fulfilled in many ways, then; it does not necessarily dictate a specific moral duty to give tissue to the needy.

How might a moral duty to donate tissues be derived? Two leading strategies adopt different interpretations of Kant's argument. Proponents of the first argue, on the ethos

307. See David A. Peters, "An Individualistic Approach to Routine Cadaver Organ Removal" (1988) 69 Health Progress 25. See also *supra*, note 239.

308. See Ramsey, *supra*, note 243 at 185-86 ("Gifts are not rights to be claimed or duties to be imposed").

309. See Immanuel Kant, *Grounding for the Metaphysics of Morals*, trans. J.W. Ellington (Indianapolis: Hackett, 1981).

310. *Ibid.* at 32.

311. *Ibid.* at 30 n. 12.

of individualism,[312] in favour of a moral duty to donate tissue effective at death. The argument is based on prudence.[313] Rational, self-interested individuals recognize a duty not to harm others because it permits them to live free of threats of harm from others. A similar[314] kind of self-interest may ground a duty to benefit others:

> [T]he same reasoning would lead individualists to adopt the *rule (requirement) of easy rescue*. Such a rule demands that individualists give up, as bystanders in an emergency, their freedom to choose whether they will aid the endangered party. The rule requires that a witness give a victim any significant assistance that involves little or no cost or risk to the witness. ... The gain-to-risk ratio of such a rule would be highly attractive to individualists. In exchange for accepting a modest inconvenience as witnesses to an emergency, individualists gain increased assurances that they will be rescued if in peril. The promised protection allows individuals to better plan activities, which enhances freedom.[315]

Although planning for emergencies seems an awkward notion of freedom, it is plausible that self-interest would compel many to strike a social contract that includes a moral duty of beneficence. Similar logic might also support post-mortem tissue procurement policies of presumed consent or routine procurement. In short, rational, self-interested individuals might choose a societal procurement policy that maximizes their probability of receiving a transplant while alive, if they need one, at the risk of having their tissues taken posthumously.[316]

The second approach to deriving a duty to help others is based on a less individualist, more Golden-Rules view — namely, helping simply for the sake of helping, as embodied in the notion of good Samaritanism. The moral appeal is made painfully persuasive by example:

> A woman's head-dress catches fire: water is at hand: a man, instead of assisting to quench the fire, looks on, and laughs at it. A drunken man, falling with his face downwards into a puddle, is in danger of suffocation: lifting his head a little on one side would save him: another man sees this and lets him lie. A quantity of gunpowder lies scattered about a room: a man is going into it with a lighted candle: another knowing this, lets him go in without warning.[317]

If the moral duty to be a good Samaritan is readily acknowledged, the difficulty lies in the third task of practical ethics — that is, formulating a policy to implement an attractive

312. Peters, *supra*, note 307 at 25.

313. *Ibid.* ("Rational individuals who preemiently value liberty would find it prudent to accept the duty of easy rescue and the duty to consent on the ground that personal liberty and welfare are likely to be better protected and advanced in a society that abides by these rules than in a society that does without them").

314. See Robert Lipkin, "Beyond Good Samaritans and Moral Monsters: An Individualistic Justification of the General Legal Duty to Rescue" (1983) 31 U.C.L.A. L. Rev. 252.

315. Peters, *supra*, note 307 at 26.

316. See Muyskens, *supra*, note 252 at 97.

317. J.H. Burns and H.L.A. Hart, eds, *An Introduction to the Principles of Morals and Legislation* (London: Athlone, 1970) at 293 n. u.

theoretical position. Indeed, this difficulty is often invoked to explain why the law may not follow morality in this regard.[318] Specifically, what are the practical implications for bad Samaritans in tissue procurement law?

One attempt at a solution was enacted in Singapore in 1987. Its presumed-consent law for the posthumous procurement of kidneys treats persons unwilling to give differently than those willing to give:

> For the purposes of this proposed law Muslims would be presumed to object [on religious grounds] and are thus to be classified along with objectors. ... Such persons are put in a lower priority group for receiving kidneys.[319]

In essence, the law creates a two-tiered system of entitlement to kidney transplant resources, based on willingness to give. Is this fair?

The answer may depend on how much one is impressed by the claim that persons most prepared to give should be most eligible to receive.[320] Is the moral basis of the claim contractual self-interested individualism, charitable humanitarian benevolence or both?

Moral and practical intricacies also arise in any attempt to enforce on living potential donors a moral duty to donate. In an oft-cited case on the issue, a leukemia patient sought a court order compelling his cousin to donate bone marrow to him.[321] Legal formulations of a duty to rescue typically relieve the duty if it would involve appreciable risk.[322] But the judge did not reach that stage of the inquiry:

> The common law has consistently held to a rule which provides that one human being is under no legal compulsion to give aid or to take action to save another human being or to rescue ... For our law to *compel* defendant to submit to an intrusion of his body would change every concept and principle upon which our society is founded. To do so would defeat the sanctity of the individual, and would impose a rule which would know no limits, and one could not imagine where the line would be drawn.[323]

The court, while apparently agreeing that the potential donor had a moral obligation to help his needy cousin,[324] refused to translate the moral duty into a legal duty. The case suggests that in concrete conflicts between the moral values of beneficence and autonomy, beneficence may not prevail.

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318. For a fuller discussion of a legal duty to rescue, see pages 89-91 below.

319. T.K.K. Iyer, "Kidneys for Transplant — 'Opting Out' Law in Singapore" (1987) 35 Forensic Sci. Int'l 131 at 135. Muslims comprise 16% of the Singapore population. *Ibid.* at 132. For the text of the law, see *The Human Organ Transplant Act 1987*, reproduced in (1990) 41:2 Int'l Dig. Health Leg. 257. See also Peters, *supra*, note 307 at 27.

320. See Peters, *supra*, note 307 at 27-28.

321. *McFall* v. *Shimp*, *infra*, note 533. See also Scott, *supra*, note 268 at 127-39.

322. See the discussion in chap. 3, pages 89-91 below.

323. *McFall* v. *Shimp*, *infra*, note 533 at 91.

324. But see Beauchamp and Childress, *supra*, note 236 at 201.

IV. Our Bodies, Our Selves

Our earlier discussion of cadaveric transplantation exposed how different views on procuring tissues from the dead reflect different views on the relationship between one's body and one's self. Those who hold that persons do not merely live in their bodies, but rather are "lived bodies," accord substantial respect to the dead body, because it is emblematic of humanity and personhood. When body and self are inextricably one, the respect owed to persons perfuses human bodies and continues after death. This view rejects regarding or treating the body as a storehouse of parts to be used for refurbishing other bodies.

By contrast, those who perceive a tenuous link between body and self view the body as necessary for the expression and facilitation of the self but of no inherent value in its own right. For them, the body possesses instrumental value; it may, therefore, be used as an instrument for benefitting other selves. This view is more accommodating of routine procurement: "Since the human identity with the body is incidental, one need not seek permission from the predeceased or the family for extracting, in a good cause, organs, blood, or tissue."[325] The following discussion explores the philosophical sources of these opposing views and applies them to notions of bodily commerce and bodily property.

The concept of persons as embodied selves is embedded in several religious traditions. A current within Protestant ethics adheres to the "very realistic view of the life of man who is altogether flesh."[326] Traditional Jewish ethics also "expresses this concern for man's embodied existence and joyfully affirms the integrity of the flesh."[327] Such views may impose strict religious and moral strictures on the posthumous invasion and use of the body.[328]

By contrast, the concept of persons as disembodied selves stems as far back as seventeenth-century secular thought:

> ... Cartesian mentalism and dualism of mind (soul, person) and body ... is endemic to the modern mentality and an epidemic afflicting almost all contemporary outlooks. Our culture is already prepared for technocratizing the bodily life into collections of parts in which consciousness somehow has residence for a time. ... The contagious dualism of modern culture has already placed [man], as a spiritual overlord, too far above his physical life. To most of us a part of the body or the bodily life as a whole is already only a thing-in-the-world, not to be identified with the person.[329]

Modern scientific thought, the cornerstone of contemporary medical practice, is a result of the Enlightenment. Perhaps science and medicine could have evolved in the absence of the Cartesian dualism of mind and body. Nevertheless, it is firmly entrenched in both.

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325. May (1985), *supra*, note 245 at 39.

326. Ramsey, *supra*, note 243 at 187.

327. *Ibid.* See also May (1985), *supra*, note 245 at 39 (summarizing religious outlooks on the self and the body).

328. See further discussion in chap. 3, pages 140-42 below.

329. Ramsey, *supra*, note 243 at 193.

Indeed, the success of modern medicine is largely a result of the preoccupation with the body. As such, some thinkers even blame science for contemporary moral ills:

> At the bottom of the trouble ... is the hegemony of modern natural science, to whose view of nature even the partisans of personhood and subjectivity adhere, given that their attempt to locate human dignity in consciousness and mind presupposes that the subconscious living body, not to speak of nature in general, is utterly without dignity or meaning of its own.[330]

Modern moral theory has not been immune from the mind-body dualism that has pervaded Western thought for centuries. Some critics maintain that "the theorists of personhood, consciousness, and autonomy ... treat the essential human being as pure will and reason, as if bodily life counted for nothing, or did not even exist."[331] One school of philosophy, the Anglo-American analytic tradition, encompasses and reflects the Cartesian dualism.

A different school of philosophy, the Continental phenomenological tradition, "emphatically aims at the dissolution of the mind-body dichotomy."[332] This school rejects the objectifying, reductionist methodology of science, and takes subjective experience as the starting-point for the view that we live as embodied selves.[333] To phenomenologists, fragmenting human experience into distinct physical and mental realms is "an artifice, necessary for the scientific study of man but obstructive to philosophical thought as well as moral action."[334] Once dualism is rejected, the body is "neither an object immersed in the material world nor a consciousness positing the world."[335] Rather, it is "a structure enabling the appearance of both world and consciousness":[336]

> [T]his objectified body has a status of its own in our perceptions. Only because we drag it with us as a material object are we able to take notice of other objects as well. The same ambiguity crops up as we feel that things are not "given" to our perception but are "lived" by us. Yet as we "live" them, we make them take the shape of an objective reality because our body is geared ... to the world. Thus the human body is a primordial phenomenon for itself, but it is as well attached to a natural world in itself.[337]

These competing philosophies on the body-self relation colour our views on the good or ills of bodily property and bodily commerce.

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330. Leon R. Kass, "Thinking about the Body" (1985) 15:1 Hast. Cent. Rep. 20.

331. *Ibid.* The dualism also manifests itself in ethical criteria of "personhood." See White, *supra*, note 91 at 132.

332. Wim J. van der Steen and P.J. Thung, *Faces of Medicine* (Boston: Kluwer, 1988) at 198.

333. *Ibid.* at 150.

334. *Ibid.* at 119.

335. *Ibid.* at 155.

336. *Ibid.* See also *ibid.* at 153 ("[I]n the course of various centuries, the body came to take the shape of an artifact [cf. 14th-century anatomy, Harvey's experimental physiology, 19th-century discoveries of Röntgen photography and of spinal reflexes]. Throughout this development, man's natural ... body was gradually emptied of soul and sense, and matter was substituted for meaning. Descartes' dualism was a formal recognition of the changes suffered by the body, long before Röntgen rays and reflexes completed the process.").

337. *Ibid.* at 155.

A. Bodies, Selves and Property

What are the ethical implications of regarding the body as property? Such considerations raise a tangled skein of issues:

> My body may or may not be mine or God's, but as between you and me, it is clearly mine. And yet I wonder. What kind of *property* is my body? Is it mine or is it *me*? Can it be alienated, like my other property, like my car or even my dog? And on what basis do I claim property *rights* in my body? Have I labored to produce it? Less than did my mother, and yet it is not hers. Do I claim it on merit? Doubtful: I had it even before I could be said to be deserving. Do I hold it as a gift — whether or not there be a giver? How does one possess and use a gift? Is it mine to dispose of as I wish — especially if I do not know the answer to these questions?[338]

These questions suggest how relative and indeterminate the concept of property may be. In certain contexts and for certain reasons, it might be appropriate to regard bodies as property. In other contexts and for other reasons, it will be inappropriate. The crucial task, then, is to delineate the contexts and reasons.

What is property? Ethically, there is no simple answer, only a host of associations and distinctions accompanied by decisions about whether fulfilling certain indicia is sufficient to call something property. One legal analysis of the concept of ownership, for example, lists eleven "standard incidents" of ownership:

> Ownership comprises the right to possess, the right to use, the right to manage, the right to the income of the thing, the right to the capital, the right to security, the rights or incidents of transmissibility and absence of term, the prohibition of harmful use, liability to execution, and the incident of residuarity.[339]

If I have the rights to possess, use and manage, the right to security and the prohibition of harmful use with respect to my body, do I therefore "own" my body? These "incidents" would seem to argue yes. If so, this affirmation must itself be qualified, for it does not necessarily follow that I have other "incidents" such as the right to my body's "capital" or the right of alienation. The complete answer, then, must be: Yes, I own my body, in a sense, or for certain purposes.

Such an analysis has strengths and limits. It helps us to understand what those various senses or purposes are. In particular, it reveals that the inclination to equate property with commerce must be resisted. It is tempting, for those who want to forestall a commercial market in organs, to contend that bodies are not property. But that stance makes it difficult to explain how we can then donate organs. If this is not my kidney, what right do I have

338. Kass, *supra*, note 330 at 23.

339. A.M. Honore, "Ownership" in A.G. Guest, ed., *Oxford Essays in Jurisprudence*, 1st ser. (Oxford: Clarendon, 1961) 107 at 113.

to give it away?[340] The issue must be refined to recognize that bodily parts may be property that carries the right of alienation, even if they cannot be property that carries a right to capital.

Such conceptual analysis also has its limits. It may expose problems without solving them. It provides a lucid answer to the question, Are bodies property? — an answer that approves the giving but not the selling of bodily parts. Yet, it does not answer implicated ethical questions, because it fails to identify the moral grounds for permitting giving but not selling. It provides little moral guidance on why we may have bodily property in one sense but not in another:

> [I]t is clear that to stare at the meaning of the word "thing" will not tell us which protected interests are conceived in terms of ownership. When the legislature or courts think that an interest should be alienable and transmissible they will reify it and say that it can be owned, that it is property. They will not say that it can be owned and is a *res* because of a prior conviction that it falls within the appropriate definition of "thing." The investigation of "things" seems to peter out in a false trail.[341]

Decisions about what "incidents" of property should attach to what objects must be made on substantive moral grounds.

Why, then, should bodies not be regarded as ordinary property? An important answer may be that notions of bodily property do violence to our concepts of personal autonomy and human dignity. Property is traditionally associated with things, not with the human body. To equate the body with a thing is to dehumanize human existence; in the extreme, it suggests the repulsive notion that human beings may be owned. This answer hinges both on a thing-person[342] dualism, and an inference that human bodily parts are reflective of our notion of self. Both are central to substantive objections to the buying and selling of human tissue.

Thus, there is difficulty in providing a general explanation of what is wrong with "alienating" one's body. Just as "property" and "ownership" have different senses, so does "alienate." Alienating a kidney by giving it for transplantation is praiseworthy; alienating a kidney by selling it is suspect. Therefore, the moral issue does not revolve around alienation *per se*, but alienation for money. So what are the substantive objections to the buying and selling of bodily tissues?

B. Bodies, Selves and Commerce

Pervasive tissue scarcity in recent years has made the buying and selling of human tissue a contentious issue in national and international communities.[343] Some analysts

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340. See Childress, *supra*, note 249 at 89, 100 ("We often think about property only in commercial terms, but even the donation of HBPs [human body parts] presupposes some conception of property").

341. Honore, *supra*, note 339 at 130.

342. See Radin, *infra*, note 460 at 1891, discussing Kant.

343. For a discussion of international concerns, see chap. 4, pages 162-63 below.

advocate sales as a means of relieving the tissue shortage.[344] Others steadfastly oppose both pre-mortem and post-mortem sales.[345] In between are those who, while concerned about potential abuses, do not object in principle to monetary exchanges for tissue. Roman Catholic moral theology may fall into the middle camp. For instance, Pope Pius XII, relying on an analogy with the sale of blood, refused to condemn payment for bodily tissue:

> [M]ust one, as is often done, refuse on principle all compensation? This question remains unanswered. It cannot be doubted that grave abuses could occur if payment is demanded. But it would be going too far to declare immoral every acceptance or every demand of payment. The case is similar to blood transfusions. It is commendable for the donor to refuse recompense: it is not necessarily a fault to accept it.[346]

What, then, are the moral merits and demerits of tissue sales? Many of these parallel the legal and policy considerations over sales that are explored below.[347] Proponents tend to base their position on the ethical value of preserving life, by couching their arguments in terms of the visible consequences of pure altruism. They contend, among other things, that: sales would significantly alleviate the current organ shortage; an increase in the supply of cadaveric tissue would reduce the need for donations from living persons and thus their exposure to the risks of surgery; an enlarged supply of tissue would improve immunological matching, thereby reducing the incidence of rejection; and any potential for major abuses or moral ills may be controlled by a limited or regulated market.[348]

Opponents base their position on both consequentialist and formalist concerns. They argue, among other things,[349] that: sales would undermine public altruism, by reducing the number of tissues that are freely given for transplantation;[350] tissue sales would undermine social justice by allowing a *laissez-faire* market to allocate tissues by the individual's ability to pay, meaning that the poor would regularly be outbid and denied equal access to life-saving opportunities.[351]

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344. See David A. Peters, "Marketing Organs for Transplantation" (1984) 13:1 Dialysis and Transplantation 40; Henry Hansmann, "The Economics and Ethics of Markets for Human Organs" (1989) 14:1 J. Health Pol. Pol'y L. 57; Lori B. Andrews, "My Body, My Property" (1986) 16:5 Hast. Cent. Rep. 28.

345. See Ramsey, *supra*, note 243 at 213.

346. *Papal Teachings: The Human Body* (Boston: St. Paul Editions, 1960), quoted in White, *supra*, note 91 at 142. See also Charles Joseph McFadden, *Medical Ethics*, 6th ed. (Philadelphia: F.A. Davis, 1967) at 297.

347. See pages 82-83 below.

348. *Ibid.* See also Theodore Silver, "The Case for a Post-Mortem Organ Draft and a Proposed Model Organ Draft Act" (1988) 68 B.U.L. Rev. 681 at 699-703. Silver, interestingly, challenges the assumption that organ sales would alleviate the prevailing shortage. *Ibid.* at 701.

349. See pages 82-83 below.

350. *Ibid.*; Titmuss, *supra*, note 244 at 225-29. If the number of altruistic tissues were likely to decrease, while the number of overall tissues increased, then the probabilities would morally pit the less tangible, less quantifiable benefits of altruism against a mixed tissue procurement regime that more effectively meets therapeutic demand.

351. Thomas H. Murray, "On the Human Body as Property: The Meaning of Embodiment, Markets, and the Meaning of Strangers" (1987) 20 U. Mich. J.L. Ref. 1055 at 1084. Sales proponents respond that any injustice of sales will be outweighed by more lives saved and that these concerns may be addressed by a regulated market. See chap. 3, section I.C(2), below.

A leading objection of opponents transcends the balancing of disadvantages and advantages. It rests on the formalist claims that human tissue sales are intrinsically immoral and dehumanizing and that they violate the respect due persons. The argument is based on the moral philosophy of Kant:

> Whatever has a price can be replaced by something else as its equivalent; on the other hand, *whatever is above all price, and therefore admits of no equivalent, has a dignity.* . . .
>
> Now morality is the condition under which alone a rational being can be an end in himself. . . . Hence morality and humanity, insofar as it is capable of morality, alone have dignity.[352]

Human dignity is the basis of the respect that is owed to all persons and that makes them priceless.

How does this intrinsic human dignity apply to our physical persons? According to one view, the apparent moral protection does not cloak the human body. For Kant, persons possess dignity and are owed respect by virtue of their rationality. If what must be morally respected is rationality, and if the capacity for rationality is located in a discrete part of the human body — say, the mind — then the rest of the body lacks special moral status. A view that reduces morality to rationality seems to end up derogating the body.[353]

Thus, the cogency of the Kantian concern seems to hinge on the now familiar competing views of the body-self relation. One's view of the strength of that relation will influence one's view of the good or ill of thinking of human bodily entities in commercial market terms. For those who regard the body as simply a physical substratum for the self, there seem few intrinsic impediments to tissue sales. There is no basic moral objection to using the body to further the ends of self. Since the body has only instrumental value, there is no reason why that instrumental value should not receive a price. For those who reject the mind-body dualism and equate the body with self, human dignity permeates the entire human body and should keep it priceless:

> The dispute between those who believe that commercialization of the human body is justified and those who think it is not seems mostly to be an argument between those who accept a dualistic view of the separation between body (material, physiological being) and mind (immaterial, rational being), and those who do not.[354]

For those sensitive to the Kantian concern, but mindful of the degree to which monetary exchanges already help supply and speed therapeutic human tissue transfers, pragmatic distinctions may offer a moral basis for tolerating some monetary tissue exchanges as not violative of human dignity. For it might be argued that some bodily by-products, substances or subparts surely do not connote the dignity of persons, but rather resemble things:

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352. Kant, *supra*, note 309 at 40-41 (emphasis added). The notion of "price" here should not be understood narrowly to include only a price determined by a market.

353. See White, *supra*, note 91 at 132-34, discussing J. Fletcher and H.T. Engelhardt.

354. White, *supra*, note 91 at 143.

> Even if selling HBPs [human body parts], such as solid organs; would be potentially dehumanizing to the society, there is debate about whether dehumanization results from the sales of all human biological materials, including surplus tissues and fluids (e.g., hair and urine) and renewable tissue (e.g., blood). . . . In addition, some proponents of a market would distinguish living vendors from cadavers and exclude situations in which a conflict of interest existed (e.g., the sale of aborted fetuses or fetal tissues). Furthermore, it would be possible to distinguish types of valuable consideration, such as direct payments and indirect incentives. For example, could the line be drawn between direct payment and coverage of a donor's medical expenses, compensation of a living donor's lost wages, and payment for the burial expenses of a deceased donor?[355]

Are such distinctions morally persuasive? While they may appeal to the balancing needs of public policy, they still sometimes offer thin ethical bases. It is not clear, for example, how an ethically meaningful line can be drawn between direct payments and indirect incentives. There might appear to be a principled difference between offering cash as an incentive to donate and reimbursing out-of-pocket expenses. But in practice the difference may vanish. Direct payment may be thought objectionable because it constitutes an undue incentive. Reimbursement for expenses, in contrast, may be thought unobjectionable because it functions to remove disincentives rather than to create incentives. Yet, social reality indicates that what counts as an incentive depends as much upon the situation of the potential recipient as it does upon the amount and spirit of the offering. The sum of $250 for participating in a drug research protocol does not have the same economic value for a salaried professional as for a poor student. To the former it does not approach adequate compensation; to the latter it might tend towards undue incentive.[356] Some analysts thus regard such distinctions as illusory or fictitious.[357]

Still, a strategy that recognizes meaningful differences between human tissues, and then defines the conditions under which monetary exchanges might occur, may prove more accommodating of diverse ethical concerns than a flat yes-or-no approach to an open sales market. Both a limited and an open sales market, however, remain subject to a basic concern: namely, do less ethically hazardous alternatives exist? Given the different ethical objections to sales, courting such objections would be ill-advised, if society could rely on other procurement policies to produce similar results without the attendant costs.[358] This concern has been persuasively argued in the required-request experiment ongoing in the United States.[359] The concern leads opponents of tissue sales to argue that, even

355. Childress, *supra*, note 249 at 101.

356. Some might prefer the word "coercion." Others distinguish financial incentives from coercion. See H.J. McCloskey, "Coercion: Its Nature and Significance" (1980) 18 Southern J. Phil. 335 at 339. Indeed, assessing the moral status of undue or "irresistible" inducements is important, but that inquiry may be clouded by labelling them "coercive." "Coercion" seems to function as a conclusion, so that if an inducement is regarded as morally wrong, it is described as "coercive," to take advantage of the negative moral connotations that attach to the term.

357. See, *e.g.*, Murray, *supra*, note 351 at 1074. See also chap. 3, section I.C(3), below.

358. Childress, *supra*, note 249 at 100-01.

359. See the intellectual author of U.S. required request, Caplan, *infra*, note 987.

if a commercial tissue market is "ethically acceptable,"[360] it still needs to be proven "ethically preferable" to other acceptable procurement policies that might be identified on the spectrum from altruism to routine procurement.[361]

V. Fashioning Policies

Our discussion of the basic tasks of practical ethics — identifying, weighing and practically implementing human values — suggests some conclusions about fashioning policies to facilitate and speed the transfer of human therapeutic tissue.

First, the values that underlie and animate tissue procurement policies are diverse and dynamic. They range from the conspicuous goal of saving life to such cherished values as autonomy, justice and human dignity, and to the core ethical commands of doing good and doing no harm. These values and principles bespeak broad, sometimes amorphous, moral concepts. Many are considered fundamental. Few are considered absolute or pre-eminent. As a result, values will sometimes complement and sometimes compete against one another for primacy in diverse tissue procurement policies.

Secondly, the very nature of the moral concepts, competing values and philosophical disputes embedded in tissue procurement policy reminds us that, even amidst dire medical needs for our physical beings, we remain much of what we think, believe and value. The foregoing analysis has shown that our conscious and unconscious beliefs on the body-self relation constantly shape thought and conduct towards the living and dead human body. Indeed, divergent visions of the strength of that body-self relation colour our views on whether the dead suffer "harms," on what conduct we find ethically tolerable or abhorrent in medical use of recently deceased patients, on whether tissue sales intrinsically contravene human dignity, on whether bodily property concepts do violence to our moral picture of human beings, and on whether one procurement policy, more than another, is likely to beget harmful attitudes and practices.

Thirdly, despite the philosophical divides and difficulty in measuring, comparing and prioritizing tissue procurement values, practical ethics proves helpful in outlining potential ethical approaches and policy options. It may suggest, for example, that if a gift-of-life ethic is preferred and policy makers cannot solve the philosophical dispute over emotion in morality, a dispute that divides proponents of altruism and of routine procurement, then policy makers could judge whether the prevailing model of altruism has received a fair and sufficient test. This judgment would flow from an initial endorsement of altruism as a preferred public policy, a policy that may be modified or abandoned when it proves ineffective or too costly.

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360. This judgment must ultimately include an evaluation of when a tissue procurement policy becomes "sufficiently effective": satisfying 50%, 75%, 90% of demand? See Childress, *supra*, note 249 at 101. Similarly, for potential recipients on transplant waiting lists, how long is a reasonable wait?

361. *Ibid.* at 89. Some analysts prefer a system of family credits and routine taking to buying and selling. See May (1973), *supra*, note 245 at 4.

Similar practical judgments may suggest policy options on tissue sales. Beyond the debate over formal and consequentialist objections to sales, tissue sales might simply be judged to be a policy alternative that is ethically less preferable, especially if it can be shown that human tissue may be adequately supplied by less ethically costly options. If searching for a global prohibition or authorization proves unhelpful, drawing pragmatic distinctions between the least and most ethically offensive tissue sales might reveal viable, morally acceptable public options. Of course, because even pragmatic distinctions demand moral choice, policies based on them will also stir and touch those core societal values that seem so embedded in tissue procurement ethics.

CHAPTER THREE

Existing Tissue Transfer Law — Rights, Duties and Ambiguities

The law offers some answers to questions provoked by the increasing medical use, transfer and storage of human tissue and bodily substances. The following examination of relevant criminal, civil and common law legislation and constitutional principles addresses the major consent, property and sales issues identified in chapter 1. Because the law often concerns itself with the rights and duties of competing players, much of the focus centres on how the law allocates the interests of donors and their families, recipients, medical professionals and the community or state.

I. Common Law and Civil Law Perspectives

What rights and duties do the common law and the civil law provide as to the donation and transfer of human bodies, tissues and bodily substances from living and deceased donors? Answers to the question are not only important for historical purposes. They inform and sometimes govern legal relations regarding tissue storage and sales, consent to autopsies and like areas where legislation may be ambiguous or absent.

A. Bodily Integrity and Consent

Bodily integrity, the Supreme Court of Canada recently declared, ranks high on our scale of societal values and implicates basic rights.[362] Not surprisingly, the law gives practical effect to these values. Non-consensual touching may ground civil or even criminal liability.[363] Thus, the principle of informed consent[364] and the Quebec *Civil Code* principle of the inviolability of the human person[365] generally provide that health providers may invade a patient's person after securing his or her consent.[366]

362. *E. (Mrs.)* v. *Eve*, [1986] 2 S.C.R. 388 at 406, 434.

363. A claim for civil liability would typically be laid in respect of battery. See, *e.g.*, *Malette* v. *Shulman* (1990), 67 D.L.R. (4th) 321 (Ont. C.A.). For discussion of criminal assault, see section II, below.

364. See Ellen I. Picard, *Legal Liability of Doctors and Hospitals in Canada*, 2d ed. (Toronto: Carswell, 1984) c. 3 at 41.

365. See *Civil Code of Lower Canada*, arts 19, 19.1, 984, 1053 [hereinafter *C.C.L.C.*]; *Chouinard* v. *Landry*, [1987] R.J.Q. 1954 (C.A.). See generally François Heleine, "Le dogme de l'intangibilité du corps humain et ses atteintes normalisées dans le droit des obligations du Québec contemporain" (1976) 36 R. du B. 2. For further discussion of tissue transfer provisions of the *Civil Code*, see section III, below.

366. For criminal law protection of the right to bodily integrity, see the discussion of assault in section II, below.

The principles are of ancient origin. Indeed, the law has for centuries recognized the obligation of physicians to seek the consent of their patients prior to initiating treatment.[367] First articulated as an action in trespass,[368] and later as an action in battery, the legal doctrine today requires physicians to disclose the purpose, the material risks of and options to a proposed medical procedure, so that patients may consent voluntarily, knowingly and intelligently.[369] Patient consent generally includes the right to decline treatment.[370] Yet, the consent requirement is not absolute. It does not apply in emergencies,[371] when the patient waives the right or, in rare instances, when it is unequivocally contrary to the patient's medical interests for the health professional to disclose information.[372]

Consent requirements are designed to effect personal autonomy, preserve bodily integrity, promote patient-physician understanding and, so, favourably affect medical outcomes. Conceptually, these requirements envisage the patient-physician relationship as a forum for a candid, mutual exchange of information,[373] one that thus becomes a partnership in rational decision making. It is presumed that patients will, despite their fears, comprehend the choices before them with the help of expert medical advice. They would likely be more co-operative and engaged in the treatment process, by virtue of heightened participation. The doctor is thought to benefit as well from the shared decision making,[374] because a more comprehending, participating patient is thought to increase the likelihood of effective treatment. Conceived as such, the right is at once functional and humanistic. It has both "an instrumental value in achieving subjectively defined well-being and an intrinsic value as an element of personal worth and integrity."[375]

Consent principles apply to the range of the medical and surgical procedures involved in the tissue donation and transplantation process, including the use of innovative or

367. See *Slater* v. *Baker* (1767), 95 E.R. 860 (K.B.).

368. See *Mulloy* v. *Hop Sang*, [1935] 1 W.W.R. 714 (Alta C.A.).

369. See *Reibl* v. *Hughes*, [1980] 2 S.C.R. 880. See also Robert P. Kouri, "L'influence de la Cour suprême sur l'obligation de renseigner en droit médical québécois" (1984) 44 R. du B. 851. See generally Margaret A. Somerville, *Consent to Medical Care*, Study Paper prepared for the LRC (Ottawa: Supply and Services Canada, 1980).

370. *Couture-Jacquet* v. *Montreal Children's Hospital*, [1986] R.J.Q. 1221 (C.A.); *Malette*, *supra*, note 363. See also LRC, *Medical Treatment and Criminal Law*, Working Paper 26 (Ottawa: Supply and Services Canada, 1980).

371. *Murray* v. *McMurchy*, [1949] 2 D.L.R. 442 (B.C.S.C.).

372. See generally Paul S. Appelbaum, Charles W. Lidz and Alan Meisel, *Informed Consent: Legal Theory and Clinical Practice* (New York: Oxford University Press, 1987) c. 4 at 66.

373. See generally Note, "Restructuring Informed Consent: Legal Therapy for the Doctor-Patient Relationship" (1970) 79 Yale L.J. 1533. See also President's Commission, *Making Health Care Decisions: A Report on the Ethical and Legal Implications of Informed Consent in the Patient-Practitioner Relationship*, vol. 1 (Washington, D.C.: The Commission, 1982) at 41-50.

374. See Katz and Capron, *supra*, note 281 at 79, 87.

375. President's Commission, *Deciding to Forego Life-Sustaining Treatment: A Report on the Ethical, Medical, and Legal Issues in Treatment Decisions* (Washington, D.C.: The Commission, 1983) at 26. See also *Making Health Care Decisions*, *supra*, note 373 at 41-50.

experimental therapy.[376] If the ideals behind the model of informed medical choice do not easily translate into clinical practice,[377] the theory itself encounters difficulty with regard to minors[378] and mentally disabled persons when they lack the capacity for exercising choice.[379] In such instances, the parents of the minor or a legal guardian may have authority to consent to the medical procedure. Under the Quebec *Civil Code*, for example, a minor "capable of discernment" may donate tissue, if the risk assumed is not disproportionate to expected benefits, those having parental authority consent and a court authorizes the procedure.[380]

Parental or judicial power to authorize transplant-related medical interventions involving incompetent minors is not without its limits, however. The risks to the donor, any potential psychological benefits to the donor and the expected benefits to the recipient must be closely weighed in a justification of invasive, irreversible procedures such as the donation of a kidney by one minor sibling to another:

> The discretion is to be exercised for the benefit of that person, not for that of others. It is a discretion, too, that must at all times be exercised with great caution, a caution that must be redoubled as the seriousness of the matter increases. . . . Marginal justifications must be weighed against what is in every case a grave intrusion on the physical and mental integrity of the person.[381]

B. Bodily Property and Possessory Interests

In the transplantation and biotechnological age of the late twentieth century, should the law affirm or abandon the seventeenth-century legal maxim that there is no property in a body? Modern medical practice and the evolution of the law have called into question

376. Compare *Halushka* v. *University of Saskatchewan* (1965), 52 W.W.R. 608 (Sask. C.A.), and *Karp* v. *Cooley*, 493 F. 2d 408 (5th Cir. 1974) (consent to implanting experimental mechanical heart). See also *Weiss* v. *Solomon*, [1989] R.J.Q. 731 (Sup. Ct). See generally Working Paper 61, *supra*, note 295.

377. See William A. Silverman, "The Myth of Informed Consent: In Daily Practice and in Clinical Trials" (1989) 15:1 J. Med. Ethics 6; Katz, *supra*, note 68 at 84.

378. See *Saskatchewan (Minister of Social Services)* v. *P. (F.)* (1990), 69 D.L.R. (4th) 134 (Prov. Ct) (parental authority not to consent to infant liver transplant), and W.F. Bowker, "Minors and Mental Incompetents: Consent to Experimentation, Gifts of Tissue and Sterilization" (1980-81) 26 McGill L.J. 951. For ethical considerations, see chap. 2, above. For analogous criminal law considerations, see section II, below.

379. See Paul S. Appelbaum and Thomas Grisso, "Assessing Patients' Capacities to Consent to Treatment" (1988) 319:25 N. Engl. J. Med. 1635. See also *Re Spring*, 405 N.E. 2d 115 (Mass. 1980) (court authorizing termination of renal dialysis treatment for mentally disabled man).

380. *C.C.L.C.*, art. 20. See *Cayouette et Mathieu*, [1987] R.J.Q. 2230 (Sup. Ct) (authorizing 5-year-old to donate bone marrow to brother suffering from leukemia under *C.C.L.C.*, art. 20). Amendments to these provisions have been proposed. See Robert P. Kouri, "Le consentement aux soins médicaux à la lumière du projet de loi 20" (1987) 18 R.D.U.S. 27, and Bill 125, *Civil Code of Quebec*, 1st Sess., 34th Leg. Que., 1990, which received Royal assent while this working paper was in preparation for publication. See S.Q. 1991, c. 64.

381. *Eve*, *supra*, note 362 at 427, 434 (limiting court power to authorize non-therapeutic sterilization of mentally incompetent adult). See also Bernard M. Dickens, Case Comment "*Eve* v. *E.*" (1987) 2 Can. Fam. L.Q. 103.

the validity of that rule. Human bodies, bodily parts, tissues and substances are increasingly given, transferred, taken and preserved for years, for a variety of therapeutic uses and purposes. Some bodily substances are sold. If we cannot own our bodies or bodily parts, what may we do with them?

Our analysis suggests that the common law recognizes limited property interests in the human body for particular purposes. Seeking to avoid abhorrent ethical and commercial connotations, the common law reiterates the no-property rule. At the same time, it recognizes an executor's or a family's rights of possession to the body of a deceased potential donor. Such limited possessory interests protect familial, moral and religious sentiment. For living donors, the law has also been loath to recognize property concepts in the body. It tends to depend on important, but sometimes limited, principles of informed consent and emotional distress damages, to govern the control, transfer or non-consensual use of extracorporeal tissue. In the face of the new biomedical and biotechnological imperative, our legal concept and definition of property seem increasingly critical. New developments challenge the traditional legal ambivalence of the no-property rule. They invite society to rethink its choices for a tissue transfer regime that continues to advance human dignity, privacy and bodily integrity in this new age.

(1) Deceased Donors

Both the common and the civil law have traditionally maintained that the human corpse is not the subject of property.[382] The sacrosanct nature of the dead human body understandably traces much of its origins to religious custom. The *Civil Code of Lower Canada* refers in burial matters to dead bodies as "sacred by their nature."[383] Similarly, the common law no-property rule is traced to the sixteenth- and seventeenth-century English case law and Sir Edward Coke's commentary that burial matters were within the domain of the Church, and the burial of cadavers is *nullis in bonis* (among the property of no one).[384] As the courts of England began to hear matters formerly within the jurisdiction of the courts of the Church, they imported Coke's statement into English jurisprudence concerning dead bodies.[385]

Despite the no-property rule, the common and civil law still recognized a number of interests that continue to enjoy legal protection today. For example, although the common law did not grant an absolute right to the control of one's body after death through one's

382. For commentary on the civil law perspective, see R. Dierkens, *Les droits sur le corps et le cadavre de l'homme* (Paris: Masson, 1966) at 157-58.

383. *C.C.L.C.*, art. 2217.

384. See Edward Coke, *The Third Part of the Institutes of the Laws of England*, 5th ed. (London: A. Crooke, 1671) at 103, relying partially on *Haynes's Case* (1614), 77 E.R. 1389 (larceny of burial wraps, not of body).

385. See Paul Matthews, "Whose Body? People as Property" (1983) 36 Current Legal Problems 193 at 197-204 and 240, discussing *Williams* v. *Williams* (1882), 20 Ch.D. 659 at 665.

will,[386] it and the civil law have long recognized one's right to a decent burial.[387] To effect the deceased's right to a decent burial, the law imposed on the deceased's executor or family a duty of burial and a corresponding right to possession of the decedent's body for burial:

> In Canada, this duty of burying a dead body falls upon the executors of the deceased's estate. In the absence of a will naming executors, the right to possession for burial goes to the surviving spouse . . . If no spouse survives, the right belongs to the next of kin.[388]

Some courts and jurisdictions refer to the right of possession as a "quasi-property" right.[389] It empowers spouses or the next of kin who are wronged by interference to sue for damages. The essence of such suits is damages for injury to the emotional or mental tranquillity of the next of kin, in the legal form of the wrongful infliction of emotional distress.[390] Thus, instances of interference with the right of possession arise in diverse cases, including the negligent handling or transporting of dead bodies,[391] the withholding of a body for payment of funeral expenses,[392] the unauthorized removal of hair from the deceased by a funeral home,[393] the withholding of a body for an unreasonable length of time to determine organ donor status[394] and the mutilation of the deceased during the course of an unauthorized autopsy.[395]

Indeed, the cases involving unauthorized autopsies in Canada and foreign jurisdictions suggest that the next of kin's right to possession for burial may include the right to receive the body generally free of mutilation. The issue sometimes arises in the context of hospital autopsies, which are distinct from the forensic autopsies ordered by a medical examiner or coroner in cases of sudden, unexpected, unnatural or suspicious deaths.[396]

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386. *Ibid.*

387. *Re Atkins*, [1989] 1 All E.R. 14 at 16; *Hunter* v. *Hunter*, [1930] 4 D.L.R. 255 (Ont. S.C.). *Lambert* v. *Dumais* (1942), B.R. 561. For U.S. jurisprudence, see cases collected in Annotation, "Validity and Effect of Testamentary Direction as to Disposition of Testator's Body," 7 A.L.R. 3d 747.

388. Lorne Elkin Rozovsky, "Death, Dead Bodies and the Law" (1970) 47:7 Can. Hosp. 52. See also *Lambert*, *supra*, note 387 and *Hunter*, *supra*, note 387.

389. See *Edmonds* v. *Armstrong Funeral Home*, [1931] 1 D.L.R. 676 (Alta S.C.) (spouse may sue for mental damages for unauthorized autopsy); *Philipps* v. *The Montreal General Hospital* (1908), 33 S.C. 483 at 489 (spouse may sue for mental damages for unauthorized autopsy). For the U.S. position, see *Prosser and Keeton on the Law of Torts*, 5th ed. (St. Paul, Minn.: West Publishing, 1984) at 63 and *Restatement of the Law, Second of Torts*, 2d, rev. & enl., vol. 4 (St. Paul, Minn.: American Law Institute Pub., 1979-) s. 868.

390. See S.M. Waddams, *The Law of Damages* (Toronto: Canada Law Book, 1983) at 452.

391. *Miner* v. *Canadian Pacific R.W. Co.* (1911), 18 W.L.R. 476 (Alta S.C.).

392. See *R.* v. *Fox* (1841), 2 Q.B. 242, and *Hunter*, *supra*, note 387.

393. *Mensinger* v. *O'Hara*, 189 Ill. App. 48 (1914).

394. *Strachan* v. *John F. Kennedy Memorial Hospital*, 538 A. 2d 346 (N.J. 1988).

395. *Edmonds*, *supra*, note 389.

396. See generally Christopher Granger, *Canadian Coroner Law* (Toronto: Carswell, 1984).

Forensic autopsies are governed by provincial statute.[397] Because a coroner's duties are quasi-judicial, the societal interest in the determination of unusual deaths and the administration of justice may authorize coroners to order forensic autopsies without the consent of the deceased's family.[398] Non-forensic or hospital autopsies generally require the consent of the deceased or his or her next of kin.[399] To the extent that hospital autopsies are within the scope of provincial gift-tissue legislation provisions authorizing next of kin consent to donate for transplant or "medical education and research," the consent and liability provisions of the legislation may also govern hospital autopsies.[400]

The common law principles suggest that any autopsy exceeding either normal autopsy procedures or the scope of consent may give rise to a claim for mental distress damages by the deceased's spouse or next of kin.[401] The issue apparently has yet to present itself in a reported Canadian decision. But other jurisdictions have invoked the right-of-possession principle recognized in Canadian law to decide claims of unnecessary retention of bodily parts after an authorized autopsy. Thus, the wrongful removal, destruction or unnecessary retention of organs from a body for which the family has authorized an autopsy has been found to inflict compensable mental shock and distress on the spouse or next of kin.[402] Even a coroner's retention of organs excised in a forensic autopsy has been the subject of liability when the scope of a legislatively authorized autopsy has been exceeded.[403] A recent case in the United States illustrates how the right of possession may also protect religious beliefs. In awarding damages against the hospital's unauthorized retention and cremation of organs, the court declared:

> Most religions in the world hold that the remains of a deceased must be treated with honor and respect. Judaism believes in the principle that body and soul are sacred because both are the handiwork of God and hence are entitled to reverence. . . .

397. See, *e.g.*, *An Act respecting the determination of the causes and circumstances of death*, R.S.Q., c. R-0.2. See also Granger, *supra*, note 396.

398. See *Davidson* v. *Garrett* (1899), 5 C.C.C. 200 (Ont. H.C.). See also *Religieuses Hospitalières de l'Hôtel-Dieu de Montréal* v. *Brouillette* (1943), B.R. 441. For cases discussing when autopsy laws may unconstitutionally burden fundamental religious beliefs, see section IV.C, below.

399. See *Ducharme* v. *Hôpital Notre-Dame* (1933), 71 C.S. 377; *Edmonds*, *supra*, note 389 and *Philipps*, *supra*, note 389. See also *C.C.L.C.*, art. 20.

400. See Rozovsky, *supra* note 388. See also section III, below. For consent to autopsy requirements in foreign jurisdictions, see Einar Svendsen and Rolla B. Hill, "Autopsy Legislation and Practice in Various Countries" (1987) 111 Arch. Pathol. Lab. Med. 846.

401. See Susan Schmidt, "Consent for Autopsies" (1983) 250:9 JAMA 1161 at 1163. Compare *Edmonds*, *supra*, note 389, and *Hendriksen* v. *Roosevelt Hospital*, 297 F. Supp. 1142 (S.D. N.Y. 1969) (retention of internal organs exceeding scope of consent to autopsy may be actionable). For the Scottish approach, see *Hughes* v. *Robertson* (1913), Sess. Cas. 394 (Ct Sess. Scot.). See also *Hill* v. *Travelers' Insurance Co.*, 294 S.W. 1097 (Tenn. 1927) (non-consensual retention of deceased spouse's vital organs post-autopsy states cause of action).

402. See, *e.g.*, *Palmquist* v. *Standard Accident Insurance*, 3 F. Supp. 358 (D.C. Cal. 1933) (emotional distress damages for doctor's refusal to return organs removed during autopsy). See generally cases collected in James O. Pearson, "Liability for Wrongful Autopsy" 18 A.L.R. 4th 858.

403. See *Hassard* v. *Lehane*, 128 N.Y.S. 161 (1911); *Kirker* v. *Orange County*, 519 So. 2d 682 (Fla. App. 1988). Compare *Arnaud* v. *Odom*, *infra*, note 872.

> The applicable law thus requires those who deal with the body to do so with due regard to the feelings and beliefs of the next of kin. In other words the next of kin have an interest in the respectful treatment of the corpse, and in the case of those holding the views such as the plaintiff's, an interest akin to that protected by the First Amendment [Constitutional protection of religious freedom].[404]

The unauthorized autopsy cases suggest that the law protects the bodily integrity of the deceased as it relates to the emotional and religious interests of his or her spouse or next of kin.

The familial right to possession of the deceased is not absolute, however. Since the right to possession of the deceased is a function of the duty to bury, treatment of the body of a deceased in a manner inconsistent with burial may subject the possessor of the body to liability.[405] Moreover, reasonable legislation that advances the interests of the state may also supersede the right of the spouse or next of kin to possession. Forensic autopsies and their role in the criminal justice system have been discussed. The state's public health interest in embalming and, in some instances, destroying dead bodies may also override a spouse's or next of kin's right of possession.[406] Societal interest in the preservation of life may justify the procurement of organs or bodies under exigent circumstances or when no identifiable family member may reasonably be found.[407]

The non-absolute right of possession means that families of a potential donor have, through custom and law, a long-recognized right of possession to the deceased's body. In the absence of statutes modifying that right, it generally imposes a duty on hospitals and physicians to respect and accommodate the interests of the family of a deceased patient who has been identified as a candidate for organ donation. These rights and duties highlight a conspicuous ambivalence in the law. Technically, possession is a legal property interest that includes the basic rights of dominion and control. On the one hand, the traditional rule maintains that there is no property in the corpse; on the other hand, the law recognizes formal possessory or property interests in the dead.

The ambivalence springs, in part, from competing, evolving notions of property. One view of property focuses on how we relate to things. Another view emphasizes how people legally relate to other people, regarding things:

> In modern western societies, the property right is no longer regarded as absolute if, indeed, it ever was. . . .
>
> The term "property" is used in a wide variety of meanings. It may refer to a person's physical assets, to his real property, or to the totality of his wealth which consists of physical objects and various incorporeal rights which he is entitled to exercise, such as debts due

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404. *Kohn* v. *United States*, 591 F. Supp. 568 at 572-73 (1984). Compare *Disinterment of Body of Jarvis*, 58 N.W. 2d 24 at 28 (Iowa 1953) (consent to autopsy implies consent to retention of tissue shavings in accordance with customary pathology practices).

405. See Matthews, *supra*, note 385.

406. See Frank P. Grad, *Public Health Law Manual* (New York: American Public Health Association, 1970).

407. See discussion of unclaimed bodies legislation and *C.C.L.C.*, art. 22 (authorization of non-consensual organ procurement) in section III, below.

to him, rights in a trust fund, stocks, patent rights, and so on. Thus it may refer to physical objects and to rights. It may also refer to the legal relations between persons and such objects and rights ...

It is, therefore, the content of the property right, namely, the several rights, privileges, powers and immunities which comprise it, that is of significance in law and not the physical thing or right itself. The physical objects or rights may, after all, be multifarious, while the powers or rights are definite. ... This simple generic list can be broken down further to give a list of specific powers, rights, privileges and immunities with respect to property. *Property, therefore, is not just a single right, but a bundle of rights or powers.*[408]

The distinction proves subtle and important. To define property in terms of rights and duties between people with regard to things makes the apparent ambivalence of the law more coherent. The distinction also frees society to rank and define, broadly or narrowly, particular rights, duties and powers. For example, if human tissue should generally be an object of neither commerce nor inheritance, does this mean that the law should not recognize any property interests in human bodily parts and substances? The answer depends, in part, on how property is conceived and defined, and for what purposes. Notions of bodily property may conjure up ethically abhorrent images of slavery — the ownership of human beings. The law of cadavers has shown, however, that a next of kin's right of possession does not include the right to sell. Nor does a housing tenant's right of possession normally include the right to sell the apartment. While property and commerce overlap, a right to sell may or may not be added to the bundle of property interests that the law confers.[409]

The no-property rule may suffer other limitations in the modern context. Both society and the medical use of the body have evolved significantly in the 300 years since the no-property rule was fashioned, when most bodies were buried in the consecrated grounds of a church cemetery.[410] Do the logic and utility of the rule fade centuries later, when confronted with unburied whole bodies and bodily parts, substances or tissues preserved as anatomical specimens, preserved in tissue banks for therapeutic use or transplanted into the living?

(2) Living Donors

Does the no-property rule encompass living donors? In Canada, there appears to be no case that specifically addresses the issue. In cases in the United States, the courts have tended to apply the no-property rule to tissue disputes involving living donors, although there are recent trends to the contrary. Four general areas in which property concepts have been at issue involve the non-consensual discarding of donated tissue, the control and transfer of deposited bodily substances, the use of non-consensually extracted bodily tissue or substances and the commercial value of bodily substances and tissue.

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408. A.H. Oosterhoff and W.B. Rayner, *Anger and Honsberger Law of Real Property*, vol. 1, 2d ed. (Aurora, Ont.: Canada Law Book, 1985) s. 102 at 5-6 (emphasis added).

409. See also chap. 2, section IV.B, above.

410. See text accompanying note 384, above.

(a) Non-consensual Discard Cases

Cases in the United States have arisen over the discarding of donated or deposited human tissue without the consent of the patient-depositor. In two cases, one involving lost eye tissue that was being examined for cancer and another involving the disposal without consent of reproductive matter in an infertility clinic, courts have avoided resolving patients' damage claims in terms of property. Instead, they have preferred to analyse them in terms of mental shock or distress to the patient.[411] Those cases seem to suggest that some courts in the United States have extended the no-property-in-a-corpse rule to a no-property-in-bodily-parts rule.

Commentators have critiqued the no-property-in-bodily-parts tendency for living donors.[412] Some jurisdictions significantly limit nervous shock claims.[413] It is argued that even when nervous shock claims and damages are available, they do not address instances when the return of valuable human tissue or material is sought.[414] The suggestion is that property concepts would better protect an individual's autonomy and person, in addition to clarifying legal rights and duties regarding the control of human tissue in particular circumstances. For example, when an institution destroys valuable human tissue without consent in a jurisdiction that limits mental damages, common law property principles concerning the destruction or spoilage of materials rightfully in one's possession might prove helpful in defining legal rights, duties and grounds of recovery.[415]

(b) Control and Transfer Cases

The issue of rights and duties regarding the control and transfer of human tissues has arisen most acutely in some recent cases involving human reproductive material. While there are no reported Canadian cases on this point, an American couple was recently successful in litigating the control of and right to transfer their frozen embryo from an

411. See *Del Zio* v. *Manhattan's Columbia Presbyterian Medical Center* (14 November 1978), New York 74-3558 (S.D.) (reproductive matter), described in Andrews, *supra*, note 344 at 29; *Mokry* v. *University of Texas Health Science Center*, 529 S.W. 2d 802 (Tex. App. 1975) (eye tissue). Compare *Browning* v. *Norton-Children's Hospital*, 504 S.W. 2d 713 (Ky App. 1974) (patient's amputated leg).

412. See, *e.g.*, P.D.G. Skegg, "Human Corpses, Medical Specimens and the Law of Property" (1975) 4 Anglo-Am. L. Rev. 412 at 418 n. 39 ("The reason behind the traditional refusal of the common law courts to recognise property in a corpse does not apply to parts removed from living bodies. Property should vest initially in the person from whose body the part has been severed. However, he would often be taken to have abandoned or transferred his interest.").

413. See *McNeil* v. *Forest Lawn Memorial Services* (1976), 72 D.L.R. (3d) 556 (B.C.S.C.) (damages only for wilful breaches of duty); John G. Fleming, *The Law of Torts*, 6th ed. (Sydney: Law Book, 1983) at 30-31 and 146-47. But see *Restatement of the Law*, *supra*, note 389; *St. Elizabeth Hospital* v. *Garrard*, 730 S.W. 2d 649 (Tex. 1987) (awarding mental distress damages for parents of stillborn child disposed of contrary to parental wishes).

414. See Bernard M. Dickens, "The Control of Living Body Materials" (1977) 27 U.T.L.J. 142 at 147-49.

415. *Ibid.* See also *York* v. *Jones Institute*, 717 F. Supp. 421 (E.D. VA 1989) (applying bailment and detinue theories).

east-coast infertility clinic to a west-coast clinic.[416] In France, the wife of a deceased sperm depositor argued that she had a right to her husband's frozen sperm, which he had deposited for preservation after learning that he would undergo cancer treatments that risked making him sterile.[417] The court expressly rejected the argument that frozen semen was property, on grounds that human reproductive material was neither inheritable nor an object of commerce.[418] Nevertheless, it ruled that the sperm bank must return the frozen semen to the wife of the depositor, as a result of an understanding between the depositor and the sperm bank.[419] That decision suggests that agreements between tissue banks and depositors, as reflected in well-drafted informed consent forms, might help minimize disputes over the control of deposited tissues, in the absence of legislation or professional standards that sufficiently address the issue.

Disputes over reproductive substances are helpful in identifying concerns and values at issue in potential disputes over other human tissue and substances. For example, the growth in tissue banking may make the rights and duties in controlling other deposited, valuable human tissue a more prominent medical-legal issue.[420] Consent forms for autologous blood banking in Canada have referred to deposited blood in terms of property, as have professional protocols for the banking of reproductive[421] and genetic materials in the United States.[422]

(c) *Non-consensual Invasion Cases*

As the consent doctrine of medical malpractice law protects against the non-consensual invasion of a patient's body, so too might bodily-property principles help protect against the non-consensual use or disposition of bodily substances or tissues that have been removed from the body.[423] The idea was recently broached by the Supreme Court of Canada.

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416. *York*, *supra*, note 415 at 425-27, especially n. 5 (upholding patients right to sue on contractual and property interests bases, finding implied bailment contract within informed consent form governing frozen reproductive matter). Shortly after the court upheld the infertile couple's right to sue on the above grounds, the parties to the suit agreed to a settlement under which the couple transferred the embryo.

417. Trib. gr. inst. Créteil, 1 August 1984, *Parpalaix* v. *CÉCOS*, Gaz. Pal. 1984. 2e sem. Jur. 560. For an English discussion of the case, see Jones, *supra*, note 163. See also R.P. Jansen, "Sperm and Ova as Property" (1985) 11:3 J. Med. Ethics 123.

418. See Jones, *supra*, note 163 at 528-29.

419. See *ibid.* at 529.

420. See chap. 1, pages 22-27 above.

421. Ethics Committee of the American Fertility Society, "Ethical Considerations of the New Reproductive Technologies" (1986) 46:3 (Supp. 1) Fertil. Steril. 89 ("It is understood that the gametes and concepti are the property of the donors").

422. See autologous blood banking consent forms used by Autologous Inc., a company discussed in Gilmore, *supra*, note 183. See also ASHG, *supra*, note 167 at 782 ("Banked DNA is the property of the depositor unless otherwise stipulated").

423. See Dickens, *supra*, note 414.

The court held a physician's non-consensual taking and use of a patient's blood to be an unreasonable seizure under the *Canadian Charter of Rights and Freedoms*.[424] After taking a blood sample from an unconscious, hospitalized patient who had been injured in an automobile accident, the physician gave the sample to a police officer. The blood was analysed and later offered as evidence of drunken driving. The opinion may suggest a relationship between bodily property, patient autonomy, physical integrity and human dignity:

> As I have attempted to indicate earlier, *the use of a person's body without his consent to obtain information about him, invades an area of personal privacy essential to the maintenance of his human dignity*. ... It was a perfectly reasonable thing for a doctor who had been entrusted with the medical care of a patient to do. However, I would emphasize that the doctor's sole justification for taking the blood sample was that it was to be used for medical purposes. He had no right to take Mr. Dyment's blood for other purposes. *I do not wish to put the matter on the basis of property considerations, although it would not be too far-fetched to do so.* Some provinces expressly vest the property of blood samples in the hospital, a matter I consider wholly irrelevant. ... Specifically, I think the protection of the *Charter* extends to prevent a police officer, an agent of the state, from taking a substance as intimately personal as a person's blood from a person who holds it subject to a duty to respect the dignity and privacy of that person.[425]

(*d*) *Property and Personhood Cases*

The concept of property as a protectorate of fundamental values of personhood has been debated in a recent American case of international significance. In *Moore* v. *Regents of the University of California*,[426] a leukemia patient claimed that, without his knowledge or consent, his university doctors used his cells and tissue to develop and patent a commercially valuable anticancer drug. The drug is based on a cell line derived from the patient's diseased spleen which had been surgically removed for treatment. The patient argued that he is owed a rightful share of money generated by the patent, owing to the misappropriation of his bodily tissues.

Important aspects of the case were recently decided by the California Supreme Court. A lower court had upheld the patient's right to sue on the basis of a property interest:

> We have approached this issue with caution. The evolution of civilization from slavery to freedom, from regarding people as chattels to recognition of the individual dignity of each person, necessitates prudence in attributing the qualities of property to human tissue. There is, however, a dramatic difference between having property rights in one's own body and being the property of another. ...
>
> *The essence of a property interest — the ultimate right of control — therefore exists with regard to one's own human body.* ...

