
Retrospective on the Future: Brain Death and Evolving Legal Regimes for Tissue Replacement Technology

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In North America, the medico-legal definition of death has played an important role in facilitating organ transplantation. In the quarter century since the initial proposal of "brain death" criteria, acceptance of the criteria has helped standardize medical practice for the termination of life support, organ procurement and post-mortem donor patient management. In the author's view, it has provided a foundation for the reflection and judgments of North American courts in so-called "right to die" cases and even criminal trials; it has helped some families with loved ones who lie in a coma. Some would say that the new death standard has, in practice, advanced the societal value for human life. The author argues, however, that even with such benefits the new standard raises daunting "second generational questions" for law, medicine and bioethics. Seen in a broader perspective, brain death stands as one of the many fundamental pillars in the legal regime which North American society has erected to govern modern tissue replacement technology. The author demonstrates how this currently evolving regime parallels previous and foreshadows emerging legal regimes for the therapeutic transfer of human tissue, bodily parts and substances.

En Amérique du Nord, la définition médicale et juridique de la mort joue un rôle important dans les transplantations d'organes. Depuis vingt-cinq ans, l'adoption du concept de « mort cérébrale » a aidé la médecine dans plusieurs domaines, comme la cessation de traitement, l'obtention et le don d'organes. L'auteur nous dit que ce concept a guidé la réflexion et les jugements des tribunaux nord-américains dans des causes dites « droit de mourir » et même dans des procès criminels; il a également aidé des familles dont un des membres était dans le coma. Certains seraient tentés de dire que l'adoption du critère de la mort cérébrale a eu pour effet de protéger davantage la vie. L'auteur prétend cependant que cette définition de la mort n'est pas sans poser d'importants problèmes en droit, en médecine et en bioéthique. Dans une perspective plus large, la mort cérébrale constitue un élément fondamental du régime juridique nord-américain régissant la technologie moderne de remplacement des tissus. L'auteur termine en examinant les liens entre le régime actuel et les régimes précédents et futurs en matière de transplantation thérapeutique de tissus, parties et substances du corps humain.

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Introduction

Brain death,¹ it would seem, is a generally accepted concept in the medical and legal communities in North America. Evidence of the acceptance comes from the fact that hospitals, neurologists and transplant specialists now routinely rely on brain death protocols for the determination and timing of death.² Moreover, the concept has been adopted by provincial and model uniform legislation³ and the Law Reform Commission⁴ in Canada, some forty-nine states