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424. *R.* v. *Dyment*, [1988] 2 S.C.R. 417.

425. *Ibid.* at 431-32 (emphasis added).

426. 793 P. 2d 479 (Cal. 1990) (*en banc*), cert. denied 111 S. Ct 1388 [hereinafter *Moore* (1990)]. Weeks after the Commission had finalized its recommendations on tissue "ownership" and other issues discussed in this document, the California Justices decided *Moore* (1990) on principles consistent with Commission recommendations. See pages 188-89 below.

> *A patient must have the ultimate power to control what becomes of his or her tissues. To hold otherwise would open the door to a massive invasion of human privacy and dignity in the name of medical progress.*[427]

In reviewing the lower court decision, the California Supreme Court agreed that the patient may sue for violations of bodily integrity and human dignity, but it limited the basis for doing so to more conventional medico-legal grounds.

The majority of the court held that the patient may sue for a breach of informed-consent duties and for a breach of the duties of loyalty to the patient. The majority reasoned that if the patient's claims were proven true, those claims would show that the doctor had an undisclosed commercial interest in the patient's tissue at the time he recommended the surgical removal of the spleen, that this non-therapeutic interest might influence the doctor's recommended course of treatment and that a reasonable patient in those circumstances would generally want to be informed of potentially conflicting interests before treatment:

> Accordingly, we hold that a physician who is seeking a patient's consent for a medical procedure must, in order to satisfy his fiduciary duty and to obtain the patient's informed consent, disclose personal interests unrelated to the patient's health, whether research or economic, that may affect his medical judgement.[428]

A minority of the court agreed that the patient should be able to sue on informed-consent and fiduciary-duty grounds, but insisted that property grounds would best protect a patient's bodily integrity, privacy and dignity.

The divergent conclusions on the property claim flow, in part, from divergent views on existing law. The majority and minority views differed sharply over: (1) whether a state law that regulates the disposal of excised tissue extinguishes, or lets survive, patients' pre-excision proprietary rights to control post-excision use of the tissue; (2) whether the patented cell line and resulting drug were distinct proprietary products invented from raw materials, or the fruits of Moore's unique cellular qualities, qualifying him as a joint inventor; and (3) whether the protections of federal patent law affect a property-based claim for unauthorized use of excised tissue — especially for the six-year post-surgical, pre-patent era, when Moore's bodily substances were periodically extracted allegedly to supply the defendants' research and commercialization efforts.[429]

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427. *Moore* v. *Regents of the University of California*, 249 Cal. Rptr. 494 at 504, 506, 508 (emphasis added) (App. 2d Dist. 1988) [hereinafter *Moore* (1988)], affirmed in part, reversed in part, by *Moore* (1990), *supra*, note 426. Compare text accompanying note 424, above.

428. *Moore* (1990), *supra*, note 426 at 485. Compare American Medical Association, Council on Scientific Affairs and Council on Ethical and Judicial Affairs, "Conflicts of Interest in Medical Center/Industry Research Relationships" (1990) 263:20 JAMA 2790.

429. *Moore* (1990), *supra*, note 426 at 491-93, 501, 503. Paralleling the competing majority and minority property views, property law on the one hand recognizes principles under which one is entitled to the value added to his or her property by others; and, on the other hand, recognizes principles under which one acquires title by transforming raw materials into a new form or species of property, as in the conversion of wine from grapes. Compare *Firestone Tire* v. *Industrial Acceptance Corp.*, [1971] S.C.R. 357 (accession); *Jones* v. *De Marchant*, [1916] 10 W.W.R. 841 (C.A. Man.) (accession); *C.C.L.C.*, arts 429, 430, 433-35; Scottish Law Commission, *Corporeal Movables: Mixing Union and Creation* (Edinburgh: The Commission, 1976) (specification).

The majority and minority opinions also sharply diverged on broader policy concerns, such as the role of the courts and legislature in judging whether novel patient bodily-property claims would create liability destructive of beneficial medical research. Without absolutely ruling out such claims, the majority found "no pressing need" to recognize them, given the protection it perceived in the informed-consent and fiduciary- duty remedies. The minority rejected this view, arguing that the equities of preventing unjust enrichment and physical and moral exploitation of patients outweighed overstated liability concerns. It argued further that the commercial relations and ambiguities in the case — over whether informed consent or fiduciary duties extend to biotechnological and drug companies — meant that patients would be insufficiently protected without bodily property claims.[430]

The sharply contrasted opinions in *Moore* may help crystallize the issues for legislative or judicial deliberations in jurisdictions beyond California.[431] For the case is not an isolated incident. A United States government report has documented other disputes over the patenting of human biological materials.[432] More recently, a female patient claimed that her blood, placenta and umbilical cord were, without her knowledge or consent, transferred from a hospital to a California biotechnological company to develop an rDNA drug, Tissue Plasminogen Activator (TPA), which has been patented and is now licensed in Canada for use in dissolving blood clots after heart attacks.[433] While disputes over the development and commercial use of human tissues and biologics are noteworthy in the United States,[434] the cases may have import for other jurisdictions.

Is *Moore* relevant to Canada? Several developments and parallels in Canadian society may suggest so. The development of blood and drug products from human placenta and of vaccines from fetal tissue indicates that the therapeutic and commercial development of human biologics is part of Canadian medical history.[435] The Canadian biotechnological and drug industries are working on human biologics for commercial and non-commercial uses.[436] Biotechnology is accelerating the rate at which medical science may convert formerly useless human tissue into therapeutic substances with a commercial value. The traditional legal maxim "The law cares not for trifles" — *de minimis non curat lex* — may no longer apply to excised tissue and secreted substances long regarded as valueless and abandoned:

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430. *Moore* (1990), *supra*, note 426 at 493, 496, 500, 506, 516-17, 519-21.

431. See, *e.g.*, Ernest D. Prentice et al., "An Institutional Policy on the Right to Benefit from the Commercialization of Human Biological Material" (1990) 18:1-2 L. Med. Health Care 162.

432. See White, *supra*, note 91 at 23-27.

433. *Potts* v. *Genentech* (1 November 1988), Santa Clara Cnty 670331 (Cal. Sup. Ct).

434. See, *e.g.*, *United States* v. *Garber*, 607 F. 2d 92 (5th Cir. 1979) (taxability of "donor's" income from blood plasma sales).

435. See section III.A(1), below, and chap. 1, section I.B, above.

436. See *Canadian Biotechnology Industry Sourcebook 1988* (Ottawa: Ministry of State for Science and Technology, 1988).

> *Until recently, the physical human body, as distinguished from the mental and spiritual, was believed to have little value, other than as a source of labor. In recent history, we have seen the human body assume astonishing aspects of value.* Taking the facts of this case, for instance, we are told that John Moore's mere cells could become the foundation of a multi-billion dollar industry from which patent holders could reap fortunes. *For better or worse, we have irretrievably entered an age that requires examination of our understanding of the legal rights and relationships in the human body and the human cell.*[437]

Parallel legal developments have also emerged. Legal recognition of the patenting of life forms in the United States,[438] which increased by 300 per cent the number of patent applications for inventions involving human biologics,[439] has also proceeded in Canada, where human cell lines have received patent protection since the early 1980s.[440] Human genetic and cellular materials manipulated into therapeutic products thus appear to have been granted intellectual-property protection for exclusive commercial exploitation under Canadian law as well.

The confluence of these unprecedented legal and medical developments accentuates the potential for conflicts between the sources and the users or exploiters of human cells and tissues. Cultural and legal differences between the United States and Canada may help Canadian society avoid such disputes in transit through the biotechnological age. At the least, however, the parallel medical and legal developments challenge society to rethink its choices for a tissue-transfer legal regime consonant with this new age. *Moore*-like disputes are perhaps symptomatic of technico-legal revolutions which so jar pre-existing legal structure that society must endure a period of confusion and conflict before creating new, or recalibrating old, legal regimes.[441] In this instance, biotechnology calls into question what the moral and legal integrity of the human body will continue to mean.

Taken together, *Moore*, *Parpalaix* and *Dyment* further suggest that these biotechnological developments should proceed in a manner consistent with human rights. Will the recognition of limited property interests protect against non-consensual commercial use or development in those presumably rare, compelling circumstances in which bodily resources have been commercially exploited without the express and specific authorization of the patient? While individual rights cannot be absolute in a pluralist society, what legal tools will help maintain the sovereignty of human rights?[442] Will it help to reform patent law or to require doctors or researchers to disclose commercial or non-commercial

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437. *Moore* (1988), *supra*, note 427 at 504 (emphasis added).

438. See *infra*, note 977.

439. *Ibid.*

440. See the discussion of federal patent law, pages 123-24 below.

441. See Vincent M. Brannigan, "Biotechnology: A First Order Technico-Legal Revolution" (1988) 16 Hofstra L. Rev. 545 at 546-50.

442. The inclination or resistance to invoke property rights as a legal tool to protect human rights in this domain would seem to depend much on whether one accepts, rejects or perhaps ascribes to a personhood, labour, possessory or like theory of property in this context. See M.R. Cohen, "Property and Sovereignty" (1927) 13 Cornell L.Q. 8. See also Margaret Jane Radin, "Property and Personhood" (1982) Stan. L. Rev. 957 at 966.

potentials in research on excised human tissue?[443] Will limited bodily-property interests help? Viewed from an eighteenth-century perspective, such thoughts may seem ethically and legally abhorrent. Both law and medicine are dynamic enterprises, however. A Canadian commentator has written that "[t]he meaning of property is not constant. The actual institution, and the way people see it, and hence the meaning they give to the word, all change over time."[444] Viewed from a late twentieth-century human rights perspective, society might ponder whether a legal notion of limited property interests in human tissue may best serve to protect physical integrity, individual autonomy and the fundamental values of personhood.

To minimize disputes between the sources and commercial users of human cells and tissues, fiduciary principles may provide initial guidance. Patients seek medical care with the expectation and trust that medical interventions on their bodies will be undertaken for their benefit. Some courts have deemed this patient expectation to be a right, which imposes a corresponding duty on physicians to act with utmost good faith and loyalty.[445] The ethical and legal rights that attach to this patient-centred ethic have long been the hallmark of doctor-patient relations.[446] When an interest arises that potentially conflicts with a doctor's duty to exercise independent professional judgment on behalf of the patient, the duty of loyalty requires a disclosure of the conflict and the informed consent of the patient to continued medical treatment. Applied here, the principles require a doctor to disclose a potential commercial interest in the patient's tissues or bodily substances.[447] Full disclosure and the patient's informed consent would permit the patient to continue treatment. If the patient declines further involvement, or if it becomes reasonably clear to the doctor that his or her commercial interest compromises the exercise of independent professional judgment, the doctor would have an obligation to transfer care of the patient.

Yet, even a broad range of common law concepts — from fiduciary duties, to informed consent, to property interests — may not provide sufficient clarity or certainty on the competing interests, rights and duties of patients, doctors, researchers, hospitals or biotechnology firms. The complexity of the issues and interests indicate that they merit further multi-disciplinary study to discover how society may best balance the need to encourage creative biotechnological therapeutic human tissue development with the need to protect basic human rights.

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443. Compare Note, "Ownership of Human Tissue: Life after *Moore* v. *Regents of the University of California*" (1989) 75 Va. L. Rev. 1363 at 1391-92, and Randy W. Marusyk and Margaret S. Swain, "A Question of Property Rights in the Human Body" (1989) 21 Ottawa L. Rev. 351.

444. C.B. Macpherson, ed., *Property: Mainstream and Critical Positions* (Toronto: University of Toronto Press, 1978) at 1.

445. See Picard, *supra*, note 364 at 3 ("The doctor ... is in a fiduciary or trust relationship with his patient. This means the doctor has a duty to act with utmost good faith: he must never allow his professional duty to conflict with his personal interests; he must not mislead his patient."). See also *Rowe* v. *Grand Trunk Railway* (1866), 16 U.C.C.P. 500 at 506 (C.A.); *Kenny* v. *Lockwood*, [1932] 1 D.L.R. 507 (Ont. C.A.).

446. See Robert M. Veatch, *A Theory of Medical Ethics* (New York: Basic Books, 1981) at 22.

447. Compare Science Council Canada, *Genetics in Canadian Health Care*, Report 42 (Ottawa: Supply and Services Canada, 1991) at 75, and French National Bioethics Committee, *infra*, note 956.

C. Bodily Sales

If two parties strike a bargain for the sale and purchase of fine red hair, is the contract enforceable in the courts? Should a court reach a similar or different result if the subject-matter of the agreement is blood, cells, milk, bone marrow, organs or corpses? Does it matter that hair and teeth "have been traded for centuries" while the potential for organ and bodily part exchanges has arisen most dramatically only in the last few decades?[448]

Some answers to these questions are contained in provincial legislation or codes.[449] Principles of contract law, however, also provide insights into evolving societal thought and public policy on the sale of human tissue, organs and bodily parts or substances. Moreover, contract law principles may govern the sale of human milk, blood, sperm, cells and like substances excluded from provincial legislative or *Civil Code* prohibitions on tissue sales.[450]

Perhaps because the societal use of and value in bodily substances and parts have increased most in recent decades, there are few cases involving the sale of the body or bodily parts. Still, the existing cases and the general workings of contract law indicate that the validity of bodily sales contracts depends on two general principles: first, whether the parties to the agreement give free, uncoerced consent; and secondly, whether the agreement violates public policy or order by its illegality, immorality or clear injury to the public good.[451]

(1) Contracts, Consent and Fairness

The law has a long tradition of leaving individuals free to enter into agreements; indeed, it generally presumes in favour of enforcing agreements.[452] However, when circumstances arise in which a person has made promises under severe distress, the courts may inquire into those circumstances to see whether the parties made their promises free of coercion:

> [A] Court of Equity will enquire whether the parties really did meet on equal terms; and if it be found that the vendor was in distressed circumstances, and that advantage was taken of that distress, it will avoid the contract.[453]

The law of contracts also has long required that individuals strike their agreements within broad bounds of fairness and equality. The fairness principle is applied by asking whether an agreement was oppressive when the parties first reached their agreement, or whether it was made under duress of circumstances or undue influence. Similarly, in civil

448. See Scott, *supra*, note 268 at 180.

449. For a discussion of provincial legislative and Quebec *Civil Code* sales prohibitions, see pages 131-36 below.

450. *Ibid.*

451. See text accompanying note 466, below.

452. Patrick S. Atiyah, *The Rise and Fall of Freedom of Contract* (Oxford: Clarendon Press, 1979) at 526.

453. S.M. Waddams, *The Law of Contracts*, 2d ed. (Toronto: Canada Law Book, 1984) at 382, citing *Wood* v. *Abrey* (1818), 3 Madd. 417 at 423. See also *Mundinger* v. *Mundinger* (1968), 3 D.L.R. (3d) 338 (Ont. C.A.), aff'd [1970] S.C.R. vi (emotional distress and marital breakdown void contract for the sale of land).

law the reasonable and present fear of *un mal sérieux* may invalidate consent and be a cause of nullity of a contract.[454] Thus, a court may find that the principle of fairness requires an agreement to be unenforceable.

There are no reported Canadian cases involving the validity of agreements to sell bodily parts. Yet so-called baby-selling cases in Canada and the United States illustrate some of the principal concerns. In some American adoption cases, for example, the courts have focused on whether biological mothers have exercised their free will in consenting to have their children adopted.[455] In one instance, in which an adoption agreement was found unenforceable, the mother's poor financial status and the payment she received as part of the adoption process persuaded the court that the biological mother had been subjected to sufficient "undue influence" or "duress" that she could not have voluntarily consented to the adoption.[456] Similar concerns motivated a court to strike down a surrogate-motherhood contract in the celebrated *Baby M* case.[457] By contrast, a Canadian court found that a biological mother "had made a free decision" to consent to her child's adoption, after receiving from the adopting parents reasonable legal and travel expenses incurred in the adoption process.[458]

Do the principles and concerns expressed in those adoption cases apply to agreements to sell human tissue, bodily parts or substances? On the one hand, the sale of human tissue does not involve the legal transfer of a human being and the necessity for safeguarding the child's best interest. In the absence of an innocent third party, it might be argued that competent adults should generally be free to consent to some bodily sales agreements, and that it is illegitimately paternalistic for society otherwise to interfere.[459]

On the other hand, the paternalism argument tends to equate economic freedom with the enhancement of personal liberty; if liberty is also seen as the power to foster and

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454. See Waddams, *supra*, note 453 at 376, 384; American Law Institute, *Restatement of the Law, Second of Contracts*, 2d. ed., vol. 2 (St. Paul, Minn.: American Law Institute Pub., 1973-) ss 173, 177; Robert W. Clark, *Inequality of Bargaining Power* (Toronto: Carswell, 1987) at 93, 207. For civilist commentary see Jean-Louis Baudouin, *Les Obligations* (Cowansville, Que.: Yvon Blais, 1983) at 122-24, discussing *C.C.L.C.*, arts 994-995.

455. See generally Jack W. Shaw, "What Constitutes Undue Influence in Obtaining a Parent's Consent to Adoption of Child" 50 A.L.R. 3d 918.

456. See *In Re G*, 389 S.W. 2d 63 at 69 (Mo. App. 1965). See also *Gray* v. *Maxwell*, 293 N.W. 2d 90 at 95 (Neb. 1980). But see *Barwin* v. *Reidy*, 307 P. 2d 175 at 185 (New Mex. 1957) ("not duress of a type which renders void contracts").

457. See *Baby M*, 537 A. 2d 1227 at 1249 (N.J. 1988).

458. *Re Female Infant* (1982), 34 B.C.L.R. 177 (S.C.) (granting application for adoption).

459. Bernard M. Dickens, "Legal and Ethical Issues in Buying and Selling Organs" (1987) 4 Transplantation/ Implantation Today 15 at 20 ("The view that the freedom of choice enjoyed by the poor is protected or enhanced by denying them means to avail themselves of such an opportunity for earning is itself ethically objectionable, however, on several grounds. It denies the poor a means of income available to others, it in no way mitigates the poverty it finds an offensive cause of exploitation, and it is unjustifiably paternalistic. The poor are in no greater need of protection against exploitation than others, and can be no less trusted than others to decide for themselves to accept or decline means of earning lest their freedom of subsequent decision may be reduced.").

protect personhood, then justifying the non-saleabilty of tissue on grounds of fostering personhood might be seen as freedom enhancing.[460] In this sense, the legal terms "duress" and "undue influence" might describe both the medical and economic desperation which disables some persons from freely choosing or voluntarily consenting to tissue sales. When one's adolescent child is suffering from fatal leukemia, an offer of $5,000 to attract a matching bone marrow donor may seem reasonable to the parents.[461] Similarly, an offer to sell a kidney for $32,000 might seem reasonable to someone unemployed for three years in a society with hundreds on recipient waiting lists for a kidney transplant.[462] Indeed, analysts and task forces in Canada, the United States and Europe have argued that the sale of organs and bodily parts invites, and may result in, the economic exploitation of the poor.[463] In a broader sense, the dispute over whether sales aggravate or ease economic desperation reflects divergent views on redistributive justice — that is, how a tissue sales prohibition or authorization specifically affects the underlying problem of gross maldistributions of wealth in society.[464]

(2) Agreements Contrary to Public Policy or Order

Some bodily sales agreements may not be enforceable because the law regards them as void and contrary to public policy:

> It is the duty of the courts to give effect to contracts ... since we are under a reign of law; *but there are cases in which rules of law cannot have their normal operation because the law itself recognizes some paramount consideration of public policy which over-rides the interest and what otherwise would be the rights and powers of the individual.* It is, in our opinion, important not to forget that it is in this way, in derogation of the rights and powers of private persons, as they would otherwise be ascertained by principles of law, that the principle of public policy operates.[465]

The Quebec *Civil Code* recognizes a similar principle by requiring that contracts not be contrary to "good morals or public order."[466]

Whether a particular agreement is contrary to public policy or order depends on whether it offends several established legal principles or more general and evolving legal criteria. A contract to commit a crime, for example, is both void and illegal.[467] The eighteenth-century British common law crime of selling a corpse appears to have been adopted into

460. See Margaret Jane Radin, "Market-Inalienability" (1986-87) 100 Harv. L. Rev. 1849 at 1899.

461. See Gina Kolata, "Transplant Reward Offer Raises Furor" *New York Times* (23 June 1989) A6.

462. See Mike King, "Unemployed Nurse Offers to Sell Kidney" *The [Montreal] Gazette* (17 July 1989) A3.

463. See USTF, *supra*, note 29 at 98; Titmuss, *supra*, note 244 at 219 (blood); Margaret A. Somerville, "Access to Organs for Transplantation: Overcoming 'Rejection'" (1985) 132:2 C.M.A.J. 113. But see Dickens, *supra*, note 459.

464. See Radin, *supra*, note 460 at 1911.

465. *Re Millar*, [1938] S.C.R. 1 at 4 (emphasis added).

466. *C.C.L.C.*, art. 990 ("The consideration is unlawful when it is prohibited by law, or is contrary to good morals or public order"); see also s. 1062 ("The object of an obligation must be something possible and not forbidden by law or good morals").

467. See *Byron* v. *Tremaine* (1899), 29 S.C.R. 445 (extortion agreement). See also Waddams, *supra*, note 453 at 413-14.

the Canadian *Criminal Code*;[468] if so, an agreement to sell a corpse is void and contrary to public policy as an illegality.[469] Other illegalities in modern Canadian society are often defined in statutes such as provincial laws prohibiting the sale of organs or babies.[470] Such agreements would also be generally unenforceable because they are contrary to public policy.[471]

But what of human blood, skin, bone marrow, semen, hair and like tissues or bodily substances that may not be prohibited from being sold by provincial statutes or codes?[472] It is not clear whether such bodily sales agreements are "contrary to public policy and order." That some Quebec *Civil Code* provisions are suggestive of bodily sales being *hors du commerce* while others appear to contemplate the non-gratuitous exchange of regenerative tissue suggests that the *Code* has not definitely resolved the matter.[473] Tissue sales contracts clearly do not fit within such other established areas of unenforceable agreements as "restraint of trade" or "sales of public offices."[474] They come closer to fitting within other established areas of unenforceable contracts such as "immoral bargains" or "agreements that impair family relations."

It might be argued, for example, that the sale of sperm or gametes should be contrary to public policy because it violates public morals and impairs family relations.[475] A Paris court has found a contract involving the sale of tattooed skin to be [TRANSLATION] "illicit, immoral, and against the public order."[476] Typically, though, "immoral bargains" have referred to sexually reprehensible conduct.[477] Whether the sale of semen for use in infertility treatment is immoral or sexually reprehensible conduct today is open to question. While courts in the nineteenth and early part of the twentieth century regarded artificial insemination as adultery, immoral and a threat to family relations, they now tend to regard it as medical treatment with particular legal consequences.[478] Cohabitation agreements that

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468. See pages 109-10 below, discussing *Criminal Code* s. 182.

469. See Waddams, *supra*, note 453 at 412.

470. See note 499, *infra* (babies) and section III, below (organs).

471. See Waddams, *supra*, note 453 at 421.

472. See pages 134-35, below.

473. Compare *C.C.L.C.*, arts 19, 20, 1059. For a description of the *vénalité-gratuité* debate in drafting the *Civil Code* sections, see Heleine, *supra*, note 365 at 55-63. Compare Jean-Christophe Galloux, "Réflexions sur la catégorie des choses hors du commerce: l'exemple des éléments et des produits du corps humain en droit français" (1989) 30 C. de D. 1011 and Marie-Angèle Hermitte, "Le corps hors du commerce, hors du marché" (1988) 33 Arch. Phil. Dr. 323. Recently proposed reforms to the *Civil Code* would abandon the regenerative/non-regenerative distinction, and require that the alienation of bodily parts, tissues and organs be gratuitous. See Bill 125, *supra*, note 380, art. 25.

474. See Waddams, *supra*, note 453 at 416-19.

475. See *Bonisteel* v. *Saylor* (1890), 17 O.A.R. 505 (immoral selling scheme); see also Waddams, *supra*, note 453 at 413; *Farrar* v. *MacPhee* (1971), 19 D.L.R. (3d) 720 (P.E.I.S.C.) (immoral cohabitation).

476. Trib. gr. inst. Paris, 3 June 1969, *Dlle X...* v. *Soc. Ulysse-Productions et cons.*, Gaz. Pal. 1969. 2e sem. Jur. 57.

477. Diana Brahams, "Kidneys for Sale" (1989) 139:6393 New L.J. 159. See also Baudouin, *supra*, note 454 at 189 n. 33, citing *Langelier Limitée* v. *Demers* (1928), 66 S.C. 120.

478. Compare *Orford* v. *Orford* (1921), 58 D.L.R. 251 (Ont. S.C.) and *Parpalaix* v. *CÉCOS* discussed in Jones, *supra*, note 163 at 530-31.

were once considered immoral now tend to be enforced and may even be advisable.[479] In short, legal and societal views of what is an acceptable or an immoral agreement and public policy are not static:

> Decisions on a question of this sort cannot be crystallized into categories established at some date in the past for, as an American court said, the public policy of one era may be wholly opposed to that of another. A society's view of public policy does not alter only by radical political change, but also by gradual evolution. . . . These categories reflect the values of the era. An evolving society must, however, have changing values, and the law fails in its service to society if it cannot also evolve.[480]

Absent determinative legislation or common law or civil law principles, the answer to whether some bodily sales agreements are contrary to public policy or public order may depend on the merits of the competing considerations that follow:

— **Physical integrity versus medical risks**: On the one hand, selling human tissue, bodily parts and substances may invite sellers to compromise their health and take undue physical risks; on the other hand, the physical and medical risks associated with giving some bodily parts or substances — hair, blood, sperm, sweat, milk or cell lines — arguably are so minuscule that they diminish concerns about physical exploitation or risks that may result from some authorized bodily sales.[481] In the latter instances, the legal maxim "The law cares not for trifles" — *de minimis non curat lex* — applies to such sales.

— **Medical disclosure and recipient safety**: Some argue that because sellers fear that payments will not be made for defective tissues, the lure of money discourages sellers from disclosing damaging medical information — diseases, genetics, medical history — that medical authorities need to evaluate whether the tissue should be used for transplant.[482]

— **Autonomy and privacy**: Arguably, the ethical and legal presumptions of autonomy, privacy and liberty properly include the right to exchange bodily substances or parts, when such exchanges visit no material harms on third parties.[483] Some have even argued that such rights attain a constitutional dimension.[484] On the other hand, it is argued that individual privacy and liberty do not include a right to sell bodily parts or substances.[485]

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479. Compare Walter H.E. Jaeger, *Williston on Contracts*, 3d ed. (New York: Lawyers Co-operative Pub., 1972) s. 1745 and Alberta Law Reform Institute, *Towards Reform of the Law Relating to Cohabitation outside Marriage*, Report 53 (Edmonton: The Institute, 1989) at 23-27.

480. See Waddams, *supra*, note 453 at 409-10. See also Jaeger, *supra*, note 479 at 93 ("Agreements having an immoral object are unenforceable on the ground of public policy which, in some instances, is dependent upon the attitudes prevailing at the time").

481. See *National Organ Transplant Act*, Pub. L. No. 98-507, 1984 U.S. Code Cong. & Ad. News (98 Stat.) 3975, 3982 (1984) (in formulating U.S. organ sales ban, alienation of regenerative bodily parts judged not to compromise health of donor).

482. See Titmuss, *supra*, note 244 at 151-53, 219; Jones, *supra*, note 163 at 534 n. 52; 50 Fed. Reg. 35,458 and 35,459 (1985) (data showing paid donor blood presents higher risk of transmitting hepatitis than unpaid donor blood). See also *Gilmore* v. *St. Anthony Hospital*, 598 P. 2d 1200 (Okl. 1979).

483. See John Stuart Mill, *On Liberty* (Cambridge: Cambridge University Press, 1989).

484. See *infra*, note 873.

485. See *Doe* v. *Kelley*, 307 N.W. 2d 438 (Mich. App. 1981); Radin, *supra*, note 460 at 1893.

— **Personhood and inalienable rights**: Some argue that rights accorded by society to persons include an inalienable right not to be the subject of barter or treated as a commodity.[486] These concerns are expressed in ethical prohibitions against commodifying the human body (that is, treating it as a commodity) and in maintaining the inviolability of the human body. Others respond that these concerns should be weighed against increased supplies that may result from sales.[487] Moreover, they argue that some bodily parts and substances — for example, those that are regenerative — are so distinct from personhood as to be free from any legal or ethical prohibitions on the sale of human beings.

— **Equity, universality and scarce resources**: Some argue that access to scarce human therapeutic tissues or substances should be decided neither on the basis of one's ability to pay nor on the basis of the highest bidder, because to do so compromises equity and skews more important allocative criteria such as medical need.[488] On the other hand, concerns about precious tissues going to highest bidders prove most cogent when *laissez-faire* practices prevail. In societies in which payment for tissue transfers or transplants are covered and regulated by government health insurance, highest-bidder concerns and arguments are less persuasive. The medical expenses of kidney and bone marrow donors, for example, may be covered by the transplant recipient's provincial health insurance or by separate insurance.[489] Regulations establishing customary, standard and reasonable payments would thus erode incentives for donors to shop for the highest bidder.[490]

— **Enforcement and access**: Some argue that, on balance, bodily sales agreements should not be authorized because they would pose perplexing enforcement and logistical problems.[491] On the other hand, it may be argued that bodily sales agreements for some bodily substances will generally be self-policing and may well increase the supply of precious and life-saving human sources and substances.[492]

— **Altruism and access**: Some argue that authorizing bodily sales discourages people from donating for charitable purposes and erodes a public policy of altruism, the gift-of-life ethic.[493] Other analysts respond that pure altruism has never existed, that the policy has failed to increase the supply of precious human bodily tissues and substances and that continued adherence to the system prolongs avoidable human suffering and

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486. See *Adoption of B.A.B.*, 534 A. 2d 1050 at 1052 (Pa. 1987) (human beings not merchandise); Radin, *supra*, note 460 at 1899.

487. J. Robert S. Pritchard, "A Market for Babies" (1984) 34 U.T.L.J. 341 at 352.

488. See *Baby Girl D*, 517 A. 2d 925 at 927 (Pa. 1986) ("choice not rest solely on wealth of parties" in adoption cases). See also Susan Rose-Ackerman, "Inalienability and the Theory of Property Rights" (1985) 85 Colum. L. Rev. 931 at 948.

489. See Blake and Cardella, *supra*, note 121 at 774; Buskard, *supra*, note 51.

490. See Sharpe, *supra*, note 201; Dickens, *supra*, note 459 at 21. See also French milk bank regulations, *infra*, note 934.

491. MLRC, *Report on The Human Tissue Act*, Report 66 (Winnipeg: The Commission, 1986) at 110.

492. Russell D. Roberts and Michael J. Wolkoff, "Improving the Quality and Quantity of Whole Blood Supply: Limits to Voluntary Arrangements" (1988) 13:1 J. Health Pol. Pol'y L. 167.

493. Titmuss, *supra*, note 244 at 225-29; USTF, *supra*, note 29 at 96, 98. See generally chap. 2, section I.A, above.

illness.[494] If the failings of pure altruism need not necessitate pure commercialism, modified altruism — a mixed public policy recognizing an appeal to both non-monetary and monetary personal benefits — may be in order to increase supplies.[495]

Many of these considerations, such as the impact upon safety and the enforcement of tissue sales agreements, address the practical consequences of authorizing or prohibiting tissue sales. Other considerations, such as the impact on altruism, echo the deeper ethical debate on defining emerging tissue transfer regimes for bodily substances that have not traditionally been associated with the marketplace.[496] For some analysts, allowing even limited tissue sales, or applying market rhetoric to the human body, does violence to how we think of human dignity, our bodies, our selves and concepts of personhood.[497]

(3) Payment of Reasonable Expenses

The public policy and legal considerations on bodily sales should also be guided by an understanding of the precise purposes of allowing or forbidding payments to donors. The purposes have important practical, legal and ethical consequences.

The practical consequences are plain. The transfer of human bodily tissue, parts or substances may be done: (1) gratuitously, meaning that the donor receives no payment; (2) for profit, meaning that the donor receives payment beyond expenses incurred; (3) for reasonable out-of-pocket expenses, meaning that the donor receives a nominal payment to cover associated travel, meal, lodging and like expenses; or (4) for reimbursement to the donor for expenses, lost income *and* pain and suffering. How does and should the law and public policy account for these different purposes and levels of payment?

If society deems profiting from the exchange of human bodily substances abhorrent, should it flatly prohibit all payments associated with the donation process? If yes, implementation may have undesired consequences that may prove counter-productive in practical terms. For those already undergoing medical procedures involving the removal of donated tissue, donation may simply involve an extension of planned procedures. Otherwise, the donation process requires donors to spend time and money and undertake medical risk to effect their charitable or altruistic intentions. Depending on the donor's financial situation, the lost income and travel and meal expenses may erect financial barriers that so severely tax the donor's charitable intentions that donation may become, in practice, unfeasible.

494. Lloyd R. Cohen, "Increasing the Supply of Transplant Organs: The Virtues of a Futures Market" (1989) 58 Geo. Wash. L. Rev. 1 at 2, 33 (recommending $5,000 payment to seller/donor's estate or designee upon actual post-mortem organ procurement); Jack Kevorkian, "Marketing of Human Organs and Tissues Is Justified and Necessary" (1989) 7:6 Med. Law 557.

495. Roberts and Wolkoff, *supra*, note 492.

496. See pages 57-61, above.

497. See Radin, *supra*, note 460 at 1877-87 (market rhetoric fosters a morally inferior concept of personhood). See also pages 57-61 above.

The frequency of donation and the time and travel necessary to make the donation vary according to the tissue to be donated. Still, these considerations suggest that a policy or law that flatly forbids any payments in the donation process may itself undermine donations, because of the associated expenses, lost income, pain and suffering and the medical risks which donors often incur.

An alternative approach, as a federal working group on organ transplants has urged, is "that the donor should neither gain nor lose financially by the donation."[498] There are pros and cons to that approach. On the one hand, it arguably departs from the principle of charitable and gratuitous donations, creates a financial incentive for donation and, in the extreme, might attract and exploit the poor; moreover, it may offend and discourage the truly altruistic from donating. By recognizing the validity of some payments, it may also draw society into considerations about what are good and reasonable or bad and unreasonable payments.

On the other hand, several advantages may flow from a public policy principle that tissue donors neither gain nor lose financially from the donation process. Depending on what donation expenses are covered as "reasonable," the principle helps eliminate financial barriers to the donation process. Donors from all financial strata of society might thus have an equal opportunity to donate. Moreover, donations from reimbursed donors need not necessarily erode altruism. They might be seen as promoting it. A policy that aims at reimbursing donors for reasonable expenses and lost income still does not compensate for voluntarily assumed medical risks, pain and suffering. The uncompensated assumption of risk and pain still expresses altruism.

Finally, the approach may preserve altruism by its emphasis on payment for reasonable expenses incurred in service for society, as opposed to payment for the tissue itself. Such considerations have proven persuasive to policy makers in several jurisdictions. The distinction between reimbursement for reasonable service expenses and sales has thus been recommended for or incorporated into provincial adoption law, provincial gift tissue legislation, national ethical guidelines on research, laws prohibiting organ sales in Great Britain and the United States, and in European legislative guidelines on tissue and semen donation.[499]

A policy of reimbursing for reasonable expenses incurred in a voluntary service, in contrast to payment for the tissue itself, does have limits. In the extreme, the policy may

498. FEDS, *supra*, note 29 at 65.

499. For the distinction in the adoption laws, see *Re Female Infant*, *supra*, note 458 (construing B.C. *Adoption Act*, R.S.B.C. 1979, c. 4, and baby-selling prohibitions); see also *Child and Family Services Act, 1984*, S.O. 1984, c. 55, s. 159; *Child Welfare Act*, R.S.O. 1980, c. 66, s. 67. In the medical research context, see MRC, *supra*, note 118 at 24-25 ("Remuneration limited to compensation for expenses actually incurred and losses reasonably assessed, including loss of wages, is ethically acceptable, provided that it does not distort freedom of choice but facilitates collaboration by indemnifying subjects for their direct and indirect expenditures. Payments for time and inconvenience, if nominal, are similarly acceptable. Excessive remuneration, or other advantages or benefits, however, are an improper inducement to participate in a research project."). In the provincial tissue law context, see pages 131-36 below. For the U.S. and European legislative context, see chap. 4, below.

create a *de facto* sales market such that the voluntary-services versus commercial-sales-of-tissue distinction pales to a fiction.[500] Still, the distinction may have other important legal consequences. It may prove significant in negligent screening suits. A negligent screening claim would likely be tested by general principles of negligence: namely, whether a tissue bank owed a transplant recipient a duty or standard of screening, had violated that standard and so caused the transmission of diseased tissue and illness or injury to the recipient.[501] If the tissue bank were regarded as being involved in the buying and selling of tissue, legal theories regarding the selling of "defective products" might also apply.[502] In this sense, some courts in the United States have debated whether tissue banks that behave more like commercial entities should be held to a stricter standard of liability.[503]

II. Criminal Law Perspectives

As an expression of fundamental societal values and as a regulator of individual conduct, criminal law also offers guidance on several tissue transfer and procurement issues.[504] It defines some of the standards, duties and responsibilities of living donors and transplant professionals in the medical treatment process. It has long played a modest but noteworthy role in the sales and provision of bodies for medicine. Moreover, although common law crimes were largely abolished in Canada in 1955,[505] the common law criminal heritage exerts a quiet, abiding influence on notions of societal harms and the mistreatment of deceased donors. Beyond its historical traditions and evolution, criminal law principles may help clarify the status of anencephalic infants and other potential donors who lie on the life-death line.

In this sense, the *Criminal Code*[506] protects rights and defines duties and criminal liability in three general areas of tissue procurement and transplantation: (1) donations

500. See Murray, *supra*, note 351 at 1074. See also *Baby M*, *supra*, note 457 at 1247-49.

501. See *Ravenis* v. *Detroit General Hospital*, 234 N.W. 2d 411 (Mich. App. 1975) (hospital negligent in screening cadaver donor eyes for transplant). See also *Zanne*, *infra*, note 951 and *Kitchen*, *infra*, note 1028.

502. See Dickens, *supra*, note 414 at 195-97, discussing *Perlmutter* v. *Beth David Hospital*, 123 N.E. 2d 792 (N.Y. 1954) (donor payment is for service, not blood product). Several U.S. jurisdictions have codified the distinction into "blood/tissue shield" statutes that explicitly define the procurement, processing and distribution of blood and tissue as services, not the sale of products. See *McKee* v. *Cutter Laboratories*, 866 F. 2d 219 (6th Cir. 1989). The laws immunize tissue banks and hospitals from liability for "defective products" claims. This leaves banks potentially liable to negligence claims.

503. See *Gilmore*, *supra*, note 482 at 1203-07, and *Coffee* v. *Cutter Biological*, 809 F. 2d 191 (2nd Cir. 1987). See generally cases collected in Jay M. Zitter, "Liability of Blood Supplier or Donor for Injury or Death Resulting from Blood Transfusion" 24 A.L.R. 4th 508.

504. See generally Working Paper 26, *supra*, note 370 at 5-6.

505. See *Criminal Code*, R.S.C. 1985, c. C-46, ss 8, 9.

506. *Ibid.* For a discussion of the penal aspects of provincial tissue Acts, see section IV, below. See also Don Stuart, *Canadian Criminal Law*, 2d ed. (Toronto: Carswell, 1987) at 2, discussing the *Constitution Act 1867* (U.K.), 30 & 31 Vict., c. 3, s. 92(14), (15) (formerly *British North America Act, 1867*), authorizing provinces to impose fines, penalties, or imprisonment for enforcing provincial legislation as administration of justice function.

from living donors; (2) donations from deceased donors; and (3) the standard that divides those two donor pools, the legal criteria for the determination of death. How do the *Criminal Code* provisions on assault,[507] surgical and medical treatment,[508] assault causing bodily harm,[509] duties to provide necessaries of life,[510] criminal negligence[511] and homicide[512] apply to tissue donation from living donors to recipients? Do they appropriately balance the underlying values of promoting autonomy, protecting bodily integrity and preserving life? Proposals previously made by the Commission for the general reform of some of the *Code* provisions[513] prove helpful in resolving apparent conflicts or ambiguities.

For deceased donors and their families, what is the modern meaning of the eighteenth-century-based *Criminal Code* offence of indecent interference with or indignities to the dead human body?[514] Is it an indignity to sell bodily parts? How does or should this mistreatment provision apply to medical interventions on the brain-dead, mechanically maintained cadaver, which is the source of most organ transplants? Perhaps because these latter questions are unprecedented, they have received scant attention in the Canadian criminal literature. Accordingly, they are explored, as is the historic role played by criminal law in directly providing dead bodies to medical science.

In these life-death contexts, the definition of death has obvious importance. If the donor is alive, the criminal law provisions governing live donations may apply. If not, the provision relating to mistreatment of the dead body might apply. In the face of new calls that the definition of death be amended to facilitate organ procurement from a particular group of dying infants, the Commission's decade-old recommendation on criteria for the determination of brain death is revisited. Applying the pertinent medical and ethical considerations to the principles and policies on which the Commission based its initial recommendation persuades us that current invitations to amend the brain-death criteria should be declined.

A. Living Donors and Recipients

Criminal law imposes a "rule of beneficence" on some tissue transfer procedures, meaning that the benefits derived from the tissue donation and transplanting should not be disproportionate to the harms.[515] By imposing such standards on consent procedures, the donation process and surgical operations, the criminal law protects and promotes bodily integrity, life preservation and autonomy.

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507. See *infra*, note 516.

508. See text accompanying note 540, *infra*, and notes 560-562, *infra*.

509. See text accompanying notes 516-519, *infra*.

510. See text accompanying notes 528-530, *infra*.

511. See text accompanying notes 560-564, *infra*.

512. See Working Paper 26, *supra*, note 370 at 34.

513. See generally LRC, *Omissions, Negligence and Endangering*, Working Paper 46 (Ottawa: The Commission, 1985) and Report 31, *supra*, note 116.

514. See text accompanying note 675, *infra*.

515. See Working Paper 46, *supra*, note 513 at 6. See also Report 31, *supra*, note 116 at 62.

(1) Donor Rights and Responsibilities

Concerns about bodily integrity and the value of life are expressed in the responsibilities of the living donor. While the *Criminal Code* provision on assault[516] gives effect to the common law right and ethical imperative to consent to the physical invasion of one's person, other legal considerations help govern the existing model of tissue donation. For example, the recent criminal conviction of a Canadian donor for creating a common nuisance by knowingly donating HIV-infected blood underlines the concern for protecting the lives, health and safety of the public.[517] In contrast to the concern for the public health, criminal law provisions against consenting to death[518] and maiming or unlawfully causing bodily harm[519] express a concern for protecting the autonomy, health and bodily integrity of both donors and recipients, by defining the outer extremes of consent to the physical invasion of one's person. The implication of the consent-to-death prohibition is clear:

> This principle would thus preclude the altruistic donation of a liver or other organ without which the donor cannot live.[520]

The implications of the principles against maiming and unlawfully causing bodily harm have historically been more clouded in the surgical context. This principle derives from the medieval crime of mayhem, which involved permanently disabling or weakening an individual.[521] Some have argued that such principles should not be extended to organ transplants because of their significant social benefits.[522] Do such social benefits justify

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516. *Criminal Code* s. 265 provides in pertinent part, that: "A person commits an assault when (*a*) without the consent of another person, he applies force intentionally to that other person, directly or indirectly; ..." See also Report 31, *supra*, note 116 at 61-63. For a recent medical case involving a criminal assault conviction for unauthorized rectal examinations of institutionalized mentally disabled persons, see *R.* v. *Wiens* (22 June 1985), (Ont. Prov. Ct) [unreported], discussed in Harvey Savage and Carla McKague, *Mental Health Law in Canada* (Toronto: Butterworths, 1987) at 202-203. The case further demonstrates that in protecting bodily integrity, consent requirements protect human dignity and privacy.

517. *R.* v. *Thornton* (1991), 1 O.R. (3d) 481 (C.A.). See also Tonda MacCharles, "Conviction Stuns AIDS Blood Donor" *The [Ottawa] Citizen* (16 June 1989) A1 (discussing applicability of criminal negligence and public mischief charges for such circumstances). The *Criminal Code* offence of creating a common nuisance (s. 180) provides that:

> Every one who commits a common nuisance and thereby
>
> (*a*) endangers the lives, safety or health of the public, or
>
> (*b*) causes physical injury to any person,
>
> is guilty of an indictable offense and liable to imprisonment for a term not exceeding two years.

518. *Criminal Code*, s. 14:

> No person is entitled to consent to have death inflicted on him, and such consent does not affect the criminal responsibility of any person by whom death may be inflicted on the person by whom consent is given.

519. See *Criminal Code*, s. 269; *R.* v. *Daigle* (1987), 39 C.C.C. (3d) 542 at 551-52 (Que. C.A.); *R.* v. *Innes* (1972), 7 C.C.C. (2d) 544 (B.C.C.A.). See also Report 31, *supra*, note 116 at 62.

520. J.K. Mason and R.A. McCall Smith, *Law and Medical Ethics*, 2d ed. (London: Butterworths, 1987) at 221.

521. Scott, *supra*, note 268 at 63, and *Innes*, *supra*, note 519 at 547-48.

522. See Note, "The Sale of Human Body Parts" (1973-74) 72 Mich. L. Rev. 1182 at 1240.

kidney donation from a living donor who may be related or unrelated to the recipient, when "an estimated twenty donors have died after the removal of one kidney" in transplant procedures at established institutions?[523] Some argue that a restriction against such donations is overly paternalistic, denies some donors the privilege of exercising altruism and counters the public interest in overcoming organ scarcity problems.[524] These considerations suggest that public necessity generally justifies the practice as lawful and immunizes one against the potential offence of unlawfully causing bodily harm.[525] Other concerns about potential assaults on the bodily integrity of the donor, exploiting the vulnerable and organ sales have led to recent proposals to prohibit such donations, save in limited, strictly regulated circumstances.[526] The current practice in most transplant centres is still restrictive of the use of living unrelated donors.[527]

Concerns over bodily integrity, preservation of life and harm-benefit calculi intertwine in considerations about a legal duty to donate. Are there circumstances in which the criminal law imposes a duty to donate? The *Criminal Code* requires spouses or parents to provide "necessaries of life" to their spouse or child.[528] The unexcused failure to provide such necessaries as routine tissue replacement procedures, insulin injections or blood transfusions may thus constitute a criminal offence.[529] The Commission has extended these principles

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523. Thomas E. Starzl, "Will Live Organ Donations No Longer Be Justified?" (1985) 15:2 Hast. Cent. Rep. 5.

524. See Martyn Evans, "Organ Donations Should Not Be Restricted to Relatives" (1989) 15:1 J. Med. Ethics 17.

525. See Mason and McCall Smith, *supra*, note 520 at 221. See also *Criminal Code*, s. 45, in text accompanying note 540, *infra*; Report 31, *supra*, note 116.

526. See *Human Organ Transplants Act 1989* (U.K.), 1989, c. 31, discussed in chap. 4, below.

527. See Levy et al., "Kidney Transplantation from Unrelated Living Donors" (1986) 314:14 N. Engl. J. Med. 914 at 915; Evans, *supra*, note 524.

528. *Criminal Code*, s. 215, provides, in pertinent part, as follows (emphasis added):

> (1) *Every one is under a legal duty*
>
> (*a*) *as a parent*, foster parent, guardian or head of a family, to provide necessaries of life for a child under the age of sixteen years;
>
> (*b*) *as a married person*, to provide necessaries of life to his spouse; and
>
> (*c*) *to provide necessaries of life to a person under his charge if that person*
>
> (i) is unable, by reason of detention, age, illness, insanity or other cause, to withdraw himself from that charge, and
>
> (ii) is unable to provide himself with necessaries of life.
>
> (2) *Every one commits an offence who, being under a legal duty* within the meaning of subsection (1), *fails without lawful excuse*, the proof of which lies on him, *to perform that duty*, if
>
> (*a*) with respect to a duty imposed by paragraph (1)(*a*) or (*b*),
>
> (i) the person to whom the duty is owed is in destitute or necessitous circumstances, or
>
> (ii) *the failure to perform the duty endangers the life of the person to whom the duty is owed, or causes or is likely to cause the health of that person to be endangered permanently*; or
>
> (*b*) with respect to a duty imposed by paragraph (1) (*c*), the failure to perform the duty *endangers the life of* the person to whom the duty is owed or causes or is likely to cause the health of that person to be injured permanently.
>
> (3) Every one who commits an offence under subsection (2) is guilty of
>
> (*a*) an indictable offence and is liable to imprisonment for a term not exceeding two years; or
>
> (*b*) an offence punishable on summary conviction.

529. Compare *R.* v. *Tutton*, [1989] 1 S.C.R. 1392 (intentional parental withholding of insulin injections from 5-year-old diabetic, on religious grounds subjects parents to criminal negligence resulting in death for failing to provide necessaries of life without lawful excuse) and *R.* v. *Cyrenne* (1981), 62 C.C.C. (2d) 238 (Ont. Dist. Ct) (finding parents not guilty of criminal negligence, since not proved beyond reasonable doubt that lack of blood transfusion caused death). See also *R.* v. *Lewis*, *infra*, note 909.

in a proposal that individuals be obliged to take "reasonable steps to assist" a person "perceived to be" in immediate danger of serious harm or death.[530] Such a duty has been imposed by penal codes in Belgium, France, Greece and Vermont; it addresses such classic situations as when an individual who is clearly in the process of drowning receives no assistance from companions who might help without jeopardizing their own well-being.[531] There is no duty where the rescue involves a risk of serious harm or where the would-be rescuer has other valid reasons.[532]

Applying these principles to the tissue donation process would seem to indicate that organ donation is seldom, if ever, legally required. There are no reported Canadian cases on a duty to donate *per se*. Five North American cases involving the donation of bone marrow, in the non-criminal law context, illustrate the complexity of the problem. In one, a man suffering from aplastic anemia sought a court order compelling his first cousin, who was the only identified suitable donor, to donate bone marrow.[533] The anemic man was unlikely to survive without the transplant. Despite the exigencies of the circumstances, the court denied the order on the grounds that the forceable extraction of living bodily tissue would violate the autonomy and physical integrity of the cousin. The man died shortly thereafter. While this case appeared to be decided on the basis of autonomy, the risks associated with bone marrow transplantation[534] might constitute a risk of serious harm or otherwise constitute a lawful excuse sufficient to relieve one of any duty to donate. For tissue donation involving less bodily invasion and fewer medical risks to the donor, concerns about a risk of serious harm seem less compelling.

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530. See Report 31, *supra*, note 116 at 67, cl. 10(2) ("(a) General Rule. Everyone commits a crime who, perceiving another person in immediate danger of death or serious harm, does not take reasonable steps to assist him. (b) Exception. Cl. 10(2)(*a*) does not apply where the person cannot take reasonable steps to assist without risk of death or serious harm to himself or another person or where he has some other valid reason for not doing so."). See also Working Paper 46, *supra*, note 513 at 17-20.

531. *Ibid.* See also Clare Elaine Radcliffe, "A Duty to Rescue: The Good, the Bad and the Indifferent — The Bystander's Dilemma" (1986) 13 Pepperdine L. Rev. 387. Thomas C. Grey, *The Legal Enforcement of Morality* (New York: Alfred A. Knopf, 1983) 157-97.

532. Report 31, *supra*, note 116 at 67.

533. *McFall* v. *Shimp*, 10 Pa. D. & C. 3d 90 (Allegheny Cnty Ct 1978); Case Comment, "Coerced Donation of Body Tissues: Can We Live with *McFall* v. *Shimp*" (1979) 40 Ohio St. L.J. 409; Alan Meisel and Loren H. Roth, "Must a Man Be His Cousin's Keeper?" (1978) 8:5 Hast. Cent. Rep. 5. See chap. 2, section III, above.

534. The risks associated with bone marrow transplantation have been recently summarized:

> The procedure requires hospitalization; it is performed under spinal or general anesthesia with little associated morbidity other than moderate to significant pain at the aspiration sites that persists for several days. Life-threatening complications occurred in only 9 of 3,290 reported procedures, yielding a frequency of .027 percent. These complications included nonfatal cardiac arrest, pulmonary embolism, aspiration pneumonitis, ventricular tachycardia, and cerebral infarction. The death of a donor was reported due to cardiac arrest during induction of general anesthesia. Other adverse consequences of marrow donation included bleeding, which required transfusion, one case of a broken aspiration needle where surgical removal was necessary, and a few transient episodes of hypotension, atrial arrhythmia, and laryngospasm.

U.S. Department of Health and Human Services, Public Health Service, National Center for Health Services Research and Health Care Technology Assessment, *Reassessment of Autologous Bone Marrow Transplantation* (Washington, D.C.: U.S. Government Printing Office, 1988) at 2.

Four other cases raise the issue of what a duty to take reasonable steps may encompass, short of donation. A court in the United States recently denied a petition to order three-year-old twins to submit to tests for possible bone marrow donation to a half sibling.[535] The court was asked to decide the issue when an estranged couple disputed whether the twins, who were in the custody of the mother, should submit to blood tests that would indicate their compatibility for bone marrow donation to their dying thirteen-year-old half brother whom they had never met. In an earlier case, a cancer patient sought to compel a transplant centre to disclose information, and to take further steps to recruit Mrs. X, a potential bone marrow donor with apparently compatible bone marrow.[536] The court refused the request. It found the tissue type information contained in the centre's computer to be a confidential medical record to which the cancer patient had no special right of access.[537] In other disclosure cases, involving leukemia patients' access to confidential records, courts have both denied and granted access. A Quebec court granted a child's petition to access sealed adoption records for the narrow purpose of determining whether the patient's biological parents might be potential bone marrow transplant donors.[538] An American court denied such access.[539]

The results in most of these cases may seem harsh. Laws in the jurisdictions in which the courts denied access generally do not recognize a duty to rescue. If nothing else, the cases help illustrate that, beyond concerns for respecting the bodily integrity of would-be donors, competing needs for privacy and confidentiality also inform considerations on any duty to donate. Jurisdictions seeking to impose a reasonable duty to rescue while respecting confidentiality might, as the Quebec court held, require efforts to contact potential donors on the understanding that identities not be disclosed.

(2) Reasonable Harms and Benefits

The *Criminal Code* generally protects from criminal responsibility doctors who undertake organ transplants involving reasonable patient benefit.

> Every one is protected from criminal responsibility for performing a surgical operation on any person *for the benefit of that person if*
>
> (*a*) the operation is performed with reasonable care and skill; and
>
> (*b*) *it is reasonable to* perform the operation, having regard to the state of health of the person at the time the operation is performed and to all the circumstances of the case.[540]

535. *Curran* v. *Bosze*, 566 N.E. 2d 1319 (Ill. 1990).

536. *Head* v. *Colloton*, 331 N.W. 2d 870 (Iowa 1983); "Mrs. X and the Bone Marrow Transplant" (1983) 13:1 Hast. Cent. Rep. 17.

537. *Head* v. *Colloton*, *supra*, note 536.

538. *Droit de la famille-140*, [1984] R.J.Q. 2049 (T.J.).

539. *Application of George*, 630 S.W. 2d 614 (Mo. App. 1982).

540. *Criminal Code*, s. 45 (emphasis added).

How is the provision that surgical transplantation must benefit the patient to be reconciled with the reality that blood, bone marrow or kidney donations do not physically benefit the donor? First, by applying to surgical operations, the provision appears not to extend to blood or like donations that generally are considered medical procedures. Secondly, while the provision may appear to exclude tissue and organ transplants between family members, a number of approaches have been proposed to resolve the tension.

One approach involves construing "patient benefit" broadly, to include the psychological benefits presumed to accrue to the donor in organ transplantations and donations involving family members.[541] Yet, the psychological-benefits theory may be limited by circumstances in which presumed psychological benefits appear reduced, where, for example, donations are from unrelated donors. Moreover, some commentators question the validity of the psychological-benefits theory.[542] An alternative approach stresses that the requirement of donor benefit is presumed when consent is present.[543] This approach stems from a view that the *Criminal Code*'s fundamental premise is the protection of the person, and that it is reasonable to presume that persons act self-protectively to benefit themselves, as evidenced by consent.[544] The Law Reform Commission has adopted this view,[545] meaning that the *Criminal Code* provisions defining intentional crimes against bodily integrity[546] should not apply to tissue and organ donation undertaken with properly obtained informed consent and involving risks not disproportionate to expected benefits. Since the *Code* seems not to contemplate these medical procedures undertaken for another's benefit, appropriate reforms would seem advisable.[547] The more a procedure tends towards non-therapeutic benefit to the donor, the more stringent would seem the physician's duty of disclosure to promote consent.[548]

Neither the psychological-benefits nor consent and risk-benefits approach easily resolve the intractable complexities of organ donations from minors and mentally disabled individuals.[549] A mature minor who has the capacity[550] to understand and appreciate the risks, benefits and consequences of donating an organ to a sibling would seem to parallel

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541. See cases discussed in chap. 2, section II.B, above. See also Working Paper 26, *supra*, note 370 at 57.

542. See, *e.g.*, Margaret A. Somerville, "Medical Interventions and the Criminal Law: Lawful or Excusable Wounding?" (1980-81) 26 McGill L.J. 82 at 88 n. 16.

543. See *ibid.* at 92. See also Bernard Starkman, "A Defence to Criminal Responsibility for Performing Surgical Operations: Section 45 of the *Criminal Code*" (1980-81) 26 McGill L.J. 1048.

544. Working Paper 26, *supra*, note 370 at 58-59.

545. See Report 31, *supra*, note 116 at 63 and Working Paper 61, *supra*, note 295. See also MRC, *supra*, note 118 at 12, 21.

546. See section II.A(1), above.

547. See Working Paper 61, *supra*, note 295 at 35-36; Report 31, *supra*, note 116 at 63.

548. See *Halushka*, *supra*, note 376.

549. See generally Bernard Starkman, "*Inter Vivos* Transplantation: The Child and Dependent Adult as Donors" (1985) 17:6 (Supp. 4) Transplant. Proc. 40.

550. For a discussion of minors' competence to decide, see Margaret A. Somerville, "Refusal of Medical Treatment in 'Captive' Circumstances" (1985) 63 Can. Bar Rev. 59.

an adult in similar circumstances. The deep emotional consequences of donation or non-donation in such circumstances make consent for even the mature[551] a delicate, trying process.

For potential donors judged incompetent to consent, and thus unable to act self-protectively, the net "benefits" of the donation may justify transplants on grounds of necessity in exceptional circumstances.[552] The ethical principles of doing no harm and of beneficence[553] indicate that donations that pose no serious risks and that offer a likelihood of psychological benefits to the donor and life-saving benefits to the recipient may be justifiable. The beneficence requirement that the risk of harm not be disproportionate to expected benefits is most likely ensured by a restriction of such transfers to members of the same family. Thus, a minor sibling's donation of bone marrow to his or her brother may be seen as consistent with ethics, public policy and law.[554] However, as the invasiveness, irreversibility and risks of the transplant procedure increase — as in the case of a kidney transplant — so do concerns for the bodily integrity of all donors. To ensure that incompetent donors are protected from potential harms and that their particular vulnerability is not exploited, donations might best be considered only after other reasonable medical alternatives have been exhausted, and only if the guardian's consent has been obtained. To accord full respect to potential donors' wishes, their consent should be sought and their refusal respected. Such considerations have moved foreign analysts, such as the Australian Law Reform Commission[555] and the Council of Europe[556], to restrict donations from incompetent persons to those that can be made under similarly circumscribed conditions. Such concerns have more recently prompted the Uniform Law Conference of Canada to recommend a requirement of an "independent assessment" for

551. See John E. Thomas, "Am I My Brother's Keeper?" (Oct. 1987) Can. Doctor GP8. See generally George Thomson, "Minors and Medical Consent" (1981) 2:4 Health L. Can.; Bowker, *supra*, note 378 at 969.

552. Report 31, *supra*, note 116 at 63; Working Paper 26, *supra*, note 370 at 59.

553. See *supra*, note 283 and section II.B, below.

554. See, *e.g.*, *Cayouette et Mathieu*, *supra*, note 380. Though no criminal law issue was raised in this case, it suggests that transplants not physically benefitting the donor may be consistent both with public policy and criminal law and ethical principles of necessity and beneficence. See Working Paper 26, *supra*, note 370 at 57.

555. See Australian Law Reform Commission, *infra*, note 1010 at 50-51 (recommending (1) that donation of regenerative tissue from minors be lawful, if the minor is of sound mind and consents to donation, a parent consents, and independent medical advice is provided; (2) that donation of non-regenerative tissue be generally prohibited, subject to exception when the following conditions are met: the donor and recipient are members of the same family, independent medical advice is provided on the nature and effect of the donation and transplantation, written parental consent, the donor has sufficient mental capacity and agrees to donation, and an independent committee unanimously agrees to the donation; and (3) that it be unlawful to take tissue from mentally disabled persons).

556. See Final Text, *infra*, note 965 at 276 (recommending a general rule against procurement from the "legally-incapacitated, subject to (1) an exception for regenerative tissue, when justified on therapeutic grounds for the recipient, the legal representative consents, and the donor consents, if the donor has the capacity to do so (s. 10); and an exception for (2) the donation of a single kidney, when neither dialysis nor a cadaveric organ is, respectively, "feasible" or "available," the donor and recipient are "genetically closely related," the legal representative and appropriate authorities consent, and the donor consents, if the donor has the capacity to do so (ss 8, 10). The recommendation generally precludes procurement that "presents a significant and foreseeable risk to the life, health or functioning of the donor." (s. 13)).

all donors of non-regenerative tissue, as well as for all tissue donors under sixteen years of age.[557] The Law Reform Commission of Canada's recommendation that decisions for such interventions proceed on a case-by-case basis would seem consistent with the Uniform Law Conference approach.[558] Even when the donation of a kidney by an incompetent minor seems ethically justified by beneficence and is immune from criminal sanction on grounds of necessity, recent concerns expressed by the Supreme Court of Canada still raise questions as to whether and when invasive, irreversible medical interventions performed on one person for the benefit of another person are legally justified.[559]

(3) Reasonable Medical Skills

Finally, the criminal law protects the bodily integrity of transplant donors and recipients, by requiring medical professionals to perform transplants and related medical procedures with reasonable knowledge, skill and care;[560] surgical-medical procedures must not be done with wanton or reckless disregard for health and safety.[561] Otherwise, performance of the procedures theoretically risks subjecting a medical practitioner to criminal negligence charges for causing bodily harm or death.

In practical terms, medical malpractice seldom subjects health care professionals to criminal liability.[562] Most claims of negligence arise in civil disputes between an injured patient and a hospital or physician.[563] In rare instances when medical mistreatment invokes potential criminal negligence, the conduct is judged by a standard that differs from that of civil lawsuits. Generally, criminal negligence requires "a marked departure"[564] from

557. See text accompanying note 834, *infra*.

558. See Working Paper 26, *supra*, note 370 at 59. See also 1989 Uniform Act, ss 6, 7, discussed, *infra*, notes 833ff. (providing that (1) those under 16 may donate only if the results of an independent assessment indicate that the transplant should be carried out (s. 6(4)); (2) the tissue to be donated is regenerative (s. 6(1)); and (3) the minor understands the nature and consequences of the donation — a rule that is excepted by bone marrow that may be donated on behalf of the minor to the minor's biological sibling, by a guardian (s.6)).

559. See *Eve*, discussed in text accompanying note 362, *supra*.

560. *Criminal Code*, s. 266:

> Every one who undertakes to administer surgical or medical treatment to another person or to do any other lawful act that may endanger the life of another person is, except in cases of necessity, under a legal duty to have and to use reasonable knowledge, skill and care in so doing.

See also s. 45, in text accompanying note 540, *supra*.

561. *Ibid.*, ss 219, 220.

562. Working Paper 26, *supra*, note 370 at 1, 48. See also Ellen I. Picard, *Legal Liability of Doctors and Hospitals in Canada*, 1st ed. (Toronto: Carswell, 1978) at 298, 300. Compare *Wiens*, *supra*, note 516 and *R.* v. *Sullivan*, [1991] 1 S.C.R. 489 (midwives' aquittal of criminal negligence).

563. See generally Picard, *supra*, note 364.

564. Report 31, *supra*, note 116 at 25. The Supreme Court of Canada remains divided over whether an objective (reasonable person) standard or more subjective standard should govern criminal negligence. See *R.* v. *Waite*, [1989] 1 S.C.R. 1436. See also *Tutton*, *supra*, note 529. See generally Stuart, *supra*, note 506 at 183-98.

the ordinary standard of reasonable care. The standard theoretically applies to grave deviations from acceptable medical practices in diagnosing brain death,[565] or to other aspects of the transplant process.

B. Living or Deceased Donors — Anencephalic Newborns

In 1981, the Law Reform Commission of Canada proposed an "irreversible cessation of all . . . brain functions" standard for the determination of death in matters of federal jurisdiction, including the *Criminal Code*.[566] Developments in the last few years have led to calls to amend the whole-brain-death standard or to exempt from that standard a pool of patients who are born "incompatible with life": namely, anencephalic newborns. The proposal implicates criminal law principles and policy in two general respects. First, as with any potential organ donor, if the anencephalic newborn is not dead, the criminal law provision concerning medical treatment duties, failure to provide necessaries of life, criminal negligence, acceleration of death, homicide and like criminal law provisions governing live organ donors and recipients apply.[567] If live-born anencephalic infants do not meet the criteria for death,[568] this provokes a policy question in criminal law. Should the definition of death be modified for these infants who are born without most of their upper brain and who usually die within seventy-two hours after birth? Or should they be exempted from the definition so that their organs may be transplanted into those who might live? This question arises in part from the medical demand for the organs of newborns and in part from the poor medical status of the newborn anencephalic infant.

Anencephaly, which literally means "without brain,"[569] refers to a birth defect characterized by the "absence of a major portion of the brain, skull, and scalp."[570] This

565. See *People* v. *Eulo*, 472 N.E. 2d. 286 at 297 (N.Y. 1984) ("If, however, the pronouncements of death were premature due to the gross negligence or the intentional wrongdoing of doctors, as determined by a grave deviation from accepted medical practices or disregard for the legally cognizable criteria for determining death, the intervening medical procedure would . . . become the legal cause of death"). Compare *R.* v. *Kitching* (1976), 32 C.C.C. (2d) 159 (Man. C.A.) (adopting brain-death definition of death, holding that organ procurement from brain-dead patient, who had been criminally assaulted, did not cause death).

566. Report 15, *supra*, note 1 at 25. ("For all purposes within the jurisdiction of the Parliament of Canada, (1) a person is dead when an irreversible cessation of all that person's brain functions has occurred. (2) The irreversible cessation of brain functions can be determined by the prolonged absence of spontaneous circulatory and respiratory functions. (3) When the determination of the prolonged absence of spontaneous circulatory and respiratory functions is made impossible by the use of artificial means of support, the irreversible cessation of brain functions can be determined by any means recognized by the ordinary standards of current medical practice."). For a discussion of its proposed application to the *Criminal Code*, see Report 15, *ibid.* at 23. See also *Kitching*, *supra*, note 565.

567. For a discussion of *Criminal Code* provisions affecting living organ donors and recipients, see text accompanying note 516, *supra*.

568. Such infants generally receive death certificates, suggesting that they are considered born "alive."

569. *Dorland's Illustrated Medical Dictionary*, 27th ed. (Philadelphia: Saunders, 1988) at 78.

570. The Medical Task Force on Anencephaly, "The Infant with Anencephaly" (1990) 322:10 N. Engl. J. Med. 669 [hereinafter MTFA].

condition, of still unknown causes,[571] afflicts a reported one in 3,226 newborn infants; 40 to 60 per cent of anencephalic infants are born alive.[572] Tragically, even those born alive survive for only a few hours or days, although in rare instances some live for weeks or months.[573] Some fifty newborns appear to die from anencephaly and like anomalies annually in Canada;[574] the number ranges from 300 to 600 annually in the United States.[575] More frequent prenatal screening may reduce the incidence of anencephalic births.[576] The estimated 500 to 600 newborn livers and 1,200 hearts needed annually in the United States[577] may suggest a corresponding need for fifty to sixty newborn livers and 120 newborn hearts for Canada.[578]

The poor medical status of the infant, parental desires to make some good of the circumstances and the need for organs have led to proposals and initiatives to facilitate organ procurement from live-born anencephalic infants. Some of the initiatives appear to have been medically successful:

> Baby Gabrielle, born in Canada and subsequently transferred to the Loma Linda University Medical Center in California, was anencephalic. When her parents learned of their daughter's condition and of the devastating ramifications of anencephaly, . . . they faced the inexorable reality that their daughter would be born into a process of imminent dying. . . .
>
> In the hope that their infant daughter "would touch others and contribute to life in some way," Baby Gabrielle's parents arranged for their daughter's organs to be donated to infants who were in dire need of healthy organs for transplantation. One such infant was Baby Paul Holc, who was afflicted with hypoplastic left-heart syndrome. Baby Paul received Gabrielle's heart; one month after the successful transplant operation, he was discharged from Loma Linda with a second chance for a healthy, productive life.[579]

Other medical initiatives have proven less fruitful.[580]

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571. See Jack A. Pritchard, Paul C. MacDonald and Norman F. Gant, *Williams Obstetrics*, 17th ed. (Norwalk, Conn.: Appleton-Century-Crofts, 1985) at 802.

572. Jeffrey R. Botkin, "Anencephalic Infants as Organ Donors" (1988) 82:2 Pediatrics 250 at 251.

573. See Statistics Canada, *Mortality, Summary List of Causes, Vital Statistics, Volume III* (Ottawa: Statistics Canada, 1984-1988) No. 84-206, for the years 1981-86 (reporting that a few anencephalic newborns lived 1-10 months after birth).

574. *Ibid.* Deaths from "anencephaly and similar anomalies" (int'l listing No. 740) have been reported as follows for the respective years: 1986-52; 1985-66; 1984-52; 1983-78; 1982-76; 1981-87.

575. Botkin , *supra*, note 572 at 251. See also D. Alan Shewmon et al., "The Use of Anencephalic Infants as Organ Sources — A Critique" (1989) 261:12 JAMA 1773 at 1774.

576. Botkin, *supra*, note 572 at 255.

577. *Ibid.*

578. This assumes a Canadian need equal to 10% of the U.S. need.

579. Andrea K. Scott, "Death unto Life: Anencephalic Infants as Organ Donors" (1988) 74 Va. L. Rev. 1527 at 1528. See also T.C. Frewen et al., "Anencephalic Infants and Organ Donation: The Children's Hospital of Western Ontario Experience" (1990) 22:3 Transplant. Proc. 1033; George J. Annas, "From Canada with Love: Anencephalic Newborns as Organ Donors?" (1987) 17:6 Hast. Cent. Rep. 36.

580. See Joyce L. Peabody, Janet R. Emery and Stephen Ashwal, "Experience with Anencephalic Infants as Prospective Organ Donors" (1989) 321:6 N. Engl. J. Med. 344 (Loma Linda University finding that it is usually not feasible, with the restrictions of current law, to procure solid organs for transplant). See also "Anencephalic Organ Donor Program Suspended: Loma Linda Report Expected to Detail Findings" (1988) 260:12 JAMA 1671.

Practically, the dilemma presents at least four options for attempting tissue and organ procurement from anencephalic infants. Each raises varying criminal law and ethical concerns:

(1) Customary Care and Comfort: Provide customary care and comfort until the infants expire, which would reduce the likelihood of procuring viable organs, but permit the donation of tissue.[581]

(2) Brain Dead: Consider live-born anencephalic infants as brain dead,[582] born dead,[583] "brain-absent"[584] or stillborn,[585] to exempt them from the traditional heart-lung or the newer whole-brain-death standard, and thus permit a greater range of medical interventions likely to increase the number of viable organs procured for transplantation.

(3) Medical Protocols: Work within the whole-brain-death standard, by developing medical cooling[586] or ventilator support[587] protocols, in an attempt to maximize the likelihood of successful organ procurement.

(4) Special Category: Consider living anencephalic newborns to be a special category of beings — non-persons, who warrant special treatment.

The customary-care and medical-protocol options generally involve medical practices. While the legal issues they raise are not negligible, many of them may be addressed by examining the brain-death and special-category proposals.

(1) Redefining Brain Death

The proposals to deem live-born anencephalic infants to be brain dead, brain absent, stillborn, or exempt from the brain-death standard invite reconsideration of the brain-death standard. In doing so, they also invite modification or reaffirmation of the purpose, functions and principles underlying the existing whole-brain-death standard.

It has been twenty years since the first landmark proposal was made in North America to change the traditional definition of death from heart and lung cessation to the irreversible

581. Shewmon et al., *supra*, note 575 at 1778.

582. See Conference of Medical Royal Colleges (Great Britain), The Working Party on Organ Transplantation in Neonates" (1988) 14:3 J. Med. Ethics 164 ("In the adult the diagnosis of brain death plus apnoea is recognised as death. The working party felt by analogy that the absence of the forebrain in these infants plus apnoea would similarly be recognised as death.").

583. Scott, *supra*, note 579 at 1565. See also Jay A. Friedman, "Taking the Camel by the Nose: The Anencephalic as a Source for Pediatric Organ Transplants" (1990) 90 Colum. L. Rev. 917.

584. Michael R. Harrison, "The Anencephalic Newborn as Organ Donor" (1986) 16:2 Hast. Cent. Rep. 21.

585. See Bernard M. Dickens, "The Infant as Donor: Legal Issues" (1988) 20:4 (Supp. 5) Transplant. Proc. 50 at 52.

586. A. Kantrowitz et al., "Transplantation of the Heart in an Infant and an Adult" (1968) 22:6 Am. J. Cardiology 782.

587. See Peabody et al., *supra*, note 580.

cessation of all brain functions.[588] Like the old definition, the new definition was based on the medical technology and needs of the day. Mechanical respirators and circulators had joined the stethoscope as standard tools of medicine. Yet, if a patient could be maintained indefinitely on an artificial respirator and have no responsiveness and no brain functions, what was the legal status of the patient? Under traditional definitions of life and death, both law and medicine tended to regard the patient as alive, despite the absence of spontaneous respiration and circulation.

In 1970, Kansas became the first North American jurisdiction to pass a law adopting a brain-death definition.[589] Manitoba legislatively adopted a brain death definition in 1975.[590] By the time that the Law Reform Commission of Canada studied the issue five years later, a medical, legal and ethical consensus had largely emerged in North America that the irreversible cessation of all brain functions was the equivalent of the death of the person. The new standard was designed to supplement the traditional standard. Today, Canadian criminal case law,[591] the amended uniform tissue law[592] and the medical

588. Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death, "A Definition of Irreversible Coma" (1968) 205:6 JAMA 337.

589. Kan. Stat. Ann. s. 77-202 (1970).

590. *The Vital Statistics Act*, R.S.M. 1987, c. V60.

591. See *Kitching*, *supra*, note 565. But see *R.* v. *Green* (1988), 43 C.C.C. (3d) 413 (B.C.S.C.). Green involved the rather "exceptional" circumstances of a defendant claiming that he could not be charged with murdering someone already dead. See Stuart, *supra*, note 506 at 109. Defendant Green had fired two shots into a victim's head, shortly after another defendant had first shot the victim in the head. Apparently all three shots, if fired alone, would have proved fatal. Green's claim that the victim was already dead presented the court with a legal question over the time and determination of death for purposes of liability for homicide. When the time of death is legally controverted, courts properly attempt to resolve the question on the basis of expert medical testimony. See *Defining Death*, *infra*, note 594 at 78.

In *Green*, the court rejected applying brain-death criteria to help answer the question. It chose to use the traditional criteria for death — heart/lung cessation — for two apparent reasons. First, there was some indication that while the victim had stopped breathing after the first shot, his heart may have still been beating when he received defendant Green's two shots. Secondly, owing apparently to brain trauma the victim had suffered, the court seemed concerned that the Crown might not be able to prove that the victim was still alive ("brain alive") if the brain-death standard were used. The court characterized brain-death criteria as "a completely impractical standard to apply in the criminal law."

The medical evidence presented in the case is limited. Still, we would emphasize three points about "brain death." First, the LRC proposal refers to *whole* brain death (versus brain death), and the irreversible cessation of brain functions (versus brain function). Secondly, under the LRC standard, whole brain death may "be determined by the prolonged absence of spontaneous circulatory and respiratory functions." See Report 15, *supra*, note 1. Depending on the precise medical facts, then, a beating heart may be evidence that whole brain death has not occurred. See *Defining Death*, *infra*, note 594 at 15.

Thirdly, Canadian, British and American courts have, in fact, adopted the brain-death standard to aid in determining the time and cause of death in more typical modern homicide cases: namely, when a homicide victim enters an emergency room of the hospital, is placed on mechanical life support which is withdrawn after the pronouncement of death, and the defendant argues that the withdrawal of life support was either the cause, or determined the time, of death. *Kitching*, *supra*, note 565; *R.* v. *Malcherek*; *R.* v. *Steel*, [1981] 2 All E.R. 422; *Eulo*, *supra*, note 565. See generally David B. Sweet, "Homicide by Causing Victim's Brain-Dead Condition" 42 A.L.R. 4th 742. The courts' uniform rejection of defendants' arguments in these cases, and their adoption of the brain-death standard to clarify the cause or time of death, would seem to indicate that the brain-death standard does prove helpful in establishing liability in homicide cases. Fuller examination of such criminal liability concerns may be afforded by future cases and commentary.

592. See *infra*, note 835.

profession[593] have adopted a brain-death standard. Some forty-nine jurisdictions in the United States[594] and most of Western Europe[595] have similarly done so.

A primary purpose behind the whole-brain-death standard was to clarify legal rights and duties with a legal standard more consonant with the times. A clear definition of death reduces uncertainty and confusion over when a person is legally dead. It gives families a contemporary societal standard for making difficult decisions concerning treatment and non-treatment; it clarifies professional duties, patient rights and the limits of criminal liability. A clear definition of death thus facilitates organ procurement and transplantation.

The Law Reform Commission of Canada was convinced that a reform of the legal standard of death should adhere to several legal and public policy principles. First, the reform must be aimed at eliminating confusion; it should provide clarity and guidance to professionals and the lay public.[596] Secondly, it must advance uniformity and apply equally in all circumstances in which the determination of death is at issue.[597] This principle borrows from the reliability and uniformity of the traditional heart-lung cessation standard, and aims to reduce a proliferation of conceptions and definitions of death, which would foster confusion. As the U.S. President's Commission has stated, a new standard "ought not to reinforce the misimpression that there are different 'kinds' of death, defined for different purposes, and hence that some people are 'more dead' than others."[598]

Thirdly, the reform must "recognize standards and criteria generally accepted by the Canadian public."[599] The consensus-building process that had unfolded in North American society in the decade before the Commission announced its proposal meant that the public had already benefitted from the debate and deliberations of the medical, legal and bioethical community on a brain-death standard of death. The acceptability principle, in fact, was an influential factor in the Commission's view that adoption of a higher-brain-death standard would be ill-advised:

> In the opinion of the Commission, many members of the public and many professionals are definitely not prepared to consider as dead a person whose cortex [brain] is irreversibly destroyed, but who still enjoys spontaneous cardiac and respiratory functions. The Karen Quinlan case in the United States appears to be a good illustration of that point.[600]

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593. Canadian Congress on Neurological Sciences, *supra*, note 194; Canadian Congress Committee on Brain Death, *supra*, note 194.

594. See New Jersey Commission on Legal and Ethical Problems in the Delivery of Health Care, *Problems and Approaches in Health Care Decision-Making: The New Jersey Experience* (New Jersey: The Commission, 1990) at 11. The New York State Task Force on Life and the Law, *The Determination of Death*, 2d ed. (New York: The Task Force, 1989) at 4 [hereinafter NYTF]. See generally President's Commission, *Defining Death: A Report on the Medical, Legal and Ethical Issues in the Determination of Death* (Washington, D.C.: The Commission, 1981) [hereinafter *Defining Death*].

595. See chap. 4, section II.C, below.

596. LRC, *Criteria for the Determination of Death*, Working Paper 23 (Ottawa: Supply and Services Canada, 1979) at 51.

597. *Ibid.* at 53.

598. *Defining Death*, *supra*, note 594 at 60.

599. Working Paper 23, *supra*, note 596 at 55.

600. Report 15, *supra*, note 1 at 16.

Karen Ann Quinlan, who lay in a persistent vegetative state with no likelihood of recovery and whose parents requested court permission to turn off her respirator, had lost higher brain functions but retained brain-stem activities.[601] Whereas patients who are brain dead can neither breathe spontaneously nor respond to light, pain and sound stimuli, patients having lower brain-stem activities do breathe spontaneously.[602] Indeed, after the removal of life support, Karen lived for years. Today, there is still no consensus in North American or even in Canadian society that higher brain death is or should be equated with the death of the person.[603] Adoption of a higher-brain-death standard would mean that anencephalic newborn infants and an estimated 1,000 to 10,000 patients who, like Karen Quinlan, lie in a persistent vegetative state in Canada would become candidates for organ donation, although they enjoy spontaneous heart and lung activity.[604]

Finally, the Commission was and still is of the opinion that the criteria for death should not be determined "by reference only or mainly to the practice of organ transplantation."[605] The neutrality principle — that the reform be conceived neither to hinder nor to aid organ transplantation — recognizes the equality of other legitimate competing social interests in the determination of official death and seeks to avoid undue bias in the definition of death.

These principles bear directly on current considerations to exempt anencephalic newborn infants from, or to amend, the whole-brain-death standard. Such proposals violate the neutrality principle because they are motivated specifically to aid organ procurement from a class of severely disabled newborns. Organ transplant benefits alone do not justify shifting the life-death criteria because, beyond its medical implications, death is also a theological, moral and legal concept.[606] A redefinition based simply on organ transplant needs, moreover, may create the impression of arbitrariness and unequal treatment, because the law may appear to be trading the interests of potential organ recipients against the interests of severely disabled infants and their families.[607] Leading medical texts have,

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601. *Re Quinlan*, 355 A. 2d 647 (N.J. 1976), cert. denied 429 U.S. 922. For the recent landmark sequel to Quinlan, see *Cruzan* v. *Missouri*, 110 S. Ct 2841 (1990).

602. See B. Young, W. Blume and A. Lynch, "Brain Death and the Persistent Vegetative State: Similarities and Contrasts" (1989) 16:4 Can. J. Neurol. Sci. 388; American Medical Association, Council on Scientific Affairs and Council on Ethical and Judicial Affairs, "Persistent Vegetative State and the Decision to Withdraw or Withhold Life Support" (1990) 263:3 JAMA 426; American Academy of Neurology, "Position of the American Academy of Neurology on Certain Aspects of the Care and Management of the Persistent Vegetative State Patient" (1989) 39:1 Neurology 125.

603. See NYTF, *supra*, note 594 at 10.

604. See Taylor, *supra*, note 250. See also David Randolph Smith, "Legal Recognition of Neocortical Death" (1986) 71 Cornell L. Rev. 850.

605. Report 15, *supra*, note 1 at 12; Working Paper 23, *supra*, note 596 at 56.

606. NYTF, *supra*, note 594 at 6. But see Edward W. Keyserlingk, "A Legal Definition of Death: Can It Affect Supply of Tissue and Organs?" (1985) 17:6 (Supp. 4) Transplant. Proc. 47 at 48-49 ("None of which is to deny that organ transplantation claims are a major, if not the major, justification and reason for these statutes. Nor is there any good reason for the frequently expressed or implied fear that it is somehow unethical that this should be so. After all, as has been observed, preserving life and health is the highest of values in our society, transplanting organs is one way of achieving those goals in some cases.").

607. See "World Medical Association Adopts Declarations and Statements on Bioethical and Other Matters" (1988) 39:1 Int'l Dig. Health Leg. 267, excerpted in appendix A, *infra* at 200-201. ("A potential organ transplant offers no justification for a relaxation of the usual standard of medical care. The same standard of care should apply whether the patient is a potential donor or not.").

for years, referred to anencephalic children as monsters.[608] Given the evolving and heightened attitudes on the rights and protections of minimally or severely disabled individuals, shifting the legal criteria for the determination of death for a particular class of patients "raises troubling questions about evaluating the quality of life as part of the determination of death."[609] In the extreme, such an amendment also raises serious legal questions over whether some deaths and some brains are "more equal than others,"[610] and whether it would subject anencephalic infants to unjustified discrimination on the basis of physical disability.[611] These concerns underscore the need for reforms consistent with, and not violative of, basic human rights.

Secondly, the enactment of such proposals is not likely to clarify or help dispel lingering confusion over the existing brain-death standard. A disturbing minority of health professionals who work in the area still evidence confusion over the diagnosis and determination of brain death.[612] Changing the definition of death to apply to one group of patients may thus undermine uniformity, begin a proliferation of standards of death and foster confusion about which criteria do and should apply to what group of patients:

> As society contemplates the expansion of the potential donor pool to include other brain-damaged patients, who are clearly alive by today's legal and medical standards, the confusion may be compounded. Those who have accepted the whole-brain criterion because they have a higher brain concept or merely think brain dead patients are hopelessly dying may find it acceptable to take organs from certain patients currently defined as living, e.g. anencephalics or patients in persistent vegetative state, because such patients have clinical characteristics that are compatible with a less conservative concept of death. Some might seek to change the legal standards for death, thereby removing any obstacle to using other types of severely brain-damaged patients as donors. Without a greater consensus on a concept of death, such "conceptual gerrymandering" will only sow further confusion about, and perhaps resistance to, organ retrieval.[613]

Thirdly, then, a change will not satisfy the acceptability principle. That the medico-legal literature on anencephalic infants abounds with brain-absent, brain-dead and born-dead proposals suggests that medicine, bioethics and the law are still in the early phases of seeking a consensus on the legal and moral status of anencephalic infants. While the diversity of opinions, interests and alternatives is necessary for and healthy to proper debate on the

608. Compare Pritchard, MacDonald and Gant, *supra*, note 571 at 802 ("monster") and F. Gary Cunningham, Paul C. MacDonald and Norman F. Gant, eds, *Williams Obstetrics*, 18th ed. (Norwalk, Conn.: Appleton & Lange, 1989) at 575 ("child"). See generally James W. Walters, "Are Anencephalic Infants Monstrosities?" (1989) 2:28 BioLaw S:211.

609. NYTF, *supra*, note 594 at 10.

610. B. Freedman, "The Anencephalic Organ Donor: Affect, Analysis, and Ethics" (1988) 20:4 (Supp. 5) Transplant. Proc. 57 at 61.

611. See section IV, below.

612. Stuart J. Youngner et al., "'Brain Death' and Organ Retrieval: A Cross-sectional Survey of Knowledge and Concepts among Health Professionals" (1989) 261:15 JAMA 2205 (of 195 health professionals surveyed, 35% correctly identified brain death, 58% failed to use a coherent concept of death consistently, 19% had a concept of death consistent with changing whole-brain standard to classify anencephalic infants and PVS patients as dead). See also ONT, *supra*, note 29 at 235.

613. Youngner et al., *supra*, note 612 at 2210.

issue, it provides little basis for erecting a new legal standard. The lack of consensus at this societal juncture also means that adoption of any of the current alternatives would not be based on "standards and criteria generally accepted by the Canadian public."[614] For by either the traditional heart-lung or more modern whole-brain-death criteria, a live-born, severely neurologically impaired anencephalic infant is born living:

> Manipulating the definition of death — by including anencephalic infants, whose spontaneous breathing, sucking, crying, and the like separate them from the dead bodies that society is usually willing to label cadavers and bury — may undermine the public's already tenuous confidence in brain-based determinations of death. The predictable result will be a decline in the donation of organs from all categories of potential donors, as occurred in England following a highly publicized television program that called into doubt the accuracy of brain-death diagnoses.[615]

Some might be inclined to dismiss such remarks as overstatement. Yet, there is evidence that the public is reluctant to participate in the organ donation process, in part, because of fear about premature determination of death.[616] While the standard of death may work to facilitate organ transplantation, undue bias in the standard setting may itself erode public confidence in both the law and the organ donation process.[617] Thus, concern about the relationship between medical practice, the legal definition of death and the public's confidence and willingness to participate in the organ donation process is legitimate. The delicacy of that relationship itself would seem to suggest prudence and caution.[618]

(2) Redefining Persons

The opportunity to bring about an immediate, tangible good for potential recipients and for the donor parents, and the apparent "lack of harm" to the anencephalic infant, prompt some analysts to assign them a unique status:

> [I]nfants born with the top half of their brains missing are so very different from other living infants — and their future so radically limited — that it is permissible, with the fully informed and freely given consent of the parents, to remove their organs for transplantation. "... anencephaly is a condition so special, so very different from all others ... that infants in this most unfortunate condition should be viewed as in a class that is entirely *sui generis*, and one for which special rules and laws should apply."[619]

This approach would permit organs to be taken although the criteria for brain death are not satisfied.

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614. See Report 15, *supra*, note 1 at 12; Working Paper 23, *supra*, note 596 at 55.

615. Shewmon et al., *supra*, note 575 at 1778.

616. See Nolan and Spanos, *supra*, note 225. See also USTF, *supra*, note 29, and Areen, *supra*, note 226 at 562.

617. Even apart from possibly slighting other legitimate legal interests that are influenced by the determination of death, such as inheritance rights, criminal law prosecution, civil suits and withdrawing artificial life support for non-transplant purposes. See Keyserlingk, *supra*, note 606 at 47-48.

618. Accord, *Defining Death*, *supra*, note 594 at 58-59.

619. Ethics and Social Impact Committee Transplant Policy Center, "Anencephalic Infants as Sources of Transplantable Organs" (1988) 18:5 Hast. Cent. Rep. 28 [hereinafter ESIC].

From the criminal law perspective, the special-category option raises several general concerns. On the one hand, the Commission's view that it may sometimes be acceptable to withdraw "therapeutically useless" care[620] from and to administer palliative, life-shortening care[621] to the dying may offer guidance in treatment decisions. On the other hand, the Commission has expressed its views on the criminal law as proposed reforms; they remain unenacted. Accordingly, medical treatment that causes[622] or accelerates death,[623] or that involves a premature diagnosis of death[624] for any living human being, risks running afoul of the existing *Criminal Code*.[625]

In such instances, it has been suggested that the medical status of the anencephalic infant and the life-saving purposes of the initiative might establish a "necessity" defence to excuse criminal liability.[626] Others are unpersuaded by the argument.[627] The tenor of the criminal liability concerns and the general difficulty of applying brain-death criteria to anencephalic and other newborns[628] would seem to undermine the utility of designing and medically implementing a special-category option.

The special-category option also raises ethical concerns[629] involving a clash between beneficence and non-maleficence, and contested views on the relation between the body and self.

In terms of the ethical duty to do good, the special-category approach may hold promise. For potential recipients, although the long-term success and quality of life of infant

620. LRC, *Euthanasia, Aiding Suicide and Cessation of Treatment*, Report 20 (Ottawa: Supply and Services Canada, 1983) at 27-28.

621. Report 31, *supra*, note 116 at 60.

622. See *Kitching*, *supra*, note 565. See also *Criminal Code*, s. 269 (unlawfully causing bodily harm).

623. *Criminal Code*, s. 226: Acceleration of Death—

> Where a person causes to a human being a bodily injury that results in death, he causes the death of that human being notwithstanding that the effect of bodily injury is only to accelerate his death from a disease or disorder arising from some other cause.

624. See *Eulo*, *supra*, note 565, and *Kitching*, *supra*, note 565.

625. Some of these concerns may also apply to the medical protocols option.

626. See M.J. Tuttle, "Transplanting Organs from Anencephalic Infants" (letter) (1987) 136:8 C.M.A.J. 797. See also Diana Brahams, "Fetal Spare Parts" (1988) 1:8582 Lancet 424. For discussion of the necessity and public policy defences, see Working Paper 26, *supra*, note 370 at 42, 61.

627. See Dickens, *supra*, note 585 at 51 ("It is doubtful that causing homicide by precipitation of death of an anencephalic could be justified or excused by the defense of necessity to save the recipient's life. The wrong done must be objectively minor in comparison with the benefit sought, but even saving a salvageable life of a child may be insufficient to excuse ending the life of another, even an anencephalic likely to die relatively soon thereafter.").

628. See MTFA, *supra*, note 570 at 672; Canadian Congress on Neurological Sciences, *supra*, note 194 at 200B ("Brain death has not been sufficiently well studied in neonates, infants and young children to determine whether the clinical criteria listed above apply to these groups"). See also Task Force for the Determination of Brain Death in Children, "Guidelines for the Determination of Brain Death in Children" (1987) 37 Neurology 1077; David L. Coulter, "Neurologic Uncertainty in Newborn Intensive Care" (1987) 316:14 N. Engl. J. Med. 840.

629. As indicated above, the ethical aspects of organ procurement from anencephalic newborns are discussed here to provide a more concentrated analysis.

transplants remain uncertain,[630] the initiative may still mean life. For parents, the opportunity to donate the organs of their dying anencephalic child to help save life likely offers them solace and some meaning from the tragedy. Such prospective benefits appear compelling.

The above-mentioned benefits may not prove conclusive, however, as detractors are quick to underline, because of the possible related harms. Possible harm springs from medical-ethical uncertainty, slippery-slope concerns and potential intrinsic moral wrongs associated with categorizing anencephalic infants as non-persons. First, claims that[631] "[a]nencephalic infants lack the neurologic capacity to feel pain,"[632] and that the diagnosis of anencephaly is determined with near 100-per-cent accuracy[633] are not beyond dispute. Leading authorities agree that the diagnosis of anencephaly is not infallible, but is best made following precise criteria.[634] The claim that anencephalic newborns have no capacity to feel pain, moreover, rests on a comparison of them with older patients in a persistent vegetative state[635] — a comparison that some continue to question.[636] Analysts also argue that because anencephaly leaves some newborns with more intact brain-stems than others, degrees of consciousness or unconsciousness may vary.[637] Doubt about these medical premises may make potential harms to anencephalic newborns more appreciable than some special-category enthusiasts would seem to allow. To the extent that the medical premises of the position present problems, those problems may infect the ethical analysis.[638]

Secondly, the special-category proposal raises consequentialist concerns. Will the procuring of organs from newborns before they are dead undermine public confidence in the procurement and transplant process?[639] Will women diagnosed with an anencephalic fetus find their autonomy compromised by pressure to carry the fetus to term for transplant purposes? Will it lead to a denial of the respect ordinarily given to non-disabled infants and parents?[640] If anencephalic newborns are deemed non-persons, will other individuals

630. See Abbyann Lynch, "Use of the Anencephalic Infant as Organ Donor: Some 'Public' Questions" (1988) 1:2 Westminster Aff. 1 at 3. Compare Frewen et al., *supra*, note 579.

631. D. Alan Shewmon, "Anencephaly: Selected Medical Aspects" (1988) 18:5 Hast. Cent. Rep. 11 at 14.

632. Arthur L. Caplan, "Ethical Issues in the Use of Anencephalic Infants as a Source of Organs and Tissues for Transplantation" (1988) 20:4 (Supp. 5) Transplant. Proc. 42 at 47. See also Robert C. Cefalo and H. Tristram Engelhardt, "The Use of Fetal and Anencephalic Tissue for Transplantation" (1989) 14:1 J. Med. Phil. 25 at 32.

633. Caplan, *supra*, note 632 at 48; ESIC, *supra*, note 619 at 29.

634. See MTFA, *supra*, note 570 at 670; Shewmon, *supra*, note 631 at 15.

635. Shewmon, *supra*, note 631 at 14.

636. See MTFA, *supra*, note 570 at 672; Shewmon, *supra*, note 631 at 14; Young, Blume and Lynch, *supra*, note 602 and K.J.S. Anand and P.R. Hickey, "Pain and Its Effects in the Human Neonate and Fetus" (1987) 317:21 N. Engl. J. Med. 1321. Anesthesia is generally not used for those considered brain dead. Thomas Leggans, "Anencephalic Infants as Organ Donors" (1988) 9:3 J. Legal Med. 449 at 460-61.

637. See Shewmon, *supra*, note 631 at 15.

638. *Ibid.* at 14.

639. See, *e.g.*, Caplan, *supra*, note 632 at 43-44. See also *supra*, notes 225-227.

640. See Leggans, *supra*, note 636 at 455.

also lose their status as human beings, to slip into an expanded organ donor pool? Potential candidates include infants with other neurological malformations (for example, spina bifida and hydrencephaly), severely mentally retarded persons[641] and the Karen Anne Quinlan type of hospital patients who, although not brain-dead, lie in a persistent vegetative state.[642]

Lastly, treating anencephalic infants as a special category may raise intrinsic wrongs by violating a Kantian-inspired ethical duty.[643] The injunction — treat people as ends and never as means alone — applies to potential recipients, health professionals, parents of anencephalic newborns and society at large. Proponents of anencephalic infant organ procurement argue that the duty to respect persons does not apply to these infants, because of their "uncertain moral status."[644] The claim rests on a view that moral respect is owed to "persons," not merely because they are members of the human species, but because of their "sentience, consciousness, or self-awareness,"[645] and "the capacity for autonomy and choice."[646] The claim is buttressed by the further argument that since anencephalic newborns lack mental capacities that generate interests, they have none or few of the interests that usually command respect:

> [I]t becomes difficult to know how to interpret the desire to respect the interests of such children. Those who wish to respect the dignity of all human beings must show why such a principle is violated when it is not extended toward children who lack any possible means of having interests.[647]

Thus, the duty to respect persons has been reduced to the duty not to harm persons by infringing their interests[648] — that is, to the duty of non-maleficence.[649]

Paralleling the ethical debate over harms to the dead, proponents and detractors of the special-category or non-person approach to anencephalic newborn organ procurement

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641. *Ibid.* at 640, and Lynch, *supra*, note 630 at 2.

642. See "New Arguments Voiced over Use of Anencephalics as Organ Donors" (May/June 1989) Hosp. Ethics 6 [hereinafter New Arguments]. If the moral bases of tissue procurement are considered to be "to assure respect for autonomous choice, voluntarism, and deliberative rationality while at the same time preventing serious harm to the donor," then it is hard to see how extensions to these other classes of "donors" could be resisted. See Caplan, *supra*, note 632 at 46.

643. New Arguments, *supra*, note 642 at 7. See also chap. 2, above.

644. Caplan, *supra*, note 632 at 47.

645. *Ibid.* at 48; Leggans, *supra*, note 636 at 455; New Arguments, *supra*, note 642 at 6-7. See also ESIC, *supra*, note 619 at 29.

646. Caplan, *supra*, note 632 at 48. But see Freedman, *supra*, note 610 at 57. ("People, it is believed, are valuable; and the quality which distinguishes people — from each other, as well as from other species — is mentation. It does not follow that all human worth is owing to mentation. That which distinguishes a species need not characterize the individual. In the case of humans incapable of mentation, other sources of value come to the forefront — factors which, for those of normal capacities, are obscured in the blinding light of mentation.").

647. Caplan, *supra*, note 632 at 48.

648. See also Cefalo and Engelhardt, *supra*, note 632 at 35-36.

649. This parallels the argument that dead persons cannot be harmed because, not being sentient, they have no interests that can be infringed. See chap. 2, section I.C, above. If anencephalic infants are morally no different than the dead, then why not treat them as if they were dead?

seem to differ fundamentally in their views on the relation between the body and self.[650] Proponents tend to reduce persons to their sentient or cognitive capacities, by equating persons with their rational selves. The body tends to become morally irrelevant. Those reluctant about taking organs from anencephalic infants seem more inclined to view persons as embodied selves, wherein moral respect is owed to the body as well as to its sentient, rational attributes. A conception of persons as embodied selves[651] may not be amenable to rational justification, because the respect it accords the body likely derives from fundamental sentiments that transcend rational argument.[652]

In all, currently declining the options to create a special category of "non-persons" and declining to amend the brain-death criteria essentially means that anencephalic infants will generally be treated like other potential organ "donors."[653] This still leaves medicine free to explore potential benefits from tissue and organ transplantation from anencephalic infants through the customary-care and reasonable-medical-protocols options.[654]

C. Deceased Donors and Crimes against the Dead

Criminal law protects interests and defines duties regarding the dead. Historically, criminal law has for centuries played the dual role of mandating respect for the dead human body and of directly contributing to the supply of dead human bodies for medical science purposes. Indeed, the existing *Criminal Code* offence[655] of improper interference with or offering indignities to the dead derives from that tradition. The tradition has now begun to exert its influences in the modern context of the procurement and transplant process, which depends on the dead as the major source of donated organs.

(1) Dissecting and Donating as Punishment

An American doctor recently proposed that condemned prisoners pay their debts to society by donating organs for transplantation upon execution.[656] The proposal to supply medical science with the bodies or bodily parts of the malefactors of society has historical

650. *Ibid.*

651. For Caplan, this conception seems to be tantamount to incorrectly predicating moral respect on the basis of mere membership in the human species. *Supra*, note 632 at 48. See also Cefalo and Engelhardt, *supra*, note 632 at 38.

652. See, *e.g.*, Freedman, *supra*, note 610 at 57. See also chap. 2, section I.B, above.

653. "[T]here are no sound reasons for treating newborns with anencephaly as a qualitative exception to transplantation practices." Freedman, *supra*, note 610 at 63. Accord, Canadian Pediatrics Society, Bioethics Committee, "Transplantation of Organs from Newborns with Anencephaly" (1990) 142:7 C.M.A.J. 715 ("The criteria and ethical principles that apply to organ transplantation involving children and adults also apply to the newborn, as either recipient or potential donor").

654. This appears to be the course that will be adopted at the Children's Hospital of Western Ontario. See Dahlia Reich, "Organ Donations: Brain Death Guidelines to Be Tested" *The London Free Press* (23 August 1989) A1.

655. For a discussion of *Criminal Code* s. 182(*b*), see text accompanying note 675, *infra.*

656. B.-J. C., "An Eye for an Eye" (1989) 19:2 Hast. Cent. Rep. 3.

precedent. The idea dates from the third or fourth century B.C. when, at the University of Alexandria, bodies of executed criminals were supplied to university physicians for the study of anatomy.[657] Even the vivisection of condemned criminals was practised.[658]

The approach of using the criminal law to provide bodies for human dissection eventually made its way to Europe and North America. In 1376, King Louis d'Anjou granted the University of Montpellier permission to receive one executed criminal annually for dissection.[659] When the London Barber-Surgeons' Guild received its Royal Charter in 1540, the Act uniting the two crafts authorized the Guild to receive four executed felons annually for dissection and anatomical study.[660] The law gave the Guild the exclusive right to conduct anatomical demonstrations, and the United Company of Barbers and Surgeons "jealously guarded" the privilege for some 175 years.[661] As anatomical practice eventually became the sole province of surgeons and physicians, the number of bodies of executed criminals was later increased from four to include all murderers executed in London and Middlesex.[662]

The purpose behind such laws appears to have been twofold. First, it appears that some of the laws were intended to add dissection as a "peculiar infamy" to the punishment for murder.[663] This purpose was expressed in the Lord Justice-Clerk's 1829 sentencing of William Burke, who was convicted and executed for murdering several individuals whose bodies he sold to Scottish anatomists:

> William Burke, You now stand convicted, by the verdict of a most respectable Jury of your country, of the atrocious murder charged against you in this indictment . . . if ever it was clear, beyond all possibility of a doubt, that the sentence of a Criminal Court will be carried into execution, in any case, yours is that one, . . . I am disposed to agree that your sentence shall be put in execution in the usual way, but accompanied with the statutory attendant of the punishment of the crime of murder, viz. — that your body should be publicly dissected and anatomized. And I trust, if it is ever customary to preserve skeletons, yours will be preserved, in order that posterity may keep in remembrance your atrocious crimes.[664]

The surgeon to whom Burke had supplied many of the bodies performed a public dissection of Burke, whose skeleton may now be viewed at the University of Edinburgh Anatomy Department. It stands as an irony of history that one of the most infamous criminals in the trafficking of dead bodies for anatomical study in the nineteenth century was ultimately

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657. See Kevorkian, *supra*, note 17 at 20-22.

658. *Ibid.*

659. Lassek, *supra*, note 15 at 81.

660. *For Barbers and Surgeons* (U.K.), 32 Hy. 8, c. 42.

661. Ball, *supra*, note 19 at 59.

662. See *An Act for better preventing the horrid Crime of Murder* (U.K.), 25 Geo. 2, c. 37, as rep. 9 Geo. 4, c. 31. See also Ball, *supra*, note 19 at 63.

663. See Frederick C. Waite, "The Development of Anatomical Laws in the States of New England" (1945) 233:24 N. Engl. J. Med. 716 at 717, quoting Preamble to the 1752 Act.

664. See D. William Roughead, *Burke and Hare* (Toronto: Canada Law Book, 1921) at 256-57.

snared and punished by provisions permitting the dissection of criminals executed for murder. The punishment purpose is echoed in the recent proposal that executed criminals in the United States serve as organ sources.[665]

A secondary purpose of such criminal law provisions was to help provide medical science with bodies, which were in scarce supply. Not surprisingly, some of the settlers in the New World brought this cultural and legal tradition with them. Thus, a law to supply the bodies of executed criminals for anatomical dissection was enacted in the Massachusetts Bay Colony in the mid-1600s.[666] The practice was adopted into federal criminal law in the United States and remained in effect until 1987.[667] It was also considered in Canada,[668] although there is no apparent evidence that the practice was pursued.[669] While the supply theory behind the enactment of such laws may have relevance to current organ scarcity in Canada, the general abolition of the death penalty in the 1970s means that the proposal can have little current application in Canadian society.[670]

(2) Mistreating and Stealing the Dead

Humankind has long accorded respect to the dead human body and its remains.[671] Although the bodies of some non-citizens or *persona non grata* have, on occasion, not benefited from such respect,[672] the general attitude is reflected in the burial customs, religious practices and moral customs of Western civilization. The criminal law has not escaped these influences. In a nineteenth-century criminal case involving the neglected burial of a child, a Canadian judge echoed these sentiments by stating that "[e]very dead human body is entitled to a decent burial."[673]

Today, the Canadian *Criminal Code* requires respectful treatment of the dead. In doing so, it reflects abiding and evolving attitudes on respect for the dead. It specifically

665. See *supra*, note 656.

666. Waite, *supra*, note 663 at 717.

667. See 35 Stat. 1152 (codified at 18 USC 3567), as rep. P.L. 98-473, Title II, c. II, § 212(a) (1) and P.L. 99-217, § 4, 99 Stat. 1728.

668. See Debates, *infra*, note 803 at 467 n. 33, discussing *Anatomy Act* debates.

669. The first federal criminal law of Canada, in 1869, simply provided that criminals sentenced to death be executed "in the manner provided by law." Their bodies were to be buried within the prison walls, *An Act respecting Procedure in Criminal Cases, and other matters relating to Criminal Law*, 32 & 33 Vict., c. 29, ss 106, 117.

670. See *An Act to amend the Criminal Code*, S.C. 1973-74, c. 38, ss 2, 3; *Criminal Law Amendment Act (No. 2), 1976*, S.C. 1974-75-76, c. 105 (abolishing death penalty for *Criminal Code* offences). The death penalty theoretically remains for military personnel convicted of treason and like conduct. See *National Defence Act*, R.S.C. 1985, c. N-5, ss 73, 74, 139, 203, 206, *inter alia*.

671. See generally Lassek, *supra*, note 15 at 20.

672. Kevorkian, *supra*, note 17 at 26 ("Slaves were no different to the Romans than mere material objects of their environment; and killing a slave was not murder, but simply damaging an object. Dead slaves and prisoners of war were often left unburied and thus offered a good source of material for the sporadic dissections which were done.").

673. *R.* v. *Newcomb* (1898), 2 C.C.C. 255 at 256 (N.S. Co. Ct).

reflects societal expression of the Judeo-Christian tradition of according decent burials to the dead, by making it an offence to neglect, without lawful excuse, one's burial duties.[674]

The *Criminal Code* also penalizes indignities to or indecent interferences with a dead body or human remains:

> Everyone who ...
>
> (*b*) improperly or indecently interferes with or offers any indignity to a dead human body or human remains, whether buried or not,
>
> is guilty of an indictable offence ... .[675]

There are several overlapping purposes behind the provision. It expresses the long-held view that the dead human body is entitled to respect. Furthermore, it expresses respect for the emotional and religious sentiments of the next of kin and the moral tranquillity of society at large. In practical terms, the provision aims at preventing physical abuse of the dead body, protecting the public health and minimizing public nuisances. A review of the common law heritage of Canada, Great Britain and the United States shows how courts have articulated these purposes in cases involving sales of bodily parts, sexual indecency and theft, and even in the more modern contexts of medical experimentation.

Concern over the moral integrity of the community has been a traditional basis in definitions of criminal mistreatment of the dead body or human remains. Leading British jurists and Continental thinkers of the eighteenth and nineteenth century regarded the mistreatment of corpses as a high moral offence.[676] The existing Canadian offence derives directly from an unenacted 1879 draft British criminal code, which essentially codified British common law criminal misdemeanours against dead bodies.[677] While preventing the commission of sexual indecencies[678] upon the dead is an example of the obvious moral

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674. *Criminal Code*, s. 182(*a*). The Commission has proposed that the failure-to-bury provision be repealed, as archaic. See Report 31, *supra*, note 116 at 102.

675. *Criminal Code*, s. 182(*b*).

676. See James Fitzjames Stephen, *A Digest of the Criminal Law: Crimes and Punishments*, 4th ed. (London: Macmillan, 1887) art. 175 (morality offence); William Blackstone, *Commentaries on the Laws of England. Book the Fourth* (Oxford: Clarendon Press, 1779) at 236 ("a matter of great indecency"). Compare 1983 *Criminal Code Act* of Northern Territory of Australia, art. 140 (misconduct regarding corpse as morality offence); *New Zealand Crimes Act, 1961*, s. 150 (crimes v. human remains and crime against person); and crimes against sepulchres, under s. 360 of the French Penal Code. As a morality offence, s. 360 has broadly been interpreted to extend to the cemetery monuments, buried bodies, and bodies not yet buried, *Code pénal*, 88th ed. (Paris: Dalloz, 1991). See Dierkens, *supra*, note 382, para. 311. In this respect, see also the potential use of French criminal assault and battery provisions, *infra*, note 717.

677. See U.K., Criminal Code Bill Commission, *Report of the Royal Commission Appointed to Consider the Law Relating to Indictable Offences* (London: HMSO, 1879) at 22 ("sections 153 and 158 are declaratory of the common law"); Stephen, *supra*, note 676 at 117, 122; *The Criminal Code*, 55 & 56 Vict., c. 29, s. 206. For a general description of the first 100 years of the Canadian *Criminal Code*, see Alan W. Mewett, "The Criminal Law, 1867-1967" (1967) 45 Can. Bar Rev. 726.

678. *R.* v. *Ladue*, [1965] 4 C.C.C. 264 (Y.T.C.A.).

basis of the existing criminal offence, the common law crime actually arose in the context of supplying dead bodies for medical science.[679] In the 1788 English case that established the rule, a man was fined five marks for unburying a dead body he intended to sell to a doctor for anatomical dissection.[680] The historic no-property-in-a-corpse view meant that the man could not be convicted of having stolen the body.[681] Nor was unburying a dead body for dissection found by the court to be explicitly forbidden by a law prohibiting disinterment for purposes of witchcraft.[682] Still, the court found the practice highly indecent, against good morals (*contra bonos mores*), and therefore a criminal offence. The case illustrates how the common law historically sought to prevent the sale of dead bodies: namely, by criminal "indecency or mistreatment" offences, rather than the more direct route of a criminal theft rule. With the historic exception of criminalizing the theft of bones from Indian graves,[683] the Canadian *Criminal Code* seems to have continued this tradition through section 182(*b*).

Before the enactment of the Canadian *Criminal Code*, British courts extended the common law crime to physicians who received and possessed dead bodies known to have been illegally disinterred.[684] This view was also apparently applied in mid-nineteenth-century Canada before the Canadian *Criminal Code* was enacted. Medical professors who paid $30 to $50 for bodies obtained from local cemeteries were fined $50 for committing "offences against decency."[685] Such sales practices apparently resulted in harsher punishment in the United States as, for example, when a county undertaker was fined $750 and sentenced to eleven months in prison in 1900 for selling bodies for dissection.[686] These cases[687] and the historic legal basis of the existing mistreatment offence indicate that the sale of human remains or of a dead body may still fall under the existing criminal offence of mistreating the dead.[688] To the extent that sales of the human body or human bodily parts and tissues continue to be seen as violating basic human integrity and dignity,[689] the offence enforces the commonly shared sentiment that the dead human form is entitled to respect.

679. Compare "W. German Universities Spark Furor over Using Remains of Nazi Victims" *The [Toronto] Globe and Mail* (12 June 1989) A12.

680. *R.* v. *Lynn* (1788), 100 E.R. 394.

681. See section I.A, above. See also A.T.H. Smith, "Stealing the Body and Its Parts" [1976] Crim. L. Rev. 622.

682. See *Lynn* , *supra*, note 680, discussing *Witchcraft Act of 1735*.

683. See *The Larceny Act*, R.S.C. 1886, c. 164, s. 98, codified in *Criminal Code*, R.S.C. 1927, c. 36, s. 385, as rep. *Criminal Code*, S.C. 1953-54, c. 51, s. 745.

684. See *R.* v. *Cundick* (1822); *R.* v. *Davies* (1828) (Lancaster assizes), described in *Select Committee*, *supra*, note 22 at 6, 7.

685. See text accompanying note 809, *infra*.

686. See *Thompson* v. *State*, 58 S.W. 213 (Tenn. 1900).

687. For more recent cases of bodily sales as a criminal offence, see *People* v. *Bullington*, 80 P. 2d 1030 (Cal. 1938) and *Commonwealth of Pennsylvania* v. *Spector* (28 October 1988), Philadelphia 87-01-2441-2445 (Court of Common Pleas). See also *infra*, note 694.

688. See *Criminal Code*, s. 182(*b*), in text accompanying note 675, *supra*.

689. See section I.C, above, and chap. 2, section IV.B, above.

An offence of "criminal mistreatment of the dead" body also expresses concern for protecting the public health and preventing nuisances. Leaving dead bodies exposed in public places, or casting them into rivers, may expose the public to disease or contaminated water, and for this reason has been regarded as improper treatment.[690] Such conduct may constitute a common nuisance by creating material annoyances and discomforts to the public. In fact, the Canadian *Criminal Code* has always classified indignities or mistreatment of corpses as nuisances.[691]

Beyond protecting the interests and sensibilities of the community, criminal rules against mistreating dead bodies promote respectful physical conduct toward the dead. As such, they protect the bodily integrity of those who are deemed worthy of respect but who cannot protect themselves. This purpose is illustrated in some American jurisdictions which criminalize mutilation or abuse of a dead body.[692] The provisions guard against the unlawful and unnecessary disfigurement, physical invasion or abuse of the dead.[693] They have recently been invoked to prosecute a physician, funeral home and hospital morgue workers for the mutilation or abuse of corpses and trafficking in human bodily parts.[694]

Finally, the offence against mistreatment of, or offering indignities to, the human body and human remains protects the next of kin's emotional and religious interests, which may stringently oppose physical invasions of the dead body.[695] Those interests may be violated by physical abuse, mutilation, sexual indecency or like conduct that would outrage ordinary family sensibilities.[696] In this sense, the criminal law protections parallel and reinforce familial interests recognized in common law and civil law.[697]

In many respects, then, the existing criminal offence of visiting indecencies or indignities on a corpse, or mistreating it, expresses abiding, fundamental values about

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690. See *R.* v. *Clark* (1883), 15 Cox C.C. 171; *State* v. *Hartzler*, 433 P. 2d 231 (N.M. 1967); *Kanavan's Case*, 1 Me. 226 (1821).

691. Compare Stephen, *supra*, note 676 at 117, 122.

692. See, *e.g.*, California Health & Safety Code, s. 7052, (West 1988 Supp.) (felony crime to mutilate corpse). See also 18 Pennsylvania Cons. Stat. Ann. 18, s. 5510 (Purdon 1990 Supp.) (criminal abuse of corpse).

693. See *Bullington*, *supra*, note 687 (removal of two gold crowns, without maiming or disfiguring body or teeth, is not felonious mutilation of corpse).

694. See *Spector*, *supra*, note 687 (physician fined $35,000 and sentenced to 16,000 hours of medical service in city prisons for 15-year practice of selling bodily parts acquired from a university hospital morgue to medical research facilities). See also *People of California* v. *Sconce* (24 May 1988), Los Angeles A573189 (Sup. Ct); "Reward Offered in Case against Mortician" *New York Times* (8 June 1989) A16 (funeral home worker receives 5 years jail for 21 criminal charges including unlawful mutilation of human remains and removal of bodily parts, for alleged sales to medical schools). See also *infra*, note 717.

695. See *Kohn*, *supra*, note 404.

696. See American Law Institute, *Model Penal Code and Commentaries: Part II* (Philadelphia, Pa.: The Institute, 1980) s. 250.10, comment 2 at 420-21 (Abuse of Corpse: "Except as authorized by law, a person who treats a corpse in a way that he knows would outrage ordinary family sensibilities commits a misdemeanor").

697. See text accompanying notes 386-395, *supra*. See generally John S. Herbrand, "Validity, Construction, and Application of Statutes Making It a Criminal Offense to Mistreat or Wrongfully Dispose of Dead Body" 81 A.L.R. 3d 1071.

death and human dignity. The offence practically functions to protect diverse affected societal interests. It commands simple respect for the dead human form, encourages respect for the sensibilities and emotional interests of family members, helps curtail public nuisances and curbs unlawful and unnecessary disfigurement, mutilation or physical abuse of the dead. Historically, the moral concern for indecency has targeted necrophilic tendencies and the sale of dead bodies.

To the extent that these concerns — historically addressed by the *Criminal Code* offence — would be more directly and clearly covered by modern statutes, modification of the existing offence may be advisable. Burial duties, public health and nuisance concerns and legal regulation of the supply of bodies for medical science are now addressed in provincial anatomy, public health and cemetery Acts.[698] Some of the sales prohibition functions arguably may also be served, or complemented, by effective statutory sales offences.[699] Yet, the role of the offence in encouraging respectful conduct, and in policing physical abuse and moral harms, remains. For if unlawful and knowing mutilation, desecration, sexual assault or general abuse of the dead body or human remains violate the physical integrity of the dead body, they also violate the dignity of the dead, violate humanity and are repugnant to fundamental moral values.

Lastly, in an examination of how and why the mistreatment offence has historically functioned as a surrogate for what might otherwise be sales and theft offences, it becomes evident that a notable ambiguity has survived the centuries. Can skeletons and anatomical specimens that are prepared from parts of dead bodies, or that were once part of the human body, technically be stolen? Leading British and Canadian analysts have been asking the question since the nineteenth century.[700] The historic basis of the offence arguably suggests that even human remains that have been lawfully procured and transformed, by dint of skill and labour, into museum mummies, human anatomical specimens or similarly processed, preserved human tissue are not protected from theft by the criminal law today; if historically they could not be subject of property, they could not be stolen.[701] Indeed, the logic of the 300-year-old common law view that one cannot steal a dead body, only

698. See, *e.g.*, *Bodies of Deceased Persons Amendment Regulation*, Alta Reg. 298/86; *Bodies of Deceased Persons Amendment Regulation*, O.C. 82/18, A. Gaz. 1918.II.991; *Cemeteries Act*, R.S.O. 1980, c. 59. See also section III.B(1), below.

699. See section III.B, below.

700. Compare Stephen, *supra*, note 676, art. 292; G.W. Burbidge, *Digest of the Criminal Law of Canada: Founded by Permission on Sir James Fitzjames Stephen's Digest of the Criminal Law* (Toronto: Carswell, 1890) at 284, 288 (things not capable of being stolen) and Matthews, *supra*, note 385 at 219-20.

701. *Ibid.* Compare *Doodward* v. *Spence* (1907), 7 S.R. 727 (N.S.W. Austr.) (although there is no property in a corpse, skill and labour significantly modifying body may establish protectable possessory interest); J.W. Cecil Turner, ed., *Kenny's Outlines of Criminal Law*, 19th ed. (Cambridge: Cambridge University Press, 1966) at 294-95 ("It is not entirely certain whether the rule must be taken to be 'once a corpse, always a corpse'; if so the protection of the criminal law would perhaps not extend even to skeletons and similar anatomical preparations on which great labour has been expended or to ethnological collections of skulls or mummies — a conclusion which does not seem reasonable"); and J.C. Smith and Brian Hogan, *Criminal Law* (London: Butterworths, 1983) at 490-91.

its burial sheets,[702] continues to suggest, by the same token, that one cannot steal a laboratory skeleton, only the wire that binds it together,[703] nor extracorporeal bodily substances, only the vials or test tubes containing them.[704] Today, this would seem contrary to common sense, the basic values of the criminal law and broader contemporary concepts of property that now include, within criminal law protections against theft, things animate or inanimate, telecommunications services, wild animals and even electricity, all of which were not formerly within concepts of property.[705]

(3) Respecting the Newly Dead

Many of the concerns for respecting the dead, the wishes and beliefs of the family and the community sense of acceptable conduct merge into considerations on a "new class of dead patients": so-called "neomorts."[706] Modern medicine may now maintain a brain-dead individual for hours or days for transplant purposes, or for weeks or months for purposes of delivering the child of a brain-dead, pregnant woman.[707]

What is criminal mistreatment of the dead body in this context?[708] The answer is clouded partly by the ambiguous moral status of neomorts. Should they be treated as dead bodies, "dead patients"[709] or respiring, heart-beating cadavers,[710] even though they seem neither alive nor dead by conventional standards? Under what conditions, if any, is it acceptable to practice clinical instruction techniques, medical research or experimentation on the neomort? Does or should the offence against mistreatment require consent for such medical interventions? The questions are intriguing and unsettling. Moreover, they transcend the strict confines of the criminal law. The literature suggests that the answers depend largely on competing views as to the level of respect or dignity that should be accorded to the newly dead and the medical benefits of their use.

The newly dead may help advance medical science, treatment and education. A patient who has recently died from a heart attack in a hospital emergency room may afford medical

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702. See *Haynes's Case*, *supra*, note 384.

703. Skegg, *supra*, note 412 at 417-18 nn. 35, 39.

704. See *R.* v. *Welsh*, [1974] R.T.R. 478 (C.A.) (urine sample) and *R.* v. *Rothery*, [1976] R.T.R. 550 (C.A.) (blood sample).

705. See Report 31, *supra*, note 116, chap. 1(2) at 10; *Criminal Code*, s. 322.

706. See Youngner et al., *supra*, note 266 at 323.

707. See David R. Field et al., "Maternal Brain Death during Pregnancy" (1988) 260:6 JAMA 816 (brain-dead woman maintained 9 weeks at cost of $217,784 to give birth to male infant). See generally Note, "Incubating for the State: The Precarious Autonomy of Persistently Vegetative and Brain-Dead Pregnant Women" (1988) 22 Ga L. Rev. 1103.

708. See *Criminal Code*, s. 182(*b*), in text accompanying note 675, *supra*.

709. Youngner et al., *supra*, note 266 at 323.

710. Robert M. Veatch, *The Patient as Partner* (Bloomington: Indiana University Press, 1987) at 190; Field et al., *supra*, note 707 at 818-19.

students an opportunity to practice resuscitation, drug administration[711] or intubation (breathing-tube insertion) techniques.[712] Such practices are justified by arguments that they make for effective education, and that the health and safety of society are advanced by medical training on "non-persons" whose entitlement to respect in this context means "avoiding disfigurement or ridicule."[713] Similar concerns are offered to justify medical research and experimentation on cadavers ranging from blood sample collection[714] to the testing of organ transplant anesthesia, artificial respirators[715] and hearts.[716] In the public debate and criminal charges that followed experimentation on a brain-dead man hospitalized after being killed in an automobile accident in France, it was noted that medical science cannot advance without clinical research and experimentation.[717]

The benefits to medicine and to society from the use of neomorts must be weighed against competing concerns about respecting the dead and the meaning of mistreatment. In the debate following the French experimentation incident, the French national bioethics committee called for "the primacy of respect" of the person and his or her human remains; the President of France echoed those sentiments, asking society [TRANSLATION] "never to forget that the human being is not an instrument."[718] Those remarks seem to stem from a view that accords more respect to the dead because holders of that view value the symbolic dignity and humanity of the body. Moreover, they may be more apt to regard a heart-beating, respiring dead body as being more like a person than a corpse.[719]

What emerges from these competing considerations over medical benefits, potential mistreatment and respect for the dead is disagreement over the necessity for consent as a means of balancing the concerns. Minimally invasive experimentation or medical

711. See Kenneth V. Iserson and Charles M. Culver, "Using a Cadaver to Practice and Teach" (1986) 16:3 Hast. Cent. Rep. 28.

712. See Orlowski, Kanoti and Mehlman, *supra*, note 279 and (1989) 320:6 N. Engl. J. Med. 396-97 (correspondence).

713. Orlowski, Kanoti and Mehlman, *supra*, note 279 at 440-41.

714. Barry S. Coller et al., "Inhibition of Human Platelet Function *In Vivo* with a Monoclonal Antibody: With Observations on the Newly Dead as Experimental Subjects" (1988) 109:8 Ann. Intern. Med. 635.

715. Veatch, *supra*, note 710.

716. See Susan R. Martyn, "Using the Brain Dead for Medical Research" (1986) 1 Utah L. Rev. 1 at 7 n. 37.

717. See "L'expérimentation sur les comateux"*Le Monde* (21 December 1988) 22. See also D. Dickson, "Human Experiment Roils French Medicine" (1988) 239:4846 Science 1370. Criminal assault and battery charges have apparently been brought, under s. 309 of the French Penal Code, *supra*, note 676, for [TRANSLATION] "voluntarily wounding and striking persons who, by reason of their physical or mental condition, are incapable of defending themselves"; Jean-Yves Nau, "Un texte sur les comas dépassés est à l'étude" *Le Monde* (8 March 1988) 12.

718. "L'être humain n'est pas un instrument" *Le Monde* (27 February 1988) 17. See Comité Consultatif National d'Éthique pour les Sciences de la vie et de la santé, "Avis sur l'expérimentation médicale et scientifique sur des sujets en état de mort cérébrale" (7 November 1988) in *Éthique et recherche biomédicale: rapport 1988* (Paris: La Documentation française, 1989) at 23 [hereinafter Comité]. See also Franck Nouchi, "Les expérimentations en cas de mort cérébrale autorisées sur les patients ayant fait don de leur corps à la science" *Le Monde* (8 November 1988) 32 (describing national bioethic opinion).

719. See chap. 2, sections I.C and IV, above. See also John La Puma, "Discovery and Disquiet: Research on the Brain-Dead" (1988) 109:8 Ann. Intern. Med. 606 at 607 ("The dignity and humanity of the body should never be violated, even in the pursuit of the most valuable scientific knowledge").

education techniques may not disfigure or mutilate the newly dead or otherwise violate their bodily integrity. However, even marginally invasive techniques such as intubation might be considered an indignity or mistreatment, if consent is not obtained from a family that considers such techniques offensive, outrageous or violative of religious beliefs.[720]

Should consent to such procedures be required, or should it reasonably be presumed? On the one hand, few palatable options appear to be available. Seeking consent from family members may seem awkward, inhumane and time-consuming. Moreover, these minimally invasive practices derive public health and safety benefits. All of these considerations are said to justify a policy that presumes consent to such techniques, unless there is evidence that the deceased or the next of kin object.[721]

On the other hand, other considerations mitigate in favour of a more express-consent requirement. First, by failing to ask permission a practitioner runs the risk of violating the religious and moral beliefs, or simple preference, of the next of kin. Such a practice seems inconsistent with the normal expectations of a grieving family. Even a signed general hospital consent form[722] likely fails to address what the typical, reasonable patient or next of kin would expect of, or find material to, post-mortem hospital treatment. Some, therefore, argue that presumed consent rests on an unjustified deception that may well erode doctor-patient and hospital-community trust and confidences.[723]

Secondly, non-disclosure of the practice arguably contravenes the general duty of loyalty owed by a doctor to the patient.[724] A patient gives his or her body, trust and confidences to a doctor in the belief that the doctor's medical expertise will be exercised, and interventions will be undertaken for the patient's benefit. Intervention practices that proceed without inquiry into the dead patient's or the next of kin's wishes undermine the spirit of these duties and the balance of trust. The practices reflect a unilateralism that risks denigrating or violating the legitimate interests, rights and confidences of others intimately affected. From this perspective, death does not convert the rightful possession of a patient for treatment purposes into a right to intervene on the dead patient's body for non-treatment purposes.

Thirdly, even if in some instances there are clear benefits that would justify a policy of presuming consent for use by medical science of the dead body, the benefits from medical education and research are significantly less immediate and tangible.[725] Presumed consent to organ and tissue transplantation might be legitimized, for example, because procurement has the immediate, likely and identifiable benefit of saving lives or healing.[726]

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720. Compare American Law Institute, *supra*, note 696; Orlowski, Kanoti and Mehlman, *supra*, note 279 at 441, and *Strachan*, *supra*, note 394 at 351 (hospital failure to honour family members' request to return son's body impinges familial dignity and autonomy and imposes unnecessary distress).

721. Orlowski, Kanoti and Mehlman, *supra*, note 279 at 441.

722. See Picard, *supra*, note 364 at 43.

723. See Iserson and Culver, *supra*, note 711 at 29 (Culver's commentary).

724. See text accompanying note 445, *supra*.

725. See La Puma, *supra*, note 719 at 607.

726. See *infra*, note 842.

However, the benefits from direct therapy are not morally equivalent to those from research and training.[727] The French bioethics committee so concluded in rejecting the application of the presumed-consent provisions of tissue transplant law to experimentation on neomorts.[728] The Committee recommended that such experimentation should only proceed where the individual had bequeathed, in writing, his or her body to medical science.[729]

Lastly, a presumed-consent policy of using neomorts for either medical or experimental purposes seems to counter the medical-legal ethic in Canada. While this need not prove binding, prevailing public policy often enshrines the fundamental values which so animate criminal law.[730] Anatomy and tissue donation law,[731] and medical experimentation guidelines[732] that may apply to medical interventions on neomorts,[733] generally rely on consent as the societal means for individuals or the next of kin to donate the human body to medical science. These policies are, in turn, an extension and refinement of common law principles that recognize executors and the deceased's family as proper custodians and guardians of the deceased's body.[734]

As such it appears that, absent laws that clearly authorize non-consensual interventions, the medical circumstances and benefits that would result from the use of neomorts are neither so unique nor so compelling as to justify an exception to normal consent requirements. Typically, consent means asking the family. Such a requirement seems a practical way to balance traditional criminal law and ethical concerns about respect for the dead and for familial and community interests against the evolving needs of medicine. Such a condition for use of the deceased's body may be refined in statutory[735] and institutional requirements.

Under this analysis, evidence of lawful consent to the medical intervention would raise a presumption of legality for the existing *Criminal Code* offence of mistreating the dead human body. The difficulties of a consent requirement include the time frame and the manner of asking. The delicacy of the process has been summarized in the context of experimentation on a brain-dead child:

727. See La Puma, *supra*, note 719 at 607.

728. See Comité, *supra*, note 718.

729. *Ibid.*

730. See LRC, *Our Criminal Law*, Report 3 (Ottawa: Supply and Services Canada, 1976) at 5-9.

731. See section III.B. below.

732. See Working Paper 61, *supra*, note 295.

733. See Somerville, *supra*, note 369 at 70 (medical experimentation on cadaver may be within the "therapeutic purposes, medical education or scientific research" provisions of provincial gift tissue Acts); President's Commission, *Implementing Human Research Regulations* (Washington, D.C.: The Commission, 1983) at 39-41 (recommending research ethics board's review of cadaver experimentation).

734. See section I, above.

735. See Working Paper 61, *supra*, note 295 at 11 (federal statute on human experimentation).

> It would be essential that the experiment honor the mechanically sustained body and the parents' memory of the person who was (is, still — death is not "the end" for the parent) their child. What is likely to matter above all will be the attitude and tone of voice of the investigator seeking the parents' permission. If he bears in mind that he is a supplicant, that he is asking for something precious, and incorporates that knowledge in the asking, there is no reason not to ask. The decision is the parents'.[736]

The challenge lies in how and when to ask.

The trust, confidence and loyalty that have long been the bedrock of the provider-patient relationship thus would seem to impose special duties on medical professionals, patients and the families of patients. There may be an obligation on health care providers and hospitals to develop, refine and constantly reassess humane methods of obtaining consent in these delicate circumstances. As well, health care consumers, who will become patients, may have a moral duty to reflect on and discuss the giving of their bodies to science. These needs and delicacies strongly parallel those of the voluntary organ donation system. The use of neomorts for medical education and research would seem to be permissible "when an important social purpose is being served, when consent from a suitable guardian [*e.g.*, family member] is obtained, and when the invasion is done in a way that seeks to avoid desecration and preserves respect for the human form."[737]

III. Federal and Provincial Laws

For over a century, the federal and provincial governments have shared legal responsibilities for regulating the transfer and use of human tissue. Beyond its duties in defining relevant *Criminal Code* offences, the federal government is charged with ensuring the safety and efficacy of tissue replacement technology through the *Food and Drugs Act*. Other statutes, for example, the *Quarantine Act, Customs Tariff, Immigration Act, Income Tax Act* and *Canada Health Act*, impose on the federal government, on behalf of all Canadians, diverse roles and public responsibilities that bear on national tissue transfer issues. At the provincial level, anatomy, corneal and gift tissue Acts have largely defined the rules in Canada for the tissue donation process.

A. Federal Tissue Transfer Laws

(1) Drug and Medical Device Law

The *Food and Drugs Act*[738] (FDA) aims at ensuring the safety and efficacy of drugs

736. Veatch, *supra*, note 710 at 192, quoting R.A. Carson, J.L. Frias and R.J. Melker, "Research with Brain-Dead Children" (1981) 3:1 IRB: Rev. Human Subjects Res. 5.

737. Norman Fost, "Research on the Brain Dead" (1980) 96:1 J. Pediatr. 54 at 56. Accord Iserson and Culver, *supra*, note 711 at 29 (Culver's commentary); Coller et al., *supra*, note 714 at 638; Comité, *supra*, note 718; Veatch, *supra*, note 710 at 190. But see Orlowski, Kanoti and Mehlman, *supra*, note 279 at 441 and Iserson and Culver, *supra*, note 711 (Iserson's commentary).

738. R.S.C. 1985, c. F-27 [hereinafter FDA].

or devices intended for medical use by the consuming Canadian public. Administered by Health and Welfare Canada, the Act is based on the federal criminal law power.[739] Its historic purpose and functions have been to prohibit or regulate the manufacture or sale of adulterated or misbranded food, drugs, medical devices and like products potentially "injurious to health" and safety.[740] Cosmetics and medical devices have been regulated by the Act since 1939.[741] That such devices and drugs are designed, represented and intended for therapeutic, often internal, use in the treatment of illness and injury would seem to indicate a more compelling need for strict controls than is the case with cosmetics:

> It is obvious . . . that as the potential health hazard, both as regards constituents, as well as representations to the public as provided by drugs is greater, the control which must be exercised in the interest of the consuming public is necessarily more complete and strict, than would be necessary in the case of foods or cosmetics.[742]

In practical terms, the FDA sets out minimum uniform, national standards for tissue, mechanical and synthetic tissue replacement technologies. Older tissue replacement technologies — for example, blood products — are subject to the historic FDA authority to regulate biologics. "Biologics" refers to a special category of drug products, such as the polio vaccines or anti-hemophilia factors, that are derived from human and animal tissue.[743] Thus, Health and Welfare Canada's Bureau of Biologics administers FDA regulations that outline requirements for donor consent and screening, frequency of donation and the processing, labelling, licensure and sales of blood products in Canada.[744] Indeed, for decades the FDA has required that placenta used for therapeutic purposes be contaminant-free.[745] Such requirements have helped ensure the safety of albumin, a blood derivative historically processed from placenta and used in the treatment of shock, burns and hemorrhages.[746] The safety and efficacy of newer biologics technologies, such as

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739. See *R.* v. *Wetmore*, [1983] 2 S.C.R. 284 (upholding FDA deceptive drug labelling offence as criminal law power).

740. See Robert Emmett Curran, *Canada's Food and Drug Laws* (New York: Commerce Clearing House, 1953) at 137, 146 (discussing the *Adulteration Act* of 1884).

741. See *Food and Drugs Act Amendments*, R.S.C. 1939, c. 3, discussed by Curran, *supra*, note 740 at 180, 289. See also current FDA, *supra*, note 738, ss 16, 17.

742. Curran, *supra*, note 740 at 1071.

743. See Regulations under the *Food and Drugs Act*, P.C. 1942-9056, C. Gaz. 1942.I.2151 at 2172 [hereinafter P.C. 9056].

744. See HWC, *Departmental Consolidation of the Food and Drugs Act and of the Food and Drug Regulations* (with amendments to December 1990) (Ottawa: HWC, 1981) [hereinafter FDA regs], s. C.04.400 *et seq.* (plasmapheresis donation regulations). See also *Food and Drugs Act — Amendment* (Schedule No. 671), C. Gaz. 1988.I.3660 (proposing to include whole blood in existing blood derivative regulations). See generally Sanda Rodgers, "The Canadian Blood Delivery System: Liability for Blood Related Injuries" (1989) 21 Ottawa L. Rev. 311 at 322; D.W. Boucher and J. Furesz, "Regulatory Control of Blood Products in Canada" (1987) 67 Dev. Biol. Stand. 221.

745. "A manufacturer shall obtain human placenta and cord used in the manufacture of preparations from human sources only from women confined in public hospitals, and the donor of such placenta and cord shall been free from the toxemias of pregnancy, and the placenta and cord shall not show gross evidence of any pathological condition." FDA regs, *supra*, note 744, s. C.04.234. The regulation at least dates from the early 1940s. See P.C. 9056, *supra*, note 743 at 2179.

746. Hagen, *supra*, note 38 at 93. The Institut Mérieux of France, which recently purchased Connaught Laboratories of Toronto, specializes in placental blood derivatives. Canadian albumin today is derived from fractioned plasma.

genetically engineered human growth hormone and insulin, are also ensured by having them meet the regulatory standards for new drugs. Other new transplant technologies — like donated, excised organs — may be indirectly regulated, when the solutions in which they are preserved contain articles or drugs subject to FDA regulations.

The FDA also imposes health and safety responsibilities for medical device tissue replacement technology through Health and Welfare Canada's Bureau of Medical Devices.[747] The artificial kidney and heart machines are perhaps the most familiar examples of such technology.[748] For instance, the recent Health and Welfare Canada decision to continue to authorize the use of the American-made Jarvick-7 artificial heart — after the Government of the United States suspended its use for reasons of manufacturing quality control — directly affects research, clinical practices and patients at Canadian hospitals using the device.[749] The *Medical Devices Regulations* now also cover "implants." These are devices intended for implantation in the human body for thirty days or more,[750] such as cardiac pacemakers, implantable infusion pumps, nylon sutures, silicone breast implants and synthetic blood vessels. To be allowed to sell an implant in Canada, a company must generally provide substantial evidence that the implant may be produced with adequate quality and performance controls, is effective, poses no undue risk when used as intended and has proper labelling.[751] In recent years, Health and Welfare Canada has partially relied on its implant safety duties to oversee the recall by manufacturers of defective mechanical heart valves and processed brain tissue implant material.[752]

When and whether the FDA directly applies to other tissue replacement technology is less clear. Does treated, preserved or frozen bone marrow, tissue, human heart valves or semen fall within the statutory definitions and scope of the FDA so as to be subject to its requirements? Are those substances and tissues "drugs" or "medical device implants" to the extent that they are represented, sold or manufactured for use in treating disease or disorders or in correcting bodily or organic functions?[753] The answer seems to

747. See FDA, *supra*, note 738, ss 19-21. See also *Medical Devices Regulations*, C.R.C., c. 871 [hereinafter Devices].

748. See chap. 1, section II.C, above.

749. See Christie McLaren, "Canada Allows Jarvik Heart after U.S. Ban" *The [Toronto] Globe and Mail* (12 January 1990) A8.

750. See *Medical Devices Regulations*, amendment, SOR/82-914 (amending Part V of Devices, *supra*, note 747).

751. See Devices, *supra*, note 747, ss 33-41.

752. See *ibid.*, s. 29. See also page 161 below.

753. Section 2 of the FDA, *supra*, note 738, defines drugs:

> "drug" includes any substance or mixture of substances manufactured, sold or represented for use in
>
> (*a*) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or the symptoms thereof, in man or animal,
>
> (*b*) restoring, correcting or modifying organic functions in man or animal, ...;

Section 2 also defines medical device:

> "device" means any article, instrument, apparatus or contrivance ... manufactured, sold or represented for use in

depend on the use of the particular tissue or substance and on the interpretations given the Act.

On the one hand, one may argue that the language, structure and intent of the Act indicate that such tissues or substances fall within the scope of the Act. They all treat or mitigate diseased, disordered or non-functional human tissues; the Act does not require curative use. Some of the tissues, such as blood products and sperm, are sold in the normal sense of the term. Almost all are sold under the FDA meaning of "sell," which requires that the object be available for exchange, distribution or sale, regardless of whether the transfer involves money or value.[754] Increasing types of human tissues gain broad, safe and effective use in the treatment of bodily disorders, as a result of extensive processing, preservation and preparation through multi-step derivation processes that, in essence, yield "manufactured" therapeutic agents not unlike more conventionally manufactured therapeutic agents. The classic example is anti-hemophiliac factors manufactured by the international plasmapheresis industry. The living contact lens — which results from sculpting procured, processed and preserved human eye tissue to the individual patient's specification before implantation — is a lesser known example.[755] Under this view, then, the broad remedial purposes of the Act — to protect the public health — and the suggestive, as opposed to exhaustive, definitional language, combine to indicate that Parliament intended the definitions and reach of the *Act* to be interpreted broadly.[756]

An opposing view imparts more restrictive meaning to the language and reach of the FDA. One may argue that tissues are distinct from conventional therapeutic agents, which directly interact with human physiology, and which are commonly recognized by the drug industry and the public as conventional drugs or medical devices. Moreover, while some of the tissues are processed, few are manufactured in the normal commercial sense of the term.[757] Such considerations have, in the past, divided American courts over whether particular tissues fall within the meaning of language that is nearly identical to that used in the FDA.[758] Table 2, below, illustrates some tissue replacement technologies that are, or may be, subject to the FDA.

(*a*) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state ...,

(*b*) restoring, correcting or modifying a body function or the body structure of man ... .

754. See *ibid.*, definition "sell."

755. See Jonathan M. Frantz, Marguerite B. McDonald and Herbert E. Kaufman, "Results of Penetrating Keratoplasty after Epikeratophakia for Keratoconus in the Nationwide Study" (1989) 96:8 Ophthalmology 1151.

756. This approach was adopted in *United States* v. *Bacto-Unidisk*, 394 U.S. 784 (1969) (antibiotic sensitivity disc subject to federal food and drug regulations).

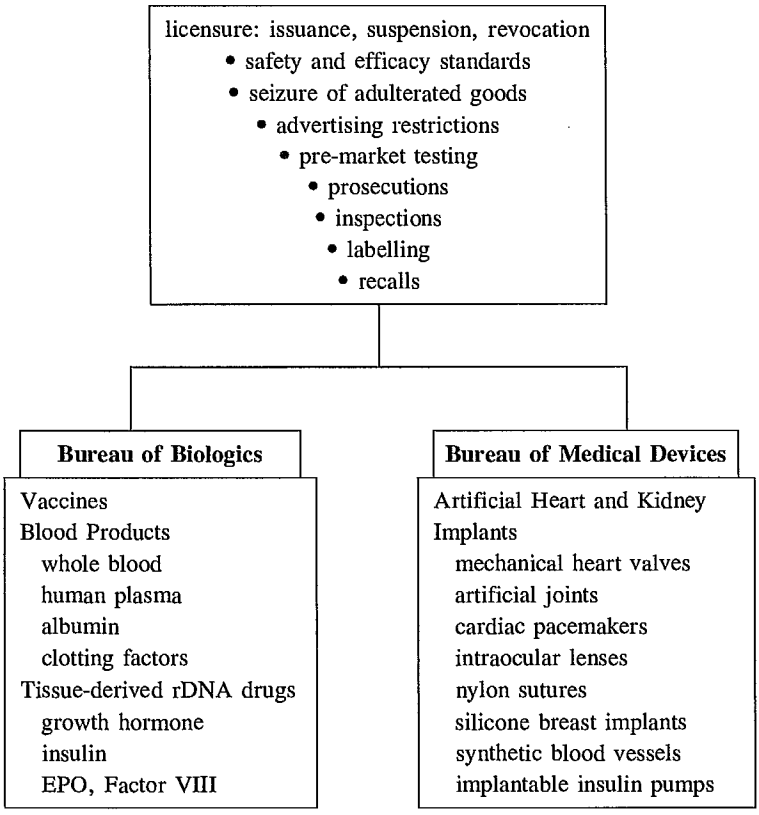
757. Although the Act does not define "manufacture," Division 2 — *Good Manufacturing Practices*, adopted under the Act, defines "produce" to mean "manufacture, prepare, preserve, package, label, test or store a drug for the purpose of sale." See FDA regs, *supra*, note 744, s. C.02.002.

758. Compare *United States* v. *Calise*, 217 F. Supp. 705 (1962) (whole blood is a drug); *United States* v. *Steinschreiber*, 219 F. Supp. 373 at 383 (1963) (human blood plasma is a drug), aff'd 326 F. 2d 759 (2d Cir.); *Blank* v. *United States*, 400 F. 2d 302 at 303-04 (5th Cir. 1968) (citrated whole blood and packed red blood cells are not drugs). Following the *Blank* case, U.S. drug law was amended. See Pub. L. No. 91-515, 84 Stat. 1297, 1308 (1970).

TABLE 2

Health and Welfare Canada:
Ensuring the Safety of Tissue Replacement Technologies

Pre- and Post-Market Controls on Drugs and Devices



Biologics? Devices? Implants?

processed, preserved, implanted bioprosthetic heart valves
• processed, implanted bioprosthetic umbilical veins
• processed, cryolathed, implanted eye lenses
• processed, preserved bone marrow
• processed, preserved semen
• processed dura mater

The biotechnological innovations of the last decades have expanded and accelerated the trend from natural to synthetic and biosynthetic tissue replacement technologies and techniques. As the processing and preservation of therapeutic human tissues proliferate, questions over whether the FDA applies to particular tissue products seem likely to become more pronounced, even as the need for minimum uniform, national standards becomes more evident. If processed and preserved heart valves,[759] bone marrow and semen[760] and processed cryolathed eye tissue are subject to the Act, then Canadian citizens in every geographic locale are protected by identical, minimum safety requirements.[761] If not, national standards depend on the consistency of pertinent provincial laws and medical professional standards and practice. From a public health and historical perspective, does the frequency and volume of interprovincial and international tissue transfers, for use as therapeutic implantable agents, make a less compelling case for protecting the consuming public than does cosmetics, which became subject to the Act fifty years ago? These considerations would seem to argue in favour of regulating preserved or processed therapeutic tissues and substances that may not strictly fall under the FDA. If construing the FDA to include such tissue unduly strains its language, function and parliamentary purpose, then perhaps the health and safety of Canadians would best be served by legislative clarification.

(2) Import-Export Laws

The FDA generally requires imported tissue replacement technology to meet the same safety and efficacy standards as do Canadian technologies.[762] Again, technologies not clearly within the scope of the FDA — such as currently imported, processed and preserved human heart valves[763] — may escape these requirements and protections. The general FDA exemption of exports from Canadian standards, as discussed below, raises basic questions about the duties owed by Canada to foreign importing nations and international consumers.[764]

FDA controls are complemented by those in the *Quarantine Act* and the *Customs Tariff*. Established pursuant to the authority of the Parliament of Canada to enact laws regarding quarantine,[765] the *Quarantine Act* empowers Health and Welfare Canada to inspect and detain imported goods reasonably suspected of being inimical to public health.[766] Thus, regulations made under the *Quarantine Act* currently provide that imported bodily parts

759. See text accompanying note 1027, *infra*.

760. *Ibid.*

761. The FDA, *supra*, note 738, s. 30, empowers the Governor in Council to make regulations on the importation of drugs (s. 30(2)) and medical devices (s. 30(1)(*d*)).

762. See *ibid.*, s. 30(1)(*d*); Devices, *supra*, note 747, ss 14, 16-22; FDA regs, *supra*, note 744, s. G.002.008.

763. See text accompanying note 1027, *infra*.

764. See the discussion of international trade, chap. 4, below.

765. See *Constitution Act 1867*, *supra*, note 506, s. 91(11).

766. See *Quarantine Act*, R.S.C. 1985, c. Q-1, s. 5.

enter Canada on the condition that they be accompanied by a medical certificate indicating that the bodily part is free from disease.[767] Customs regulations also provide for the expedited entry into Canada of human organs.[768] Regulations made under the *Customs Tariff*[769] impose duties on imported goods and set out the tariff treatment that is to be accorded to Canada's trading partners. Under existing *Customs Tariff* Schedules, for example, while blood plasma, bones, organs and other human tissue for transplantation enter Canada duty free, hormonal extracts from human glands are subject to a duty.[770] Similarly, immigration regulations provide that medical teams accompanying brain-dead mechanically assisted cadavers or organ retrieval teams be granted expedited entry through Customs.[771]

(3) Patent Law

Federal patent law is designed to encourage public ingenuity, by generally granting to inventors an exclusive right to make, use or sell an invention for twenty years in Canada.[772] In theory, this helps to promote the development of inventions that may require years of intellectual labour and financial investment. Patent law may also help seed other inventions, by requiring patent holders to disclose into the public domain technical information on which an invention is grounded.[773]

Inventors of mechanical heart valves, new extended organ preservation solution[774] and the rDNA human growth hormone that has replaced cadaveric pituitary human growth hormone, have availed themselves of these incentives and protections, to bring therapeutic tissue replacement technologies to market. Patents have also recently been granted in the United States, and seem likely to be filed in Canada, for synthetic blood and genetically engineered hormones that help grow cartilage and bone.[775] Thus, the patent law system has helped confer health benefits on the public.

Such health benefits do not seem to come without disputes and novel questions, however. Even as Health and Welfare Canada was in the process of approving the licensure and sales of erythropoietin (EPO) — the biotech drug that stimulates red blood cell

767. See Revenue Canada Customs and Excise, Memorandum D19-9-3, "Bodies and Body Parts for Internment in Canada" (1 June 1986).

768. Revenue Canada Customs and Excise, Memorandum R19-9-4, "Shipment of Human Organs" (1 June 1986).

769. R.S.C. 1985, c. 41 (3rd Supp.).

770. See Tariff Items 3001.90.20 and 3001.90.90, *Canada-United States Free Trade Implementation Act*, S.C. 1988, c. 65, s. 106 (Sch., Part B).

771. See *Immigration Regulations, 1978*, s. 19(1) (*j*) as am. SOR/84-849, Sch., subitem 1(1).

772. *Patent Act*, R.S.C. 1985, c. P-4, as am. R.S.C. 1985, c. 33 (3rd Supp.), ss 2, 44, 46.

773. See *Pioneer Hi-Bred*, *infra*, note 777.

774. See *supra*, note 137.

775. See Edmund L. Andrews, "Patents: Synthetic Blood" *New York Times* (21 October 1989) 34; Edmund L. Andrews, "Patents: Gains on Interleukin 3 and Formation of Bone" *New York Times* (4 November 1989) 34.

production and helps reduce blood transfusion needs for kidney dialysis and kidney transplant patients — biotechnology firms in the United States were in the court-house trying to resolve patent rights over EPO and its $300 million in annual sales.[776] While such disputes may be a conventional incident of the patent law system, other questions presented by biotechnology are novel. It may be asked whether there is something intrinsically wrong with patenting life,[777] particularly human life forms. That human cell lines have formally been patentable subject-matter in Canada since the early 1980s may suggest that it is not.[778] If not, the *Moore*[779] case nonetheless underlines a need to address the consequences of patenting some human life forms. How do we protect the bodily integrity and dignity of such human tissue sources as patients, and still provide proper incentives and protection for the creative genius of biotechnologists who cultivate potentially lucrative therapeutic fruits that benefit the public?

(4) The *Canada Health Act*

Parliament has deemed that access to high quality health care is "critical" to the continuing health and welfare of the people of Canada.[780] Accordingly, it has proclaimed "reasonable access" to health services without "financial or other barriers" to be a primary objective of Canadian health care policy.[781] The tissue transfer context suggests at least two instances in which financial and non-financial barriers might deny access.

First, tissue scarcity may erect a non-financial barrier.[782] Patients on transplant waiting lists across Canada understandably view organ scarcity as life-threatening. If national demand for blood products, corneal tissues or kidneys repeatedly outpaces available supply so that shortages become persistently acute, then scarcity imperils individual lives and national objectives. Scarcity may thus become a significant barrier to continuing

776. *Amgen Inc.* v. *Chugai Pharmaceutical Co.*, 927 F. 2d 1200 (Fed. 1991), cert. denied, 112 S. Ct 169. See also OTA, *Recombinant Erythropoietin: Payment Options for Medicare* (Washington, D.C.: U.S. Government Printing Office, 1990). For medical discussion of EPO see chap. 1, section II.C(3), above.

777. Simple microbial life appears to be patentable subject-matter in North America. Compare *Pioneer Hi-Bred* v. *Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623 at 1643 and *Diamond* v. *Chakrabarty*, 477 U.S. 303 (1980). See generally OTA, *New Developments in Biotechnology: Patenting Life* (Washington, D.C.: U.S. Government Printing Office, 1989); Rachel E. Fishman, "Patenting Human Beings: Do Subhuman Creatures Deserve Constitutional Protection?" (1989) 15 Am. J.L. Med. 461; Michèle Rivet, "Patenting Life-Forms and Owning Human Tissue" (Address to the Canadian Institute for the Administration of Justice, August 1990, Vancouver).

778. Compare *Application of Abitibi Co.* (1982), 62 C.P.R. (2d) 81 at 89 (Pat. App. Bd. & Pat. Commr.), *Pioneer Hi-Bred*, *supra*, note 777, and patent # 999, 546 of 9 November 1976 (human liver cell line). See also Patent Office, *Manual of Patent Office Practice* (Ottawa: Consumer and Corporate Affairs Canada, 1979), s. 12.03.02 (1/90 revision) ("inventions for new microbial life forms such as bacteria, yeasts, ... cell lines, ... may be patentable").

779. See *Moore* (1990), *supra*, note 426.

780. See Preamble to *Canada Health Act*, R.S.C. 1985, c. C-6 [hereinafter CHA].

781. *Ibid.*, s. 3.

782. See chap. 1, above, especially table 1 at page 9, and section V.

health. While some analysts may dispute whether these dynamics have attained national dimensions in Canada, they surely have inspired national law reform initiatives in foreign jurisdictions.[783] As such, legal reforms that successfully erode the scarcity barrier may save lives and advance national health policy.

Secondly, scarcity of funds may impose a barrier to access. The *Canada Health Act* (CHA), and provincial health insurance plans adopted in conformity therewith, announce a commitment to minimizing financial barriers through universal health insurance. The CHA specifically imposes a statutory duty on the provinces to provide "reasonable access" to "medically necessary" hospital and health services on a uniform basis.[784] Reasonable access is not synonymous with absolute access, however. As well, recent transplant funding litigation in the United States suggests that the term "medically necessary" is open to interpretation.[785] Still, a provincial funding choice — such as a decision to terminate funding for kidney transplants — that precludes or impedes reasonable access to transplant procedures judged medically necessary, risks subjecting the province to a loss of federal health moneys.[786]

Given these financial and scarcity concerns, it is not surprising that transplant cost data, the establishment of a national organ waiting list and the supply and demand of Canadian tissue and organ replacement technology have, in recent years, been on the agenda of federal-provincial committees that advise on administration of the CHA.[787]

(5) Health Services Laws

The Canadian government has certain responsibilities for the medical care of individuals not covered under provincial health insurance plans,[788] and for that of other specific populations in Canadian society. These groups range from active military personnel and

783. See, *e.g.*, U.S. and Australia in chap. 4, below.

784. See CHA, *supra*, note 780, ss 12, 2, (provincial health care insurance plans "must provide for insured health services on uniform terms and conditions and on a basis that does not impede or preclude . . . reasonable access to those services . . . 'insured health services' means hospital services . . . 'hospital services' means . . . services provided at a hospital, if the services are medically necessary for the purpose of maintaining health, preventing disease or diagnosing or treating injury, illness or disability"). For a discussion of allocating scarce resource issues in this context, see chap. 1, section IV.C, above.

785. See cases collected in note 1001, *infra*.

786. See CHA, *supra*, note 780, ss 14-17.

787. See FEDS, *supra*, note 29. See also HWC, *Canada Health Act, Annual Report* (Ottawa: HWC, for the years 1984 to 1989).

788. The CHA expressly excludes from provincial responsibility Canadian Forces members, the RCMP, federal prisoners and individuals who have not resided long enough in a province to be entitled to health services coverage. See the definition of "insured person" in the CHA, *supra*, note 780, s. 2.

the Royal Canadian Mounted Police,[789] to federal prisoners[790] and veterans,[791] to native peoples.[792] Some of these responsibilities are made explicit in federal law.

The federal *Penitentiary Act*[793] and *Criminal Code*,[794] for instance, require Correctional Services Canada to provide necessary or essential medical care to some 10,000 inmates under its charge. This statutory duty, which may be buttressed by fundamental human rights obligations,[795] encompasses such medically necessary tissue replacement technologies as the artificial kidney, blood transfusions, bone marrow and like tissue transplants.[796] Similarly, the Ministry of National Defence's medical responsibilities for some 100,000 members of the Canadian Forces has resulted in its overseeing some two dozen tissue or organ transplant procedures performed on its personnel in recent years.[797] When such tissue and organ replacement technologies are medically indicated, but unavailable at federal health facilities, the need typically will be addressed through contractual arrangements with, or medical referrals to, non-federal hospitals. Thus, military personnel in need of heart transplants are sometimes referred from the National Defence Medical Centre to the Ottawa Heart Institute.

(6) The *Income Tax Act*

The *Income Tax Act* is relevant to tissue transfers because of its potential to provide tax incentives for donation:

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789. *Ibid.*

790. *Ibid.*

791. See *Veterans Treatment Regulations*, C.R.C., c. 1585, and *Veterans Health Care Regulations*, SOR/90-594, adopted under the *Department of Veterans Affairs Act*, R.S.C. 1985, c. V-1, s. 5(1).

792. An 1876 Treaty, for example, obligates the Canadian government to provide medical services to native peoples on reserves in parts of western Canada. See *Treaty No. 6 between Her Majesty the Queen and the Plain and Wood Cree Indians and other tribes of Indians* discussed in *R.* v. *Swimmer* (1970), 17 D.L.R. (3d) 476 (Sask. C.A.). *Indian Health Regulations*, C.R.C., c. 955, have been adopted under the *Indian Act*, R.S.C. 1985, c. I-5, s. 73(1)(*g*), by virtue of the federal responsibilities outlined in s. 91(24) of the *Constitution Act 1867*, *supra*, note 506. See also the *Department of National Health and Welfare Act*, R.S.C. 1985, c. N-10 (federal health responsibilities for the people of Canada). Though the trend is towards transferring health and hospital administrative responsibilities to native peoples, HWC still runs seven native peoples' hospitals, including the only acute-care facility in the Yukon, Whitehorse General Hospital.

793. R.S.C. 1985, c. P-5, s. 37. Section 16 of the *Penitentiary Services Regulations*, C.R.C., c. 1251, mandates that "[e]very inmate shall be provided, in accordance with directives, with the essential medical and dental care that he requires."

794. Section 215(1) (*c*). See also *Attorney General of British Columbia* v. *Astaforoff* (1983), 6 C.C.C. (3d) 498 (C.A.).

795. See section IV.B, below.

796. See Correctional Service Canada, "Commissioner's Directive 800: Medical, Dental and Health Care Services" (1 January 1987), para. 26 (major surgery); Correctional Service Canada, "Commissioner's Directive 830: Prostheses and Appliances" (1 January 1987), para. 1 ("To ensure that offenders are provided with artificial devices as appropriate, which compensate for defective bodily functions").

797. National Defence Headquarters statistics indicate that 9 bone marrow, 7 cornea, 2 kidney, 1 heart/lung, 2 heart transplants, and a kidney dialysis procedure were performed on its personnel from 1984-88. Source: Department of National Defence, Office of the Surgeon General, 1990.

> Payment offered by the government might be in the form not of cash payments or credits, but through having confirmed offers as posthumous donation stand as charitable donations for taxation purposes. A taxpayer submitting a completed organ donor card might receive a receipt which, when filed with the next following annual statement of income for taxation purposes, would entitle the named recipient to an income deduction of a given amount.[798]

It is far from clear, under existing provisions of the *Income Tax Act*, whether the donation of an organ or tissue would meet the qualifications for a charitable gift or deduction.[799] The question has prompted legislative consideration in the United States.[800] While tax incentives for donation might increase the supply of scarce human tissues and organs, the economic benefits of such a policy may accrue largely to higher income taxpayers. Moreover, it could well undermine deeply held public sentiments on altruism.[801]

B. Provincial Tissue Transfer Laws

In contrast to the general focus of federal law on safety and commerce, provincial law structures the procedural framework for the donation and transfer of human bodies, organs, tissues and bodily parts. The laws result from three waves of legislation that began in the mid-nineteenth century.

(1) Anatomy Acts

The first wave of legislation started in 1849, with the enactment of a Bill designed to supply medical schools with cadavers for anatomical dissection and medical education. When the Medical Board of Montreal petitioned the Legislative Assembly of the Province of Canada, in 1843, the Board sought a legislative solution to a medical and societal dilemma, which was summarized in the Preamble to the legislation:

> WHEREAS it is impossible to acquire a proper or sufficient knowledge of Surgery or Medicine, without a minute and practical acquaintance with the structure and uses of every portion of the human economy, which require long and diligently prosecuted courses of dissections; And whereas the difficulties which now impede the acquisition of such knowledge amount almost to a prohibition of the same, and it has become necessary, in consideration of the rising importance of Medical Schools in this Province, and for the relief of suffering humanity, to make some legislative provision, by which duly authorized teachers of Anatomy or Surgery may be provided with the bodies necessary for the purpose of instructing the pupils under their charge . . . .[802]

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798. Dickens, *supra*, note 459 at 21.

799. See *Income Tax Act*, R.S.C. 1952, c. 148; S.C. 1970-71-72, c. 63, s.118.1(1) (*a*), added by S.C. 1988, c. 55, ss 77(1), 92(1) (replacing charitable donation deduction with credit). Compare *Garber*, *supra*, note 434.

800. See H.R. 540, 98th Cong., 1st Sess. (1983). See generally Note, "Tax Consequences of Transfers of Bodily Parts" (1973) 73 Colum. L. Rev. 842.

801. See Dickens, *supra*, note 459 at 21.

802. *Anatomy Act*, *supra*, note 8 (Preamble).

Proponents of the legislation described the study of anatomy as "legally impossible."[803] To receive a licence, medical students needed to have undertaken "cadaver surgery," when the supply of cadaver specimens was scarce. The scarcity prompted students to resort to body-snatching from local cemeteries, thereby running the risk of criminal punishment for desecrating human remains.[804] Those opposing the legislation suggested that it would legalize a traffic in corpses and make public property of some of the dead. They also suggested that executed criminals would be a preferred source of supply.[805]

The Legislative Assembly was persuaded by arguments that legislation would aid the healing arts in their life-saving ethic and rid communities of the nuisance of, and black markets created by, grave-robbing. The legislation adopted the principle that unclaimed bodies, publicly exposed or in such public institutions as hospitals or prisons, should be made available to medical schools.[806] The unclaimed-bodies principle derived directly from an administrative practice developed in Paris[807] in the nineteenth century, which had in turn been adopted into anatomy Acts of a decade earlier in Great Britain and Massachusetts.[808]

If the incidence of grave-robbing after 1843 is indicative of the success of the unclaimed-bodies legislation, it would seem that the Act did not prove immediately successful. As late as the 1870s, a demonstrator of anatomy at McGill University Medical School was fined for receiving dead bodies through the black market:

> Occasionally they prosecuted me for receiving the body. Now, as there is no property in a dead body and no clothes were taken, the only count on which they could summon me was, "Offence against decency," and I was usually fined $50. The judge, a Mr. Coursol, recognised the necessity of obtaining material for dissection, always fined me and nothing more was said.[809]

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803. See *Debates of the Legislative Assembly of United Canada 1841-1867: Volume III* (Montreal: Presses de l'École des hautes études commerciales, 1972) at 464 [hereinafter Debates]. See also *Journal of the Legislative Assembly of the Province of Canada*, 28 September — 9 December Session (1843) at 200.

804. See Lawrence, *supra*, note 4 at 409. See also *Lynn*, *supra*, note 680 (grave-robbing as common law criminal misdemeanour).

805. See Debates, *supra*, note 803 at 464-66.

806. "Be it therefore enacted ... that the bodies of persons found dead publicly exposed, or who immediately before their death shall have been supported in and by any Public Institution receiving pecuniary aid from the Provincial Government, shall be delivered to persons qualified as hereinafter mentioned, unless the person so dying shall otherwise direct: provided always, that if such bodies be claimed within the usual period for interment, by *bona fide* friends or relatives, or the persons shall have otherwise directed as aforesaid before their death, they shall be delivered to them or decently interred." *Anatomy Act*, *supra*, note 8 (Preamble).

807. See Debates, *supra*, note 803 at 466. See also *Select Committee*, *supra*, note 22 at 9-10, 137.

808. *Anatomy Act* (U.K.), 2 & 3 Will. 4, c. 95; *An Act more effectively to Protect the Sepulchres of the Dead and to Legalize the Study of Anatomy in Certain Cases*, 1831 Laws of the Commonwealth of Massachusetts, c. 57. See also *Report of the Select Committee of the House of Representatives, on Legalizing the Study of Anatomy* (Boston: Dutton and Wentworth, 1831).

809. Francis J. Shepherd, *Reminiscences of Student Days and Dissecting Room* (Montreal, 1919) at 25. See also Edward Dagge Worthington, *Reminiscenses of Student Life and Practice* (Sherbrooke, Que.: Walton, 1897).

While such prosecutions may have been isolated events, the activity apparently was not. Dead bodies were even reportedly smuggled in from the United States.[810] Increases in the number of both medical schools and medical students increased the demand for anatomical subjects. In Quebec, municipalities went to extraordinary lengths to police local cemeteries from grave-snatching.[811] Non-enforcement of the Act, non-compliance by hospitals, legislative ambiguity as to the period that must elapse before a body is declared unclaimed, the absence of a clause prohibiting medical schools from receiving "black market" bodies — all purportedly contributed to undermining the workings of the legislation.[812]

Today, provincial anatomy Acts or their equivalents help supply medical schools with some 600 bodies annually for medical education and research.[813] Amendments since the nineteenth century have clarified the ambiguities and weaknesses of the initial legislation. Thus, most Acts now specify twenty-four to forty-eight hours as the waiting period after which the body becomes unclaimed.[814] With the introduction of a bequeathal principle into tissue transfer legislation, individuals are now authorized to donate their bodies to medical science.[815] In fact, the vast majority of bodies used by medical schools today are donated.

(2) Cornea Acts

A century after Canadian, British and American jurisdictions enacted laws to facilitate the medical need for anatomical studies, a second wave of legislation began. In the 1950s, medical science started to treat some forms of blindness and severely impaired vision by the surgical transplantation of eye issue from cadaver donors.[816] Since anatomy Act provisions for the donation of one's body for "anatomical examination" neither contemplated nor authorized the retention of tissue for transplantation, legislative reforms were in order.[817] Thus Great Britain enacted *The Corneal Grafting Act, 1952*, to authorize the removal of corneas from corpses, for "therapeutic purposes."[818] Five years later,

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810. See Lawrence, *supra*, note 4 at 414.

811. The following notice appeared in a Montreal paper in 1871:

> We saw to-day a tremendous weapon just finished for the watchman at the Cote des Neiges Cemetery. The gun is of enormous proportions, and will be loaded with about eight ounces of buck-shot. Parties meditating a raid on the above place of burial, will do well to recollect the formidable shooting iron now in the hands of the wide-awake watchman. A pot shot at a gang of grave desecrators would most likely supply the dissecting room with enough subjects for several weeks.

See Lawrence, *supra*, note 4 at 415, citing *Montreal Evening Star* (11 February 1871).

812. See Lawrence, *supra*, note 4.

813. See chap. 1, above.

814. See, *e.g.*, *Anatomy Act*, R.S.O. 1980, c. 21, s. 3, and *Public Health Protection Act*, R.S.Q., c. P-35, s. 57.

815. See, *e.g.*, 1971 Uniform Act, s. 4, discussed in section III.B(3), below.

816. See chap. 1, section I.B(1), above.

817. See W.A.J. Farndale, *Law on Human Transplants and Bequests of Bodies* (Beckerman: Ravenswood, 1970) at 16.

818. (U.K.) 15 & 16 Geo. 6 & 1 Eliz. 2, c. 28.

New Brunswick enacted legislation drawing largely on the British model.[819] The Canadian Conference of Commissioners on Uniform Legislation subsequently proposed a *Uniform Cornea Transplant Act*[820] which was eventually adopted by eight provinces and two territories.[821]

The *Uniform Cornea Transplant Act* both drew on and departed from the unclaimed-bodies principle. It introduced a donation principle by authorizing living donors to indicate an intention to donate one's eyes, effective after death.[822] The donation principle extended to situations where a person had made no intention to donate known, by providing that the deceased's spouse, children, parents or siblings could authorize donation.[823] A variant of the unclaimed-bodies principle took effect when family members of the deceased could not be located by permitting a person "lawfully in possession of the body" to authorize the procurement of corneal tissue.[824]

The term "lawfully in possession" was defined so as to exclude medical examiners and funeral directors.[825] Those otherwise in lawful possession of the body could be an executor of the deceased's estate or, in the absence thereof, a surviving family member. The language also meant that when an unclaimed body was in the lawful possession of a hospital, then theoretically a hospital administrator or medical physician had the authority to consent to corneal tissue procurement. In this sense, the Act introduced a narrow version of presumed consent. In those limited circumstances when an undeclared donor died in a hospital with no identifiable family who might lawfully claim the body, society presumed consent to authorize corneal donation.[826] This provision appears to have modified traditional private law rights and duties respecting the next of kin's right of possession.[827]

(3) Human Tissue Laws

The organ transplantation age generated a third wave of statutory reform. By the early 1960s, kidney transplantation had nearly a decade of experience as a therapeutic intervention

819. *Corneal Grafting Act*, S.N.B. 1957, c. 7.

820. *1959 Proceedings of the Forty-first Annual Meeting of the Conference of Commissioners on Uniformity of Legislation in Canada* (Victoria, B.C.: The Conference, 1959) at 77.

821. See J.-G. Castel, "Some Legal Aspects of Human Organ Transplantation in Canada" (1968) 46:3 Can. Bar Rev. 345 at 394.

822. *Uniform Cornea Transplant Act*, *supra*, note 820, s. 4.

823. *Ibid.*, s. 5.

824. *Ibid.*

825. *Ibid.*, s. 2.

826. It should also be noted that a provision in the Act, removing presumed-consent authority when those empowered to give consent had reason to believe the deceased would have objected (*e.g.*, on religious grounds), apparently did not extend to instances of unclaimed bodies. See *Uniform Cornea Transplant Act*, *supra*, note 820, ss 6, 2.

827. See section I, above.

for end-stage renal disease.[828] The catalyst and model for legal accommodation of organ donation and procurement again came partially from abroad. In 1961, Great Britain broadened *The Corneal Grafting Act, 1952* to include all human tissues by enactment of the *Human Tissue Act, 1961*.[829] Ontario followed suit, in 1963, by replacing its *Cornea Transplant Act* with the *Human Tissues Act*.[830] Model Uniform Canadian legislation was proposed in 1963, adopted in 1965 and revised in 1971 and 1989.[831]

Today, the major sources of provincial law governing the transfer of bodily parts and tissues are provincial versions of the 1971 Uniform *Human Tissue Gift Act*.[832] Because the 1989 revision to the Uniform Act was so recently adopted by the Uniform Law Conference and proposed to the provinces, it has yet to receive widespread legislative enactment.[833] While the 1989 Act introduces important clarifications and amendments, it continues a general commitment to consent and altruism as the uniform model of tissue donation from living and deceased donors.

For living donors, both the 1971 and 1989 Uniform Acts predicate donation on prior consent. The 1989 Act further proposes an independent assessment, by a three-person panel, of cases involving the donation of non-regenerative tissue and those involving minors donating either regenerative or non-regenerative tissue.[834] For post-mortem donation, both Acts require a pre-transplantation determination of death. The 1989 Act also makes clear that "death includes brain death as determined by generally accepted medical criteria."[835] Both generally predicate post-mortem procurement on prior consent by the deceased. For undeclared donors, consent by the deceased's "family"[836] is substituted. When the family of undeclared potential donors cannot be located, the 1989 Act authorizes coroners to consent; the 1971 Act precludes coroners or hospital administrators from such consent, but generally authorizes consent by others "lawfully in possession of the body."[837] Finally, both Acts forbid the sale of tissues, organs or bodily parts, but not blood.[838] The

828. See chap. 1, section II.C(1), above.

829. (U.K.) 9 & 10 Eliz. 2, c. 54, repealing *The Corneal Grafting Act, 1952*, *supra*, note 818.

830. S.O. 1962-63, c. 59.

831. For a description of this process through the 1970s, see Castel, *supra*, note 821 at 397-99.

832. *1971 Proceedings of the Fifty-third Annual Meeting of the Conference of Commissioners on Uniformity of Legislation in Canada* (Jasper, Alta: The Conference, 1971) at 152 [hereinafter 1971 Uniform Act].

833. *Uniform Human Tissue Donation Act* (1989) (repealing and replacing 1971 Uniform Act, *supra*, note 832), Uniform Law Conference of Canada, *Consolidation of Uniform Acts* (Fredericton, N.B.: The Conference, 1990) at 22-1 [hereinafter 1989 Uniform Act] reprinted in appendix B, *infra* at 209-14. See also "Report of the Alberta Commissioners: Uniform Human Tissue Act" in Uniform Law Conference of Canada, *Proceedings of the Sixty-ninth Annual Meeting* (Victoria, B.C.: The Conference, 1987) at 199.

834. Compare 1989 Uniform Act, *supra*, note 833, ss 5-7, and 1971 Uniform Act, *supra*, note 832, ss 2-4. Notably, the 1989 Uniform Act eliminated the requirement of written consent.

835. Compare 1989 Uniform Act, *supra*, note 833, ss 1, 11 and 1971 Uniform Act, *supra*, note 832, s. 7.

836. Compare 1989 Uniform Act, *supra*, note 833, ss 3, 4 and 1971 Uniform Act, *supra*, note 832, ss 4, 5.

837. Compare 1989 Uniform Act, *supra*, note 833, s. 4(4) and 1971 Uniform Act, *supra*, note 832, s. 5.

838. Compare 1989 Uniform Act, *supra*, note 833, ss 15, 1 and 1971 Uniform Act, *supra*, note 832, ss 10, 1.

nine provinces and two territories that have based their tissue donation laws on the 1971 Act may be expected to study the 1989 Act for possible legislative amendment of their respective laws.[839]

In Quebec, the *Civil Code* establishes a process of tissue donation that is similar to that of the Uniform model, but with notable exceptions. Living donors may consent to donation and transplantation, if the risks assumed are not disproportionate to the expected benefits:[840] An individual may provide for the post-mortem disposition of his or her remains; in the absence of such instructions, the spouse or family of the deceased may consent.[841] The *Civil Code* provides a narrow exception to donor or familial consent, by authorizing physicians to procure organs or tissues from a recently deceased individual without consent in exigent circumstances:

> This consent is not necessary when two physicians attest in writing to the impossibility of obtaining it in due time, the urgency of the operation, and the serious hope of saving a human life.[842]

Finally, the *Code* requires that tissue transfers from living donors be done gratuitously, unless the tissue is regenerative.[843]

Taken together, the Quebec *Civil Code* and Uniform Acts represent the general model for the donation and procurement of human tissues and organs in Canada today. First, the model is generally premised on consent of the living donor or of the family of the

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839. See *Human Tissue Gift Act*, R.S.A. 1980, c. H-12; *Human Tissue Gift Act*, R.S.B.C. 1979, c. 187; *The Human Tissue Act*, S.M. 1987-88, c. 39 [hereinafter MHTA]; *Human Tissue Act*, R.S.N.B. 1973, c. H-12; *The Human Tissue Act, 1971*, S.N. 1971, No. 66; *Human Tissue Ordinance*, R.O.N.W.T. 1974, c. H-4; *Human Tissue Gift Act*, R.S.N.S. 1989, c. 215; *Human Tissue Gift Act*, R.S.O. 1980, c. 210; *Human Tissue Gift Act*, R.S.P.E.I. 1988, c. H-13; *The Human Tissue Gift Act*, R.S.S. 1978, c. H-15; *Human Tissue Gift Act*, R.S.Y.T. 1986, c. 89. See also "Report of the Alberta Commissioners", *supra*, note 833.

840. *C.C.L.C.*, art. 20.

841. *C.C.L.C.*, arts 21, 22. Art. 21 provides:

> A person of full age may, in writing, determine the nature of his funeral and the disposal of his remains. A minor capable of discernment may do likewise with the consent of his father or mother. The consent must be in writing; it may be revoked in the same way. In the absence of instructions by the deceased, usage is followed.

842. *C.C.L.C.*, art. 22:

> A physician may remove a part of the remains, if in the absence of instructions by the deceased, he obtains the consent of the consort or nearest relative of the deceased. This consent is not necessary when two physicians attest in writing to the impossibility of obtaining it in due time, the urgency of the operation, and the serious hope of saving a human life. The death of the donor must be ascertained by two physicians who do not participate in any way in the removal or in the transplantation.

843. *C.C.L.C.*, art. 20:

> 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. A minor capable of discernment may do likewise with the authorization of a judge of the Superior Court and with the consent of the person having parental authority, provided that no serious risk to his health results therefrom. *The alienation must be gratuitous unless its object is a part of the body susceptible of regeneration.* The consent must be in writing; it may be revoked in the same way (emphasis added).

Compare Bill 125, *supra*, notes 380, 473.

undeclared deceased potential donor. There are exceptions. The *Civil Code* provides for non-consensual organ procurement from a deceased donor in exigent circumstances. The anatomy Acts presume consent to the procurement of dead unclaimed bodies. The 1989 Uniform Act appears to have introduced a similar provision for tissue and organ procurement from unclaimed bodies.[844] Legislative provisions in the provinces of Alberta, Manitoba, Ontario, Prince Edward Island and Nova Scotia presume consent to the removal of pituitary glands in cases involving the medical examiner or coroner in which the examining physician or coroner has no notice of objection.[845] Saskatchewan, Prince Edward Island and Manitoba have similar provisions for corneal tissue.[846] While the existing provincial presumed-consent provisions are limited to particular tissues and circumstances, they may afford models for broader legislative reforms intent on increasing the general supply of scarce tissue and organs.[847]

Secondly, the general-consent model indicates that, thus far, Canadian society has struck a balance between the interests of donors, their families and potential recipients. The statutory provisions are largely consistent with the allocation of possessory interests, rights and duties under private law. As organ or tissue scarcity becomes more critical or prominent,[848] the life-saving potential likely from increased organ availability exerts pressure on the principles of autonomy, voluntarism, bodily integrity and respect of the dead — all of which underlie the existing tissue and organ procurement system. In the two decades since the formal introduction of the existing voluntarism model, advances in medical sciences have increased the demand for organs and tissues. Heart and liver transplants have now joined kidney and corneal transplants as effective therapies. Transplant waiting lists of over 2,500 people at the end of 1989 may seem indicative of a national scarcity. If such statistics are seen as reflecting the limits of the existing system, the societal interest in the preservation of life and health argues cogently for a reconsideration or potential reform of the system. From this perspective, calls for reform translate into an opportunity to reaffirm and modify or reallocate the principles, rights and values of the current system.

Thirdly, the current Canadian system of tissue and organ procurement is based largely on the gift ethic. Organ and tissue sales are generally prohibited in Canada. However, if pure altruism is responsible for some of the existing tissue scarcity, then non-altruistic

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844. See text accompanying note 837, *supra*. This provision parallels the presumed-consent provision for medical examiner cases recently introduced into the revised anatomical gift law in the U.S. See notes 1004 and 1007, *infra*.

845. See *Fatality Inquiries Act*, R.S.A. 1980, c. F-6, s. 27; MHTA, *supra*, note 839, s. 6.1; *Coroners Act*, R.S.O. 1980, c. 93, s. 29; *Human Tissue Gift Act*, S.P.E.I., 1980, c. 27; *Fatality Inquiries Act*, R.S.N.S. 1989, c. 164, s. 20. The development of rDNA human growth hormone would seem to call into question the continuing need for such provisions. See page 17, above.

846. See Saskatchewan, *The Coroners Amendment Act, 1984*, S.S. 1983-84, c. 32; MHTA, *supra*, note 839, s. 7(2); *Cornea Transplant Act*, R.S.P.E.I. 1974, c. C-22.

847. See Margaret A. Somerville, "'Procurement' vs. 'Donation' — Access to Tissues and Organs for Transplantation: Should 'Contracting Out' Legislation Be Adopted?" (1985) 17:6 (Supp. 4) Transplant. Proc. 53.

848. See chap. 1, above.

incentives, including cash or tax benefits, might boost supplies.[849] Any such reforms of the existing system, given the values and interests implicated, would seem to be of national importance.

The existing procurement system also suffers from some practical and legal ambiguities. If the family of a recently deceased, potential donor objects to a donation of the organs, even though the donor has signed his or her donor card, whose wishes are legally required to prevail?[850] Respect for the individual's autonomy may suggest that the deceased individual's wishes ought to prevail;[851] legislative clarifications directed at eliminating this uncertainty should provide both declared donors and transplant teams with greater assurance of the authority to act on the express consent of the donor.[852] Yet, even if the declared donor's wishes are legally entitled to prevail, will not or should not continued family objections dissuade the hospital from effecting those wishes? Hospitals that seek to avoid conflict in such scenarios may decline to act on the consent despite the legal authority to do so. As such, the law has its limits.

There are ambiguities, as well, in the area of tissue sales. Does the Quebec *Civil Code* sales provision, which requires that the alienation of regenerative tissue by living donors be gratuitous, affect or apply to the sale of organs procured from the dead? Are the nullity provisions of the *Civil Code* a sufficient deterrent against organ sales, as contrasted with the penal sanctions incurred for sales under the 1971 Uniform Act? Should advertising for the purchase or offer of organs be prohibited? Both the *Civil Code* and the 1971 Uniform Act are silent on the latter question.

What is the precise legal meaning of "sales" under the Uniform Act? For example, the 1989 Uniform Act proposes to prohibit and penalize, with a fine of $100,000 or one year's imprisonment or both, tissue sales:

> No person shall buy, sell or otherwise deal in, directly or indirectly, any tissue, body or body part for the purpose of a transplant or for a therapeutic purpose, medical education or scientific research.[853]

The 1989 Uniform Act deletes the former common law definition of sales — that is, exchanges "for valuable consideration." By providing no definition, the 1989 Act appears to leave the precise legal meaning of tissue sales to court interpretation. Manitoba and many foreign jurisdictions have diverged from this approach by specifically incorporating sales definitions into their reforms.

The 1989 Uniform Act does offer clarity on the scope of the sales prohibition. The redefinition of "tissue" helps remove ambiguity over whether semen and like human

849. See Roberts and Wolkoff, *supra*, note 492.

850. See Bill Trent, "An Old Woman, Prepared to Die: What Should the ER Doctors Do?" (1989) 141:5 C.M.A.J. 456.

851. See *supra*, notes 268, 325.

852. See 1989 Uniform Act, *supra*, note 833, s. 9.

853. *Ibid.*, s. 15(1).

reproductive substances are subject to the Act as "tissue."[854] By expressly excluding them, the 1989 Act invites legislators either to address directly human reproductive tissue sales or to allow common law principles to govern.[855] The new definition of "tissue" would also appear to remove ambiguities over whether the Act prohibits regenerative tissue sales,[856] because the 1989 Uniform Act prohibits all tissue or bodily parts sales, save blood, gametes or human concepti.[857]

Even these clarifications, however, may not prevent modern developments from provoking questions on the meaning and scope of the tissue sales prohibition. That a jurisdiction in the United States has opted to exempt cell lines from its prohibition raises a parallel query — whether the Uniform Act tissues sales ban is intended to apply to cellular or sub-cellular entities.[858] Moreover, since both the 1971 and the 1989 Uniform Acts prohibit sales only for "therapeutic purposes, medical education or scientific research," do they proscribe sales for more strictly commercial purposes such as cosmetics?[859] Some jurisdictions have adopted broader language by prohibiting tissue sales "for any purposes."[860]

(4) Provincial Tissue Law Reform

Recent legislative initiatives have been undertaken to address some of these questions and shortcomings. Beyond the 1989 revision to the Uniform Act,[861] reforms have been undertaken by such jurisdictions as Ontario, Manitoba and Quebec.[861a] Ontario and Manitoba, for example, have pursued legislative and regulatory initiatives that parallel organ donation law reform in the United States. In 1990, Ontario began requiring hospitals to adopt "procedures to encourage the donation of organs and tissues," including

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854. See 1971 Uniform Act, *supra*, note 832, s. 1.

855. See 1989 Uniform Act, *supra*, note 833, s. 1.

856. Relevant provisions of the 1971 Uniform Act sales prohibition are excerpted in appendix B, *infra* at 207. Under one view, the s. 10 sales prohibition applies only to non-regenerative tissue, because the s. 1 definition of "tissue" includes organs but excludes "tissue that is replaceable by natural processes of repair." As such, one may argue that skin, bone marrow, bone and like regenerative tissues are not covered by the prohibition. Under another view, the specific language of s. 10 controls, to prohibit both regenerative and non-regenerative tissue. Arguably, the language "any tissue for a transplant" refers to both regenerative and non-regenerative tissues, and is not qualified by the definition of tissue. Had the intention been to exclude all regenerative tissue, the provision would not explicitly and redundantly exclude blood. The exclusion phrase "other than blood or a blood constituent" may be seen to rely on language and structure apparently indicative of broad intent. 1971 Uniform Act, *supra*, note 832.

857. 1989 Uniform Act, *supra*, note 833, ss 1, 15.

858. Compare Minn. Stat. Ann. s. 145.422 (West 1988 Supp.) and 1989 Uniform Act, *supra*, note 833, ss 15, 1.

859. See 1971 Uniform Act, *supra*, note 832, s. 10; 1989 Uniform Act, *supra*, note 833, s. 12; and Dickens, *supra*, note 414 at 166.

860. See discussion of Manitoba law reforms, section III.B(4), below.

861. See 1989 Uniform Act, *supra*, note 833.

861a. Nova Scotia amended its *Human Tissue Gift Act* while this document was in preparation for publication. See S.N.S. 1991, c. 13.

(1) hospital protocols "to identify potential donors," and (2) protocols "to make potential donors and their families aware of the options of organ and tissue donations."[862]

In 1987, Manitoba amended its *The Human Tissue Act*, following a report by the Manitoba Law Reform Commission.[863] A key recommendation of the Commission concerns adoption of the encouraged-voluntarism principle and rejection of organ sales. Basing its recommendation on evidence that 72 per cent of all relatives of deceased potential donors agree to donate when approached, the Commission recommended that hospitals consider adopting procedures to ensure that those relatives are routinely sought out and given an opportunity to donate.[864] The Commission recommended this approach, in part, because such a practice appeared less likely to violate the emotional and religious interests of the potential donor's family than, for example, a presumed-consent model.[865]

Secondly, reaffirming the prohibition on the sale of human bodies and tissues, the Manitoba Law Reform Commission recommended that the definition of "sales" recognize the distinction between prohibiting the exchange of human tissue and prohibiting the payment of reasonable associated expenses.[866] Indeed, even if society deems profiting from the exchange of human bodily parts and substances abhorrent, a flat prohibition on "exchanges for valuable consideration" risks undermining organ donations that involve numerous associated expenses for travel, procurement and preservation.[867] A definition of "sales" that distinguishes between "valuable consideration" and reasonable acceptable expenses may have a less chilling effect on transfers that involve associated expenses. The legislation, adopted on the basis of the report, therefore, excludes from the definition of "selling or buying" payments of reasonable associated expenses.[868] The legislation prohibits tissue sales "for any purposes."[869]

Amendments to some of the organ transplant provisions of the *Civil Code* of Quebec have been proposed.[870]

IV. Constitutional Human Rights Law

The coming into force, in 1982, of the *Canadian Charter of Rights and Freedoms*[871]

862. Regulation to amend Ontario Regulation 518/88 made under the *Public Hospitals Act*, O. Reg. 34/90.

863. See MHTA, *supra*, note 839. See also MLRC, *supra*, note 491.

864. See MLRC, *supra*, note 491 at 28, 54-57.

865. See *ibid.* at 35, discussing constitutional challenges of presumed-consent legislation.

866. See MLRC, *supra*, note 491 at 111-12.

867. See section I.C, "Bodily Sales," above.

868. MHTA, *supra*, note 839, s. 15(2), (3), (4).

869. *Ibid.*, s. 15(2).

870. See Bill 125, *supra*, note 380.

871. Part I of the *Constitution Act, 1982*, being Schedule B of the *Canada Act 1982* (U.K.), 1982, c. 11 [hereinafter *Charter*].

obliges government-related tissue procurement initiatives to meet a new requirement: they must be consistent with constitutionally protected human rights and fundamental freedoms.

Of course, the novelty of the *Charter* means that its influence on many aspects of Canadian society is just beginning to be appreciated. Tissue transfer law and policy issues are no exception. They provoke challenging human rights questions. Does liberty or privacy encompass a constitutionally protected right of the next of kin to be free from state-occasioned mutilation of the body of a deceased relative?[872] Does liberty include a constitutional right to sell bodily substances?[873] Does a prohibition on advertising related to organ sales infringe rights of free speech?[874] Does the body of a recently deceased person, who may be a potential donor, enjoy *Charter* protections? Or, do constitutional rights end upon death?

Settled answers to many such questions must await the developing *Charter* jurisprudence. While some recent cases have implicated tissue replacement technologies,[875] none has directly presented the constitutional aspects of organ transplantation in Canada. Nor do any cases appear to have done so under analogous provisions of the European *Convention for the Protection of Human Rights and Fundamental Freedoms*.[876] Nevertheless, some of the basic *Charter* principles may be explored to understand their relevance to tissue procurement and transfer laws. Moreover, initiatives to deal with tissue and organ scarcity in the United States have provoked a number of cases in recent years involving presumed-consent statutes. By drawing on such cases, the *Charter* principles may be given a context. Not surprisingly, the analysis reveals recurrent tension between the principles of religious freedom, privacy, bodily integrity and fair treatment of the individual, on the one hand, and the governmental or societal interests in preserving life and protecting the public health, on the other.

A. Government Initiatives

The *Charter* generally applies to government action[877] — that is, it binds both federal and provincial legislative, executive and administrative activities.[878] Thus, organ donation

872. See *Arnaud* v. *Odom*, 870 F. 2d 304 (5th Cir. 1989) (medical examiner's unauthorized head-drop experiments on infant bodies do not violate constitutional interests of parents). Compare *Kirker*, *supra*, note 403.

873. See Karen L. Johnson, "The Sale of Human Organs: Implicating a Privacy Right" (1987) 21 Val. U.L. Rev. 741. In this respect, it should be noted that some jurisdictions would limit applicable sales prohibitions to post-mortem sales. See, *e.g.*, UAGA, *infra*, note 1004, s. 10.

874. See *Rocket* v. *Royal College of Dental Surgeons of Ontario*, [1990] 2 S.C.R. 232.

875. See, *e.g.*, *Dyment*, *supra*, note 424 and *Re L.D.K.* v. *Children's Aid Society of Metropolitan Toronto*, *infra*, note 883.

876. For a discussion of the European Convention, see *infra*, note 964.

877. *Charter* s. 32(1) provides that:

> 32. (1) This Charter applies
>
> (*a*) to the Parliament and government of Canada in respect of all matters within the authority of Parliament including all matters relating to the Yukon Territory and Northwest Territories; and
>
> (*b*) to the legislature and government of each province in respect of all matters within the authority of the legislature of each province.

878. See *RWDSU* v. *Dolphin Delivery Ltd.*, [1986] 2 S.C.R. 573.

legislation must conform to the *Charter*, as must the tissue-procurement activities of provincial coroners and medical examiners. While a recent Supreme Court decision indicates that the internal policies of Canadian hospitals may generally not be subject to the *Charter*, hospital practices must nonetheless conform to provincial human rights law.[879] As such, hospital organ-procurement policies and initiatives are still required to meet the basic commands of human rights.

B. Bodily Integrity and Privacy

The *Charter* protects bodily integrity and privacy through its protections of "life, liberty and security of the person,"[880] and its prohibition against "unreasonable search or seizure"[881] and "cruel and unusual treatment."[882] For example, the non-consensual administration of a blood transfusion has been deemed violative of a twelve-year-old child's bodily integrity and the security of his person.[883] In the criminal law context, the Supreme Court of Canada has applied the search and seizure provision of the *Charter*, and found that the non-consensual taking of a blood sample from an unconscious patient violated personal privacy and human dignity.[884] The court has construed the right to security of the person to include protection of one's physical and mental integrity.[885] Other Canadian courts have declared that for the state to incarcerate an individual, and then deny him or her meaningful access to essential health services, constitutes cruel and unusual treatment or contravenes the fundamental right to security of the person.[886] These principles may encompass medically necessary tissue replacement technology.[887]

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879. See *Stoffman* v. *Vancouver General Hospital*, [1990] 3 S.C.R. 483 at 533-48. See also *Peters* v. *University Hospital Board*, [1983] 5 W.W.R. 193 (Sask. C.A.) and *Human Rights Code, 1981*, S.O. 1981, c. 53, s. 1.

880. *Charter*, s. 7.

881. *Ibid.*, ss 8, 24(2).

882. *Ibid.* s. 12.

883. *Re L.D.K.* v. *Children's Aid Society of Metropolitan Toronto* (1986), 48 R.F.L. (2d) 164 (Ont. Fam. Ct).

884. See *Dyment*, *supra*, note 424 and accompanying text.

885. See *R.* v. *Morgentaler*, [1988] 1 S.C.R. 30 at 53.

886. See *R.* v. *Downey* (1990), 42 C.R.R. 286 (Ont. Dist. Ct) (holding deprivation of essential medical treatment from a prisoner with AIDS to be cruel and unusual treatment); *McNamara* v. *Caros*, [1978] 1 F.C. 451 (T.D.); *Collin* v. *Lussier*, [1983] 1 F.C. 218 at 237 (T.D.) (prisoner's right to security of person includes protection of bodily integrity and right to medical care and other necessities of life), partially rev'd on other grounds [1985] 1 F.C. 124 (A.D.). Federal prisoners also have a statutory right to "essential medical ... care." See *Penitentiary Services Regulations*, *supra*, note 793, s. 16. The U.S. constitutional analogue of security of the person, the due process clause, entitles pre-trial unconvicted detainees to necessary medical care. See *City of Revere* v. *Massachusetts General Hospital*, 463 U.S. 239 (1983). See also *Thompson* v. *City of Portland*, 620 F. Supp. 482 (D.C. Me. 1985). For convicted, incarcerated individuals in the U.S., "deliberate indifference to a prisoner's serious medical needs" constitutes "cruel and unusual punishment." *Estelle* v. *Gamble*, 429 U.S. 97 at 103-104 (1976) ("An inmate must rely on prison authorities to treat his medical needs; if the authorities fail to do so, those needs will not be met. In the worst cases, such a failure may actually produce physical 'torture or a lingering death,'... In less serious cases, denial of medical care may result in pain and suffering which no one suggests would serve any penological purpose. ... The infliction of such unnecessary suffering is inconsistent with contemporary standards of decency"). For general commentary on prisoners' *Charter* rights see A. Wayne MacKay, "Inmates' Rights: Lost in the Maze of Prison Bureaucracy?" (1987-88) 11 Dalhousie L.J. 698.

887. *Thompson* v. *City of Portland*, *supra*, note 886 (failure to provide necessary medical care to former transplant recipient in police custody contravenes the constitutional protection of due process).

As such, the right to security of the person applies to and protects living donors and potential recipients. Some commentators query whether it also applies to deceased donors — that is, whether the non-consensual taking of organs from a cadaver violates security of the person.[888] The concern may have particular force in considerations over the exemption of minors or mentally disabled persons from post-mortem presumed-consent laws. Such laws generally permit individuals to rebut the presumption of consent, by registering an objection. However, applying those laws to persons incapable of meaningfully registering their intentions might deny them an equal opportunity to protect the bodily integrity or security of their persons after death.[889]

Assuming that the right to security of the person applies to both living and deceased donors, where a governmental law or policy infringes that right, the infringement still may or may not be constitutionally permissible. For while the right to bodily integrity ranks high on the scale of societal values,[890] it is not absolute. It may be abridged if this is done in accordance with principles of fundamental justice, or if the right is reasonably limited by a law "demonstrably justified" by the needs of a "free and democratic society."[891] The balancing of human rights and basic democratic needs, under the Supreme Court of Canada jurisprudence, requires the government to show (1) an important legislative purpose that bears on a "pressing and substantial concern," and (2) proportionality — the means chosen to advance the government objective must relate rationally to the purpose, impair the right in question as little as possible and show proportionality between the government objective and the actual effects of the means chosen to advance that objective.[892] Those requirements are designed to give constitutional rights breathing space even when they are infringed, by stipulating that infringements be done with alternatives that are least restrictive of fundamental freedoms.[893]

Analogous principles have guided courts in the United States in examining whether presumed-consent practices and legislation violate human rights. In the few cases that have directly presented the question, the courts have upheld the constitutionality of the practice or law. Some courts have differed over whether the underlying right in question — for example, interference with the next of kin's right of possession for burial purposes — arises to a constitutional dimension.[894] Other courts have emphasized that narrowly drawn

888. See Picard, *supra*, note 364 at 132 n. 649.

889. For a discussion of the French exclusion and Belgian inclusion of minors from presumed-consent law, see text accompanying notes 961-962, *infra*.

890. See *Eve*, *supra*, note 362.

891. See *Charter*, ss 7, 1.

892. *R.* v. *Oakes*, [1986] 1 S.C.R. 103 at 138-39. See generally Peter W. Hogg, "Section 1 Revisited" (1990) 1 Nat'l J. Const. L. 1.

893. See Peter W. Hogg, *Constitutional Law of Canada*, 2d ed. (Toronto: Carswell, 1985) at 686-87. Laurence H. Tribe, *American Constitutional Law*, 2d ed. (Mineola, N.Y.: Foundation, 1988) at 1032, 1256, 1377.

894. See *Brotherton* v. *Cleveland*, 923 F. 2d 477 (6th Cir. 1991); *Georgia Lions Eye Bank* v. *Lavant*, 335 S.E. 2d 127 (Ga. 1985), cert. denied 475 U.S. 1084 (1986); *Tillman* v. *Detroit Receiving Hospital*, 360 N.W. 2d 275 (Mich. App. 1984). Compare, Erik S. Jaffe, "She's Got Bette Davis['s] Eyes: Assessing the Nonconsensual Removal of Cadaver Organs under the Takings and Due Process Clauses" (1990) 90 Colum. L. Rev. 528 and Donald R. McNeil, "The Constitutionality of 'Presumed Consent' for Organ Donation" (1989) 9 Hamline J. Pub. L. & Pol'y 343.

legislation reasonably advances the state interests in the promotion of health and preservation of life:

> Our review of section 732.9185 reveals certain safeguards which are apparently designed to limit cornea removal to instances in which the public's interest is greatest and the impact on the next of kin the least: corneas may be removed only if the decedent is under the jurisdiction of the medical examiner. . . .
>
> In conclusion, we hold that section 732.9185 is constitutional because it rationally promotes the permissible state objective of restoring sight to the blind. In so holding, we note that laws regarding the removal of human tissues for transplantation implicate moral, ethical, theological, philosophical, and economic concerns which do not readily lend themselves to analysis within a traditional legal framework.[895]

C. Freedom of Conscience and Religion

Adopting narrow, proportionate means to advance legitimate government and societal interests may prove equally important in governmental tissue procurement and transfer initiatives that burden religious beliefs. The *Charter*[896] protects the exercise of religion as a fundamental freedom:

> Freedom must surely be founded in respect for the inherent dignity and the inviolable rights of the human person. The essence of the concept of freedom of religion is the right to entertain such religious beliefs as a person chooses, the right to declare religious beliefs openly and without fear of hindrance or reprisal, and the right to manifest religious belief by worship and practice or by teaching and dissemination.[897]

Thus, the compelled transfusion of blood into Jehovah's Witnesses, whose religious dictates do not permit them to receive transfusions, may burden their religious beliefs.[898] Orthodox Judaism forbids post-mortem dissection and like invasions of the body.[899] The tenets of other believers, for example, adherents to some Far Eastern religions, strictly forbid any mutilation of the body after death, including organ procurement or autopsy.[900]

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895. *State* v. *Powell*, 497 So. 2d 1188 at 1191, 1193-94 (Fla. 1986), cert. denied 481 U.S. 1059 (1987).

896. Section 2(*a*).

897. *R.* v. *Big M Drug Mart Ltd.*, [1985] 1 S.C.R. 295 at 336.

898. See *L.D.K.*, *supra*, note 883. See also *Malette*, *supra*, note 363. For a recent U.S. case, see *Public Health Trust of Dade County* v. *Wons*, 541 So. 2d 96 at 102 (Fla. 1989) ("Mrs. Wons did not, and does not, wish to die should her condition recur. However, because of her strong religious beliefs, she has chosen to face death rather than to accept a blood transfusion. . . . As a parent, however, she also must consider the example she sets for her children, how to teach them to follow what she believes is God's law if she herself does not. The choice for her cannot be an easy one, but it is hers to make. It is not for this Court to judge the reasonableness or validity of her beliefs. Absent a truly compelling state interest to the contrary, the law must protect her right to make that choice.").

899. *Atkins* v. *Medical Examiner*, 418 N.Y.S. 2d 839 (1979); *Kohn*, *supra*, note 404. See also D.W. Weiss, "Organ Transplantation, Medical Ethics, and Jewish Law" (1988) 20:1 (Supp. 1) Transplant. Proc. 1071.

900. See *You Vang Yang* v. *Sturner*, 728 F. Supp. 845 at 846 (D.R.I. 1990) (autopsy law and Hmong religious practices) withdrawn, 750 F. Supp. 558.

Still others' religions, such as those of some native peoples, orthodox Islam and Shintoism, may proscribe either post-mortem organ procurement or the receipt of cadaveric tissue.[901]

These views of conscience and religion may well be held by the minority in Canadian society. Should the numbers matter, and disentitle minority adherents of conscience from a right to exercise their beliefs on the integrity of the dead human body as a necessity for ensuring passage to an afterlife?[902] To the contrary, part of the purpose of the *Charter* guarantee is to entitle all individuals — be they in the minority or in the majority — to freedom of conscience and religion.[903] Indeed, to protect against coercion and to provide meaningful equality of religious autonomy, more protection may be warranted for those holding unfamiliar, non-majoritarian religious views.[904] Such concerns appear to have prompted the Alberta Office of the Chief Medical Examiner to exclude Hindus, Christian Scientists, orthodox Jews, Moslems, native Canadian Indians, Metis and Inuit peoples from its five-year-old practice of routinely consulting the families of deceased individuals, under its jurisdiction, to inquire whether they wish to donate tissue.[905] The exemption would seem responsive to *Charter* duties to accommodate and to minimize the impairment of the free exercise of religion.[906]

This is not to say that religious freedom in a pluralistic, democratic society is absolute and cannot be restricted:

> Freedom in a broad sense embraces both the absence of coercion and constraint, and the right to manifest beliefs and practices. Freedom means that, subject to such limitations as are necessary to protect public safety, order, health, or morals or the fundamental rights and freedoms of others, no one is to be forced to act in any way contrary to his beliefs or conscience.[907]

Thus, a compelling societal interest in determining the cause of unusual deaths, for the administration of criminal justice or to safeguard public health, may justify the performance of a forensic autopsy, despite the religious beliefs of the decedent or surviving family.[908] State interests in the preservation of life and protection of health, particularly

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901. See *Begay* v. *State*, 723 P. 2d 252 (N.M. App. 1985) (autopsy law violates native American religious beliefs). Orthodox Muslims construe the Koran, traditionally regarded as the literal word of God and a major source of Islamic law, as proscribing the procurement or receipt of cadaveric organs. See Iyer, *supra*, note 319; Claude Jacquinot, "Sur les Prélèvements d'organes" Gaz. Pal. 1979. 1er. sem. Doctr. 57.

902. See John Dwight Ingram, "State Interference with Religiously Motivated Decisions on Medical Treatment" (1988) 93 Dick. L. Rev. 41 at 65 ("The very essence of most religious beliefs is the relationship of a person to a supreme being and the determination of the relative value of one's physical life on earth and a potential spiritual life hereafter").

903. *Big M Drug Mart Ltd.*, *supra*, note 897 at 337.

904. See *ibid.* See also Note, "Burdens on the Free Exercise of Religion: A Subjective Alternative" (1988-89) 102 Harv. L. Rev. 1258 at 1277.

905. See Alberta Attorney General, Office of the Chief Medical Examiner, *Protocol for Making Request for Donation of Tissue* (April 1987).

906. See *Oakes*, *supra*, note 892 at 136 and Hogg, *supra*, note 893 at 712.

907. *R.* v. *Edwards Books and Art Ltd.*, [1986] 2 S.C.R. 713 at 758, citing *Big M Drug Mart Ltd.*, *supra*, note 897.

908. See *Snyder* v. *Holy Cross Hospital*, 352 A. 2d 334 (Md. App. 1976). But see *Atkins*, *supra*, note 899 and *You Vang Yang*, *supra*, note 900. Following *Snyder*, relevant Maryland law was amended to be more accommodating of religious objections. See William J. Curran, "Religious Objection to a Medicolegal Autopsy: Case and a Statute" (1977) 297:5 N. Engl. J. Med. 260. Compare *Époux Canara*, *infra*, note 950.

of those who cannot protect themselves, have motivated the prosecution and conviction of Christian Scientists for failing to provide dependent minors with customary, life-saving medical treatment.[909] These interests have also persuaded courts to uphold the authority of the state to administer life-saving blood transfusions to infants, over parental religious objections.[910]

In essence, then, the *Charter* seeks to strike a dynamic balance to give effect to the principle of religious freedom. When societal interests of paramount importance are at issue that cannot be advanced by other viable alternatives, the government-chosen objective and means may necessitate infringing or overriding individual religious practices. Otherwise, the societal valuing of religious freedom as a fundamental human right bespeaks a duty to accommodate individual beliefs and acts of conscience. A particular instance of societal balancing may depend, delicately, on the degree and effects of religious infringement, and on the strength of the government objective, means of achieving its objectives and its accommodation of the religious beliefs. Hence, in the United States constitutional transplant and autopsy jurisprudence, the degree to which state legislation burdens and accommodates the exercise of religion has proved important. When a woman contended that her religious beliefs were violated by a medical examiner's retention of her husband's organs following an autopsy, the court upheld the law by finding it accommodated religious beliefs in providing the family with an opportunity to object in advance to any such retention.[911] More recently, a court initially found that state autopsy law violated religious beliefs, in part, because it failed to adopt less burdensome alternatives for achieving the government goal.[912]

D. Non-discrimination and Equality

The constitutional requirement of equality protects against government discrimination by mandating the equal benefits and burdens of the law:

> Every individual is equal before and under the law and has the right to the equal protection and equal benefit of the law without discrimination and, in particular, without discrimination based on race, national or ethnic origin, colour, religion, sex, age or mental or physical disability.[913]

A complainant alleging discrimination must show unequal treatment, or the effects and discriminatory impact of a government initiative, based on one of the above-enumerated

909. See *R.* v. *Lewis* (1903), 7 C.C.C. 261 (Ont. C.A.) (affirming manslaughter conviction for Christian Scientist's failure to provide medical necessities for son who died of diphtheria). See also *Tutton*, *supra*, note 529.

910. *Re McTavish and Director, Child Welfare Act* (1986), 32 D.L.R. (4th) 394 (Alta Q.B.). But see *B.(R.)* v. *Children's Aid Society of Metropolitan Toronto* (1988), 47 D.L.R. (4th) 388 (Ont. C.A.).

911. *Fuller* v. *Marx*, 724 F. 2d 717 (8th Cir. 1984).

912. *You Vang Yang*, *supra*, note 900 at 857.

913. *Charter*, s. 15.

grounds or on one analogous thereto.[914] The Supreme Court of Canada has indicated a willingness to construe the constitutional requirement of equality broadly.[915]

The requirement imposes on government a duty to act impartially and to avoid arbitrary and unreasonable classifications of or actions against individuals. Government decisions to fund or not fund a particular transplant procedure might discriminate, if they are sufficiently arbitrary and irrational as to deny equal protection of the law.[916] If hospitals are subject to the *Charter* or statutory human rights protections, then criteria for organ transplant waiting lists must comport with basic human rights principles.[917] Thus, criteria that give priority on a basis such as ethnic or national origin, or ambiguous "medical" criteria that effectively exclude particular classes of disabled transplant recipients, must offer cogent reasoning to withstand legal scrutiny.[918] Similar equality concerns may apply to initiatives to apply a different criterion of death for anencephalic infants, to the extent that it unreasonably and disproportionately discriminates against them on the basis of physical disability. If the government interest in the preservation of life might be advanced by organ procurement initiatives less burdensome of the right to life or security of the person, the *Charter* may well require such alternatives.

Indeed, that approach should, perhaps, inform all governmental tissue transfer and procurement initiatives, including law reform options and recommendations. For if one such initiative challenges the human right to equality, and another challenges the freedom of religion or security of the person, the *Charter* would seem to oblige all to respect at least one human rights lesson: If, in the choice between competing law reform options, one emerges that is (1) least burdensome of fundamental human rights, (2) likely to prove relatively more accommodating of those rights, and (3) depends on rational, narrowly tailored means that substantially advance a pressing and substantial government objective, then that option would seem constitutionally preferred.

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914. See *Andrews* v. *Law Society of British Columbia*, [1989] 1 S.C.R. 143 at 182. See also *R.* v. *Turpin*, [1989] 1 S.C.R. 1296 at 1330-35.

915. *Ibid.*

916. See *Brillo* v. *Schaller* (13 June 1986), Arizona 233587 (Sup. Ct) (ordering state funding of adult liver transplant after holding denial thereof to be irrational and violative of equal protection). This argument was also advanced in litigation that helped persuade the state of Vermont to amend its policy of non-funding of adult liver transplants. The intended transplant recipient in the case died before she could avail herself of the funding change. See *Schmokel* v. *Secretary of State* (6 December 1988), Washington S-578-88 (Sup. Ct). See also Sally Johnson, "Vermont Case May Upset Transplant Policy" *New York Times* (15 January 1989) 34.

917. For example, transplant waiting list procedures that seem not to discriminate on the enumerated or analogous grounds of s. 15, arguably may abridge s. 7 protection of life and security of person, by denying an equal opportunity to life in a manner inconsistent with principles of fundamental justice. Compare *Stoffman*, *supra*, note 879 and *Turpin*, *supra*, note 914 at 1334-35. See also text accompanying notes 221-224, *supra*.

918. See *Brillo*, *supra*, note 916 and Note, "Patient Selection for Artificial and Transplanted Organs" (1969) 82 Harv. L. Rev. 1322 at 1338. Compare *supra*, note 221, and *infra*, note 1001.

CHAPTER FOUR

Comparative and International Law Perspectives

To the extent that reforms to tissue transfer laws in Canada may be in order, the leading approaches and recommendations of foreign jurisdictions might provide models for, or at least inform, Canadian legislative initiatives. A survey of the pronouncements of Australia, Great Britain, France, Belgium, the Council of Europe and the United States on organ procurement from deceased, potential donors generally reveals variations of the express-consent, presumed-consent and required-request models. All of the surveyed jurisdictions have struggled with defining the precise legal role that surviving family members should play in the donation process. In some, legal disputes have arisen over safety concerns and over issues involving deposited tissue and ownership. All jurisdictions have also devoted particular attention to regulating payments associated with tissue transfers and to prohibiting organ sales. In a broader sense, these national approaches to tissue procurement, safety and sales help sketch evolving legal controls over tissue transfers between nations in the international community.

I. Great Britain: Express Consent — Opting In

For over a century, the anatomy, cornea and gift tissue laws of Great Britain have exerted enormous influence on the anatomy and tissue transfer laws of Canada.[919] In Great Britain, gift tissue legislation requires evidence of either consent from the potential donor before death or the post-mortem consent of the family for the removal of organs from cadavers.[920] This express-consent approach to procuring cadaver organs has been described as "opting in."[921] In the absence of evidence that the deceased or the deceased's family has expressly consented, society does not authorize the procurement of tissues or organs from the dead body. While this approach seems consistent with common and civil law traditions respecting dead bodies,[922] it may be criticized for failing to take into account the need for advancing life-preservation principles through the law: without express consent, organs that might have been used for transplantation perish.

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919. See pages 127-35, above.

920. *Human Tissue Act, 1961*, *supra*, note 829.

921. See Somerville, *supra*, note 847.

922. See pages 66-69, above.

Indeed, in recent years, national and international organ scarcity has exerted pressure on the existing British organ donation system, prompting law reform initiatives. Some 3,500 individuals were on kidney transplant waiting lists for 1988.[923] Underlying reasons for this scarcity in Great Britain parallel those identified in North America. Studies suggest that potential donors do not become actual donors in Great Britain owing to the failure to diagnose brain death, the failure of professionals to request donation and the failure of potential donors or their families to consent to donation.[924] For such reasons, the British Department of Health has recently required hospital authorities to adopt written procedures for identifying potential donors, diagnosing brain death and facilitating the consent process for organ donation with relatives.[925] The British are also considering the merits of increased professional training and a general statutory requirement that medical professionals sensitively approach the families of recently deceased undeclared potential donors in order to provide them with an opportunity to donate on behalf of the deceased.[926] Similar required-opportunity and required-request approaches to undeclared donor circumstances have been adopted in other traditionally express-consent jurisdictions such as Canada and the United States.[927]

Recent reports about the involvement of British doctors in international organ sales have fuelled the debate over options for increasing organ donation. While the sale of human bodies for anatomical purposes was established as a criminal misdemeanour in the eighteenth century, nineteenth- and twentieth-century British transplant laws created regulatory tissue transfer regimes that were silent on penal sanctions for organ sales.[928] The silence was broken in 1989. Allegations that impoverished Turks received £2,000 to £3,000 for "donating" a kidney to needy Turkish recipients in London[929] prompted the British Parliament to enact an organ sales prohibition.[930] The *Human Organ Transplants Act 1989* provides for a maximum £2,000 fine or three months' imprisonment or both for the offer, solicitation, purchase or sale of an organ. The Act does not preclude payment for the cost of removing, transporting or preserving organs or for expenses or lost earnings reasonably and directly incurred by the organ donor.[931] As such, it parallels the recently enacted

923. John Warden, "Kidneys Not for Sale" (1989) 298:6689 Br. Med. J. 1670.

924. Sheila M. Gore, Charles J. Hinds and Annabel J. Rutherford, "Organ Donation from Intensive Care Units in England" (1989) 299:6709 Br. Med. J. 1193. But see A. Bodenham, J.C. Berrialge and G.R. Park, "Brain Stem Death and Organ Donation" (1989) 299:6706 Br. Med. J. 1009. See also Pamela E. Buckley, "The Delicate Question of the Donor Family" (1989) 21:1 Transplant. Proc. 1411.

925. Department of Health, HC (88)63 (Provision of Donor Organs for Transplantation). See also (February 89) 47 I.M.E. Bull. 6.

926. J. Wallwork, "Organs for Transplantation" (1989) 299:6711 Br. Med. J. 1291.

927. See chap. 3 above.

928. See *ibid.*, page 109 and notes 808, 818, 829, *supra.*

929. See Brahams, *supra*, note 477; Richard Beeston, "Mother Tells of Selling Kidney" *The* [*London*] *Times* (26 January 1989) 1. Turkish law penalizes the sale of organs. See "Law No. 2238 of 29 May 1979 on the Removal, Storage, Transfer and Grafting of Organs and Tissues" *T.C. Resmî Gazete*, No. 16655 (3 June 1979), reprinted in (1980) 31:4 Int'l Dig. Health Leg. 866.

930. *Human Organ Transplants Act 1989*, *supra*, note 526.

931. *Ibid.*

tissue sales prohibition in Manitoba.[932] It also severely restricts transplants between non-genetically related individuals, on the theory that the motivation for such transplants ought to be subject to close scrutiny. The Act also prohibits advertising related to organ sales — an approach that has not been pursued in Canada to date.[933]

II. France, Belgium and the Council of Europe: Presumed Consent — Opting Out

The procurement and transplant laws of France and Belgium at once parallel and differ from those of Great Britain. All three prohibit organ sales. Indeed, in approaches that parallel both the British law and French regulations requiring human milk and blood banks to operate on a non-profit basis,[934] the French and Belgian transplant laws prohibit payments beyond reimbursement for costs.[935] Yet Belgium, France and many civil law nations[936] have not followed the express-consent approach of Great Britain to post-mortem organ procurement. The fifteen-year-old French and four-year-old Belgian laws have adopted, and thus provide insight into, the presumed-consent approach. Related French initiatives also reflect societal efforts to clarify and understand the moral and legal status of the human body today.

A. France

The French have relied on presumed consent for cadaver organ procurement since 1976. The law authorizes the post-mortem retention of one's organs or tissues for therapeutic and scientific uses unless, prior to death, one objects to such use.[937] Thus, when identifying a potential donor, a physician is required to check the hospital registry to confirm an absence of objection.[938]

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932. See MHTA, *supra*, note 839, s. 15.

933. See pages 127-36, above.

934. For French milk bank regulations, see *Loi n° 89-899 du 18 décembre 1989*, J.C.P. 1990.III.15736, and *Arrêté du 15 juillet 1987*, J.O., 4 August 1987, 8769. For French blood bank regulations, see *Codes de la santé publique, de la famille et de l'aide sociale*, 8th ed. (Paris: Dalloz, 1989) ss L-673 and L-674.

935. Compare s. 3 of *Loi n° 76-1181 du 22 décembre 1976*, J.O., 23 December 1976, 7365, reprinted in (1977) 28:2 Int'l Dig. Health Leg. 271, and *Law of 13 June 1986 on the removal and transplantation of organs* (Belgium), s. 4, reproduced in (1987) 38:3 Int'l Dig. Health Leg. 523 [hereinafter *Law of 13 June 1986*].

936. See Somerville, *supra*, note 847 at 58. See generally A. Cantaluppi, A. Scalamogna and C. Ponticelli, "Legal Aspects of Organ Procurement in Different Countries" (1984) 16:1 Transplant. Proc. 102.

937. *Loi n° 76-1181*, *supra*, note 935, s. 1.

938. See *Décret n° 78-501 du 31 mars 1978*, J.O., 4 April 1978, 1497, s. 10, as amended by *Décret n° 90-844 du 24 septembre 1990*, J.O., 25 September 1990, 11606. See also *Circulaire du 3 avril 1978*, J.O., 5 April 1978, 1530.

After more than a decade of experience, the presumed-consent approach in France appears to have had little positive impact on organ scarcity:[939]

> [T]he results of the presumed consent system in France have proven disappointing. Although the supply of organs has increased somewhat, it has been greatly exceeded by the growth of demand. In 1984 there were nearly a thousand kidney transplants performed in France, but almost three thousand people remained on the waiting list.[940]

The results may flow from certain internal tensions in the theory of presumed consent. They may also flow from difficulties in applying the presumed-consent theories to the realities of clinical practice.

Presumed-consent theory maintains that society may reasonably presume — on the basis of life-saving necessity and community altruism — that one consents to post-mortem donation, unless one objects while alive. Silence equals consent. This approach is thought to advance the life-saving interests of needy transplant recipients and to avoid tormenting the families of the recently deceased with potentially insensitive organ donation requests that may exacerbate grief.[941] The presumption of consent is not absolute, however. It may be rebutted by evidence of non-consent. Proof of one's intentions might come in the form of a formal written declaration, informal correspondence, a pattern of conduct or testimony on one's oral statements. As such, the practical question becomes, How is evidence of non-consent to be generally manifested and collected? If a registry, such as those in France, becomes the principal means of revealing the deceased's intentions, should it be the only means?

Societies that strictly limit evidence to that contained in registries likely advance procurement efficiency, by limiting the sources that medical professionals need consult before procurement. Such an approach may sometimes, however, exclude evidence that is more accurate and probative of the deceased's intentions. In contrast, societies more cautious about presuming an individual's intentions may welcome other evidence of the deceased's intentions, especially when it does not conflict with the registry. Kinship and shared experiences of life may make families apt sources of evidence. Thus, if the medical team finds no objection in the registry, should it consult the family to confirm the absence of objection by the deceased?

France has sought to resolve these tensions by encouraging medical professionals to give families the opportunity to offer evidence of the deceased's intentions:

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939. See ONT, *supra*, note 29 at 98.

940. Note, "Refining the Law of Organ Donation: Lessons from the French Law of Presumed Consent" (1987) 19 N.Y.U. J. Int'l L. & Pol. 1013 at 1024-25.

941. Conseil d'État, *Sciences de la Vie: De l'Éthique au Droit*, 2d ed. (Paris: La Documentation française, 1988) at 36. See also Jesse Dukeminier and David Sanders, "Organ Transplantation: A Proposal for Routine Salvaging of Cadaver Organs" (1968) 279:8 N. Engl. J. Med. 413 at 416.

[TRANSLATION]
Under the law, only the wishes expressed by the person before his or her death should be considered, not those of the family. However, the family is still most often the privileged depositary of these wishes, whether the deceased has confided them to relatives, or whether relatives are in possession of documents or other evidence of the deceased's refusal or consent to the procurement. Where the family is not the direct depositary of the deceased's last wishes, it is often in the best position to know or discover the deceased's motivations and communicate them to the medical professional or institution.

The role of the family in the transmission of the deceased's will is especially important where the deceased was incapable of expressing his or her wishes at the time of hospitalization.[942]

It is unclear whether such language imposes a duty on the medical team to confer with or consult the families of deceased donors who have filed no objection in the registry.[943] A duty to consult may be a practical means of accommodating the wide forms of proof that the French presumed-consent law seems to contemplate.[944] Familial confirmation may thus advance accuracy. Yet, it may also frustrate a theory of presumed consent that aims to minimize family involvement. A result may be that it undermines procurement efficiency.

In practice, French medical teams continue to solicit the consent of the families of deceased potential donors.[945] This is perhaps due to custom, to tensions in presumed-consent theory, to corresponding ambiguities in the law and its implementing regulations and to the clinical and psychological reality of sensitively dealing with bereaved families.[946] When families are consulted, the law is clear about the grounds on which they may object to procurement. A case decided seven years after enactment of the presumed-consent law has firmly established that it does not provide relatives with a right to refuse based on their own objections.[947] Hence, while the deceased's expressed religious practices may provide legal grounds for non-consent, a father's distaste for invasive high technology medicine does not.

After lengthy musings about retaining presumed consent, a government committee has recently offered minor amendments to the French organ transplant law in a global legislative proposal to define the legal-bioethical status of the human body in the face of galloping changes in medical science.[948] The proposed legislation retains presumed

942. *Circulaire du 3 avril 1978, supra*, note 938 at 1532.

943. See *Décret n° 78-501 du 31 mars 1978, supra*, note 938, s. 10.

944. See *ibid.*, ss 8-10.

945. Conseil d'État, *supra*, note 941 at 39.

946. See *ibid.*

947. See Cons. d'État, 18 March 1983, *Mme Nguyen Ti Nam, épouse Trans Van Oanh*, J.C.P. 1983.II.20111; Ruth Redmond-Cooper, "Transplants Opting Out or In — The Implications" (1984) 134 New L.J. 648.

948. See Conseil d'État, *Avant-projet de loi sur les sciences de la vie et les droits de l'homme* (Paris, 1988). See also Jean-Michel Dubernard et Jean-François Mattéi, "Bioéthique: l'urgence d'un débat au Parlement" *Le Monde* (18 April 1990) 15. The proposed legislation resulted from an extensive governmental report. See Conseil d'État, *supra*, note 941.

consent, reaffirms a gift-based ethic for tissue transfers and emphasizes the role of the family in post-mortem organ procurement. Even amidst the process of preparing and proposing this global legislative approach, French society has devoted increased attention to regulating the development, diffusion and costs of transplant technology.[949]

Thus, while the global approach may distinguish the French legislative proposal, the societal issues before France mirror those facing North America. The parents of a Muslim child, who became the subject of post-mortem medical interventions violative of Islamic religious beliefs, recently instituted a lawsuit that clarified the contours of presumed consent for minors.[950] Tissue safety is a continuing concern, as illustrated by the recent judicial award of damages to the family of a transplant recipient who died of rabies contracted from negligently screened eye tissue.[951] Concern and conflict have also surrounded the concept of death. Shortly after the National Academy of Medicine of France endorsed "brain death" as the preferred death terminology for transplants,[952] criminal battery charges were considered in the case of a twenty-four-year-old brain-dead patient who was mechanically maintained and experimented on, without anyone's consent, by a hospital physician.[953] While French commentators dispute whether a new human experimentation law applies to non-consensual experimental interventions on such neomorts,[954] the French National Bioethics Committee has advised against so applying presumed-consent notions.[955] The Committee has also begun addressing tissue ownership and control issues,[956] admist some rare and compelling French legal disputes involving tissue banks and depositors.[957]

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949. See *Décret n° 90-844 du 24 septembre 1990, supra*, note 938; *Décret n° 90-845 du 24 septembre 1990*, J.O., 25 September 1990, 11607, and six specific regulations (*arrêtés*) on waiting lists, numbers of transplant centres, etc. in J.O., 25 September 1990, 11607-10.

950. See Conseil d'État, 17 February 1988, *Époux Camara*, J.C.P. 1990.II.21421 (holding French transplant law to require express consent of legal representative of deceased minor as condition precedent to procuring organs for transplant).

951. Cour d'Appel de Paris, 19 June 1989, *Zanne* v. *Banque Française des Yeux/ Hôpital Lariboisière* [unreported]; Monique Raux, "Un chercheur nancéien était mort de la rage après une greffe de la cornée" *Le Monde* (20 June 1989) 34.

952. "National Academy of Medicine of France Adopts Statement on 'Brain Death'" (1988) 39:3 Int'l Dig. Health Leg. 762 (rejecting traditional term *coma dépassé* as ambiguous).

953. See chap. 3, section II.C(3), above.

954. Compare "L'expérimentation sur les comateux", *supra*, note 717 and Jean-Marie Auby, "La Loi du 20 décembre 1988 relative à la protection des personnes qui se prêtent à des recherches biomédicales" J.C.P. 1989.I.3384, para. 14.

955. See *supra*, note 718.

956. Comité Consultatif National d'Éthique pour les Sciences de la Vie et de la Santé, "Avis sur les problèmes posés par le développement des méthodes d'utilisation de cellules humaines et de leurs dérivés" in *Éthique et recherche biomédicale: rapport 1987* (Paris: La Documentation française, 1988) at 18-21 (tentatively finding that (1) patients may be thought to consent, impliedly, to the commercial development and utilization of cells contained in diseased tissue; (2) it is nonetheless advisable that they be informed of such potential use; (3) the patient sources of commercially cultivated, developed cells have no commercial interests in the resulting product; and (4) biomedical researchers sales of cell lines do not commercialize the human body). Compare *Moore* (1990), *supra*, note 426.

957. Compare *Parpalaix, supra*, note 417; Jean-Yves Nau, "Engendrer après la mort" *Le Monde* (17 January 1990) 17 (widow suing French sperm bank for the post-mortem restitution of the frozen sperm of husband, who had deposited sperm in the course of testicular cancer treatment, but who later died of AIDS) and "Rejet d'une demande d'insémination post-mortem" *Le Monde* (27 March 1991) 24.

B. Belgium

In 1986, Belgium enacted presumed-consent legislation that both parallels and differs in scope and impact from the French transplant legislation.[958] First, in contrast to the modest long-term impact of the French law, preliminary accounts of the workings of the Belgian law suggest that post-mortem organ procurement has nearly doubled.[959] This parallels the reported impact of recent presumed-consent legislation for corneal transplants in the United States.[960]

Secondly, the Belgian law differs from the French law in terms of its scope. The French post-mortem organ procurement Act explicitly exempts from presumed consent minors, the mentally disabled and others thought to be incapable of meaningfully registering their intentions.[961] The Belgian Act seems not to mention explicitly the mentally disabled, but its presumption of consent does apply to minors.[962] Thus, if the French legal representative does not authorize consent, post-mortem procurement may not proceed. If the Belgian legal representative does not object, procurement may proceed. Finally, the Belgian law parallels the French law by authorizing the families of the deceased to withhold consent to donation, so long as the objection does not override the expressed wishes of the donor.[963]

C. Council of Europe

As the French and Belgian experiences perhaps suggest, defining the family role in post-mortem tissue procurement has proven an equally sensitive issue in other Western European countries, many of which belong to the Council of Europe. Established in post-World-War-II Europe to promote human rights,[964] the Council of Europe has

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958. *Law of 13 June 1986*, *supra*, note 935. For recent tissue bank regulations promulgated pursuant to the 1986 law, see "Crown Order of 15 April 1988 on Tissue Banks and the Removal, Preservation, Preparation, Importation, Transport, Distribution, and Supply of Tissues", reproduced in (1990) 41:1 Int'l Dig. Health Leg. 36.

959. Georges Binamé, "Organ Transplantation: A Chronicle of a Long-Awaited Law" (1990) 41:2 Int'l Dig. Health Leg. 336 at 338; L. Roels et al., "Effect of Presumed Consent Law on Organ Retrieval in Belgium" (1990) 22:4 Transplant. Proc. 2078.

960. See text accompanying note 1008, *infra*.

961. See *Époux Camara*, *supra*, note 950. See also Conseil d'État, *supra*, note 941 at 36.

962. See *Law of 13 June 1986*, *supra*, note 935, s. 10.2. Such a presumption might raise a *Charter* issue in Canada.

963. See *ibid.*, s. 10. Quasi-presumed consent laws that provide the deceased or his or her family a right of informed refusal have been termed "routine removal" laws. See Arthur J. Mattas et al., "A Proposal for Cadaver Organ Procurement: Routine Removal with Right of Informed Refusal" (1985) 10 J. Health Pol. Pol'y L. 231.

964. See European *Convention for the Protection of Human Rights and Fundamental Freedoms*, 4 November 1950 (1955) 213 U.N.T.S. 221 (entry into force 3 September 1953). Parties to the Convention are Austria, Belgium, Cyprus, Denmark, Finland, France, West Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, the Netherlands, Norway, Portugal, San Marino, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

issued recommendations on organ transplantation and international tissue transfers. The Council has proposed recommended texts in an effort to harmonize legislative initiatives and general policy among its twenty-two member states. General principles include: (1) express consent for tissue donation involving living donors; (2) general recognition of the whole-brain-death standard; (3) presumed consent for tissue donation involving deceased donors; and (4) a prohibition on "for profit" tissue and organ exchanges that exempts from the prohibition reimbursement for living donors' lost income or expenses resulting from donation.[965] The Council has also proposed an agreement on the international exchange and transportation of human therapeutic substances, to facilitate exchanges between the member states.[966]

As a European human rights forum, the Council has declared that European organ procurement should be facilitated in a manner consistent with "individual rights and freedoms."[967] In this vein, it is interesting to note that thirteen of its twenty-two member states have adopted a presumed-consent approach to organ procurement from cadavers.[968] Such presumed consent is based on the scarcity of organs, the lives that may potentially be saved by increasing the organ supply and a view that the dead body has no rights, although it is entitled to respect:[969]

> So, when the right to life and health of the deceased person awaiting transplantation comes into conflict with the supposed "right" of a cadaver which is no longer a person, the right of the living recipient is certainly predominant over that of the dead donor. The interest of the community prevails over that of the individual dead body.[970]

This balancing of interests might appear to slight the concerns of the family of the deceased. Under Austrian and Luxembourgian presumed-consent laws, for example, the views of the family or close relations are not taken into account.[971] Still, the Council's analysis has revealed that, in practice, many of its member countries are reluctant to apply strict presumed-consent notions.[972] This reality suggests that the practice in Belgium and

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965. Council of Europe, "Third Conference of European Health Ministers (Paris, 16-17 November 1987)" (Final Text on Organ Transplantation) (1988) 39:1 Int'l Dig. Health Leg. 274 [hereinafter Final Text], and note 971, *infra*. See also Council of Europe, "Resolution (78)29 on Harmonisation of Legislations of Member States Relating to Removal, Grafting and Transplantation of Human Substances" (1978) 29:4 Int'l Dig. Health Leg. 898.

966. Council of Europe, "Recommendation No. R(79) of the Committee of Ministers to the Member States concerning International Exchange and Transportation of Human Substances" (1979) 30:4 Int'l Dig. Health Leg. 931.

967. See Final Text, *supra*, note 965 at 275.

968. See Council of Europe, Conference of European Health Ministers, *Organ Transplantation: Third Report, Legislative Measures in Relation to Organ Transplantation and to European Co-operation* (Strasbourg: The Council, 1987) at 7.

969. *Ibid.*

970. *Ibid.*

971. Council of Europe, Conference of European Health Ministers, *Organ Transplantation: Current Legislation in Council of Europe Member States and Finland and Results of European Co-operation* (Strasbourg: The Council, 1987) at 27, 29.

972. Council of Europe, *supra*, note 968 at 7.

France is perhaps illustrative of general practice in Council of Europe member states: "[The] practice in most countries shows that the relatives are consulted and though in most cases its opinion is legally not overriding, none would go against the expressed refusal of the family."[973] The Council has recommended further study of the family's role in final decisions regarding removal of a decedent's organs.[974] Whether such study will lead to changes that increase European organ procurement rates remains to be seen. In the meantime, as in North America, European transplant waiting lists continue to grow.[975]

III. The United States: Required Request and Routine Inquiry

In recent times, a consensus has emerged in United States law and public policy regarding tissue transfer and organ procurement: namely, that organ scarcity is acute, that the sale of organs is impermissible and should be prohibited, and that potential remedies to organ scarcity should be both practical and ethically founded on encouraged altruism. These policies are expressed in a wave of tissue transfer and procurement legislation that has swept the United States over the last five years.

One commentator has described the legislative approach adopted in the United States as follows:

> The statutes promote the recognition of potential donors and either require that people or the next of kin be asked to donate a dying or dead relative's organs or that they be informed of donation options. ... [A] routine inquiry policy requires neither that an unwilling person make a request, nor that the families be asked to donate. Rather, this policy requires hospitals to adopt procedures to assure that the family is offered the opportunity to donate.[976]

Over forty-four United States jurisdictions have adopted such laws since their initial enactment in Oregon, California and New York in 1985.[977] As suggested, the laws usually adopt either a routine-inquiry or required-request approach to undeclared donor circumstances. Routine-inquiry statutes have been regarded as taking the softer approach. They require hospitals to develop protocols for ensuring that families of undeclared potential donors are offered the opportunity or informed option of donation.[978] Required-request

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973. Council of Europe, *supra*, note 971 at 26.

974. Council of Europe, *supra*, note 968 at 9.

975. See B. Cohen, "Rapid Changes in the Work of an International Exchange Organization: Eurotransplant" (1988) 20:5 Transplant. Proc. 817, 818 and Council of Europe (November 1990) 2 Transplant 161. See also Jeffrey M. Prottas, "Organ Procurement in Europe and the United States" (1985) 63 Milbank Mem. Fund Q. 94.

976. Daphne Sipes, "Requesting Organ Donations: A New State Approach to Organ Transplants" (1987) 8:2 Health L. Can. 39 at 40.

977. Kathleen S. Andersen and Daniel M. Fox, "The Impact of Routine Inquiry Laws and Organ Donation" (1988) 7 Health Aff. 65.

978. American Hospital Association, American Medical Association, United Network for Organ Sharing, *Required Request Legislation: A Guide for Hospitals on Organ & Tissue Donation* (AHA, AMA, UNOS, 1988) at 1.

laws are more strongly worded. They oblige hospitals to adopt protocols to ensure that families of potential donors are actually asked to donate.[979]

Why has the United States so broadly endorsed this approach? The endorsement reflects a consensus on the major causes of, and preferred remedies to, organ and tissue scarcity. The remedy — the legislative duty to inquire — targets one of the most delicate and psychologically burdensome areas of organ donation and procurement: namely, approaching the family of a recently deceased individual who has been identified as a potential organ donor. It is designed to address an identified problem. American and Canadian studies and reports have documented the high reluctance of health professionals to approach families in such situations.[980] Canadian federal and provincial task forces have characterized the reluctance as a "major, significant" barrier to increasing donation.[981] American analysts share this view. In 1985, a special Hastings Center report found "the failure to ask about donation, the failure to recognize the key role played by family members" to be key, important hindrances to donation.[982] The report recommended legislative enactment of soft required-request or routine-inquiry statutes.[983] The Hastings Center and Canadian task force findings were echoed two years later by an organ transplant task force in the United States:

> *The Task Force finds that a major problem with the current voluntary system of organ donation is that families often are not informed of their option to donate organs and tissues after brain death is determined.* Because many families are unaware of this option, it is likely that more organs could be procured while honoring the legal commitment to voluntary consent if family members were routinely informed of the opportunity to donate organs and tissues at the time of death of a relative. . . .
>
> *The Task Force recommends that all health professionals involved in caring for potential organ and tissue donors voluntarily accept the responsibility for identifying* these donors and for referring such donors to appropriate organ procurement organizations. . . .
>
> The Task Force *recommends that hospitals adopt routine inquiry/required request policies and procedures for identifying potential organ and tissue donors and for providing next of kin with appropriate opportunities for donation.* . . .
>
> Although the concept is often called "required request," a routine inquiry policy requires neither that an unwilling person make the request, nor that families be *asked* to donate. Rather, this policy requires hospitals to adopt procedures to assure that the family is *offered* the opportunity to donate. The distinction is important because people react more positively when offered a choice.[984]

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979. *Ibid.*

980. See text accompanying notes 228-233, *infra*.

981. *Ibid.*

982. The Hastings Center, *Ethical, Legal and Policy Issues Pertaining to Solid Organ Procurement* (Hastings-on-Hudson, N.Y.: The Center, 1985) at 15.

983. *Ibid.* at 21-22.

984. USTF, *supra*, note 29 at 31, 33, 32 (emphasis added).

The task force supported its recommendation by a finding that most families of undeclared potential donors do not object to being approached; indeed, they may welcome it as part of their bereavement process.[985]

The United States endorsement of routine inquiry or required request also reflects the view that it is a preferred public policy option. When compared to a free or regulated market of organ sales[986] and a presumed-consent approach to cadaver organ procurement, the routine-inquiry or required-request approach is seen as more respectful of altruism, familial sentiments and religious interests.[987] While it generally removes the option not to inquire, it does permit families the right to decline.[988] The policy presumes that the problem lies not with engendering altruism but with helping people to act on their good intentions.[989]

The novelty of routine-inquiry and required-request legislation precludes an assessment of its effectiveness. Indeed, the evidence of its effects on organ procurement still remains inconclusive. On the one hand, some professionals have criticized the laws as impinging on necessary professional discretion, family autonomy and privacy, and as being a step in the direction of more coercive organ procurement measures.[990] On the other hand, some increases in tissue and organ donation have been recorded. For example, eye banks in Oregon reported a 135-per-cent increase in donor eye procurement.[991] A New York skin bank has experienced a 180-per-cent increase in skin donations.[992] Increases in organ procurement and referrals have also been reported in California[993] and Michigan.[994]

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985. *Ibid.* at 32 ("Organ donation and tissue donation is almost always a profound source of consolation to families of patients suffering unexpected and premature death"). See also Batten and Prottas, *supra*, note 227 at 38 (86% of surveyed donor families' main motivation to donate was to make "something positive come out of death").

986. See generally Note, "Regulating the Sale of Human Organs" (1985) 71 Va L. Rev. 1015.

987. See Arthur L. Caplan, "Ethical and Policy Issues in the Procurement of Cadaver Organs for Transplantation" (1984) 311:15 N. Engl. J. Med. 981 at 982.

988. See *ibid.*

989. See Jeffrey M. Prottas, "Encouraging Altruism: Public Attitudes and the Marketing of Organ Donation" (1983) 61 Milbank Mem. Fund Q. 278 at 279.

990. See, *e.g.*, Susan Martyn, Richard Wright and Leo Clark, "Required Request for Organ Donation: Moral, Clinical, and Legal Problems" (1988) 18:2 Hast. Cent. Rep. 27. But see Arthur L. Caplan, "Professional Arrogance and Public Misunderstanding" (1988) 18:2 Hast. Cent. Rep. 34.

991. See Terry E. Burris et al., "Impact of Routine Inquiry Legislation in Oregon on Eye Donations" (1987) 6:3 The Cornea 226.

992. See The New York State Task Force on Life and the Law, *Transplantation in New York State: The Procurement and Distribution of Organs and Tissues* (New York: The Task Force, 1988) at 155.

993. See Andersen and Fox, *supra*, note 977 at 76-77.

994. See Beverly Merz, "The Organ Procurement Problem: Many Causes, No Easy Solutions" (1985) 254:23 JAMA 3285 at 3287. But see Arthur L. Caplan and Beth Virnig, "Is Altruism Enough? Required Request and the Donation of Cadaver Organs and Tissues in the United States" (1990) 6:4 Critical Care Clinics 1007 at 1011 (mixed results).

Although the early initiatives for required request came from particular states, both uniform and federal organ transplant legislation has helped to encourage further enactment of such laws. The *National Organ Transplant Act* (NOTA) of 1984[995] was enacted by the United States Congress to facilitate and improve the national procurement and sharing of organs. The Act (1) established the national task force to study organ procurement and transplantation; (2) established a national computer registry for organ exchange data; (3) provides assistance to regional organ procurement activities; (4) established a national bone marrow donor registry;[996] (5) imposes a $50,000 fine or five years' imprisonment or both for the knowing transfer, in interstate commerce, of an organ (kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone or skin, but not blood) for valuable consideration; and (6) following the recommendations of the United States task force, requires hospitals receiving federal funds to adopt written protocols to identify organ donors.[997]

Several other aspects of the legislation are noteworthy. First, the sales prohibition and definition of human "organ" generally do not include replenishable tissues whose donation do not pose physical risks to the donor.[998] Recent amendments to the Act have expressly included "fetal organs" or "subparts of" other organs within the statutory prohibition on sales.[999] Secondly, as in the recent British and Manitoba legislation and the Council of Europe recommendation, the prohibition on "sales" does not exclude payment for retrieval, processing, preservation, transportation expenses or the donor's travel, housing or lost wages.[1000] Thirdly, related federal legislation has apparently given

995. Pub. L. No. 98-507, 98 Stat. 2339 (codified, *inter alia*, as am., at 42 USCS §§ 273, 274, 1320b-8) [hereinafter NOTA].

996. While the registry appears to be approaching its goal of 100,000 registered donors, that figure may still not satisfy U.S. needs. See "Program to Find Marrow Donors Is Falling Short" *New York Times* (11 December 1989) A18. See also "Transplant Reward Offer Raises Furor" *New York Times* (23 June 1989) A6 ($5,000 offered to attract matching bone marrow donor); "Girl Born to Couple Who Seek Marrow Donor" *New York Times* (7 April 1990) 8 (couple conceives to transplant baby's bone marrow into teenaged daughter dying from leukemia). See also *Transplant Amendments Act of 1990*, Pub. L. No. 101-616, 104 Stat. 3279 (to be codified at 42 USCS § 301), which are intended to strengthen the national bone marrow donor registry.

997. See U.S. Organ Procurement Protocols, 53 Fed. Reg. 6,526, 6,527, 6,544 (1March 1988) (to be codified at 42 C.F.R.).

998. See U.S. Code Cong. & Ad. News, *supra*, note 481 at 3982 ("It is the sense of the Committee that individuals or organizations should not profit by the sale of human organs for transplantation. This is not meant to include blood and blood derivatives, which can be replenished and whose donation does not compromise the health of the donor."). The logic of the distinction may be buttressed by the view that the invasive nature and associated risks of bone marrow or skin transplantation make the procedures more akin to vital organ transplantation than to blood or sperm donation: hence, their inclusion in the definition of "organ" for the sales prohibition. It should also be noted that while the federal organ sales ban applies to tissue from living and deceased "donors," the sales ban proposed under model uniform law applies only to cadaveric tissue. Compare NOTA, *supra*, note 995, § 274e and UAGA, *infra*, note 1004, s. 10.

999. *Organ Transplant Amendments Act of 1988*, Pub. L. No. 100-607, s. 407, 102 Stat. 3114 (1988) (amending 42 USCS, § 274e(c)(1)).

1000. See 42 USCS, § 274e.

the states discretion in their choices to fund or not to fund transplants, and those financial decisions have become the subject of transplant funding litigation.[1001]

Finally, regulations adopted under NOTA have established a National Organ Procurement and Transplantation Network, which involves some seventy certified organ procurement agencies in eleven designated regions across the United States. The national organ procurement system is administered by the United Network for Organ Sharing (UNOS), a private organization under contract to the United States Department of Health and Human Services[1002] and overseen by it. Under the auspices of that department, UNOS develops national policies and procedures, through public commentary and various national committees. Thus, for example, UNOS Foreign Relations Committee deliberations have helped shape international organ-sharing policies of the United States through UNOS policies, which generally : (1) prohibit the exportation of United States organs beyond North America, unless a suitable United States recipient cannot be found; (2) permit transplant centres in the United States to enter into formal organ exchange protocols with UNOS-registered and -approved foreign transplant centres; (3) otherwise prohibit the ad hoc importation of organs, unless it is co-ordinated through or approved by UNOS; and (4) subject to audit those centres that perform more than 10 per cent of their annual transplants on non-resident alien recipients.[1003]

Legislative provisions that parallel NOTA have been adopted under recent amendments to model, uniform anatomical gift legislation in the United States. In 1987, the twenty-year-old model gift tissue law was amended.[1004] While the new Uniform Act adopts the routine-inquiry principle,[1005] it also adopts a quasi-presumed-consent provision. The provision permits a coroner or medical examiner to authorize the removal of bodily parts from a body lawfully in the custody of the examiner, once a "reasonable effort, taking into account the useful life of the part," has been made to contact the deceased's next of kin.[1006] The duty to make a reasonable effort to contact the family of the deceased

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1001. Compare *Ellis* v. *Patterson*, 859 F. 2d 52 (8th Cir. 1988) (finding 1986 U.S. medicare amendments, to 42 USCS, § 1396b(i), give states discretion to fund, not fund, or limit funding of organ transplants, and require that limitations be neither arbitrary nor unreasonable); *Todd* v. *Sorrell*, 841 F. 2d 87 (4th Cir. 1988) (requiring state to pay patient's liver transplant costs); *Montoya* v. *Johnston*, 654 F. Supp. 511 (W.D. Tex. 1987) (finding $50,000 cap on state funded hospital expenses arbitrary and unreasonable exclusion of coverage for child requiring a $100,000 to $200,000 liver transplant). For review of U.S. government bases for funding liver transplants, see 56 Fed. Reg. 15,006 (12 April 1991). Private insurers are also not immune from transplant funding litigation. See *Dozsa* v. *Crum & Forster Insurance Co.*, 716 F. Supp. 131 (D. N.J. 1989) (requiring coverage of bone marrow transplants).

1002. See John C. McDonald, "The National Organ Procurement and Transplantation Network" (1988) 259:5 JAMA 725.

1003. See *UNOS Policy on Transplantation of Foreign Nationals* (6.0-6.6) (effective July 1991). See also *UNOS Policies: Changes as of December 6, 1988* (3.14) (U.S.-Canadian Interim Organ Sharing Agreement expired). For further discussion of restricting foreign patient access to U.S. transplant waiting lists, see USTF, *supra*, note 29 at 93-95. See also Medicare Program; Payment for Kidneys Sent to Foreign Countries or Transplanted in Patients Other Than Medicare Beneficiaries, 42 C.F.R. pt. 413.179.

1004. See *Uniform Anatomical Gift Act (1987)*, 8A U.L.A. (1990 Supp.) [hereinafter UAGA], discussed in A. McIntosh, "Regulating the 'Gift of Life' — The 1987 Uniform Anatomical Gift Act" (1990) 65:1 Wash. L. Rev. 171. See also *Uniform Determination of Death Act (1980)*, 12 U.L.A. 320 (1990 Supp.) (adopted in most jurisdictions).

1005. UAGA, *supra*, note 1004, s. 5.

1006. *Ibid.*, s. 4.

should help to avoid the civil and constitutional challenges that have been lodged against presumed-consent practices and laws for eye tissue procurement in some United States jurisdictions.[1007] The UAGA provision significantly expands the presumed-consent approach for eye tissue to include procurement of bodily parts. That approach was adopted on the view that such legislation advances legitimate state interests in the protection of health and preservation of life, and on evidence that such laws have resulted in increases in transplantations (for example, in Florida an increase from 500 to 3,000 corneal transplants).[1008] A minority of American jurisdictions have thus far adopted the new Uniform Act.[1009]

IV. Australia: Presumed Consent Following Required Inquiry

As a result of recommendations of the Australian Law Reform Commission[1010] (ALRC), most Australian hospitals approach declared cadaveric donor and undeclared donor circumstances in a uniform manner. First, the ALRC recommended that hospitals be authorized to procure tissue and organs from explicitly declared donors, despite potential objections from surviving family members.[1011] The practice is based on the ethical principles of autonomy and beneficence: respecting the wishes of the deceased person and furthering the medical needs of transplant recipients.[1012] Secondly, the ALRC recommended that hospitals be authorized to procure tissue from undeclared potential donors, if hospitals first make reasonable inquiries:

> Where a person dies in hospital or his body is brought into a hospital, the hospital itself, by a designated officer, should have the power to authorise removal of tissue for transplant or the other purposes described above after first making inquiry for the existence of consent and objection by the deceased, or, if none exists or can be ascertained, objection by relatives. The terms of any consent or objection of the deceased will have effect. The hospital's duty of inquiry should be to make "such inquiry as may be reasonable in the circumstances."[1013]

1007. Such states as Florida, Michigan, Texas and Ohio have followed the 1975 legislative model of Maryland, by authorizing procurement of eye tissue when: (1) a body is under the jurisdiction of the coroner for forensic autopsy purposes; (2) there is no "known objection" to corneal tissue procurement; and (3) procurement would result in neither disfigurement/mutilation of the body nor in interference with the autopsy. See Md Est. & Trusts Code Ann. s. 4-509.1 (1989 Supp.). Suits have been filed against procurement activities that have relied on the "no known objection" language to procure without giving families of the deceased a meaningful opportunity to object. See *Brotherton*, *supra*, note 894; *Kirker*, *supra*, note 403; *Powell*, *supra*, note 895; *Georgia Lions Eye Bank*, *supra*, note 894, *Tillman*, *supra*, note 894. Compare the "good faith" attempt to contact family required under Massachusetts eye tissue procurement law, Mass. Gen. Laws Ann., c. 113, s. 14 (1989 Supp.), and recent legislative changes in Rhode Island — R.I. Gen. Laws, c. 4, s. 23-4-4.1 (Michie 1990 Supp.) — the latter of which was prompted by *You Vang Yang*, *supra*, note 900.

1008. See UAGA, *supra*, note 1004, s. 4, comment.

1009. See UAGA, *supra*, note 1004.

1010. Australian Law Reform Commission, *Human Tissue Transplants*, Report 7 (Brisbane: Watson Ferguson and Co., 1977) [hereinafter ALRC].

1011. *Ibid.*, para. 144, at 65-66.

1012. *Ibid.*, para. 140 at 64. See also chap. 3, above.

1013. *Ibid.*, para. 144 at 66.

The ALRC proposal would seem to strike a middle course between the routine-inquiry and required-request approaches of the United States and the presumed-consent approach of western Europe for undeclared donor circumstances. It parallels the general approach of the United States, by conditioning procurement on an attempt to consult the family, to whose consent or objection the hospital must defer. However, it diverges from the general view of the United States, and parallels a minority view in North America, in that it presumes consent if family members cannot reasonably be ascertained or contacted.[1014] By so presuming consent, the ALRC recommendation parallels the general western European approach. However, it also diverges from that approach because it explicitly requires an attempt to consult the family, and makes familial objections binding, apparently whatever their basis.[1015]

The ALRC recommendations have prompted legislative reform. Between 1978 and 1985, all eight states of Australia substantially adopted the ALRC recommendations; a majority of them specifically adopted the ALRC's "required inquiry followed by presumed consent" approach to undeclared donor circumstances.[1016] Since that approach usually results in consultation with the family of the deceased undeclared potential donor, national efforts have been undertaken to ensure that hospitals fulfil this societal function in a sensitive and effective manner.[1017] The ALRC tissue sales recommendation — that is, forbid payment for tissue, but authorize payments for tissue processing services and for reimbursement of donor expenses — has also been implemented.[1018]

V. International Concerns

Advances in tissue replacement technology, which have spawned recent law reform

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1014. Compare section IV and text accompanying note 1007, *supra*.

1015. Compare section III and text accompanying notes 970-973, *supra*.

1016. *Transplantation and Anatomy Ordinance 1978*, 1978 L. Austr. Cap. Terr., No. 44, s. 27; *Transplantation and Anatomy Act 1979*, 1979 S. Qld, No. 74, s. 26; *Human Tissue Act 1982*, 1982 A. Vic., No. 9860, s. 26; *Human Tissue Transplant Act 1979*, 1979 N. Terr., No. 121, s. 18; *Human Tissue and Transplant Act, 1982*, 1982 S. W. Austr., No. 116, s. 22; *Anatomy (Human Tissue) Amendment Act, 1983*, 1983 S. N.S.W., No. 165, s. 3; *Transplantation and Anatomy Act, 1983*, 1983 S. S. Austr., No. 11, s. 21; *The Human Tissue Act 1985*, 1985/86 S.L. Tasm., No. 118, s. 23; (1987) 38:3 Int'l Dig. Health Leg. 510. In contrast to the quasi-presumed-consent approach of most Australian jurisdictions, language in the Western Australian and Tasmanian statutes would seem to indicate that if the hospital cannot locate family members of an undeclared donor, to receive their non-objection, tissue procurement may not proceed. See Western Australian and Tasmanian statutes, *ibid.*, ss 22(3) and 23(2) respectively.

1017. See National Health and Medical Research Council, *A Code of Practice for Transplantation of Cadaveric Organs* (Canberra: The Council, 1982) at 8-9 ("Any approach should be made with proper sensitivity and a feeling for the relatives' distress. Their views should be sought whenever possible at a personal interview but there may be occasions when the only practical means of discussing the matter is by telephone. ... It has been found in practice that relatives, on an initial approach, may refuse permission but may change their minds later after they have thought and felt their way through the idea. It should be remembered that where permission is given by relatives, this constitutes not only a gift of the deceased, but their gift in part as well. Bereavement counselling should also be offered, as there is now good evidence of increased morbidity and mortality in the year following unresolved grief.").

1018. Compare ALRC, *supra*, note 1010, para. 178 at 87(recommending legal prohibition on payment for removal of tissue, except for reimbursement of associated expenses or to suppliers of donated tissue processed/prepared for medical use) with tissue sales prohibitions in the statutes, *supra*, note 1016.

in several nations, have also had an impact beyond national frontiers. Indeed, concerns over the safety, sales and control of tissue transfers have prompted initiatives indicative of evolving international public policy and law.

A. Transnational Transfers

The ebb and flow of national tissue needs may occasion recourse to international transfers. Early nineteenth-century anatomical needs, for example, were sometimes addressed by Canadian-American and Irish-Scottish-English exchanges of dead bodies.[1019] Changes in medical needs have meant changes in import-export patterns. In 1987, Baby Gabriel, a moribund anencephalic newborn from Ontario, helped expand the United States organ donor pool when his organs were donated to Baby Paul in California.[1020] In a six-month period in 1988, 9 per cent of the bone issued by the University of Toronto Bone Bank was exported to countries such as Australia.[1021] In the two-year period, 1988 and 1989, over ninety kidneys, hearts and livers crossed the Canada-United States border.[1022] For years, human sperm has been imported into Canada to assist in modern infertility treatment.[1023] Moreover, international collaboration is now deemed "essential" for Canadian bone marrow transplant needs.[1024] In short, some of the extraterritorial flow owes to the benefits of expanded, international donor and recipient pools for satisfying national supply and demand.

Some of the international flow arises more specifically from insufficient technology to satisfy national medical needs. The constraint sometimes prompts patients to seek therapy abroad. Before pediatric liver transplants became available domestically, for example, Canadian physicians referred children to centres in the United States within minimal flying time of Canada. Similarly, Canadian surgeons have recently performed transplants on patients from Japan, where religious taboos concerning the dead body apparently have restrained the development of indigenous transplant technology.[1025] The "technology" constraint may also necessitate tissue imports. Canadian hemophiliacs, for example, continue to rely heavily on blood clotting factors that are manufactured in the United States and exported to Canada, largely because blood fractionation technology remains scant in Canada.[1026] Similarly, from 1988 through 1989 Canadian heart surgeons sent more than

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1019. Compare Lawrence, *supra*, note 4 at 414 and "On the Exportation of Dead Bodies from Ireland to England and Scotland" (1828-29) 1 Lancet 775 (letter).

1020. See Scott, *supra*, note 579.

1021. "Bone Bank in Desperate Search for New 'Depositors'" *The Medical Post* (21 March 1989) 39.

1022. HWC, *supra*, note 59.

1023. See Christie McLaren, "Large Ethnic Market in U.S. Creates High Interest in Toronto Sperm Bank" *The [Toronto] Globe and Mail* (19 May 1990) A1 at A2 (Canada-U.S. sperm trade). See also *Report of the Advisory Committee*, *supra*, note 161 at 14 (urging prohibition on imported sperm until federal standards are established).

1024. See Noël A. Buskard, "The Canadian Unrelated Bone Marrow Donor Registry" (1990) 7 Transplantation/Implantation Today 42.

1025. David Helwig, "Canadian Doctors and Japanese Tot Help Change Japanese Attitudes on Transplants" (1988) 139:1 C.M.A.J. 1088.

1026. See CBC, *supra*, note 35 at 17.

200 human heart valves to a tissue bank in the United States for intricate processing and initial storage, prior to their use in Canadian heart valve replacement surgery.[1027] As tissue preservation, transportation and international procurement systems advance, transnational exchanges may well increase. As variances in domestic technology continue in the face of international medical need, countries will sometimes be net exporters and sometimes net importers of both procured tissue and transplant recipients.

B. Safety

If international transfers contribute towards satisfying global therapeutic needs, they also distribute risks to continents beyond the tissue-exporting nation. Blood clotting factors processed in the United States have been implicated in the transmission of the hepatitis[1028] and AIDS viruses[1029] to Canadian hemophiliacs. Canadians have also begun settling lawsuits against the California manufacturer of defective mechanical heart valves implanted in some 8,900 Canadians and 39,000 other cardiac patients outside the United States.[1030] These statistics underline the safety dimensions of defective tissue replacement technologies that are mass-produced for use in patients abroad.

Of course, the risks of illness, injury or death from exported tissue replacement technologies extend beyond North America. In 1987, international safety alerts were issued in response to the death of an American who had received a graft of infected tissue that was procured and commercially processed in Germany, exported to Canada and imported into the United States.[1031] The tissue, used in reconstructive brain surgery, was cadaveric dura mater, a tough membrane that covers and protects the brain. Despite the international recall of the suspected material, similar deaths have been recently reported in New Zealand and Italy.[1032]

1027. HWC, *supra*, note 59.

1028. *Kitchen* v. *McMullen* (1989), 62 D.L.R. (4th) 481 (N.B.C.A.).

1029. U.S. Centers for Disease Control, "Safety of Therapeutic Products Used for Hemophilia Patients" (1988) 37:29 Morbidity Mortality Wkly Rptr 441 at 442.

1030. See Christie McLaren, "Canadian Gets Settlement for Implant Worry" *The [Toronto] Globe and Mail* (13 December 1989) A1; "F.D.A. Is Faulted on a Heart Valve" *New York Times* (26 February 1990) B8. See also, *Stangvik* v. *Shiley Inc.*, 273 Cal. Rptr. 179 (App. 4th Dist. 1990) (Norwegian and Swedish recipients), rev. granted 800 P. 2d 858; *Corrigan* v. *Bjork Shiley Corporation*, 227 Cal. Rptr. 247 (App. 2d Dist. 1986) (Australian recipient), cert. denied 479 U.S. 1049. See generally U.S. House of Representatives, Staff Report of the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, *The Bjork-Shiley Heart Valve: "Earn as You Learn"* (Washington, D.C.: U.S. Government Printing Office, 1990).

1031. See U.S. Centers for Disease Control, "Update: Creutzfeldt-Jakob Disease in a Patient Receiving a Cadaveric Dura Mater Graft" (1987) 36:21 Morbidity Mortality Wkly Rptr 324. See also Vijay Thadani et al., "Creutzfeldt-Jakob Disease Probably Acquired from a Cadaveric Dura Mater Graft" (1988) 69:5 J. Neurosurg. 766.

1032. See U.S. Centers for Disease Control, "Creutzfeldt-Jakob Disease in a Second Patient Who Received a Cadaveric Dura Mater Graft" (1989) 261:8 JAMA 1118; Carlo Masullo et al., "Transmission of Creutzfeldt-Jakob Disease by Dural Cadaveric Graft" (1989) 71:6 J. Neurosurg. 954.

C. Sales

Whether the international community tolerates or abhors a "tissue transfer" sale seems to depend, in part, on where in the spectrum — from natural tissue to processed or manufactured tissue products — the object of sale lies. Sales of safe and effective tissue replacement technologies, such as mechanical heart valves, seem an acceptable part of international trade. Sales of commercially processed blood product derivatives may raise more objection, assuming a preference for altruistically based, or non-commercially processed, tissue derivatives. Sales of these objects nevertheless appear to be countenanced by necessity.[1033]

By far, it is the non-gift-based exchanges of natural human tissue, specifically organ sales, that most provoke concern from quarters within the international community. If higher costs fail to justify higher fees for the co-ordination of international organ shipments, the transactions may seem suspect.[1034] Allegations of Turkish-British kidney sales prompted enactment of the 1989 British organ transplant law.[1035] Former eye bank employees in Florida were convicted, in 1989, of grand theft involving the transfer of corneas for $650 apiece to Saudi Arabian interests.[1036] Allegations of Canadian-American, French-Dutch and Mexican-Canadian organ sales have recently been reported.[1037]

Yet, the difficulty in tracing and substantiating alleged international organ sales has dissuaded neither nations nor international organizations from pronouncing on the issue. Since 1980, Great Britain,[1038] Australia,[1039] the United States,[1040] the Council of Europe,[1041] Canadian provincial governments,[1042] the World Medical Association,[1043] Pan American[1044] and international transplant societies[1045] and international criminal law

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1033. Compare CBC, *supra*, note 35, and Britten, *supra*, note 203 and accompanying text.

1034. See U.S. Congress, Hearings before the Subcommittee on Investigations and Oversight of the Committee on Science and Technology, *Procurement and Allocation of Human Organs for Transplantation* (7, 9 November 1983) (Washington, D.C.: U.S. Government Printing Office, 1984) at 99 (Japan-U.S. fees).

1035. See *Human Organ Transplants Act 1989*, *supra*, note 526.

1036. See *State of Florida* v. *Grant* (19 January 1989), Hillsborough Cnty 87-4613 (Cir. Ct). See also "5 Accused of Selling Corneas" *New York Times* (12 January 1989) A24.

1037. See text accompanying notes 461-463, *supra*; Paul Taylor, "Kidneys Sold by Poor for Transplants, MD Says" *The [Toronto] Globe and Mail* (22 August 1989) A1; Alexander Dorozynski, "European Kidney Market" (1989) 299:6709 Br. Med. J. 1182.

1038. See *Human Organ Transplants Act 1989*, *supra*, note 526.

1039. See *supra*, note 1018.

1040. See NOTA, *supra*, note 995, § 274e.

1041. See *supra*, note 965.

1042. See, *e.g.*, MHTA, *supra*, note 839, s. 15.

1043. See appendix A, *infra* at 200-201.

1044. Pan American Society for Dialysis and Transplantation, "Document on Transplant Ethics" (1989) 5:2 UNOS Update 7.

1045. See The Council of the Transplantation Society, "Commercialisation in Transplantation: The Problems and Some Guidelines for Practice" (1985) 2:8457 Lancet 715.

societies,[1046] among others, have either declared organ sales ethically abhorrent or enacted penal prohibitions to deter them and punish offenders.

Whether or not the pronouncements and practices announce a rule of international public law, it is clear that the views are shared by the World Health Organization. In 1989, Canada exercised a leadership role in co-sponsoring a World Health Organization organ sales resolution which was eventually supported by more than 151 nations. The resolution urges nations to join an international effort to curb the risks and incidence of organ sales:

> The Forty-second World Health Assembly,
>
> Concerned by the commercial trafficking in the organs of healthy donors, which exploits human distress and puts at increased risk the health of the donors ...
>
> Aware that commercial arrangements for organ transplants are nevertheless being undertaken ...
>
> Anxious to prevent the exploitation of human distress ...
>
> 1. CALLS UPON Member States to take appropriate measures to prevent the purchase and sale of human organs for transplantation ...[1047]

D. International Controls

In addition to formal resolutions, the international community may pursue several options, ranging from treaties and national legislation to ethical codes of conduct, to ensure safe and adequate, speedy and ethically acceptable tissue transfers for global therapeutic needs. For instance, the ethical pronouncements of the international Council of the Transplantation Society, and World Medical Association may sketch an international code of ethical conduct for transplant physicians. The organ transplant principles that the World Health Organization is expected to adopt in 1991 may have this effect.[1048] While such pronouncements lack the force of law, they may still be given legal effect if they become the operative standard of conduct in national disciplinary proceedings, such as those undertaken by the General Medical Council of Great Britain in which doctors implicated in British-Turkish organ sales were recently found guilty of serious professional misconduct.[1049]

Beyond formal resolutions and codes of conduct, international agreements offer a direct means of controlling tissue safety and supply, organ sharing and technical information sharing, as well as offering means of applying ethical principles. The agreements may take the form of transnational contracts. For instance, the Canadian Blood Committee has

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1046. See International Association of Penal Law, "XIV International Congress on Penal Law" (1990) 1 IAPL Newsletter (Draft Resolution 3.10 on Organ Transplants and Artificial Organs) at 60.

1047. "World Health Assembly Adopts Resolution on 'Preventing the Purchase and Sale of Human Organs'" (1989) 40:3 Int'l Dig. Health Leg. 724, reproduced in part in appendix A, *infra* at 202-203.

1048. See appendix A, *infra* at 201-203.

1049. Diana Brahams, "Kidney Sales" (1990) 335:8964 Lancet 906.

contracted with American interests to process and supply anti-hemophilia blood products.[1050] Agreements may also take the form of formal treaties. An example is a Council of Europe agreement that exempts human therapeutic substances from import-export duties, on the practical view that duty-free status eases international exchange, and on the ethical view that donated human therapeutic substances are priceless.[1051] While United States and Canadian authorities have considered systemizing cross-border organ transfers,[1052] Eastern European nations have already formalized an organ-sharing treaty.[1053] Treaties may also address tissue safety, by recognizing the right to deny import entry to substances that pose undue health risks,[1054] and by providing importing nations with a right of inspection that corresponds to an exporting nation's duty to document compliance with agreed quality control procedures.[1055]

Finally, the laws and practices in the constituent nations of the international community, by definition, help to define its laws and policies. A prime example lies in the degree to which national law mandates safety standards for tissue replacement technologies that flow between nations. For instance, Canadian and American laws authorize the export of medical devices that do not meet national regulatory standards, if the exported devices are properly labelled and do not violate the laws of the importing country.[1056] Eastern European patients implanted with Canadian exported mechanical heart valves, then, must depend on the export label warning, Canadian manufacturing or professional standards, any legislative standards of their own country and the distant threat of lawsuits[1057] to minimize the likelihood of receiving a defective product. Tissue safety, however, would seem more likely ensured by minimally rigorous, international standards reflected in the laws of both exporting and importing nations. The logic of this approach extends beyond safety. For example, in the absence of clear international law, organ trafficking also seems more likely deterred by complementary prohibitions in donor and recipient nations,[1058] especially if national prohibitions are given extraterritorial application.

VI. International Trends

In all, the comparative and international law perspective casts a broader light on national

1050. See CBC, *supra*, note 35.

1051. See Council of Europe, *supra*, note 966.

1052. See *UNOS Policies: Changes as of December 6, 1988*, *supra*, note 1003.

1053. See Council for Mutual Economic Assistance, "Agreement on the International System for Cooperation in the Field of Kidney Transplantation Known as 'Intertransplant'" (1982) 33:1 Int'l Dig. Health Leg. 23.

1054. See art. 20, *General Agreement on Tariffs and Trade*, 30 October 1947, 61 Stat. (5),(6) 1947, T.I.A.S. No. 1700, 55-61 U.N.T.S. (entry into force 1 January 1948).

1055. See European Economic Community, Council Directive No. 89/381/ECC of 14 June 1989 (on human blood products), *Official J. Eur. Commun.*, No. L 181, 28 June 1989, 44, reprinted in (1989) 40:4 Int'l Dig. Health Leg. 871, art. 3, para. 3.

1056. See FDA, *supra*, note 738, s. 37. See also 21 USC 381(e), discussed in OTA, *Federal Policies and the Medical Devices Industry* (Washington, D.C.: OTA, 1984) at 216, 219.

1057. See *Stangvik* and *Corrigan*, *supra*, note 1030 and *Kitchen*, *supra*, note 1028.

1058. See *supra*, note 929 and accompanying text.

tissue transfer issues. Ongoing legal initiatives to ensure safe and adequate, speedy and ethically acceptable tissue transfers are mirrored in both national and international communities.

The pace of legislative activity suggests that the legal framework governing tissue procurement and transplants is in the throes of moderate change. In the last decade, various nations have modified their applicable laws. The amendments have largely aimed at facilitating and regulating the transfer process, amidst dramatically increased transplant procedures and a corresponding need for scarce tissue. Some nations have begun to ponder the biotechnological implications of tissue replacement technologies.

The nations we surveyed tend to diverge most on the details of implementing commonly shared goals. Great Britain, France, Australia, the Council of Europe and the United States seem unanimous in the view that the sale of organs is so ethically abhorrent as to justify the criminal prohibition of sales. Although the precise drawing of lines differs, most nations insist on respecting human rights, the dead, religious beliefs and family wishes, in pursuing the life-preservation ethic that tissue procurement and organ transplantation promise. Most have adopted brain-death criteria. Most increasingly require hospitals to adopt protocols to facilitate tissue donation.

It is in terms of the post-mortem tissue procurement from undeclared potential donors that significant differences emerge, particularly regarding the legal role of the family. The express-consent and routine-inquiry laws of Australia, Great Britain and the United States generally require familial involvement. Competing presumed-consent theories in Western Europe have yielded laws that generally do not. Still, the actual clinical practice in Western Europe seems to involve the family; this may call into question the utility of a strict presumed-consent approach. Such small, significant differences are telling evidence of the tensions and values underlying these delicate legislative choices.

They may also suggest a simple truth: Whatever the chosen policy or law, it remains subject to the web of evolving yet constant beliefs, customs and attitudes on the human body that have coloured the human condition from the anatomical age to the transplantation and biotechnological ages.

CHAPTER FIVE

Options and Recommendations for Reform

I. The Strengths and Limits of Law

The foregoing chapters reveal the strengths and limits of law and its evolving role in responding to medical demand for the human body. Medical demand itself changes with technological innovation and changing therapeutic needs. The evolution of both law and medicine has sometimes tracked, and sometimes led, the evolution of views on the human body, as society has moved from the anatomical age of the nineteenth century into the transplantation and biotechnological ages of the present.

From the historical perspective, many of the concerns raised during deliberations on the 1843 *Anatomy Act* of the Province of Canada[1059] remain. Society continues to debate the issues surrounding bodily sales and property, respect for the dead body, the burden and fairness of laws addressing tissue scarcity and how the law might aid, and not impede, medicine in its endeavours to preserve life. The context, magnitude and implications of the concerns have changed, however.

Indeed, a century and half after the first debates on tissue transfer laws sounded in Canada, the questioning and international clamour provoked by the *Moore*[1060] case seem to signify formal rites of passage to a challenging new age in tissue transfer history. The initial phase of the journey seems to be a transitional one. In early passage through the biotechnological age, society finds itself searching to define the precise rules and applications of at least three legal regimes that seem likely to govern tissue transfer practices for the foreseeable future. The three legal regimes and their characteristics are outlined in table 3.

As indicated in table 3, a "natural" regime refers to the transfer of natural tissues, such as blood and organs. This regime is gift-based, as expressed in the word "donor." It is characterized by an ethical basis and a public policy of non-commerce, non-profit and non-property.

1059. See pages 2-3, 127-29, above.

1060. See *supra*, note 426.

TABLE 3. Tissue Transfer and Replacement Technologies: Legal Regimes

Regimes	Material Transferred	Transfer Model	Banking	Safety Standards	Ethic & Policy Discourse	Market
"Natural"	Tissues & Substances Transferred ◦ blood ◦ gametes • milk ◦ organs ◦ placenta ◦ skin	Consent ◦ donor & recipient Exceptions ◦ unclaimed bodies • forensic autopsies ◦ emergencies (Quebec) Abandoned ◦ research & disposal	Preserved ◦ blood ◦ bone marrow ◦ cells • gametes Preserved for ◦ self/family by depositors ◦ society	Professional Standards ◦ milk Private Law Suits (few)	Gift Non-commerce Non-property	Non-profit (with exceptions)
"Mixed" — Biologics & Biotech-nological	Tissues, Substances & Products Transferred ◦ bioprosthetic heart valves ◦ cell lines & cultured cells ◦ processed & synthetic rDNA hormones ◦ rDNA genetic transplants ◦ rDNA skin & organ equivalents • vaccines	Consent ◦ Donor/source & recipient Abandoned & Commercialized ◦ *Moore* case	Processed & Preserved ◦ bioprosthetic veins • DNA ◦ heart valves ◦ semen: *Parpalaix* case Preserved for ◦ self/family by depositor ◦ society	Professional Standards Federal Drug, Biologics & Medical Device Law • bioprosthetic heart valves? ◦ blood & plasma regulations ◦ frozen, processed semen? ◦ processed bone marrow & cartilage? ◦ processed dura mater? ◦ rDNA drugs (insulin, growth hormone)	Gift/Non-commerce Manufacture/Sales Property/Non-property	For Profit (with limits) Some Patents
"Artificial" & Mechanical	Products ◦ artificial kidney • mechanical heart valves • synthetic blood ◦ bioprosthetic veins ◦ contact lenses	Consent ◦ recipient • no donor	Processed & Manufactured • plasma ◦ blood products • veins ◦ "living" contact lenses	Federal Medical Device Law • safety & efficacy of medical & implanted devices, e.g.: ◦ cardiac pacemakers ◦ artificial heart, kidney ◦ implanted insulin pumps • synthetic blood vessels • synthetic eye lenses	Manufacture/Process & Sales Commerce Property	For Profit ◦ research • patents ◦ marketing ◦ sales

The artificial heart and kidney typify the products of a second regime — the "artificial-mechanical" tissue transfer legal regime. These tissue replacement technologies do not come from donors. They are products invented, designed, manufactured, marketed, sold and licensed under federal patent and medical device laws.[1061] Investment, commerce and for-profit transfers are commonplace and accepted in the ethic and policy discourse of this second regime.

For a number of years, Canadian society has been drawing on both the natural and artificial-mechanical regimes, to define a third, "mixed" tissue replacement legal regime. It operates parallel to, and simultaneously with, the above regimes. Under it, human tissues are processed or manufactured into therapeutic products. Drug companies, and now biotechnology firms, convert blood, tissue and substances from human sources into drugs, skin equivalents, bioprosthetic veins, frozen blood plasma and other useful therapeutic products. Many of these "biologics" and biotechnology products are patented, regulated and sold under federal laws. The terms "gift" and "commerce," "human substance" and "biosynthetic product," are used in the ethic and policy discourse of this mixed regime.

There is a conspicuous, increasing trend towards biosynthetic and bioprosthetic tissue replacement technologies.[1062] As biotechnology and medicine proliferate the number of therapeutic tissue products that seem to fall into the mixed regime, it is not always clear whether the products should be subject to the particular requirements of one or another regime. As a result, society observes the parties in *Moore*-[1063]like disputes drawing on both the natural and the artificial regime, to contest the precise legal content and consequences of the tissue transfer process. Disputes of this kind both stimulate and reflect broader societal dialogue. As such, the dialogue between law, medicine and, now, bioethics continues, and promises to do so into the twenty-first century.

The contents and dynamic of the dialogue also suggest that tissue scarcity today is as much a societal construct as an empirical fact.[1064] If disease and injury create incipient medical needs, it is also true that sophisticated surgical techniques and high technology medicine help amplify those needs into societal demand. On the supply side, annual death statistics indicate an abundant potential supply of cadaveric tissue and organs. Why cannot society simply and efficiently procure these tissues to help save human life?

To endeavour to tap this potential reservoir, however, is to encounter a technological and ethico-legal construct. Society currently lacks the technical capacity to provide long-term storage or banking of donated hearts, kidneys and lungs.[1065] In contrast to procuring simple tissues, organ procurement thus proceeds on a quasi-emergency basis to procure fresh organs from the recently deceased. Even if the technological constraint in organ banking were relaxed, procurement would encounter an ethico-legal construct.

1061. See pages 20-23, 117 and 123 above.

1062. See pages 22, 117-22 above.

1063. See *Moore* (1990), *supra*, note 426.

1064. For a view of organ scarcity as an arbitrary construct, see George J. Annas, "The Paradoxes of Organ Transplantation" (1988) 78:6 Am. J. Pub. Health 621.

1065. See pages 22-27 above.

The ethico-legal construct is simple in some aspects but complicated in others. It transcends analytic dualisms. The procurement process is not a simple contest between life and death, the living and the dead, hard science and soft sentiment or medicine and death mythology. Society has an evolving commitment to a range of fundamental values and interests. Our commitment to privacy, autonomy, beneficence, religious practices and beliefs, competing moral views on the equal treatment for the dying but not dead potential donor, preserving life and health, human dignity — all help create a sophisticated, textured process through which the body's tissues and organs become available for the therapeutic purposes of the living.[1066] The precise meanings and comparative importance of these values and principles are not always clear and will sometimes be contested. Some of the values are enforced by legal rights — others, by the force of ethical principle. Together, they keep defining and animating the construct.

This ethico-legal construct and the competing values on which it is structured illustrate — at times too bluntly — that while the cherished value of saving life or health determines much, it does not determine all.[1067] If this were otherwise, it might make for more efficient tissue procurement, and a simpler, albeit less rich, human existence. The very wealth of this construct and its sometimes contradictory and entwined values make it integral to our personal and community identities, if only because it reflects and structures thought and choice.

This construct, then, also highlights the helpful but necessarily limited role that the law may play in structuring legal remedies to tissue scarcity. Law is ill-equipped to solve the technical dilemmas of medicine or the philosophical divides of ethics.[1068] Rather, it more typically defines minimal rights and duties in the tissue procurement and transplant process. By doing so, the law helps structure the broad rules under which tissue transfers occur.

The law may tend to give expression to traditional attitudes and values regarding the human body. The traditions and values themselves may, and perhaps should, be called into question by the competing views and values of medical science. If the challenges and questioning spawn confusion and uncertainty, they also present the opportunity to rethink, modify or affirm current rules, practices and values.

It is within this framework — one of rethinking and examining the law, public policies and ethics of conventional and emerging national tissue transfer and replacement regimes — that we propose recommendations to some of the issues explored above. We do so mindful of the important work in this area ongoing by the World Health Organization,[1069] by neighbouring and distant nations and by the provinces across Canada.[1070]

1066. See pages 61-62 and 136-43 above.

1067. See pages 61-62 above.

1068. See pages 34-36 and 61-62 above.

1069. See page 163 above.

1070. See pages 135-36 above.

Our review also persuades us that universal solutions, unfortunately, remain elusive. Indeed, the deep philosophical nature of many of these life-death issues — particularly in the natural tissue transfer regime — indicates that many of the competing interests, values and approaches do not lend themselves to universal solutions. This is not to say that the law cannot offer acceptable options and solutions. Indeed, it can; it may even offer preferred solutions. We believe, however, that these solutions must flow from values long held to be fundamental, and from principles and goals to which Canadian society continually aspires.

II. General Goals and Principles — Towards a Safe and Adequate, Just and Efficient, Tissue Transfer and Supply System

RECOMMENDATION

1. The provision of a safe and adequate, just and efficient, tissue transfer and supply system should be a common national goal of law and public policy.

We are of the view that the diverse public and private players who affect therapeutic tissue transfers in Canada should work towards these common national goals. A commitment to any one of these broad societal goals does not, by itself, dictate the implementation of a specific tissue procurement policy. This is so largely because few, if any, of the values in our ethico-legal construct are absolute or intrinsically determinative. Rather, there is a dynamic, healthy and often conflicting tension between the goals and principles and their underlying values. The goal of achieving an "adequate" supply of tissue, for example, must be tempered and structured by our commitment to safety, human rights and efficiency.

Likewise, the goal of efficiency must be understood in terms of both abiding and contemporary notions of justice in the allocation of scarce health resources.[1071] Efficiency means an effective regional and national transfer system. It also implies a commitment to cost-effective medical interventions. In this sense, society must advance its public and ethical deliberations and its capabilities with regard to economic analysis and medical technology assessment, to evaluate the cost-efficiency and the intergenerational distribution of costs and benefits of, and associated medical learning curves on, transplants and other high technology medical interventions.[1072] Such tools will help define and refine the role of the law.

RECOMMENDATION

2. The development and reform of laws affecting tissue transfer and replacement regimes should be based on principles of

1071. See pages 32-34 above, and page 190 below.

1072. See pages 32-34 above.

(a) autonomy, inviolability and integrity of the human body;

(b) altruism and encouraged voluntarism;

(c) gratuity and universality;

(d) preserving and protecting life; and

(e) respecting the dying, the dead and their families.

We are persuaded that these five basic principles will advance the goal enunciated in Recommendation 1 and guide the development and reform of laws affecting tissue transfer and replacement regimes. Most of these are engrained in existing law and public policy. Some are extensions or refinements of abiding values or historic approaches in this area, recast in light of modern circumstance. Again, there is a noticeable and healthy tension between some of them. This tension challenges society to balance, and sometimes to choose between, competing principles.

A. Autonomy, Inviolability and Integrity of the Human Body

The *Criminal Code*, the civil law, provincial tissue laws and the *Canadian Charter of Rights and Freedoms* give legal effect to the ethical principle of autonomy. The right to be free from the non-consensual touching of one's physical person protects bodily integrity and privacy and promotes personhood and human dignity. Law, medicine and society owe special protections to, and duties of care and respect for, children, mentally disabled persons, incompetent patients and those otherwise unable to consent to or refuse physical invasions of their bodies.

B. Altruism and Encouraged Voluntarism

Unselfish donation is a laudable public ideal. The public giving of blood, organs and other gifts of life has long been, and should remain, a preferred public policy.[1073] Thus, altruism and voluntarism ought to be nurtured and practised. Increased, creative, educational tissue donation initiatives that are targeted at the public and at health professionals give practical effect to those values.

C. Gratuity and Universality

In this context, the word "gratuity" has special meaning. For nearly a decade, the Canadian Blood Committee has used the gratuity principle in national blood policy to mean that recipients of blood products should not be charged for them.[1074] The general

1073. See pages 39-41 above.

1074. See *Annual Report of the Canadian Blood Committee to the Provincial-Territorial Conference of Ministers of Health* (1989), *supra*, note 38, appendix A at 3 ("This [the gratuity] principle requires that recipients of blood, components and plasma fractions are not charged for these products provided within the insured health programs of Canada").

commitment of Canadian society to basic notions of justice and its specific commitment to universal access to health services indicate that one's ability to pay should not determine access to scarce therapeutic tissues, organs and derived products. These principles also have implications for donors. The principle that donors should neither gain nor lose financially means that potential donors from all socio-economic levels should have an opportunity to act on their altruism. Hence, insurance coverage[1075] of and payments for donor expenses are legitimate means of ensuring that the less affluent have an equal opportunity to donate. A strong, practical public policy and ethic of giving diminish risks of reducing the human body to a commodity and an object of commerce.

D. Preserving and Protecting Life

Tissue transfer law and public policy are animated by, and should remain premised on, the preservation and protection of human life.

E. Respecting the Dying, the Dead and Their Families

The dying, the dead and the emotional and religious interests of their families are entitled to respect. The legal obligation to accord respect echoes the Hippocratic duty to care. To care is to treat the dying with dignity, to respect the integrity of the dead human form and to comfort the family, honouring and accommodating their needs and wishes as they confront the death of a relative.

III. *Inter Vivos* Transfers — Living Donors

A. Maintaining the Existing Model

RECOMMENDATION

3. The existing model for living donor tissue and organ transfers, which is premised on free and informed consent and a requirement that the risk of harms incurred not be disproportionate to expected benefits in medical interventions, should generally be maintained.

Existing law and public policy on tissue transfers from living donors is generally governed by the requirements that informed consent be obtained and that the risk of harms not be disproportionate to benefits, especially in invasive medical-surgical procedures. This model is generally consistent with, and advances, the above principles.

1075. See text accompanying note 489, *supra*.

B. Donation and Crimes against Bodily Integrity

RECOMMENDATION

4. The *Criminal Code* should be amended by the addition of a provision that excludes, from offences against bodily integrity, those cases of human tissue and organ donation in which the donor's free and informed consent is properly obtained and the risk of harms incurred is not disproportionate to the expected benefits.

Criminal law concerns for protecting the life and bodily integrity of tissue or organ donors parallel the concerns in medical research and human experimentation, where the medical and surgical interventions offer no physical benefit to the subject of the intervention. As in those contexts,[1076] we are of the view that *Criminal Code* provisions defining intentional crimes against bodily integrity[1077] should not apply to tissue and organ donation, *if* (1) informed consent has been obtained from the donor, *and* (2) the risks are not disproportionate to the benefits of the procedure. The risk-benefit ratio should include both physical and psychological factors.[1078] As medical interventions undertaken for therapeutic purposes, such tissue and organ donations would fall under the "medical procedures" exception to the crimes-against-bodily-integrity reforms that the Commission recently proposed in Working Paper 61.[1079]

RECOMMENDATION

5. Tissue procurement from those persons who are incompetent to consent to donation should be regarded as lawful, when there has been a case-by-case determination by an independent third party (for example, court, review board, ombudsman and so forth) to ensure that the following conditions have been met:

(a) the donation of bone marrow and non-regenerative tissue is restricted to donors and recipients in the same family;

(b) all reasonable, potential procurement and medical treatment alternatives have been exhausted;

(c) the procedure does not involve any serious risks to the donor;

(d) the risk of harms incurred is not disproportionate to the expected benefits;

1076. See Working Paper 61, *supra*, note 295; Report 31, *supra*, note 116 at 63; Working Paper 26, *supra*, note 370 at 57-59.

1077. Compare cl. 7(1), (2)(a) and (b) of Report 31, *supra*, note 116 at 61-62, and the maiming/disfigurement assault, battery, provisions of existing *Criminal Code* (ss 244, 265, 266) — all discussed, pages 87-94 above.

1078. See Report 31, *supra*, note 116 at 63; Working Paper 26, *supra*, note 370 at 57-59.

1079. Working Paper 61, *supra*, note 295 at 35-36.

(e) the legal guardian's consent has been obtained; and

(f) where possible, the potential donor's consent has been obtained, and his or her refusal is always to be respected.

Intractable and trying circumstances surround the question of organ donations from minors and mentally disabled individuals. A mature minor who has the capacity to understand and appreciate the risks, benefits and consequences of donating tissues or an organ is similar to an adult in those circumstances.[1080] For potential donors who are incompetent to consent, and thus unable to act self-protectively, such procedures may be consistent with public policy and defensible on grounds of necessity,[1081] in exceptional cases, when specific conditions have been satisfied. First, the principle of inviolability and integrity of the human body and the ethical corollary of doing no harm require that the procedure not involve serious risks to the donor.[1082] As the invasiveness and irreversibility of the procedure increase — from blood to bone marrow to kidney transplants — so do concerns for bodily integrity. Secondly, then, to ensure that incompetent donors are most fully protected from harms, donations from them should only be considered as a last resort — that is, after all reasonable alternative avenues of procurement or alternative medical treatment have been exhausted. Thirdly, the principles of respecting bodily integrity and seeking to preserve life, as reflected in the ethical corollary of beneficence,[1083] suggest that the net benefits of donation may sometimes justify transplants. This would be so when the procedure involves no serious risk to the donor and the incompetent person is capable of appreciating the potential psychological benefits of donation[1084] and the likelihood of life-saving benefits for the recipient. The potential for psychological benefits seems likely to be greatest in intrafamilial donation. Fourthly, the requirements of consent from the guardian and consent or non-objection from the potential donor help ensure that the wishes of the incompetent individual, and of those entitled to speak on his or her behalf, are respected. Such requirements parallel, with some variations, those of the Australian Law Reform Commission[1085] and the Council of Europe[1086] — both of which propose general rules against tissue procurement from incompetent donors,with narrow exceptions governed by strict procedural protections. The Uniform Law Conference of Canada has also recently proposed restrictive requirements.[1087]

1080. See pages 65, 87-95 above.

1081. See *supra*, note 552.

1082. See Beauchamp and Childress discussing non-maleficence, *supra*, note 236 at 120, see also pages 47-48 and 93, above.

1083. See *supra*, note 285 and pages 34, 48-50 and 93 above.

1084. *Ibid.*

1085. See ALRC's recommendation, summarized in note 555, *supra.*

1086. See Council of Europe recommendation, summarized in note 556, *supra.*

1087. See 1989 Uniform Act, *supra*, note 833, ss 6, 7.

IV. Defining Brain Death — Anencephalic Newborn Donors

RECOMMENDATION

6. The "irreversible cessation of all brain functions" standard, proposed by the Commission ten years ago in Report 15, should not be modified to facilitate organ procurement from dying anencephalic infants or other patients who do not meet the whole-brain-death standard.

In Canada, anencephaly results in the death of some fifty newborns per year.[1088] The birth defect is characterized by the absence of a major portion of the upper brain. Those live-born newborns who are afflicted with this tragic birth defect typically die within seventy-two hours after birth. To facilitate organ procurement from live-born anencephalic infants, proposals have been made to consider them as being born dead, brain dead, still-born or otherwise exempt from modern life-death criteria.[1089] For the reasons elaborated above, the Commission is not persuaded that the whole-brain-death definition of death should be amended to facilitate organ procurement from anencephalic newborns. We remain of the view that the legal definition of death should not be determined "by references only or mainly to the practice of organ transplantation."[1090]

V. Post-Mortem Transfers — Deceased Donors

The options for regulating the procurement of therapeutic tissue and organs from the deceased range in a spectrum from the requirement of express consent to the routine procurement of organs regardless of consent or objection. We currently favour retention of the express-consent model for several reasons. First, the technico-ethical construct, described above, casts a necessarily limited role for the law to play in devising remedies to tissue scarcity. Secondly, before recommending reforms that significantly depart from the existing model, we are hopeful that modest reforms aimed at specified ills in the existing system will prove sufficient. Thirdly, this approach seems further advised from a human rights perspective, which cautions government to infringe implicated rights as little as possible in the pursuit of its goals.[1091]

Fourthly, while the Commission is generally committed to efficiency as a national guiding goal, it is also particularly concerned that, for now, it may be imprudent for the law to venture further than removing legal ambiguities and supporting efforts to supply high technology transplants. For legislation to go further and, for example, attempt to

1088. See text accompanying note 574, *supra*.

1089. See page 97, above.

1090. See page 100, above.

1091. See text accompanying note 893, *supra*.

increase dramatically the numbers of organs might skew important macro-allocation health care priorities. Increased organ supply may further increase the demand for transplants, to the detriment of competing, low technology and demonstrably cost-effective health care and medical procedures that deserve consideration.[1092] Both the Commission and society urgently need more information on which to base more informed decisions of this kind. We therefore urge further research in this area.

Finally, it is the view of many ethicists consulted by the Commission that while alternative models such as presumed consent are ethically acceptable, they are currently unlikely to enjoy wide public support in Canada. If this is accurate, then any significant departures from the current express-consent model should be preceded by broad, persistent educational initiatives that may help phase in models such as general presumed consent, if they prove necessary. The Commission believes that as data on refinements to the express-consent model and data on the scarce allocation of resources become available, society will be better positioned to decide whether it is appropriate to phase in a general presumed-consent approach.

A. Express Consent Required — Opting In

(1) The General Model

RECOMMENDATION

7. (1) The general express-consent model of tissue procurement from deceased donors should be maintained and strengthened, as a preferred model for public policy.

(2) Donors who have declared their wishes to donate should have those wishes legally respected.

This is the generally prevailing model for post-mortem tissue procurement in Canada.[1093] In its favour, it encourages voluntarism and altruism. It also accommodates religious preferences and the surviving family's wishes by enabling families to donate on behalf of the deceased in some circumstances. On the negative side, particular weaknesses in the model result in missed opportunities for donation.[1094] There has also been undue legal uncertainty over whether surviving family members may override the express wishes of a deceased declared donor.

1092. See pages 32-36, above.

1093. See pages 132-33, above.

1094. Compare pages 34-35 and 153-58, above.

RECOMMENDATION

8. (1) Hospitals should implement written organ donation protocols and policies, and consider the adoption of routine-inquiry protocols, to address the problem of undeclared potential donors.

(2) Health and Welfare Canada should undertake and administer a pilot program involving appropriately chosen federal hospitals, for the purpose of implementing and evaluating the impact of routine-inquiry protocols.

(3) Health and Welfare Canada should encourage the participation of non-federal hospitals and the provinces in this pilot program, by making federal funds available to non-federal hospitals prepared to implement and report on routine-inquiry protocols.

Many jurisdictions have encountered significant difficulties with the express-consent approach. Most potential organ donors do not sign tissue donor cards despite consistently high public support in the opinion polls for tissue and organ donation.[1095] This reality results in the all-too-common hospital situation in which a deceased individual, whom a medical team identifies as a potential donor, has given no indication of an intention to donate tissues or organs.[1096]

To help resolve these undeclared donor situations, we support a refinement of the express-consent model, one that has emerged in various nations in recent years, known as "routine inquiry," "recorded consideration" or "required request."[1097] All are premised on existing tissue donation laws that authorize the family of the deceased person to consent to donation on his or her behalf. All essentially require hospitals to (1) adopt protocols to identify both declared donors and undeclared potential donors, and (2) implement protocols such that the families of undeclared potential donors are generally informed of the option or are offered the opportunity of donation. For purposes of our discussion, we use the term "routine inquiry" to describe laws or policies that contain these two features. Variations of the routine-inquiry approach have been adopted in Australia and Great Britain, as well as in federal law, uniform Acts and most state laws in the United States.[1098]

If we acknowledge the merits of the approach, how might it be implemented? Should hospitals or health professionals have a general, or even statutory, duty to identify potential

1095. See *supra*, note 225. See pages 35-36, 136, 153-58 above.

1096. See pages 34-35 above.

1097. See pages 135-36, 153-59 and 199-200 below.

1098. See *supra*, note 925, and pages 153-59, above.

donors and make inquiries of the family? Since we currently see no need to adopt national tissue procurement legislation, as the United States[1099] has done, the question may be answered by the provinces. But in view of the increasingly national and international dimensions of tissue transfer regimes, the small number of federal hospitals involved in these matters and ongoing provincial law reform deliberations, we offer our analysis of the issue.

Detractors of a statutory duty to inquire generally take the view that such legislation would: (1) be an unwarranted intrusion on professional prerogative and family privacy; (2) address administrative-educative versus legal problems; (3) impose added costs on hospitals and the health care system; and (4) require the performance of duties that might subject violators to sanctions or prosecution.

Proponents of the approach consider that: (1) a prime reason for the scarcity of transplantable tissues is the failure to approach the families of undeclared, potential donors, despite evidence that most would support being given an opportunity to consent in such circumstances, as part of their bereavement process;[1100] (2) imposing an obligation on hospitals would likely result in more tissues and organs for transplantation; and (3) a statutory duty could be drafted so as to permit the exercise of professional discretion and sensitivity to the circumstance. Any such duty should recognize the need for professional discretion not to ask, in the instances where such an inquiry would clearly cause inordinate harm or would otherwise be inappropriate.

In view of these considerations, three particular points persuade us that the above routine-inquiry approaches merit further serious examination in Canada. First, the approaches would seem to offer the opportunity for public and professional education, and a reform specifically targeted at a sensitive and critical area that Canadian analysts consistently identify as a barrier to increased organ donations.[1101] The difficulty seems less in engendering altruism than in giving patients and their families a practical opportunity to act on their good intentions. Secondly, they differ from compulsory procurement and tissue sales options in two important respects: they promote altruism and encourage voluntarism. Thirdly, these approaches seem less likely to provoke legal challenges for infringement on religious freedom, autonomy and privacy. By encouraging voluntarism, and by directly accommodating familial wishes, they appear less likely to infringe basic human and constitutional rights. These considerations suggest that routine inquiry is a preferable remedy to circumstances where the wishes of the donor are undeclared.

A preferable remedy is not a guaranteed remedy, however. There has been some debate as to whether any such statutory duty should be imposed on medical professionals or, more generally, on hospitals. Clearly, surgeons, transplant co-ordinators, neurologists, nurses and hospital chaplains would play pivotal roles in implementing a statutory duty to inquire.

1099. See *supra*, note 995.

1100. See *supra*, note 985.

1101. See pages 35-36, above.

Perhaps many medical professionals already consider a duty to inquire as part of their ethical and professional duty of care. Yet, professional reluctance or resistance may prove to be an influential factor in the success or failure of these approaches. No individual should be compelled to "request donation." But it is also not in the public interest for organs to be wasted because consent was not considered by donors or their families at the critical moment.

Practical considerations may help alleviate these concerns. Since many undeclared, potential donors die in a hospital, it would seem advisable that any legal duty to ask should be imposed on the institution, as the Canadian Bar Association has suggested (see appendix A). Imposing the duty on the hospital might also allow it to be administratively creative in delegating the duty to ask to professionals who would act sensitively, efficiently and in a cost-effective manner.

Health and Welfare Canada might help evaluate any impact that hospital organ donor protocols and routine-inquiry approaches have on undeclared donor circumstances, by designing and co-ordinating a methodologically sound pilot program involving appropriate federal hospitals. By making federal funds available to hospitals prepared to undertake pilot projects implementing and reporting on routine inquiry, Health and Welfare Canada may also encourage the participation of non-federal hospitals. The data provided by participating hospitals may help society to assess the benefits of refinements to the express-consent model of post-mortem organ donation.

In this vein, the following protocol for the routine-inquiry model may prove helpful in addressing the problem of undeclared potential donors. It is a variation of an approach recommended by the Australian Law Reform Commission and adopted in most Australian states.[1102]

(1) Hospitals should implement written tissue and organ donation protocols and procedures to identify potential donors. The procedures should include professional education and training.

(2) Hospitals with such protocols should have a general authority to procure tissue and organs from undeclared potential donors, depending on the discharge of two duties. Diligent efforts, made in good faith, should be undertaken

> (*a*) to determine the existence of documentary evidence of the deceased's intentions to donate,

and, if none are found,

> (*b*) to contact the family, giving family members the opportunity to donate, by informing them of the donation option. Non-consent of the family should be legally binding. Efforts to identify and contact the family, directly and through public authorities, should continue for a reasonable period of time (for example, forty-eight hours or otherwise taking into account the reasonable survival time of the

1102. See pages 158-59, above.

tissue). Those responsible for the diagnosis of brain death or the determination of donor suitability should not be involved in the above efforts.

(3) Where diligent efforts, made in good faith, fail to identify or contact the surviving family, no procurement should take place.

Some points should be noted about item (3) of the above model protocol, which addresses procurement from undeclared potential donors who have no immediately ascertainable family members. The suggestion in the model that no procurement should proceed in such circumstances is based on an express-consent rationale. Some analysts and jurisdictions, however, have urged or adopted limited presumed-consent rationales in such instances. Australian and American legislation authorizes tissue and organ procurement in limited circumstances from undeclared potential donors having no ascertainable family members.[1103] The Uniform Law Conference of Canada's 1989 *Uniform Human Tissue Donation Act* also appears to adopt a limited presumed-consent principle for tissue procurement from such donors in medical examiner cases.[1104] This has had historic precedent in Canada since the nineteenth century, when unclaimed bodies were first made available to medical schools under provincial anatomy laws.[1105]

B. Presumed Consent — Opting Out

Presumed-consent theory maintains that society may reasonably presume that one consents to post-mortem tissue donation unless there is evidence of objection. As with express consent, presumed consent focuses on the deceased's intentions to give, and is thus more accommodating of altruism than is compulsory procurement. The presumption of consent is thought to be reasonable on the basis of community altruism, and is further necessitated by the principle of saving life that may be advanced by potential increases in available organs and tissues. The approach is also thought to avoid exacerbating familial grief that may result from insensitive requests for organ donation.

Several considerations would, however, seem to argue against immediate, general implementation of presumed consent. First, evidence from France and other European countries that have adopted this approach suggests that it may not always result in more organs.[1106] Secondly, the theories and purposes behind presumed consent may be frustrated by the practical difficulties of determining whether the deceased has actually opted out of the presumed-consent scheme, and by the clinical and psychological realities of dealing with death and the surviving family.[1107] Competing presumed-consent theories in Western Europe have yielded laws that differ with regard to the legal role of the family in conveying the deceased's intentions.[1108] The letter of the law notwithstanding, the actual clinical practice in most cases is to involve the family. This seems to call into question

1103. See chap. 4, above.

1104. See *supra*, note 837.

1105. See pages 2-3 and 127-29 above.

1106. See pages 147-53, above.

1107. *Ibid.*

1108. See pages 147-53 and 165, above.

the utility of a strict presumed-consent approach. Thirdly, some presumed-consent statutes in the United States have been challenged as violating fundamental human rights.[1109] Finally, the concept of presumed consent may decrease communication within the doctor-patient-family relationship at a time when dialogue and understanding need to be especially nurtured and encouraged. If such potential ills may be avoided by other procurement options that yield substantially equivalent therapeutic supplies, then the presumed-consent option seems less preferred.[1110] Such considerations persuade us that the currently limited application of presumed-consent laws[1111] in Canada should not be extended. We expect that, as data on the effects of routine-inquiry approaches becomes available, the relative value of a general presumed-consent approach will be better understood.

C. No Consent Required — Routine, Compulsory Procurement

Under different views of autonomy, routinely procuring tissues and organs from deceased donors, regardless of the intentions they might have expressed while alive, may violate the ethical principles of autonomy of the living potential donor and respect for the dead. The approach also seems more likely to violate religious beliefs and practices, and exclude legitimate familial considerations from procurement policy. Routine, compulsory procurement would also reverse existing post-mortem tissue procurement policy in Canada. The Commission does not favour this option, as is made clear in our endorsement of the express-consent model of post-mortem procurement.[1112]

D. Respecting the Dead

RECOMMENDATION

9. (1) Section 182 of the *Criminal Code* should be replaced by a provision making it a crime to abuse a human corpse or human remains.

(2) The Commission's Report 31 should be amended by incorporating into the proposed Crimes against Public Order (chapter 22) the following subsection:

Abuse of Corpse. Everyone commits a crime who purposely or recklessly abuses a human corpse or human remains.

The duty to respect the dead body is a duty not to violate its intrinsic dignity and humanity. It includes accommodating the expectations and the moral and religious

1109. See pages 138-42 above.

1110. See text accompanying note 893, *supra*.

1111. See text accompanying notes 845 to 848, *supra*.

1112. Accord MLRC, *supra*, note 157 at 30-31.

sentiments of the family. Mistreating the dead may, in the extreme, offend moral sentiments commonly held by society at large. Some non-consensual medical use of the recently deceased, or of a brain-dead, mechanically sustained cadaver-patient, may not disfigure, mutilate or otherwise significantly invade the physical integrity of the dead body. Yet, the practice may still offend the next of kin by breaching the relationship of trust on which doctors, patients and their families and hospitals so greatly depend.[1113]

In the criminal law context, we are concerned that the century-old *Criminal Code* provision on crimes against the dead, section 182, be coherent and clear. That section addresses both burial duties and the mistreatment of dead bodies. In Report 31, the Commission generally describes the provision as archaic. Indeed, since provincial laws now regulate burial matters, the *Criminal Code* burial provision, paragraph 182(*a*), would no longer seem necessary.[1114]

The situation regarding paragraph 182(*b*), the *Code* provision on mistreating the dead, differs. Most provincial burial laws are limited to the policing of conduct that relates to cemeteries. Most criminal sexual assault offences contemplate a living victim. Thus, neither they nor current or proposed criminal offences clearly or sufficiently cover unlawful and intentional mutilation of the dead human body, sexual interference with it or other general unlawful abuse of it. In our view, such conduct visits universal dignitary harms on both the dead and society as crimes against humanity. Both older and revised criminal codes, and provisions in force in nations such as France, Australia, the United States and New Zealand, express societal condemnation of such conduct through penal sanctions.[1115] The language in the proposed offence is broad enough to encompass a range of offences, and is based on the United States *Model Penal Code* provision.[1116] Under chapter 3(13) of Report 31, which immunizes from criminal liability those acting under legal authority, the offence would not apply to lawful interventions performed on the dead, such as autopsies, organ transplants and funeral preparations.

VI. General Considerations

A. The Safety of Tissue Replacement Technology

RECOMMENDATION

10. (1) Legislation should clearly establish the inclusion of all human therapeutic tissue replacement technologies within the "safety" ambit of the federal *Food and Drugs Act*, to subject them to minimum, uniform national safety standards.

1113. See pages 113-17 above.

1114. See pages 108-13 above, especially note 698, *supra*.

1115. See *ibid.*, especially *supra*, notes 676, 696.

1116. See pages 108-13 above, especially notes 692, 696, *supra*.

(2) Accordingly, the *Food and Drugs Act* should be amended to include a new Part for the regulation of human therapeutic tissue replacement technologies, broadly defined.

The genius of the modern biomedical and biotechnological sciences has begun to blur the lines between some of the human therapeutic tissues, bodily substances and tissue products of the regimes. As the trend towards processed, biosynthetic, bioprosthetic tissues accelerates, ambiguities in laws governing the regimes become more pronounced. Under existing law, it may not be clear whether some tissues, bodily substances and biosynthetic tissue replacement technologies — such as cryolathed and implanted eye lenses, bioprosthetic heart valves, processed, preserved bone marrow or semen — are subject to the same minimal, national safety standards as are other replacement technologies for tissues such as blood plasma and intraocular lenses.[1117] Since the *Food and Drugs Act* also affects products imported into Canada, clear inclusion of therapeutic tissue replacement technologies in the FDA would enhance national and international protection.[1118]

The proposed legislative amendment would remove these ambiguities in the law. An alternative to the recommendation would involve amending the FDA to provide Health and Welfare Canada with authority to identify, by regulation, a tissue as a biologic drug, medical device or implant. Because this alternative would essentially involve fitting a tissue replacement technology into existing regulatory regimes, it may not provide sufficient statutory breadth to regulate emerging and forthcoming technologies. The Commission, therefore, favours the addition of a Part governing tissue replacement technology to the FDA, to provide Health and Welfare Canada with broad, express authority parallel to the existing authority to regulate drugs, medical devices and cosmetics.

B. Regulating or Prohibiting Sales

RECOMMENDATION

11. (1) The purchase or sale of human bodies, organs and other non-regenerative tissue should be made a *Criminal Code* offence.

(2) In defining the scope of the sales prohibition, the legislative provision should exclude from the definition of "sale" reasonable payments for travel or lodging expenses and lost wages incurred by the donor as well as reasonable payments associated with procurement, transport, processing, preservation and implantation of tissue.

Two ethical rationales and two avenues of control are typically offered in arguments against the sale of tissues. The "formalist" views sales as a *prima facie* moral wrong.

1117. See pages 117-23 above.

1118. See *ibid.*, especially *supra*, note 761.

The "consequentialist" may reject sales on the basis of the balance between good or harmful consequences. Both views might lead to a sales prohibition. The consequentialist position, however, admits of the possibility of authorizing sales. Indeed, a true consequentialist will opt for a non-prohibition when the likely benefits of sales outweigh likely harms, or when the likelihood of potential harms is judged insufficient to warrant legal prohibition. For example, provincial gift tissue laws enacted over the last two decades have tended to adopt a consequentialist approach, opting to prohibit the sale of non-regenerative tissue.[1119]

From both formalist and consequentialist perspectives, the purchase and sale of the human body, organs and non-regenerative tissue may be prohibited. From the first perspective, the sale of the dead violates a commonly shared morality regarding respect for the dead and the respect owed to a deceased human being. This view has been the historical basis of section 182 of the *Criminal Code*. The sale of a living human body violates the intrinsic and inalienable right of human beings not to be the subject of barter. This view is currently expressed in provincial laws on adoption. The sale of human organs, too, violates human dignity, as expressed in the often heard concern about commodification.

Payments for human organs and bodies also provoke legitimate consequentialist concerns about, such as monetary incentives that invite sellers to compromise health and safety by taking undue physical risk; or, the allocation of scarce tissue on the basis of the highest bidder, which risks skewing more important allocative criteria such as medical need.[1120] While these formalist and consequentialist concerns may inhere in the sale of regenerative tissue and substances, they would seem most concentrated and compelling with respect to bodies, organs and non-regenerative tissue.[1121]

These arguments bear directly on whether organ sales should be expressly prohibited as a *Criminal Code* offence. To evaluate the merits of creating a criminal offence, the Commission has established four criteria.[1122] In the present context, they frame the following questions: Do organ sales (1) seriously harm others, or (2) seriously contravene fundamental values? If so, (3) would enforcement measures against such acts infringe fundamental values, and (4) would the criminal law significantly contribute to remedying the problem?

Applying the above-mentioned questions to organ sales reveals that the issue of whether or not to create a criminal offence hinges largely on whether the criminal law can make a significant contribution to curing the ills associated with sales. In terms of serious

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1119. See pages 130-36, especially *supra*, notes 843, 856.

1120. See pages 82-83, above.

1121. While medical technology has apparently begun to blur the once clear line between some regenerative and non-regenerative tissues and organs, the distinction still proves helpful in categorizing the general nature of physical risks, medical invasiveness and irreversibility, which accompany donation and transplant. See *supra*, note 85 and pages 19-20, 47 and 82, above.

1122. See Report 3, *supra*, note 730 at 33. See also LRC, *Crimes against the Foetus*, Working Paper 58 (Ottawa: The Commission, 1989) at 32.

harms to others, money may induce individuals to take undue physical risks, induce sellers — who fear that payment would not be made for a diseased or otherwise defective tissue — not to disclose medical information about a transmissible or genetic disease that may harm the recipient; in the extreme, the high price for organs may invite the taking of human life.[1123] In terms of fundamental values, if altruism is considered fundamental, sales may erode its gift-of-life ethic. Sales arguably violate human dignity, by exploiting economic and medical desperation, and by commodifying the human body and its parts — all of which colours how we think about and value our bodies and selves.[1124] Enforcement of a sales offence would not infringe personal liberty or privacy, unless a broad construction of its terms is thought to include a right to alienate, for profit, vital parts of the human body. Enforcement might have a disproportionate impact on persons who are economically disadvantaged and who might seek to enhance their economic status by sales. But enforcement seems unlikely to undermine the value of saving life, because more ethically acceptable alternatives may increase the supply of human therapeutic tissue.

Will a *Criminal Code* offence make a significant contribution to resolving the problems associated with organ sales? Some may argue that it will not, on the grounds that the criminal law is too blunt an instrument for such ills. They may further point out either that regulation is a more appropriate means of curbing potential ills or that sales are already prohibited under most provincial Acts. Others may argue yes, on the grounds that the moral harms to the fundamental values of human dignity, altruism and personhood, the potential for physical harms to the individual and the need for protection of the individual combine to justify invoking the full deterrent effect and stigma of the criminal law. In this view, the offence would establish minimum uniform criminal liability across Canada for increasing interprovincial tissue transfers, and have effect in provinces without, with limited or with dysfunctional sales prohibitions. In advancing the sales offence recommendation, we are mindful of the important legislative consideration the provinces are giving to the recently proposed 1989 *Uniform Human Tissue Donation Act*.[1125] In these nation-wide deliberations on the reform of tissue transfer laws, serious scrutiny ought to be given to the precise scope and definition of sales prohibitions in proposed and existing law, as well as the comparative approaches under recent American, British, Australian and European legislation.[1126]

Finally, a sales offence may prove responsive to transnational developments.[1127] Heightened concerns on north-south and east-west organ sales in the international community have recently been reported or confirmed.[1128] As such, a *Criminal Code* offence provision would respond to the recent and continuing international and World Health Organization calls, in which Canada has assumed a leadership role, for national initiatives to curb organ sales.[1129]

1123. See Roughead, *supra*, note 664 and accompanying text.

1124. See pages 54-61 and 78-86, above.

1125. See text accompanying notes 853-857, *supra*.

1126. See chap. 4, above.

1127. See pages 162-63, above.

1128. *Ibid.*

1129. See pages 162-64, above.

Hence, our recommendation implements the principles of gratuity and the inviolability of the human body. It rejects proposals to develop markets in organs as being premature and directly contrary to altruism. The shortcomings of altruism need not necessitate society's embracing commercialism. Increased tissue donation, to save and promote human life, may be advanced by mechanisms more consistent with Canadian public policy. To ensure that payments for legitimate transfer expenses would not be considered sales, our recommendation excludes from the sales definition payments for reasonable transport, processing, preservation and like expenses. This further ensures that coverage or payment of reasonable donor expenses is not penalized. Thus, donors would neither gain nor lose financially for exercising altruism.[1130]

C. Bodily Property and Theft

RECOMMENDATION

12. Human remains or bodily substances that are in one's lawful possession or that have been lawfully procured and transformed by skill and labour into such entities as human anatomical specimens, processed and preserved tissue or museum artifacts should be considered proprietary objects that fall within criminal law protections against theft.

Our research reveals a notable ambiguity which has survived the century-old *Criminal Code* provision on the mistreatment of corpses. The historic basis of the offence arguably suggests that human remains which have been lawfully procured, and transformed by dint of skill and labour into museum mummies, human anatomical specimens or similarly processed and preserved human tissue, may not be protected from theft by the criminal law because of the common law reluctance to recognize property in a corpse.[1131] This reluctance suggests that one may be prosecuted for theft of burial wraps but not of the body; for theft of the wire holding a laboratory skeleton together but not of the skeleton itself; and for theft of a capsule containing tissue or bodily substances but not of the substance itself.[1132] This position has been critiqued by the authorities.[1133] Today, it seems both anomalous and contrary to the basic values of criminal law and broader contemporary concepts of property. Modern legal analysis no longer automatically equates property with commerce. We are, therefore, of the opinion that the values of the criminal law are better served by removing this ancient ambiguity.

1130. See pages 84-86, above.

1131. See pages 65-70, above, especially *supra*, note 384, and pages 108-13 above, especially *supra*, note 701.

1132. *Ibid.*

1133. *Ibid.*, especially *supra*, note 701.

RECOMMENDATION

13. (1) Where health providers, hospitals or researchers develop a commercial interest in a patient's tissues or cellular matter, or where the development of any such interest is reasonably foreseeable, the health providers, hospitals or researchers should be obliged to disclose the interest to the patient.

(2) Where it becomes reasonably clear that the health provider with the commercial interest may compromise his or her duty to exercise independent professional judgment strictly on behalf of the patient, the health provider should be obliged to transfer care of the patient.

(3) Following the health provider's disclosure to the patient of any such commercial interest, the patient should be given the opportunity to decline further treatment and involvement, and if he or she so declines, the health provider should be obliged to transfer care of the patient.

It is currently unclear whether statutory reform of the *Patent Act*, more explicit medical research guidelines or a simple extension of common law principles will answer some of the new riddles posed by biotechnological progress.[1134] How does society protect the bodily integrity, autonomy and dignity of human tissue sources, such as patients, while providing proper incentives and protections for the creative genius of biotechnologists who develop potentially lucrative therapeutic fruits that benefit the public? Today's progress would seem to make the legal maxim "The law cares not for trifles" no longer applicable to excised tissues or secreted bodily substances long regarded as valueless and abandoned.[1135]

Some have argued that legal recognition of limited property interests — as distinct from commercial interests — will protect patients against non-consensual bodily invasions or the non-consensual commercial development or use of excised or deposited tissue.[1136] It remains to be seen whether the recognition of such interests will help clarify the legal rights of donors and the corresponding duties of medical professionals *vis-à-vis* human substances.

In the meantime, traditional medico-legal principles may offer guidance. If a physician, hospital or researcher has an interest in a patient's cells or tissues, or if the development of such an interest may be reasonably foreseen, disclosure of the interest would seem to be required under informed-consent principles. The foreseeability test here is an objective standard. The disclosure requirement is buttressed by the physician's fiduciary duty: that of loyalty, trust and good faith to the patient. If the physician has a commercial or other interest potentially in conflict with the duty to exercise independent professional judgment

1134. See pages 31-32, 73-77 and 123, above.

1135. See page 75, above.

1136. See pages 65-78, above.

and act strictly on behalf of the patient, the general rule should require disclosure to the patient and a full explanation of the conflict. The patient would then have an opportunity to consent to continued treatment or to participation. If the patient were to decline further involvement, or if it were reasonably apparent that the physician's conflict had compromised the ability to provide disinterested, professional treatment, the physician would have an obligation to transfer care of the patient. Surveillance by hospital research and ethics committees may also reduce the potential for abuse.

While the foregoing principles may curb the potential for disputes between the sources and the developers of commercial tissue interests, they may not do justice to the complexity of the competing interests and issues involved. Thus, as we specify below, further research is required in this dynamic area.

D. Tax Incentives?

RECOMMENDATION

14. The *Income Tax Act* should not be currently amended to permit credits or deductions for tissue or organ donation.

Should the charitable-gift concept of donation be given practical, monetary effect through the tax law? In foreign jurisdictions, legislative proposals have been introduced, but to our knowledge never enacted, to provide tax deductions or credits for human therapeutic tissue and organ donation.[1137] While it is unclear whether such incentives would increase supplies, it is likely that charitable deductions would benefit higher-income taxpayers the most. In the context of the prevailing tissue transfer regimes, such tax treatment may also tend to monetize the value of natural tissues, and lend the impression that they may indeed be priced[1138] like ordinary commodities — all at the risk of undermining the altruistic basis on which this public regime depends.

VII. Questions Warranting Further Research

A number of related matters of national interest warrant further attention in the expanding domain of tissue transfer and tissue replacement technology. More study is needed on: the allocation of scarce resources and transplant waiting lists; procuring, transforming and commercializing human cells and tissues; fetal tissue transplants; international transfers; and the ethical status of neomorts.

1137. See *supra*, note 800.

1138. See Kant, *supra*, note 352 and accompanying quotation in the text.

A. Allocating Scarce Resources[1139]

What is the optimal societal investment in organ and tissue transplants or primary and preventive care? To advance ethical and public deliberation on such macro-allocation questions, further study of the cost-effectiveness of transplant technologies is warranted, as part of a global societal effort to subject high technology medicine to continuing critical assessment. Indeed, it may be time to include cost-effectiveness as a national criterion of the *Canada Health Act* commitment to provide "medically necessary" health services to Canadians.[1140] The federal-provincial initiative that recently created the Canadian Co-ordinating Office for Health Technology Assessment is a welcome, commendable step in this direction. Tissue and organ replacement technology would seem an apt subject for the early attention of that Office. Society might benefit invaluably from a national resource that provides competent, unbiased information on the benefits and risks, as well as the biological, economic, legal and ethical effects, of new technologies.

Investing resources in tissue replacement technology often begets challenging micro-allocation choices as well. What are the medical, ethical and legal bases for allocating organs and priorities to persons on transplant waiting lists? Whether the bases include medical need, first-come first-served allocation, lottery, age or social standing, they should be examined to understand whether they comport with basic notions of fairness. Viewing donated tissues and organs as a precious national resource may heighten the duty to allocate them equitably and efficiently. It may also suggest a good Samaritan ethic of sharing transplant resources with nations lacking them. Because these allocation issues implicate fundamental values and pressing questions of distributive justice, they merit the immediate and continuing attention of government, professional and university groups and the public.

B. Procuring, Transforming and Commercializing Human Cells and Tissue

Who has, or should have, commercial and patent rights to therapeutic products that are biotechnologically developed from human cells and tissues? Existing law does not resolve or clearly answer this question for patients, research subjects, physician researchers or the biotechnology industry. Such uncertainty may increase the potential for disputes. A multidisciplinary examination of the issues and options should yield more legal and ethical certainty.

C. Fetal Tissue Transplants

Preliminary studies suggest that fetal tissue may be useful in the treatment of illnesses such as Parkinson's disease, a devastating neurological disorder. Under what circumstances,

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1139. See pages 32-34, above.

1140. See A. Leaf, "Cost Effectiveness as a Criterion for Medicare Coverage" (1989) 321:13 N. Engl. J. Med. 898.

if any, should it be ethically and legally permissible to use fetal cells from voluntarily and involuntarily terminated pregnancies for therapeutic transplants? Who should decide? Does it matter that there is historical precedent for such use in the development of vaccines?

D. International Tissue Transfers

To what extent should there be regional global systems for the international transfer of tissue? While the medical care systems of Canada and the United States are distinct, they regularly share medical resources, including organs and tissues. As national tissue- and organ-sharing and allocation systems develop, increased attention should be devoted to efficient and fair tissue sharing in North America. If it is sometimes more medically efficient to send organs north-south rather than east-west, how should the medical considerations weigh against considerations of national self-sufficiency? Should we adopt agreements to govern safety concerns and the exchange of therapeutic substances, as some European countries have done?

E. Neomorts

What is the ethical status of the brain-dead, mechanically sustained, cadaver-patient? Should hospital protocols governing patients apply until mechanical support is withdrawn and the cadaver resembles a traditional corpse? Such protocols may or may not resolve the ethics of maintaining brain-dead pregnant women until they give birth, or of conducting research on the neomort or using it for medical training.[1141] The ethical status of these deceased patients needs to be clarified.

1141. See pages 113-17, above.

Summary of Recommendations

1. The provision of a safe and adequate, just and efficient, tissue transfer and supply system should be a common national goal of law and public policy.

2. The development and reform of laws affecting tissue transfer and replacement regimes should be based on principles of

(a) autonomy, inviolability and integrity of the human body;

(b) altruism and encouraged voluntarism;

(c) gratuity and universality;

(d) preserving and protecting life; and

(e) respecting the dying, the dead and their families.

3. The existing model for living donor tissue and organ transfers, which is premised on free and informed consent and a requirement that the risk of harms incurred not be disproportionate to expected benefits in medical interventions, should generally be maintained.

4. The *Criminal Code* should be amended by the addition of a provision that excludes, from offences against bodily integrity, those cases of human tissue and organ donation in which the donor's free and informed consent is properly obtained and the risk of harms incurred is not disproportionate to the expected benefits.

5. Tissue procurement from those persons who are incompetent to consent to donation should be regarded as lawful, when there has been a case-by-case determination by an independent third party (for example, court, review board, ombudsman and so forth) to ensure that the following conditions have been met:

(a) the donation of bone marrow and non-regenerative tissue is restricted to donors and recipients in the same family;

(b) all reasonable, potential procurement and medical treatment alternatives have been exhausted;

(c) the procedure does not involve any serious risks to the donor;

(d) the risk of harms incurred is not disproportionate to the expected benefits;

(e) the legal guardian's consent has been obtained; and

(f) where possible, the potential donor's consent has been obtained, and his or her refusal is always to be respected.

6. The "irreversible cessation of all brain functions" standard, proposed by the Commission ten years ago in Report 15, should not be modified to facilitate organ procurement from dying anencephalic infants or other patients who do not meet the whole-brain-death standard.

7. (1) The general express-consent model of tissue procurement from deceased donors should be maintained and strengthened, as a preferred model for public policy.

(2) Donors who have declared their wishes to donate should have those wishes legally respected.

8. (1) Hospitals should implement written organ donation protocols and policies, and consider the adoption of routine-inquiry protocols, to address the problem of undeclared potential donors.

(2) Health and Welfare Canada should undertake and administer a pilot program involving appropriately chosen federal hospitals, for the purpose of implementing and evaluating the impact of routine-inquiry protocols.

(3) Health and Welfare Canada should encourage the participation of non-federal hospitals and the provinces in this pilot program, by making federal funds available to non-federal hospitals prepared to implement and report on routine-inquiry protocols.

9. (1) Section 182 of the *Criminal Code* should be replaced by a provision making it a crime to abuse a human corpse or human remains.

(2) The Commission's Report 31 should be amended by incorporating into the proposed Crimes against Public Order (chapter 22) the following subsection:

Abuse of Corpse. Everyone commits a crime who purposely or recklessly abuses a human corpse or human remains.

10. (1) Legislation should clearly establish the inclusion of all human therapeutic tissue replacement technologies within the "safety" ambit of the federal *Food and Drugs Act*, to subject them to minimum, uniform national safety standards.

(2) Accordingly, the *Food and Drugs Act* should be amended to include a new Part for the regulation of human therapeutic tissue replacement technologies, broadly defined.

11. (1) The purchase or sale of human bodies, organs and other non-regenerative tissue should be made a *Criminal Code* offence.

(2) In defining the scope of the sales prohibition, the legislative provision should exclude from the definition of "sale" reasonable payments for travel or lodging expenses and lost wages incurred by the donor as well as reasonable payments associated with procurement, transport, processing, preservation and implantation of tissue.

12. Human remains or bodily substances that are in one's lawful possession or that have been lawfully procured and transformed by skill and labour into such entities as human anatomical specimens, processed and preserved tissue or museum artifacts should be considered proprietary objects that fall within criminal law protections against theft.

13. (1) Where health providers, hospitals or researchers develop a commercial interest in a patient's tissues or cellular matter, or where the development of any such interest is reasonably foreseeable, the health providers, hospitals or researchers should be obliged to disclose the interest to the patient.

(2) Where it becomes reasonably clear that the health provider with the commercial interest may compromise his or her duty to exercise independent professional judgment strictly on behalf of the patient, the health provider should be obliged to transfer care of the patient.

(3) Following the health provider's disclosure to the patient of any such commercial interest, the patient should be given the opportunity to decline further treatment and involvement, and if he or she so declines, the health provider should be obliged to transfer care of the patient.

14. The *Income Tax Act* should not be currently amended to permit credits or deductions for tissue or organ donation.

Glossary of Medical Terms

ALBUMIN. See BLOOD PRODUCTS.

ANEMIA. A deficiency in the red blood cells that prevents sufficient oxygen from being carried to tissues and organs. A major complication of chronic kidney failure, the condition often afflicts kidney transplant and dialysis patients, and is characterized by fatigue, lethargy and loss of appetite. It is conventionally treated by iron supplements or, in more extreme cases, by blood transfusions.

ANENCEPHALY. A lethal birth defect characterized by the absence of a major portion of the brain, skull and scalp.

BIOLOGIC. A special category of drug products derived from human and animal tissues.

BIOPROSTHETIC/BIOSYNTHETIC. Terms used to describe a therapeutic agent derived partially from natural tissue and partially from synthetic, mechanical or artificial processes.

BLOOD PRODUCTS. Therapeutic products derived from the red blood cells and plasma components of whole blood.

- ALBUMIN. A derivative manufactured from human plasma and used to treat burns, shock and other conditions.
- FACTOR VIII. An antihemophilic, blood-clotting factor manufactured from human plasma.
- PLASMA. The liquid component of blood in which red blood cells, white blood cells and platelets are suspended. Plasma constitutes some 55%, and the cellular elements some 45%, of human blood.

CELL LINE. An indefinitely replicating, cellular growth derived from the *in vitro* cultivation of living cells.

DEOXYRIBONUCLEIC ACID (DNA). The organic molecule that contains genetic information in virtually all living cells.

DIALYSIS. See KIDNEY DIALYSIS.

DURA MATER. A tough membrane that covers and protects the brain. In the transplant field, processed dura mater is used for reconstructive brain surgery.

EPIKERATOPHAKIA (EPI). Surgical implantation of procured, processed, and preserved human eye tissue, which has been lathed (sculptured) to individual patient specification. The resulting implant is sometimes referred to as the living contact lens.

ERYTHROPOIETIN (EPO). A protein made in the kidneys that stimulates the production of red blood cells. Recombinant DNA EPO has recently become available as a drug to treat chronic anemia in kidney transplant and dialysis patients.

FACTOR VIII. See BLOOD PRODUCTS.

HUMAN GROWTH HORMONE (HGH). Produced in the pituitary gland, HGH helps regulate the growth of children. Traditionally derived from cadaveric pituitary glands, HGH drugs today are derived using rDNA technology.

INTRAOCULAR LENS. A (synthetic) lens implanted in the eye to affect its structure and function, and to replace the natural lens of the eye.

KERATOPLASTY. Surgical replacement of dysfunctional corneas, the outer transparent window covering the eye.

KIDNEY DIALYSIS. A treatment process through which impurities and toxic substances are filtered and removed from the blood by a dialyser, a machine commonly referred to as the artificial kidney.

PLASMA. See BLOOD PRODUCTS.

RECOMBINANT DNA (rDNA). Also referred to as gene cloning and genetic engineering, the process involves transferring portions of DNA from one cell into another, so that as the recipient cell grows it expresses and replicates the genetic make-up of the donor cell. Recombinant DNA drugs derived from human and animal tissue have emerged as important products of the biotechnology revolution.

APPENDIX A

Selected Medical, Ethical and Legal Pronouncements

(1) Canadian Medical Association (CMA)

(a) CMA Code of Ethics (Statement on Transplantation)[1]

An Ethical Physician ...

20. may, when death of the brain has occurred, support cellular life in the body when some parts of the body might be used to prolong the life or improve the health of others;

21. will recognize his responsibility to a donor of organs to be transplanted and will give to the donor or the donor's relatives full disclosure of the intent and purpose of the procedure; in the case of a living donor, the physician will also explain the risks of the procedure;

22. will refrain from determining the time of death of the donor patient if there is a possibility of being involved as a participant in the transplant procedure, or when his/her association with the proposed recipient might improperly influence professional judgement;

23. may treat the transplant recipient subsequent to the transplant procedure in spite of having determined the time of death of the donor; ...

(b) CMA Policy Summary: Organ Donation[2]

Organ transplantation is now a recognized form of treatment. No shortage of potential organ donors exists, and public opinion toward organ donation is generally favourable. The demand, however, for donor organs has outstripped the supply. A major barrier to organ donation has been the incomplete commitment of the medical profession to identify potential donors and seek consent from the nearest relatives. To help rectify this, the CMA supports the concept of "recorded consideration", which means that hospital staff are routinely required to consider the suitability of a dying or "brain-dead" patient for organ donation in time for donation to occur. To present the medical profession as a role model, the association is conducting an organ donor recruiting campaign to provide all physicians in Canada and their families with the opportunity to sign an organ donor consent card.

(2) Canadian Nurses Association

Organ Transplantation Position Statement[3]

The Canadian Nurses Association recognizes that the transplantation of organs and tissues has evolved to the state of being a replacement treatment for organ failure. Further, CNA recognizes that successful

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1. Canadian Medical Association, *Code of Ethics* (Ottawa: The Association, 1990).

2. (1987) 136:6 C.M.A.J. 752A.

3. "Statement on the Role of Nurses in Organ and Tissue Donation, Retrieval, and Transplantation" (1987) *Position Statements Canadian Nurses' Association.*

transplantation can lead to improved quality of life, increased lifespan, and decreases in illness care costs. Therefore, CNA supports the concept of organ and tissue donation, retrieval and transplantation programs recognizing that the major problem in the establishment of successful programs is the procurement of donor organs.

(3) Canadian Bar Association

Resolution to Amend the Human Tissue Gift Act(s)[4]

WHEREAS an important part of the Canadian health care system is the transplant services (which are now reliable, effective, and available across the country);

AND WHEREAS the staff of hospitals may fail to ask the deceased person's representative to consent to organ donation, even when the staff is aware of persons who will die if the donation is not made;

AND WHEREAS surveys indicate that Canadians as a whole strongly support transplant programs, but only a few Canadians make a direction that their organs be donated;

AND WHEREAS 85-90 per cent of families and/or representatives who are asked to consent to an organ donation of a deceased relative agree to the donation and families and/or representatives of deceased persons have often expressed dismay that they were not provided the opportunity to consent to such an organ donation;

AND WHEREAS families and/or representatives of deceased persons who are provided the opportunity to consent to such a donation, and who consent, report that this donation helped them in their bereavement, both shortly after the death, and in the months and years thereafter;

BE IT RESOLVED THAT The Canadian Bar Association urge the Federal, Provincial and Territorial Governments to amend or enact legislation which would impose statutory obligations on hospital staff to request permission or cause permission to be requested from the deceased person's representative to use any or all of the tissues of the deceased person.

(4) World Medical Association

Declaration of Human Organ Transplantation

39th World Medical Assembly: Madrid, October 1987[5]

The World Medical Association recommends the following guidelines for the guidance of physicians engaged in the transplantation of human organs.

1. The primary concern of physicians must at all times be the health of their patients. The concern and allegiance must be preserved in all medical procedures, including those which involve the transplantation of an organ from one person to another. Both donor and recipient are patients and care must, therefore, be taken to protect the rights of both. No physician may therefore assume a responsibility in organ transplantation unless the rights of both donor and recipient are protected.

2. A potential organ transplant offers no justification for a relaxation of the usual standard of medical care. The same standard of care should apply whether the patient is a potential donor or not.

3. When an organ is to be transplanted from a donor after the donor's death, the death of the donor shall have been determined independently by two or more physicians who are not involved in the transplantation procedure. Death shall be determined by the judgement of each physician.

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4. Resolution No. 4 carried (1989) 16:3 National 20.

5. "World Medical Association Adopts Declarations and Statements on Bioethical and Other Matters" (1988) 39:1 Int'l Dig. Health. Leg. 267.

In making this determination, each physician will use currently accepted scientific tests, and criteria that are consistent with the ethical requirements and professional standards established by the National Medical Association and other appropriate medical organizations in the community.

4. Whenever an experimental procedure such as the transplantation of animal organs or artificial organs is being considered, the physician should comply with the recommendations contained in the World Medical Association's Declaration of Helsinki, providing guidance for physicians in biomedical research involving human subjects.

(5) World Health Organization (WHO)

(a) WHO Guiding Principles on Human Organ Transplantation[6]

PREAMBLE

1. . . . Over the past 30 years, organ transplantation has become a worldwide practice and has saved many thousands of lives. It has also improved the quality of life of countless other persons. Continuous improvements in medical technology, particularly in relation to tissue "rejection", have brought about expansion of the practice and an increase in the demand for organs. A feature of organ transplantation since its commencement has been the shortage of available organs. Supply has never satisfied demand, and this has led to the continuous development in many countries of procedures and systems to increase supply. Rational argument can be made to the effect that shortage has led to the rise of commercial traffic in human organs, particularly from living donors who are unrelated to recipients. There is clear evidence of such traffic in recent years, and fears have arisen of the possibility of related traffic in human beings. Health Assembly resolutions WHA40.13 and WHA42.5 are an expression of international concern over these developments.

2. These Guiding Principles are intended to provide an orderly, ethical, and acceptable framework for regulating the acquisition and transplantation of human organs for therapeutic purposes. The term "human organ" is understood to include organs and tissues but does not relate to human reproduction, and accordingly does not extend to reproductive tissues, namely ova, sperm, ovaries, testicles or embryos, nor is it intended to deal with blood or blood constituents for transfusion purposes. The Guiding Principles prohibit giving and receiving money, as well as any other commercial dealing in this field, but do not affect payment of expenditures incurred in organ recovery, preservation and supply. Of particular concern to WHO is the protection of minors and other vulnerable persons from coercion and improper inducement to donate organs.

Organs and tissues (referred to in this text as "organs") may be removed from the bodies of deceased and living persons for the purpose of transplantation only in accordance with the following Guiding Principles.

GUIDING PRINCIPLE 1

Organs may be removed from the bodies of deceased persons for the purpose of transplantation if:

(a) any consents required by law are obtained; and

(b) there is no reason to believe that the deceased person objected to such removal, in the absence of any formal consent given during the person's lifetime.

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6. Adopted by Resolution WHA44.25 of the 44th World Health Assembly, 13 May 1991; reprinted (1991) 42:3 Int'l Dig. Health Leg. 390. Since these principles were formalized after the Commission had adopted its recommendations, the Commission has not formally considered them.

GUIDING PRINCIPLE 2

Physicians determining that the death of a potential donor has occurred should not be directly involved in organ removal from the donor and subsequent transplantation procedures, or be responsible for the care of potential recipients of such organs.

GUIDING PRINCIPLE 3

Organs for transplantation should be removed preferably from the bodies of deceased persons. However, adult living persons may donate organs, but in general such donors should be genetically related to the recipients. Exceptions may be made in the case of transplantation of bone barrow and other acceptable regenerative tissues.

An organ may be removed from the body of an adult living donor for the purpose of transplantation if the donor gives free consent. The donor should be free of any undue influence and pressure and sufficiently informed to be able to understand and weigh the risks, benefits and consequences of consent.

GUIDING PRINCIPLE 4

No organ should be removed from the body of a living minor for the purpose of transplantation. Exceptions may be made under national law in the case of regenerative tissues.

GUIDING PRINCIPLE 5

The human body and its parts cannot be the subject of commercial transactions. Accordingly, giving or receiving payment (including any other compensation or reward) for organs should be prohibited.

GUIDING PRINCIPLE 6

Advertising the need for or availability of organs, with a view to offering or seeking payment, should be prohibited.

GUIDING PRINCIPLE 7

It should be prohibited for physicians and other health professionals to engage in organ transplantation procedures if they have reason to believe that the organs concerned have been the subject of commercial transactions.

GUIDING PRINCIPLE 8

It should be prohibited for any person or facility involved in organ transplantation procedures to receive any payment that exceeds a justifiable fee for the services rendered.

GUIDING PRINCIPLE 9

In the light of the principles of distributive justice and equity, donated organs should be made available to patients on the basis of medical need and not on the basis of financial or other considerations.

COMMENTARY ...

(b) WHO Resolution Preventing the Purchase and Sale of Human Organs[7]

The Forty-second World Health Assembly,

Concerned by the commercial trafficking in the organs of healthy donors, which exploits human distress and puts at increased risk the health of the donors;

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7. "World Health Assembly adopts Resolution on 'Preventing the Purchase and Sale of Human Organs'" (1989) 40:3 Int'l Dig. Health Leg. 724.

Aware that commercial arrangements for organ transplants are nevertheless being undertaken and that to date there has been little success in preventing trafficking in human organs;

Anxious to prevent the exploitation of human distress, particularly in children and other vulnerable groups, and to further the recognition of the ethical principles which condemn the buying and selling of organs for purposes of transplantation;

1. CALLS UPON Member States to take appropriate measures to prevent the purchase and sale of human organs for transplantation;

2. RECOMMENDS that Member States introduce legislation to prohibit trafficking in organs where this cannot effectively be prevented by other measures;

3. URGES Member States, in close cooperation with professional health organizations and supervising health authorities, to discourage all practices which facilitate commercial trafficking in organs;

4. REQUESTS Member States to report as soon as possible to WHO on action taken with respect to this resolution;

5. REQUESTS the Director-General to report to the Forty-fourth World Health Assembly the measures taken by the governments of Member States in furtherance of this resolution.

APPENDIX B

Selected Statutes — Excerpts

(1) Routine Inquiry/Required Request

(a) Manitoba (*The Human Tissue Act*, S.M. 1987-88, c. 39)

Consideration by physician.

4(1) Upon the death of a person in respect of whom no direction has been given under section 2 or 3 . . . the last physician to attend the deceased person before death shall . . . consider whether

(a) the condition of the body of the deceased person and of the tissue thereof;

(b) the need for the use of the body of the deceased person or any tissue from the body for therapeutic purposes; and

(c) the emotional and physical condition of the survivors of the deceased person;

are such that it is appropriate to request permission, in accordance with subsection (2), to use the body of the deceased person for therapeutic purposes or to remove tissue from the body to be used for therapeutic purposes.

Request after consideration.

4(2) A physician who upon consideration in accordance with subsection (1) in respect of a deceased person determines that it is appropriate to do so shall . . . request permission or cause permission to be requested from the deceased person's nearest relative . . . .

Exception.

4(3) This section does not apply where the last physician to attend a person before death has reason to believe

(a) that the use of the body of the deceased person or the removal and use of tissue from the body after death would be contrary to the person's religious beliefs or that the person, if living, would have objected thereto; or

(b) that an inquiry or investigation under *The Fatality Inquiries Act* may be required to be held . . .

(b) Oregon (Chapter 379, Laws 1985, House Bill No. 2909, approved July 3, 1985)

SECTION 1. (1) When death occurs in a hospital to a person who has not made an anatomical gift, the hospital administrator or designated representative shall request the person described in ORS 97.265(2), in order of priority stated when persons in prior classes are not available at the time of death, and in the absence of actual notice of contrary indication by the decedent or one in a prior class, to consent to the gift of all or any part of the decedent's body as an anatomical gift.

(2) Where such request is made, pursuant to this section, the request and its disposition shall be noted in the patient's medical record and on the death certificate and shall be documented as provided in ORS 97.275(5).

(3) Where, based on medical criteria, such request would not yield a donation which would be suitable for use, the Assistant Director for Health may, by rule, authorize an exception to the request required by this section.

(4) The Assistant Director for Health shall establish rules concerning the training of hospital employees who may be designated to perform the request, and the procedures to be employed in making it. In addition, the assistant director shall establish such rules as are necessary to implement appropriate procedures to facilitate the delivery of donations from receiving hospitals to potential recipients.

(5) The Assistant Director for Health shall establish such additional rules as are necessary for the implementation of this section.

(c) *United States* (*National Organ Transplant Act* of 1984)

42 USC § 1320b-8. Hospital protocols for organ procurement and standards for organ procurement agencies

(a) Establishment of protocols; . . .

(1) The Secretary shall provide that a . . . hospital meeting the requirements of subchapter XVIII or XIX [42 USCS §§ 1395 et seq., 1396 et seq.] of this chapter may participate in the program established under such subchapter only if —

(A) the hospital . . . establishes written protocols for the identification of potential organ donors that —

(i) assure that families of potential organ donors are made aware of the option of organ or tissue donation and their option to decline,

(ii) encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of such families, and

(iii) require that an organ procurement agency designated by the Secretary pursuant to subsection (b)(1)(F) of this section be notified of potential organ donors; . . .

(2) For purposes of this subsection, the term "organ" means a human kidney, liver, heart, lung, pancreas, and any other human organ or tissue specified by the Secretary for purposes of this subsection.

(d) *Australia* (ALRC, *Human Tissue Transplants*, Report 7 (Brisbane: Watson Ferguson and Co., 1977) at 127-28)

25. (3) Where the designated officer, after making such inquiries as are reasonable in the circumstances, has no reason to believe that the deceased person during his lifetime —

(a) had expressed the wish for, or consented to, the removal after his death of tissue from his body for the purpose or a use referred to in sub-section (1); or

(b) had expressed an objection to the removal after his death of tissue from his body for such a purpose or use,

and after making those inquiries and such further inquiries as are reasonable in the circumstances, the designated officer —

(c) has no reason to believe that the senior available next of kin of the deceased person has an objection to the removal of tissue from the body of the deceased person; or

(d) is unable to ascertain the existence or the whereabouts of the next of kin of the deceased person or is unable to ascertain whether any of the next of kin of the deceased person has an objection to the removal of tissue from the body of the deceased person,

the designated officer may authorize under sub-section (1) the removal of tissue from the body of the deceased person for the purpose or a use referred to in that sub-section.

(2) Tissue Sales Prohibitions

(a) Canada

i. *Uniform Human Tissue Gift Act* (Sales Prohibition), Uniform Law Conference Canada 1971 Proceedings (in effect in most provinces)

Sale, etc., of tissue prohibited

10. No person shall buy, sell or otherwise deal in, directly or indirectly, for a valuable consideration, any tissue for a transplant, or any body or part or parts thereof other than blood or a blood constituent, for therapeutic purposes, medical education or scientific research, and any such dealing is invalid as being contrary to public policy.

1. In this Act, ...

(c) ''tissue'' includes an organ, but does not include any skin, bone, blood, blood constituent or other tissue that is replaceable by natural processes of repair; ...

ii. *Uniform Human Tissue Donation Act* (1989), Uniform Law Conference of Canada

Commerce prohibited

15. (1)No person shall buy, sell or otherwise Prohibiteddeal in, directly or indirectly, any tissue, body or body part for the purpose of a transplant or for a therapeutic purpose, medical education or scientific research.

(2) Any dealing in any tissue, body or body part that was lawful before this Act came into force shall continue to be lawful, provided this Act is complied with.

(3) A person who contravenes this section is guilty of an offence and liable on summary conviction to a fine of not more than $100,000 or to imprisonment for not more than 1 year, or to both.

1. In this Act,

...

''tissue'' means a part of a living or dead human body, but does not include

(a) spermatozoa or ova,

(b) an embryo or fetus, or

(c) blood or blood constituents; (''tissu'')

iii. Manitoba (*The Human Tissue Act*, S.M. 1987-88, c. 39)

Sale, purchase, trafficking prohibited.

15(2) No person shall, for any purpose,

(a) sell or buy any dead human body, or any tissue from a human body whether living or dead; or

(b) traffic in dead human bodies or tissue from human bodies whether living or dead; ...

Exception as to remuneration.

15(3) Nothing in this section prohibits the payment of reasonable remuneration to a physician or other health professional for services rendered for the purpose of carrying out a direction or complying with a consent under this Act.

Exception as to expenses.

15(4) Nothing in this section prohibits reimbursement, to the donor or recipient of a body or tissue from a body, or to the family or survivors of such a donor or recipient, or to any government or private medical or hospital plan, as the case may require, of reasonable expenses incurred in ...

Offence and penalty.

15(5) Any person who contravenes or fails to observe a provision of this section is guilty of an offence and liable on summary conviction to a fine of not more than $5,000, or to imprisonment for a term of not more than six months or to both.

(b) Great Britain (*Human Organ Transplants Act 1989*, 1989, c. 31)

Offers, acceptance, brokers

1. — (1) A person is guilty of an offence if in Great Britain he —

(a) makes or receives any payment for the supply of, or for an offer to supply, an organ which has been or is to be removed from a dead or living person and is intended to be transplanted into another person in Great Britain or elsewhere;

(b) seeks to find a person willing to supply for payment such an organ as is mentioned in paragraph (a) above or offers to supply such an organ for payment;

(c) initiates or negotiates any arrangement involving the making of any payment for the supply of, or for an offer to supply, such an organ; or

(d) takes part in the management or control of a body of persons corporate or unincorporate whose activities consist of or include the initiation or negotiation of such arrangements.

(2) ... if he causes to be published or distributed, or knowingly publishes or distributes, in Great Britain an advertisement —

(a) inviting persons to supply for payment any such organs as are mentioned [above] or offering to supply any such organs for payment; or

(b) indicating that the advertiser is willing to initiate or negotiate any such arrangement as is mentioned [above].

(3) [payment does not include]

(a) the cost of removing, transporting or preserving the organ to be supplied; or

(b) any expenses or loss of earnings incurred by a person so far as reasonably and directly attributable to his supplying an organ from his body.

(c) United States (*National Organ Transplant Act* of 1984)

42 USC § 274e. Prohibition of organ purchases (emphasis added)

(a) Prohibition

It shall be unlawful for any person to *knowingly* acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce.

(b) Penalties

Any person who violates subsection (a) ... shall be fined not more than $50,000 or imprisoned not more than five years, or both.

(c) Definitions

For purposes of subsection (a) ... :

(1) The term "human organ" means the human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any other human (or any subpart thereof, including that derived from a fetus) specified by the Secretary of Health and Human Services by regulation.

(2) The term "valuable consideration" does not include the reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ or the expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ.

(d) Council of Europe (Final Text on Organ Transplantation, (1988) 39:1 Int'l Dig. Health Leg. 274 at 277)

The Non-Commercialisation of Human Organs

16. A human organ must not be offered for profit by any organ exchange organisation, organ banking centre or by any other organisation or individual whatsoever. However, this does not prevent the compensation of living donors for loss of earnings and any expenses caused by the removal or preceding examination.

17. Neither organisations nor individuals should advertise outside their national territory either for donation or transplantation.

(3) *Uniform Human Tissue Donation Act* (1989)[1]

Definitions

1. In this Act,

"common law spouse"
"common law spouse" means [insert provincial definition]; ("conjoint de fait")

"death"
"death" includes brain death as determined by generally accepted medical criteria; ("mort")

"non-regenerative tissue"
"non-regenerative tissue" means tissue other than regenerative tissue; ("tissu non susceptible de régénération")

"regenerative tissue"
"regenerative tissue", in a living human body, means tissue that, on injury or removal, replaces itself; ("tissu[e] susceptible de régénération")

"spouse"
"spouse" includes a common law spouse; ("époux; épouse")

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1. Uniform Law Conference of Canada, *Consolidation of Uniform Acts* (1990 Supp.) 22-1. Available for adoption by the Provinces 1 January 1990.

"tissue"

"tissue" means a part of a living or dead human body, but does not include
(a) spermatozoa or ova,
(b) an embryo or fetus, or
(c) blood or blood constituents; ("tissu")

"transplant"

"transplant" means the removal of tissue from a human body and the implantation of the tissue in the living human body of another. ("transplantation")

Compliance with Act

2. A consent to the removal of tissue may be given in accordance with this Act, but not otherwise.

Consent to transplant after death

3. (1) A person who is [16] years of age or over and understands the nature and consequences of transplanting tissue from his or her body after death may consent to the removal of the tissue specified in the consent from his or her body after death for the purpose of implanting the tissue in a living human body.

(2) Not withstanding subsection (1), a consent given by a person who did not understand the nature and consequences of transplanting tissue from his or her body after death is valid for the purposes of this section if the person who acts on it has no reason to believe that the person who gave it did not understand the nature and consequences of transplanting tissue from his or her body after death.

Substituted consent

4. (1) After the death of a person who has not given a consent under section 3, who is under [16] years of age or who did not understand the nature and consequences of transplanting tissue from his or her body after death, a person referred to in subsection (2) may consent to the removal of the tissue specified in the consent from the body of the deceased

(a) for the purpose of implanting the tissue in a living human body, or

(b) for the purposes referred to in section 12(1).

(2) A consent referred to in subsection (1) may be given by any one of the following:

(a) a guardian of the person of the deceased before death;
(b) the spouse of the deceased;
(c) a child of the deceased;
(d) a parent of the deceased;
(e) a brother or sister of the deceased;
(f) any other relative of the deceased;
(g) a person, other than a spouse, who shared a residence with the deceased immediately before the deceased died and has knowledge of the wishes of the deceased.

(3) In the event of a dispute between persons in 2 or more of the classes of persons referred to in subsection (2), the dispute shall be decided in accordance with the order in which those classes are listed in subsection (2).

(4) If no consent is provided under subsection (1) and the [Coroner], after making reasonable efforts, is unable to locate any of the persons listed in subsection (2), the [Coroner] may be given a consent referred to in subsection (1).

(5) No consent may be given under this section by a person who

(a) is under [16] years of age,

(b) does not understand the nature and consequences of transplanting tissue from the body of the deceased after death, or

(c) has reason to believe that the deceased would have objected to the consent.

Consent to transplant during life

5. (1) A person who is [16] years of age or over and understands the nature and consequences of transplanting tissue from his or her body during his or her life may consent to the removal of the tissue specified in the consent from his or her body during his or her life for the purpose of implanting the tissue in another living human body.

(2) If there is reason to believe that a person who gives a consent under this section may not understand the nature and consequences of transplanting tissue from his or her body during his or her life, no transplant may be carried out pursuant to that consent unless the results of an independent assessment conducted in accordance with section 7 indicate that the transplant should be carried out.

(3) No transplant of non-regenerative tissue may be carried out pursuant to this section unless the results of an independent assessment conducted in accordance with section 7 indicate that the transplant should be carried out.

Transplant during life re person under 16

6. (1) A person who is under [16] years of age and understands the nature and consequences of transplanting tissue from his or her body during his or her life may consent to the removal of the regenerative tissue specified in the consent from his or her body during his or her life for the purpose of implanting the tissue in another living human body.

(2) Notwithstanding subsection (1), bone marrow may be removed from a person who is under [16] years of age and does not understand the nature and consequences of transplanting tissue from his or her body during his or her life for the purpose of implanting the bone marrow in a biological brother or biological sister of the donor.

(3) No transplant may be carried out

(a) pursuant to subsection (1), unless a parent or guardian of the donor also consents to the transplant, or

(b) pursuant to subsection (2), unless a parent or guardian of the donor consents to the transplant on behalf of the donor.

(4) No transplant may be carried out pursuant to subsection (1) or (2) unless the results of an independent assessment conducted in accordance with section 7 indicate that the transplant should be carried out.

Independent assessment

7. (1) If an independent assessment is required pursuant to this Act, it shall be conducted in accordance with this section and the regulations.

(2) An independent assessment shall be conducted by not fewer than 3 persons, of whom one shall be a physician.

(3) No person who has or has ever had an association with the donor of tissue in respect of whom an independent assessment is conducted or with the proposed recipient of the tissue shall conduct the independent assessment.

(4) The persons conducting an independent assessment shall provide notice of the date, time and place of the independent assessment to

(a) the donor of the tissue,

(b) if the donor is under [16] years of age, the parent or guardian of the donor and the [Official Guardian], and

(c) if the donor is [16] years of age or over and there is reason to believe that the donor may not understand the nature and consequences of transplanting tissue from his or her body during his or her life, the parent or guardian of the person of the donor and the [Official Guardian].

(5) On receiving a notice under subsection (4), the [Official Guardian] shall represent the donor at the independent assessment unless the [Official Guardian] is satisfied that another person in addition to the parent or guardian of the person of the donor will represent the donor.

(6) The persons conducting an independent assessment shall consider the following:

(a) whether the transplant is the medical treatment of choice;

(b) with respect to a transplant under section 6, whether all other members of the immediate family of the donor have been eliminated, for medical or other reasons, as potential donors;

(c) whether coercion has been exerted on the donor for the purpose of obtaining his or her consent to the transplant;

(d) whether the removal of the tissue from the body of the donor will create a substantial health or other risk to the donor;

(e) whether this Act and the regulations, as they relate to that transplant, have been complied with.

(7) The persons conducting an independent assessment shall, in the manner and within the time period prescribed in the regulations,

(a) make a decision as to whether a transplant that has been proposed pursuant to section 5 or 6 should be carried out,

(b) provide written reasons for the decision, and

(c) provide notice of that decision and the reasons for the decision to the persons who received notice of the independent assessment under subsection (4).

Appeal

8. (1) A person may, within [3 days] after a decision has been made under section 7(7), appeal to the [Supreme Court] the decision of the persons who conducted an independent assessment.

(2) On hearing an appeal, the Court may

(a) quash, vary or confirm the decision of the persons who conducted the independent assessment, or

(b) refer the matter back to the persons who conducted the independent assessment for further action in accordance with the directions of the Court.

(3) On hearing an appeal to which section 6(2) applies, the Court may make an order authorizing a parent or guardian of the donor to consent to the transplant on behalf of the donor.

(4) No transplant in respect of which an appeal has been commenced under subsection (1) shall be carried out until the appeal has been concluded.

Effect of consent

9. (1) A consent that complies with this Act is binding and is authority for a physician

(a) to make an examination necessary to assure medical acceptability of the tissue specified in the consent, and

(b) to remove the tissue specified in the consent in accordance with the consent.

(2) Notwithstanding subsection (1), no person shall act on a consent if the person has reason to believe that

(a) in the case of a consent under section 3, 5, 6 or 12, the person who gave the consent subsequently withdrew or would have objected to the consent, or

(b) in the case of a consent under section 4, the person on whose behalf the consent was given would have objected to the consent.

Coroner's direction

10. If, in the opinion of a physician, the death of a person is imminent by reason of injury or disease and the physician has reason to believe that section ... of the [Coroners Act] may apply when death does occur and a consent under section 3 has been obtained for a transplant of tissue from the body after death, a [Coroner] having jurisdiction, notwithstanding that death has not yet occurred, may give directions he or she thinks proper respecting the removal of the tissue after the death of the person, and that direction has the same force and effect as if it had been made after death under section ... of the [Coroners Act].

Determination of death

11. (1) The fact of death of a donor of tissue shall be determined by at least 2 physicians in accordance with accepted medical practice.

(2) No physician who has had an association with the proposed recipient of tissue shall take any part in the determination of the fact of death of the donor of that tissue.

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

(4) Subsections (2) and (3) do not apply to a physician in the removal of eyes for cornea transplants.

Consent for other purposes

12. (1) Notwithstanding anything in this Act, a person who is [16] years of age or over may consent to the use after death of his or her body or the parts of his or her body specified in the consent for therapeutic purposes, medical education or scientific research.

(2) If tissue that has been removed pursuant to a consent given under section 3, 4, 5 or 6 cannot for any reason be implanted in a living human body, the tissue shall be disposed of as if no consent relating to the tissue had been given, unless the donor has consented to the use of the tissue for therapeutic purposes, medical education or scientific research.

Disclosure of information

13. (1) Except where required by law, no person shall disclose or give to another person any information or document whereby the public may learn the identity of a person

(a) who has given or refused to give a consent to the removal of tissue,

(b) with respect to whom a consent to the removal of tissue has been given or refused, or

(c) into whose body tissue has been, is being or may be implanted.

(2) Notwithstanding subsection (1),

(a) a donor of tissue may disclose or authorize another person to disclose information relating only to the donor that the donor has authorized for disclosure,

(b) a recipient of tissue may disclose or authorize another person to disclose information relating only to the recipient that the recipient has authorized for disclosure, and

(c) a person who gave a consent under section 4 on behalf of a deceased may disclose or authorize another person to disclose information relating only to the deceased that the person who gave the consent has authorized for disclosure.

Protection from liability

14. No person is liable for anything done or omitted to be done in good faith and without negligence in the exercise or intended exercise of an authority under this Act.

Commerce prohibited

15. (1) No person shall buy, sell or otherwise deal in, directly or indirectly, any tissue, body or body part for the purpose of a transplant of for a therapeutic purpose, medical education or scientific research.

(2) Any dealing in any tissue, body or body part that was lawful before this Act came into force shall continue to be lawful, provided this Act is complied with.

(3) A person who contravenes this section is guilty of an offence and liable on summary conviction to a fine of not more than $100,000 or to imprisonment for not more than 1 year, or to both.

General offence

[16. A person who contravenes this Act, except section 15, is guilty of an offence and liable on summary conviction to a fine of not more that $10,000 or to imprisonment for not more than 6 months, or to both.]

Regulations

17. The Lieutenant Governor in Council may make regulations

(a) respecting the establishment and operation of independent assessments;

(b) prescribing the manner and time period in which a decision under section 7(7), reasons for the decision and notice of the decision shall be given.

Repeal

18. The Uniform Human Tissue Gift Act is repealed.

APPENDIX C

Table of Cases

Canada

Andrews v. *Law Society of British Columbia*, [1989] 1 S.C.R. 143.
Attorney General of British Columbia v. *Astaforoff* (1983), 6 C.C.C. (3d) 498 (C.A.).
B. (R.) v. *Children's Aid Society of Metropolitan Toronto* (1988), 47 D.L.R. (4th) 388 (Ont. C.A.).
Bonisteel v. *Saylor* (1890), 17 O.A.R. 505.
Byron v. *Tremaine* (1898), 29 S.C.R. 445.
Cayouette et Mathieu, [1987] R.J.Q. 2230 (Sup. Ct).
Chouinard v. *Landry*, [1987] R.J.Q. 1954 (C.A.).
Collin v. *Lussier*, [1983] 1 F.C. 218, partially rev'd [1985] 1 F.C. 125 (A.D.).
Couture-Jacquet v. *Montreal Children's Hospital*, [1986] R.J.Q. 1221 (C.A.).
Davidson v. *Garrett* (1899), 5 C.C.C. 200 (Ont. H.C.).
Droit de la Famille — 140, [1984] R.J.Q. 2049 (T.J.).
Ducharme v. *Hôpital Notre-Dame* (1933), 71 C.S. 377.
E. (Mrs.) v. *Eve*, [1986] 2 S.C.R. 388.
Edmonds v. *Armstrong Funeral Home*, [1931] 1 D.L.R. 676 (Alta S.C.).
Farrar v. *MacPhee* (1971), 19 D.L.R. (3d) 720 (P.E.I.S.C.).
Halushka v. *University of Saskatchewan* (1965), 52 W.W.R. 608 (Sask. C.A.).
Hunter v. *Hunter*, [1930] 4 D.L.R. 255 (Ont. S.C.).
Kenny v. *Lockwood*, [1932] 1 D.L.R. 507 (Ont. C.A.).
Kitchen v. *McMullen* (1989), 62 D.L.R. (4th) 481 (N.B.C.A.).
Lambert v. *Dumais*, [1942] B.R. 561.
Langelier Limitée v. *Demers* (1928), 66 C.S. 120.
Malette v. *Shulman* (1990), 67 D.L.R. (4th) 321 (Ont. C.A.).
McNamra v. *Caros*, [1978] 1 F.C. 451 (T.D.).
McNeil v. *Forest Lawn Memorial Services* (1976), 72 D.L.R. (3d) 556 (B.C.S.C.).
Miner v. *Canadian Pacific R.W. Co.* (1911), 18 W.L.R. 476 (Alta S.C.).
Mulloy v. *Hop Sang*, [1935] 1 W.W.R. 714 (Alta C.A.).
Mundinger v. *Mundinger* (1968), 3 D.L.R. (3d) 338 (Ont. C.A.), aff'd [1970] S.C.R. vi.
Murray v. *McMurchy*, [1949] 2 D.L.R. 442 (B.C.S.C.).
Orford v. *Orford* (1921), 58 D.L.R. 251 (Ont. S.C.).
Peters v. *University Hospital Board*, [1983] 5 W.W.R. 193 (Sask. C.A.).
Philipps v. *The Montreal General Hospital* (1908), 33 S.C. 483.
Pioneer Hi-Bred v. *Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623.
R. v. *Big M Drug Mart Ltd.*, [1985] 1 S.C.R. 295.
R. v. *Cyrenne* (1981), 62 C.C.C. (2d) 238 (Ont. Dist. Ct).
R. v. *Downey* (1990), 42 C.R.R. 286 (Ont. Dist. Ct).
R. v. *Dyment*, [1988] 2 S.C.R. 417.
R. v. *Edwards Books and Art Ltd.*, [1986] 2 S.C.R. 713.
R. v. *Green* (1988), 43 C.C.C. (3d) 413 (B.C.S.C.).
R. v. *Kitching* (1976), 32 C.C.C. (2d) 159 (Man. C.A.).
R. v. *Ladue*, [1965] 4 C.C.C. 264 (Y.T.C.A.).

R. v. *Lewis* (1903), 7 C.C.C. 261 (Ont. C.A.).
R. v. *Morgentaler*, [1988] 1 S.C.R. 30.
R. v. *Newcomb* (1898), 2 C.C.C. 255 (N.S. Co. Ct).
R. v. *Oakes*, [1986] 1 S.C.R. 103.
R. v. *Sullivan*, [1991] 1 S.C.R. 489.
R. v. *Swinmer* (1970), 17 D.L.R. (3d) 476 (Sask. C.A.).
R. v. *Thornton* (1991), 1 O.R. (3d) 481 (C.A.).
R. v. *Turpin*, [1989] 1 S.C.R. 1296.
R. v. *Tutton*, [1989] 1 S.C.R. 1392.
R. v. *Waite*, [1989] 1 S.C.R. 1436.
R. v. *Wetmore*, [1983] 2 S.C.R. 284.
R. v. *Wiens* (22 June 1985), (Ont. Prov. Ct) [unreported].
Re Female Infant (1982), 34 B.C.L.R. 177 (S.C.).
Re L.D.K. v. *Children's Aid Society of Metropolitan Toronto* (1986), 48 R.F.L. (2d) 164 (Ont. Fam. Ct).
Re McTavish and Director, Child Welfare Act (1986), 32 D.L.R. (4th) 394 (Alta Q.B.).
Re Millar, [1938] S.C.R. 1.
Reibl v. *Hughes*, [1980] 2 S.C.R. 880.
Religieuses Hospitalières de l'Hôtel-Dieu de Montréal v. *Brouillette*, [1943] B.R. 441.
Rocket v. *Royal College of Dental Surgeons of Ontario*, [1990] 2 S.C.R. 232.
Rowe v. *Grand Trunk Railway* (1866), 16 U.C.C.P. 500 (C.A.).
RWDSU v. *Dolphin Delivery Ltd.*, [1986] 2 S.C.R. 573.
Saskatchewan (Minister of Social Services) v. *P. (F.)* (1990), 69 D.L.R. (4th) 134 (Prov. Ct).
Stoffman v. *Vancouver General Hospital*, [1990] 3 S.C.R. 483.
Weiss v. *Solomon*, [1989] R.J.Q. 731 (Sup. Ct).

United States

Adoption of B.A.B., 534 A. 2d 1050 (Pa. 1987).
Amgen Inc. v. *Chugai Pharmaceutical Co.*, 927 F. 2d 1200 (Fed. Cir. 1991).
Application of George, 630 S.W. 2d 614 (Mo. App. 1982).
Arnaud v. *Odom*, 870 F. 2d 304 (5th Cir. 1989).
Atkins v. *Medical Examiner*, 418 N.Y.S. 2d 839 (1979).
Baby Girl D, 517 A. 2d 925 (Pa. 1986).
Baby M, 537 A. 2d 1227 (N.J. 1988).
Barwin v. *Reidy*, 307 P. 2d 175 (New Mex. 1957).
Begay v. *State*, 723 P. 2d 252 (N.M. App. 1985).
Blank v. *United States*, 400 F. 2d 302 (5th Cir. 1968).
Brillo v. *Schaller*, (13 June 1986) Arizona 233587 (Sup. Ct).
Brotherton v. *Cleveland* 923, F. 2d 477 (6th Cir. 1991).
Browning v. *Norton Children's Hospital*, 504 S.W. 2d 713 (Ky App. 1974).
City of Revere v. *Massachusetts General Hospital*, 463 U.S. 239 (1983).
Commonwealth of Pennsylvania v. *Spector* (28 October 1988), Philadelphia 87-01-2441-2445 (Court of Common Pleas).
Corrigan v. *Bjork Shiley Corporation*, 227 Cal. Rptr 247 (App. 2d Dist. 1986), cert. denied 479 U.S. 1049.
Cruzan v. *Missouri*, 110 S. Ct 2841 (1990).
Curran v. *Bosze*, 566 N.E. 2d 1319 (Ill. 1990).
Del Zio v. *Manhattan's Columbia Presbyterian Medical Center*, (14 November 1978) New York 74-3558 (S.D.).
Diamond v. *Chakrabarty*, 477 U.S. 303 (1980).
Disinterment of Body of Jarvis, 58 N.W. 2d 24 (Iowa 1953).
Doe v. *Kelley*, 307 N.W. 2d 438 (Mich. App. 1981).
Dozsa v. *Crum & Forster Insurance Co.*, 716 F. Supp. 131 (D. N.J. 1989).
Ellis v. *Patterson*, 859 F. 2d 52 (8th Cir. 1988).
Estelle v. *Gamble*, 429 U.S. 97 (1976).

Fuller v. *Marx*, 724 F. 2d 717 (8th Cir. 1984).
Georgia Lions Eye Bank v. *Lavant*, 335 S.E. 2d 127 (Ga. 1985), cert. denied 475 U.S. 1084.
Gilmore v. *St. Anthony Hospital*, 598 P. 2d 1200 (Okl. 1979).
Gray v. *Maxwell*, 293 N.W. 2d 90 (Neb. 1980).
Hassard v. *Lehane*, 128 N.Y. 161 (1911).
Head v. *Colloton*, 331 N.W. 2d 870 (Iowa 1983).
Hendricksen v. *Roosevelt Hospital*, 297 F. Supp. 1142 (S.D. N.Y. 1969).
Hill v. *Travelers' Insurance Co.*, 294 S.W. 1097 (Tenn. 1927).
In Re G, 389 S.W. 2d 63 (Mo. App. 1965).
Kanavan's Case, 1 Me. 226 (1821).
Karp v. *Cooley*, 493 F. 2d 408 (5th Cir. 1974).
Kirker v. *Orange County*, 519 So. 2d 682 (Fla. App. 1988).
Kohn v. *United States*, 591 F. Supp. 568 (1984).
McFall v. *Shimp*, 10 Pa. D. & C. 3d 90 (Allegheny Cnty Ct 1978).
McKee v. *Cutter Laboratories*, 866 F. 2d. 219 (6th Cir. 1989).
Mensinger v. *O'Hara*, 189 Ill. App. 48 (1914).
Mokry v. *University of Texas Health Science Center*, 529 S.W. 2d 802 (Tex. App. 1975).
Montoya v. *Johnston*, 654 F. Supp. 511 (W.D. Tex. 1987).
Moore v. *Regents of the University of California*, 793 P. 2d 479 (Cal. 1990), cert. denied 111 S. Ct 1388.
Palmquist v. *Standard Accident Insurance*, 3 F. Supp. 358 (D.C. Cal. 1933).
Perlmutter v. *Beth David Hospital*, 123 N.E. 2d 792 (N.Y. 1954).
People v. *Bullington*, 80 P. 2d 1030 (Cal. 1938).
People of California v. *Sconce*, (24 May 1988) L.A. A 573189 (Sup. Ct).
People v. *Eulo*, 472 N.E. 2d. 286 (N.Y. 1984).
Potts v. *Genentech*, (1 November 1988) Santa Clara Cnty 670331 (Cal. Sup. Ct).
Public Health Trust of Dade County v. *Wons*, 541 So. 2d. 96 (Fla. 1989).
Ravenis v. *Detroit General Hospital*, 234 N.W. 2d 411 (Mich. App. 1975).
Re Quinlan, 355 A. 2d. 647 (N.J. 1976), cert. denied 429 U.S. 922.
Re Spring, 405 N.E. 2d 115 (Mass. 1980).
Schmokel v. *Secretary of State*, (6 December 1988) Washington S-578-88 (Sup. Ct).
Snyder v. *Holy Cross Hospital*, 352 A. 2d 334 (Md. App. 1976).
St. Elizabeth Hospital v. *Garrard*, 730 S.W. 2d 649 (Tex. 1987).
Stangvik v. *Shiley Inc.*, 273 Cal. Rptr. 179 (App. 4th Dist. 1990), rev. granted 800 P. 2d 858.
State v. *Hartzler*, 433 P. 2d 231 (N.M. 1967).
State v. *Powell*, 497 So. 2d 1188 (Fla. 1986), cert. denied 481 U.S. 1059.
State of Florida v. *Grant*, (19 January 1989) Hillsborough Cnty 87-4613 (Cir. Ct).
Strachan v. *John F. Kennedy Memorial Hospital*, 538 A. 2d 346 (N.J. 1988).
Strunk v. *Strunk*, 445 S.W. 2d 145 (Ky 1969).
Thompson v. *City of Portland*, 620 F. Supp. 482 (D.C. Me. 1985).
Thompson v. *State*, 58 S.W. 213 (Tenn. 1900).
Tillman v. *Detroit Receiving Hospital*, 360 N.W. 2d 275 (Mich. App. 1984).
Todd v. *Sorrell*, 841 F. 2d 87 (4th Cir. 1988).
United States v. *Calise*, 217 F. Supp. 705 (1962).
United States v. *Garber*, 607 F. 2d 92 (5th Cir. 1979).
United States v. *Steinschreiber*, 219 F. Supp. 373 (1963).
York v. *Jones Institute*, 717 F. Supp. 421 (E.D. VA 1989).
You Vang Yang v. *Sturner*, 728 F. Supp. 845 (D.R.I. 1990), withdrawn 750 F. Supp. 558.

Other Countries

Dlle X. . . v. *Soc. Ulysse — Productions et cons.*, Trib. gr. inst. Paris, 3 June 1969, Gaz. Pal. 1969. 2e sem. Jur.57.
Doodward v. *Spence* (1907), 7 S.R. 727 (N.S.W. Austr.).
Époux Camara, Cons. d'État, 17 February 1988, J.C.P. 1990 II. 21421.

Haynes's Case (1614), 77 E.R. 1389.
Hughes v. *Robertson* (1913), Sess. Cas. 394 (Ct Sess. Scot.).
Mme Nguyen Ti Nam, épouse Trans Van Oanh, Cons. d'État, 18 March 1983, J.C.P. 1983 II.20111.
Parpalaix v. *CÉCOS*, Trib. gr. inst. Créteil, 1 August 1984, Gaz. Pal. 1984. 2e sem. Jur.560.
R. v. *Clark* (1883), 15 Cox C.C. 171.
R. v. *Fox* (1841), 2 Q.B. 242.
R. v. *Lynn* (1788), 100 E.R. 394.
R. v. *Rothery*, [1976] R.T.R. 550 (C.A.).
R. v. *Welsh*, [1974] R.T.R. 478 (C.A.).
Re Atkins, [1989] 1 All E.R. 14.
Slater v. *Baker* (1767), 95 E.R. 860 (K.B.).
Williams v. *Williams* (1882), 20 Ch. D. 659.
Wood v. *Abrey* (1818), 3 Madd. 417.
Zanne v. *Banque Française des Yeux/Hôpital Lariboisière*, Cour d'Appel de Paris, 19 June 1989 [unreported].

APPENDIX D

Table of Statutes and Regulations

Canada

Adoption Act, R.S.B.C. 1979, c. 4.
An Act respecting Procedure in Criminal Cases, and other matters relating to Criminal Law, 32 & 33 Vict., c. 29.
An Act respecting the determination of the causes and circumstances of death, R.S.Q., c. R-0.2.
An Act to Amend the Human Tissue Gift Act, S.P.E.I., 1980, c. 27.
An Act to amend the Public Health Protection Act, S.Q. 1990, c. 55.
An Act to establish a new Civil Code and to reform family law, S.Q. 1980, c. 39.
An Act to regulate and facilitate the study of Anatomy, S. Prov. C. 1843, c. 5.
Anatomy Act, R.S.O. 1980, c. 21.
Bill 125, *Civil Code of Québec*, 1st Sess., 34th Leg. Que., 1990, now S.Q. 1991, c. 64.
Bodies of Deceased Persons Amendment Regulation, Alta Reg. 298/86.
Bodies of Deceased Persons Amendment Regulation, O.C. 82/18, A. Gaz. 1918.II.991.
Canada Health Act, R.S.C. 1985, c. C-6.
Canadian Charter of Rights and Freedoms, Part I of the *Constitution Act, 1982*, being Schedule B of the *Canada Act 1982* (U.K.), 1982, c. 11.
Cemeteries Act, R.S.O. 1980, c. 59.
Child and Family Services Act, 1984, S.O. 1984, c. 55.
Child Welfare Act, R.S.O. 1980, c. 66.
Civil Code of Lower Canada
Corneal Grafting Act, S.N.B. 1957, c. 7.
Coroners Act, R.S.O. 1980, c. 93.
Coroners Amendment Act, 1984, The, S.S. 1983-84, c. 32.
Criminal Code, R.S.C. 1985, c. C-46.
Criminal Code of 1892, The, 55 & 56 Vict., c. 29.
Criminal Law Amendment Act (No. 2), 1976, S.C. 1974-75-76, c. 105.
Criminal Law Amendment (Capital Punishment) Act, S.C. 1973-74, c. 38.
Customs Tariff, R.S.C. 1985, c. 41 (3rd Supp.).
Department of National Health and Welfare Act, R.S.C. 1985, c. N-10.
Department of Veterans Affairs Act, R.S.C. 1985, c. V-1.
Fatality Inquiries Act, R.S.A. 1980, c. F-6.
Fatality Inquiries Act, R.S.N.S. 1989, c. 164.
Food and Drug Regulations, amendment, SOR/85-1022 (plasmapheresis).
Food and Drugs Act, R.S.C. 1985, c. F-27.
Food and Drugs Act — Amendment, C. Gaz. 1988.I.3660 (Whole Blood Regulations).
Human Rights Code, 1981, S.O. 1981, c. 53.
Human Tissue Act, R.S.N.B. 1973, c. H-12.
Human Tissue Act, The, S.M. 1987-88, c. 39.
Human Tissue Act, 1971, The, S.N. 1971, No. 66.
Human Tissue Gift Act, R.S.A. 1980, c. H-12.
Human Tissue Gift Act, R.S.B.C. 1979, c. 187.

Human Tissue Gift Act, R.S.N.S. 1989, c. 215, as am. S.N.S. 1991, c. 13.
Human Tissue Gift Act, R.S.O. 1980, c. 210.
Human Tissue Gift Act, R.S.P.E.I. 1988, c. H-13.
Human Tissue Gift Act, R.S.Y.T. 1986, c. 89.
Human Tissue Gift Act, The, R.S.S. 1978, c. H-15.
Human Tissue Ordinance, R.O.N.W.T. 1974, c. H-4.
Immigration Regulations, 1978, s. 19(1)*(j)* as am. SOR/84-849, Sch., subitem 1(1).
Income Tax Act, R.S.C. 1952, c. 148; S.C. 1970-71-72, c. 63.
Indian Act, R.S.C. 1985, c. I-5.
Medical Devices Regulations, C.R.C., c. 871.
Medical Devices Regulations, amendment, SOR/82-914.
National Defence Act, R.S.C. 1985, c. N-5.
Patent Act, R.S.C. 1985, c. P-4, as am. R.S.C. 1985, c. 33 (3rd Supp.).
Penitentiary Act, R.S.C. 1985, c. P-5.
Public Health Protection Act, R.S.Q., c. P-35.
Quarantine Act, R.S.C. 1985, c. Q-1.
Regulation to amend Ontario Regulation 518/88 made under the *Public Hospitals Act*, O. Reg. 34/90.
Regulations under the *Food and Drugs Act*, P.C. 1942-9056, C. Gaz. 1942.I.2151.
Uniform Cornea Transplant Act, (1959) Conference of Commissioners on Uniformity of Legislation in Canada.
Uniform Human Gift Tissue Act, (1971) Uniform Law Conference of Canada.
Uniform Human Tissue Donation Act, (1989) Uniform Law Conference of Canada.
Veterans Health Care Regulations, SOR/90-594.
Veterans Treatment Regulations, C.R.C., c. 1585.
Vital Statistics Act, The, R.S.M. 1987, c. V60.

Australia

1983 *Criminal Code Act* of Northern Territory of Australia.
Anatomy (Human Tissue) Amendment Act, 1983, 1983 S.N.S.W., No. 165.
Human Tissue Act 1982, 1982 A. Vic., No. 9860.
Human Tissue Act 1985, 1985/86 S.L. Tasm., No. 118.
Human Tissue and Transplant Act, 1982, 1982 S.W. Austr., No. 116.
Human Tissue Transplant Act 1979, 1979 N. Terr., No. 121.
Transplantation and Anatomy Act, 1979, 1979 S. Qld, No. 74.
Transplantation and Anatomy Act, 1983, 1983 S. S. Austr., No. 11.
Transplantation and Anatomy Ordinance 1978, 1978 L. Austr. Cap. Terr., No. 44.

Belgium

Law of 13 June 1986 on the removal and transplantation of organs.

France

Arrêté du 15 juillet 1987, J.O., 4 August 1987, 8769.
Arrêté du 24 septembre 1990 fixant le nombre d'unités de transplantations rénales, cardiaques et hépatiques.
Arrêté du 24 septembre 1990 relatif à la gestion et au financement de la liste des patients en attente de transplantation.
Arrêté du 24 septembre 1990 relatif à l'organisation de l'activité d'allogreffe de moelle osseuse par établissement et par unité.
Arrêté du 24 septembre 1990 relatif à l'organisation de l'activité de transplantation d'organes, par établissement et par unité, à l'exception de l'activité d'allogreffe de moelle osseuse.

Arrêté du 24 septembre 1990 relatif aux modalités d'évaluation des activités de transplantations d'organes.
Arrêté du 24 septembre 1990 relatif à la composition du dossier de demande d'autorisation d'effectuer les transplantations d'organes.
C. Pen., arts. 309, 360 (Dalloz 1988-89).
Circulaire du 3 avril 1978, J.O., 5 April 1978, 1530; *C. Santé Pub.*, Ann. VI.
Conseil d'État, *Avant-projet de loi sur les sciences de la vie et les droits de l'homme* (1988).
Décret n° 78-501 du 31 mars 1978, J.O., 4 April 1978, 1497.
Décret n° 90-844 du 24 septembre 1990, J.O., 25 September 1990, 11606, modifiant le décret 78-501 du 31 mars 1978 pris pour l'application de la loi no 76-1181 du 22 décembre 1976 relative aux prélèvements d'organes.
Décret n° 90-845, du 24 septembre 1990, J.O., 25 September 1990, 11607, relatif aux activités de transplantations d'organes nécessitant un traitement immunodépresseur.
Loi n° 76-1181 du 22 Décembre 1976, J.O., 23 December 1976, 7365.
Loi n° 89-899 du 18 décembre 1989, J.C.P. 1990. III. 15736.

Great Britain

An Act for better preventing the horrid Crime of Murder, 25 Geo. 2, c. 37, as rep. 9 Geo. 4, c. 31.
An Act to Regulate and Facilitate the Study of Anatomy, 7 Vict., c. 5.
Anatomy Act, 2 & 3 Will. 4, c. 95.
Constitution Act, 1867, 30 & 31 Vict., c. 3 (formerly *British North America Act, 1867*).
Corneal Grafting Act, 1952, The, 15 & 16 Geo. 6 & 1 Eliz. 2, c. 28.
For Barbers and Surgeons, 32 Hy. 8, c. 42 (London Barber-Surgeons Guild Royal Charter).
Human Organ Transplants Act 1989, 1989, c. 31.
Human Tissue Act, 1961, 9 & 10 Eliz. 2, c. 54.
Witchcraft Act of 1735.

Turkey

Law No. 2238 of 29 May 1979, on the Removal, Storage, Transfer, and Grafting of Organs and Tissues, *T.C. Resmi Gazete*, No. 16655 (3 June 1979).

United States

18 Pennsylvania Purdens Penn. Cons. Stat. Ann., s. 5510 (Purdon, 1990).
18 USC 3567 (Death sentence for federal crimes may include dissection), repealed in 1987.
An Act more effectively to Protect the Sepulchres of the Dead and to Legalize the Study of Anatomy in Certain Cases, 1831 Laws of the Commonwealth of Massachusetts, c. 57.
California Health & Safety Code, s. 7052 (West 1988 Supp.).
Food, Drug & Cosmetic Act, 21 USC 301 et seq. (especially §§ 321, 381).
Kan. Stat. Ann., s. 77-202 (1970).
Mass. Genl L. Ann., c. 139, s. 14 (1989 Supp.).
Md Estate & Trusts Code Ann., s. 4-509.1 (1989 Supp.).
Minn. Stat. Ann., s. 145.422 (West 1988 Supp.).
Model Penal Code, s. 250.10.
N.Y. Pub. Health Law, ss 2505, 4360 (McKinney 1991 Supp.).
National Organ Transplant Act 1984, Pub.L. No 98-507, 98 Stat. 2339 (codified, as am. at 42 USCS §§ 273, 274, 1320b-8).
Organ Transplant Amendments Act of 1988, Pub. L. No 100-607, § 407, 102 Stat. 3114 (1988) (amending 42 USC § 274e(c)(1)).
Restatement of the Law of Contracts (Second), ss 173, 177 (1979).
Transplant Amendments Act of 1990, Pub.L. No. 101-616, 104 Stat. 379.
U.S. Organ Procurement Protocols, 53 Fed. Reg. 6,526, 6,527, 6,544 (1 March 1988) (to be codified at 42 C.F.R.).
Uniform Anatomical Gift Act (1987), 8A U.L.A. (1990 Supp.).
Uniform Determination of Death Act (1980), 12 U.L.A. 320 (1990 Supp.).

APPENDIX E

International Treaties and Agreements

Convention for the Protection of Human Rights and Fundamental Freedoms (1950).

Council of Europe, "Recommendation No. R(79) of the Committee of Ministers to the Member States concerning International Exchange and Transportation of Human Substances".

Council of Europe, "Resolution (78)29 on Harmonization of Legislations of Member States Relating to Removal, Grafting and Transplantation of Human Substances".

European Economic Community, Council Directive No. 89/381 of 14 June 1989 (on human blood products).

Free Trade Agreement between Canada and the United States of America, being Schedule-Part A of *Canada-United States Free Trade Implementation Act*, S.C. 1988, c. 65.

General Agreement on Tariffs and Trade (1947).

United Network for Organ Sharing Policies (1988) (United States — Canadian Interim Agreement).

Selected Bibliography

Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death. "A Definition of Irreversible Coma" (1968) 205:6 JAMA 337.

American Hospital Association, Americal Medical Association, United Network for Organ Sharing. *Required Request Legislation: A Guide for Hospitals on Organ & Tissue Donation.* AHA, AMA, UNOS, 1988.

American Medical Association, Council on Scientific and Judicial Affairs. "Persistent Vegetative State and the Decision to Withdraw or Withhold Life Support" (1990) 263:3 JAMA 426.

Andersen, Kathleen S., and Daniel M. Fox. "The Impact of Routine Inquiry Laws and Organ Donation" (1988) 7 Health Aff. 65.

Andrews, Lori B. "My Body, My Property" (1986) 16:5 Hast. Cent. Rep. 28.

Annas, George J. "Brain Death and Organ Donation: You *Can* Have One without the Other" (1988) 18:3 Hast. Cent. Rep. 28.

———. "From Canada with Love: Anencephalic Newborns as Organ Donors?" (1987) 17:6 Hast. Cent. Rep. 36.

Appelbaum, Paul S., and Thomas Grisso. "Assessing Patients' Capacities to Consent to Treatment" (1988) 319:25 N. Engl. J. Med. 1635.

Australian Law Reform Commission. *Human Tissue Transplants*. Report 7. Brisbane: Watson Ferguson and Co., 1977.

Ball, James Moores. *The Sack-'Em-Up Men: An Account of the Rise and Fall of the Modern Resurrectionists*. London: Oliver and Boyd, 1928.

Batten, Helen Levine, and Jeffrey M. Prottas. "Kind Strangers: The Families of Organ Donors" (1987) 6:2 Health Aff. 35.

Beak Consultants. *Regulatory Policy Options for Canadian Biotechnology*. Mississauga, Ont.: Beak Consultants, 1987.

Beauchamp, Tom L., and James F. Childress. *Principles of Biomedical Ethics*. 3d ed. New York: Oxford University Press, 1989.

Bell, E., and M. Rosenberg. "The Commercial Use of Cultivated Human Cells" (1990) 22:3 Transplant. Proc. 971.

Blake, Peter G., and Carl J. Cardella. "Kidney Donation by Living Unrelated Donors" (1989) 141:8 C.M.A.J. 773.

Botkin, Jeffrey R. "Anencephalic Infants as Organ Donors" (1988) 82:2 Pediatrics 250.

Bowker, W.F. "Minors and Mental Incompetents: Consent to Experimentation, Gifts of Tissue and Sterilization" (1980-81) 26 McGill L.J. 951.

Brahams, Diana. "Kidneys for Sale" (1989) 139:6393 New L.J. 159.

Britten, Anthony F.H. "Worldwide Supply of Blood and Blood Products" (1987) 11:1 World J. Surg. 82.

Buskard, Noël A. "A Register of Life: The First Year of the Unrelated Bone Marrow Donor Registry" (1989) 141:6 C.M.A.J. 600.

Canadian Congress Committee on Brain Death. "Death and Brain Death: A New Formulation for Canadian Medicine" (1988) 138:5 C.M.A.J. 405.

Canadian Congress of Neurological Sciences. "A CMA Position: Guidelines for the Diagnosis of Brain Death" (1987) 136:2 C.M.A.J. 200A.

Canadian Organ Replacement Register. *1989 Report*. Don Mills, Ont.: Hospital Medical Records Institute, 1991.

Canadian Pediatric Society, Bioethics Committee. "Transplantation of Organs from Newborns with Anencephaly" (1990) 142:7 C.M.A.J. 715.
Caplan, Arthur L. "Ethical and Policy Issues in the Procurement of Cadaver Organs for Transplantation" (1984) 311:15 N. Engl. J. Med. 981.
———. "Professional Arrogance and Public Misunderstanding" (1988) 18:2 Hast. Cent. Rep. 34.
Caplan, Arthur L., and Beth Virnig. "Is Altruism Enough? Required Request and the Donation of Cadaver Organs and Tissues in the United States" (1990) 6:4 Critical Care Clinics 1007.
Capron, Alexander Morgan. "Anencephalic Donors: Separate the Dead from the Dying" (1987) 17:1 Hast. Cent. Rep. 5.
Case Comment. "Coerced Donation of Body Tissues: Can We Live with *McFall* v. *Shimp*" (1979) 40 Ohio St. L.J. 409.
Castel, J.-G. "Some Legal Aspects of Human Organ Transplantation in Canada" (1968) 46:3 Can. Bar Rev. 345.
Childress, James F. "Ethical Criteria for Procuring and Distributing Organs for Transplantation" (1989) 14:1 J. Health Pol. Pol'y L. 87.
———. "Some Moral Connections between Organ Procurement and Organ Distribution" (1987) 3 J. Contemp. Health L. Pol'y 85.
Cohen, Lloyd R. "Increasing the Supply of Transplant Organs: The Virtues of a Futures Market" (1989) 58 Geo. Wash. L. Rev. 1.
Cohen, M.R. "Property and Sovereignty" (1927) 13 Cornell L.Q. 8.
Comité Consultatif National d'Éthique pour les Sciences de la Vie et de la Santé. "Avis sur l'expérimentation médicale et scientifique sur des sujets en état de mort cérébrale" in *Éthique et recherche biomédicale: rapport 1988.* Paris: La Documentation française, 1989, p. 23.
———. "Avis sur les problèmes posés par le développement des méthodes d'utilisation de cellules humaines et de leurs dérivés" in *Éthique et recherche biomédicale: rapport 1987.* Paris: La Documentation française, 1988, p. 18.
Conseil d'État. *Sciences de la Vie: De l'Éthique au Droit.* 2d ed. Paris: La Documentation française, 1988.
Council of Europe. *Organ Transplantation: Current Legislation in Council of Europe Member States and Finland and Results of European Co-operation.* Strasbourg: The Council, 1987.
———. "Resolution (78)29 on Harmonisation of Legislations of Member States Relating to Removal, Grafting and Transplantation of Human Substances" (1978) 29:4 Int'l Dig. Health Leg. 898.
———. "Third Conference of European Health Ministers (Paris, 16-17 November 1987)" (Final Text on Organ Transplantation) (1988) 39:1 Int'l Dig. Health Leg. 274.
Council of the Transplantation Society, The. "Commercialisation in Transplantation: The Problems and Some Guidelines of Practice" (1985) 2:8457 Lancet 175.
Cowan, D.H., et al., eds. *Human Organ Transplantation Societal, Medical-Legal, Regulatory, and Reimbursement Issues.* Ann Arbor, Mich.: Health Administration Press, 1987.
Cox, Mae. *Human Transplants in Canada.* Edmonton, Alta: Human Parts Banks of Canada, 1978.
Curran, Robert Emmett. *Canada's Food and Drug Laws.* New York: Commerce Clearing House, 1953.
Danforth, M. "Cells, Sales, and Royalties: The Patients' Right to a Portion of the Profits" (1988) 6 Yale L. & Pol'y Rev. 179.
Darby, Joseph M., et al. "Approach to Management of the Heartbeating 'Brain Dead' Organ Donor" (1989) 261:15 JAMA 2222.
DeVries, William C. "The Permanent Artificial Heart" (1988) 259:6 JAMA 849.
Dickens, Bernard M. Case Comment "*Eve* v. *E.*" (1987) 2 Can. Fam. L.Q. 103.
———. "The Control of Living Body Materials" (1977) 27 U.T.L.J. 142.
———. "Legal and Ethical Issues in Buying and Selling Organs" (1987) 4 Transplantation/Implantation Today 15.
Dierkens, R. *Les droits sur le corps et le cadavre de l'homme.* Paris: Masson, 1966.
Draï, Raphaël, and Michèle Harichaux, eds. *Bioéthique et droit.* Paris: P.U.F., 1988.
Dukeminier, Jesse, and David Sanders. "Organ Transplantation: A Proposal for Routine Salvaging of Cadaver Organs" (1968) 279:8 N. Engl. J. Med. 413.
Evans, Martyn. "Organ Donations Should Not Be Restricted to Relatives" (1989) 15:1 J. Med. Ethics 17.

Federal-Provincial Advisory Committee on Institutional and Medical Services. Subcommittee on Institutional Programs. *Organ and Tissue Donation Services in Hospitals: Guidelines for Establishing Standards for Special Services in Hospitals*. Ottawa: Supply and Services Canada, 1987.

Feinberg, Joel. "The Mistreatment of Dead Bodies" (1985) 15:1 Hast. Cent. Rep. 31

Freedman, B. "The Anencephalic Organ Donor: Affect, Analysis, and Ethics" (1988) 20:4 (Supp. 5) Transplant. Proc. 57.

Galloux, Jean-Christophe. "Réflexions sur la catégorie des choses hors du commerce: l'exemple des éléments et des produits du corps humain en droit français" (1989) 30 C. de D. 1011.

Gaylin, Willard. "Harvesting the Dead" (1974) 249 Harper's 23.

Hagen, Piet J. *Blood: Gift or Merchandise*. New York: Alan R. Liss, 1982.

Hansmann, Henry. "The Economics and Ethics of Markets for Human Organs" (1989) 14:1 J. Health Pol. Pol'y L. 57.

Harrison, Michael R. "The Anencephalic Newborn as Organ Donor" (1986) 16:2 Hast. Cent. Rep. 21.

Hastings Center, The. *Ethical, Legal and Policy Issues Pertaining to Solid Organ Procurement*. Hastings-on-Hudson, N.Y.: The Center, 1985.

Health and Welfare Canada. *Guidelines for Prevention of HIV Infection in Organ and Tissue Transplantation* (October 1989) 15S4 (Supp.) Canada Diseases Wkly Rpt.

Heleine, François. "Le dogme de l'intangibilité du corps humain et ses atteintes normalisées dans le droit des obligations du Québec contemporain" (1976) 36 R. du B. 2.

Herbrand, John S. "Validity, Construction, and Application of Statutes Making It a Criminal Offense to Mistreat or Wrongfully Dispose of Dead Body" 81 A.L.R. 3d 1071.

Hermitte, Marie-Angèle. "Le corps hors du commerce, hors du marché" (1988) 33 Arch. Phil. Dr. 323.

Houlihan, P.J. *Life without End: The Transplant Story*. Toronto: NC Press, 1988.

Ingram, John Dwight. "State Interference with Religiously Motivated Decisions on Medical Treatment" (1988) 93 Dick. L. Rev. 41.

Institute of Medicine. *Assessing Medical Technologies*. Washington, D.C.: National Academy Press, 1985.

Iserson, Kenneth V. and Charles M. Culver. "Using a Cadaver to Practice and Teach" (1986) 16:3 Hast. Cent. Rep. 28.

Jaffe, Erik S. "She's Got Bette Davis['s] Eyes: Assessing the Nonconsensual Removal of Cadaver Organs under the Takings and Due Process Clauses" (1990) 90 Colum. L. Rev. 528

Jansen, R.P. "Sperm and Ova as Property" (1985) 11:3 J. Med. Ethics 123.

Johnson, Karen L. "The Sale of Human Organs Implicating Privacy Right" (1987) 21 Val. U.L. Rev. 741.

Kant, Immanuel. *Grounding for the Metaphysics of Morals*. Translated by J.W. Ellington. Indianapolis: Hackett, 1981.

Kass, Leon R. "Thinking about the Body" (1985) 15:1 Hast. Cent. Rep. 20.

Katz, Jay. *The Silent World of Doctor and Patient*. New York: Free Press, 1984.

Katz, Jay, and Alexander Morgan Capron. *Catastrophic Diseases: Who Decides What?* New York: Russell Sage Foundation, 1975.

Kevorkian, Jack. "Marketing of Human Organs and Tissues Is Justified and Necessary" (1989) 7:6 Med. L. 557.

Keyserlingk, Edward W. "A Legal Definition of Death: Can It Affect Supply of Tissue and Organs?" (1985) 17:6 (Supp. 4) Transplant. Proc. 47.

Kirn, T.F. "Tissue Banking in Midst of Revolution of Expansion as More Uses Are Found for Various Transplants" (1987) 258:3 JAMA 302.

Klein, Harvey G. "Transfusion Medicine: The Revolution of a New Discipline" (1987) 258:15 JAMA 2108.

Lassek, Arthur M. *Human Dissection: Its Drama and Struggle*. Springfield, Ill.: Charles Thomas, 1958.

Law Reform Commission of Canada. *Biomedical Experimentation Involving Human Subjects*. Working Paper 61. Ottawa: The Commission, 1989.

———. *Criteria for the Determination of Death*. Working Paper 23. Ottawa: Supply and Services Canada, 1979.
———. *Criteria for the Determination of Death*. Report 15. Ottawa: Supply and Services Canada, 1981.
———. *Medical Treatment and Criminal Law*. Working Paper 26. Ottawa: Supply and Services Canada, 1980.
Lawrence, D.G. "'Resurrection' and Legislation or Body-Snatching in Relation to the Anatomy Act in the Province of Quebec" (1958) 32:5 Bull. Hist. Med. 408.
Lombardo, Paul A. "Consent and 'Donations' from the Dead" (1981) 11:1 Hast. Cent. Rep. 9.
Macpherson, C.B., ed. *Property: Mainstream and Critical Positions*. Toronto: University of Toronto Press, 1978.
Manitoba Law Reform Commission. *Report on The Human Tissue Act*. Report 66. Winnipeg: The Commission, 1986.
Martyn, Susan R. "Using the Brain Dead for Medical Research" (1986) Utah L. Rev. 1.
Martyn, Susan, Richard Wright and Leo Clark. "Required Request for Organ Donation: Moral, Clinical, and Legal Problems" (1988) 18:2 Hast. Cent. Rep. 27.
Marusyk, Randy W., and Margaret S. Swain. "A Question of Property Rights in the Human Body" (1989) 21 Ottawa L. Rev. 351.
Mathieu, Deborah, ed. *Organ Substitution Technology: Ethical, Legal, and Public Policy Issues*. Boulder, Colo.: Westview, 1988.
Matthews, Paul. "Whose Body? People as Property" (1983) 36 Current Legal Problems 193.
May, William F. "Religious Justifications for Donating Body Parts" (1985) 15:1 Hast. Cent. Rep. 38.
Mayrand, A. *L'inviolabilité de la personne humaine*. Montreal: Wilson & Lafleur, 1975.
McDonald, John C. "The National Organ Procurement and Transplantation Network" (1988) 259:5 JAMA 725.
Medical Task Force on Anencephaly, The. "The Infant with Anencephaly" (1990) 322:10 N. Engl. J. Med. 669.
Meulders-Klein, M.T. "The Right over One's Own Body: Its Scope and Limits in Comparative Law" (1983) 6 B.C. Int'l & Comp. L. Rev. 29.
Meyers, D.W. *The Human Body and the Law*. Chicago: Aldine Atherton, 1970.
Murray, Thomas H. "Gifts of the Body & the Needs of Strangers" (1987) 17 Hast. Cent. Rep. 30.
———. "On the Human Body as Property: The Meaning of Embodiment, Markets, and the Meaning of Strangers" (1987) 20 U. Mich. J.L. Ref. 1055.
National Health and Medical Research Council. *A Code of Practice for Transplantation of Cadaveric Organs*. Canberra: The Council, 1982.
New Jersey Commission on Legal and Ethical Problems in the Delivery of Health Care. *Problems and Approaches in Health Care Decisionmaking*. New Jersey: The Commission, 1990.
New York State Task Force on Life and the Law, The. *The Determination of Death*. 2d ed. New York: The Task Force, 1989.
———. *Transplantation in New York State: The Procurement and Distribution of Organs and Tissues*. New York: The Task Force, 1988.
Nolan, Barbara E., and Nicholas P. Spanos. "Psychosocial Variables Associated with Willingness to Donate Organs" (1989) 141:1 C.M.A.J. 27.
Note. "Compulsory Removal of Cadaver Organs" (1969) 69 Colum. L. Rev. 693.
———. "Incubating for the State: The Precarious Autonomy of Persistently Vegetative and Brain-Dead Pregnant Women" (1988) 22 Ga. L. Rev. 1103.
———. "Ownership of Human Tissue: Life after *Moore* v. *Regents of the University of California*" (1989) 75 Va. L. Rev. 1363.
———. "Refining the Law of Organ Donation: Lessons from the French Law of Presumed Consent" (1987) 19 N.Y.U. J. Int'l L. & Pol. 1013.
———. "Regulating the Sale of Human Organs" (1985) 71 Va. L. Rev. 1015.
———. "Restructuring Informed Consent: Legal Therapy for the Doctor-Patient Relationship" (1970) 79 Yale L.J. 1533.
———. "Tax Consequences of Transfers of Bodily Parts" (1973) 73 Colum. L. Rev. 842.
———. "The Sale of Human Body Parts" (1973-74) 72 Mich. L. Rev. 1182.
———. "Toward the Right of Commerciality: Recognizing Property Rights and the Commercial Value of Human Tissue" (1986) 34 U.C.L.A. L. Rev. 207.

Orlowski, James P., George A. Kanoti and Maxwell J. Mehlman. "The Ethics of Using Newly Dead Patients for Teaching and Practising Intubation Techniques" (1988) 319:7 N. Engl. J. Med. 439.

Peters, David A. "Protecting Autonomy in Organ Procurement Procedures: Some Overlooked Issues" (1986) 64 Milbank Mem. Fund Q. 241.

Picard, Ellen I. *Legal Liability of Doctors and Hospitals in Canada*. 2d ed. Toronto: Carswell, 1984.

Prottas, Jeffrey M. "Encouraging Altruism: Public Attitudes and the Marketing of Organ Donation" (1983) 61 Milbank Mem. Fund Q. 278.

———. "The Rules for Asking and Answering: The Role of Law in Organ Donation" (1985) 63 U. Det. L. Rev. 183.

Quay, Paul M. "Utilizing the Bodies of the Dead" (1984) 28 St. Louis U. L.J. 889.

Radin, Margaret Jane. "Market-Inalienability" (1986-87) 100 Harv. L. Rev. 1849.

———. "Property and Personhood" (1982) 34 Stan. L. Rev. 957.

Ramsey, Paul. *The Patient as Person: Explorations in Medical Ethics*. New Haven: Yale University Press, 1970.

Report of the Advisory Committee on the Storage and Utilization of Human Sperm. Ottawa: Health and Welfare Canada, 1981.

Report of the Alberta Human Tissue Procurement Task Force. Edmonton, Alta: The Task Force, 1985.

"Report of the Committee Studying the Uniform Human Tissue Gift Act to the Uniform Law Section of the Uniform Law Conference of Canada" in Uniform Law Conference of Canada. *Proceedings of the Seventy-first Annual Meeting*. Fredericton, N.B.: The Conference, 1990, p. 219.

"Report of the Massachusetts Task Force on Organ Transplantation" (1985) 13:1 Law Med. Health Care 8.

"Report of the Working Group on Vital Organ Transplant Centres to the Deputy Ministers of Health" (September 1985) [unpublished].

Review of Organ and Tissue Donation and Transplantation in Saskatchewan. Regina, Sask.: Ministry of Health, 1987.

Roberts, Russell D., and Michael J. Wolkoff. "Improving the Quality and Quantity of Whole Blood Supply: Limits to Voluntary Arrangements" (1988) 13:1 J. Health Pol. Pol'y L. 167.

Rock, Gail, et al. "Registry of Unrelated Bone Marrow Donors" (1987) 137:3 C.M.A.J. 294.

Rodgers, Sanda. "The Canadian Blood Delivery System: Liability for Blood Related Injuries" (1989) 21 Ottawa L. Rev. 311.

Rozovsky, Lorne Elkin. "Death, Dead Bodies and the Law" (1970) 47:7 Can. Hosp. 52.

Sadler, Alfred M., and Blair L. Sadler. "A Community of Givers, Not Takers" (1984) 14:5 Hast. Cent. Rep. 6.

Schmeck, Harold M. *The Semi-Artificial Man*. New York: Walker, 1965.

Science Council of Canada. *Genetics in Canadian Health Care*. Report 42. Ottawa: The Council, 1991.

Scott, Russell. *The Body as Property*. New York: Viking Press, 1981.

Sharpe, Gilbert. "Commerce in Tissue and Organs" (1985) 17:6 (Supp. 4) Transplant. Proc. 33.

———. *The Law & Medicine in Canada*. 2d ed. Toronto: Butterworths, 1987.

Shepherd, Francis J. *Reminiscences of Student Days and Dissecting Room*. Montreal: 1919.

Shewmon, D. Alan, et al. "The Use of Anencephalic Infants as Organ Sources — A Critique" (1989) 261:12 JAMA 1773.

Sipes, Daphne. "Requesting Organ Donations: A New State Approach to Organ Transplants" (1987) 8:2 Health L. Can. 39.

Skegg, P.D.G. "Authorization of the Removal of Cadaveric Transplant Material at Common Law" (1978) 18 Med. Sci. L. 90.

———. "Human Corpses, Medical Specimens and the Law of Property" (1975) 4 Anglo-Am. L. Rev. 412.

Smith, A.T. "Stealing the Body and Its Parts" [1976] Crim. L. Rev. 622.

Smith, B. "Intimations of Life: Extra-corporeality and the Law" (1985-86) 21 Gonz. L. Rev. 395.

Smith, David Randolph. "Legal Recognition of Neocortical Death" (1986) 71 Cornell L. Rev. 850.

Somerville, Margaret A. *Consent to Medical Care*. Study Paper prepared for the Law Reform Commission of Canada. Ottawa: Supply and Services Canada, 1980.

———. "Medical Interventions and the Criminal Law: Lawful or Excusable Wounding?" (1980-81) 26 McGill L.J. 82.

———. "'Procurement' vs. 'Donation' — Access to Tissues and Organs for Transplantation: Should 'Contracting Out' Legislation Be Adopted?" (1985) 17:6 (Supp. 4) Transplant. Proc. 53.
Starkman, Bernard. "A Defence to Criminal Responsibility for Performing Surgical Operations: Section 45 of the *Criminal Code*" (1980-81) 26 McGill L.J. 1048.
Steinbrook, P. "Kidneys for Transplantation" (1981) 6:4 J. Health Pol. Pol'y L. 504.
Stuart, Don. *Canadian Criminal Law*. 2d ed. Toronto: Carswell, 1987.
Task Force on Organ Donation. *Organ Donation in the Eighties: The Minister's Task Force on Kidney Donation*. Toronto: The Task Force, 1985.
Titmuss, Richard M. *The Gift Relationship: From Human Blood to Social Policy*. London: George Allen & Unwin, 1970.
U.K. *Report from the Select Committee on Anatomy*. London: 1829.
U.S. Centers for Disease Control. "Safety of Therapeutic Products Used for Hemophilia Patients" (1988) 37:29 Morbidity Mortality Wkly Rptr 441.
———. "Semen Banking, Organ and Tissue Transplantation, and HIV Antibody Testing" (1988) 259:9 JAMA 1301.
U.S. Congress. Office of Technology Assessment. *Blood Policy & Technology*. Washington, D.C.: Office of Technology Assessment, 1985.
———. *Commercial Biotechnology: An International Analysis*. Washington, D.C.: Office of Technology Assessment, 1984.
———. *New Developments in Biotechnology: Ownership of Human Tissues and Cells*. Paper prepared by Gladys B. White et al. Washington, D.C.: U.S. Government Printing Office, 1987.
———. *New Developments in Biotechnology: Patenting Life*. Washington, D.C.: U.S. Government Printing Office, 1989.
———. *Recombinant Erythropoietin: Payment Options for Medicare*. Washington, DC.: U.S. Government Printing Office, 1990.
U.S. Department of Health and Human Services, Public Health Service. Agency for Health Care Policy and Research. *Health Technology Assessment Reports, 1990: Assessment of Liver Transplantation*. Rockville, Md.: U.S. Department of Health and Human Services, 1990.
———. National Center for Health Services Research and Health Care Technology Assessment. *Reassessment of Autologous Bone Marrow Transplantation*. Washington, D.C.: U.S. Government Printing Office, 1988.
———. *Report on the Scientific and Clinical Status of Organ Transplantation*. Washington, D.C.: U.S. Government Printing Office, 1988.
———. Task Force on Organ Transplantation. *Organ Transplantation: Issues and Recommendations*. Washington, D.C.: U.S. Government Printing Office, 1986.
U.S. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. *Defining Death: A Report on the Medical, Legal and Ethical Issues in the Determination of Death*. Washington, D.C.: The Commission, 1981.
Veatch, R.M. *Case Studies in Medical Ethics*. Cambridge, Mass.: Harvard University Press, 1977.
Vital Organ Transplant Center Guidelines. Ottawa: Supply and Services Canada, 1986.
Waite, Frederick C. "The Development of Anatomical Laws in the States of New England" (1945) 233:24 N. Engl. J. Med. 716.
World Health Organization. *Health Aspects of Human Rights: With Special Reference to Developments in Biology and Medicine*. Geneva: The Organization, 1976.
Worthington, Edward Dagge. *Reminiscences of Student Life and Practice*. Sherbrooke, Que.: Walton, 1897.

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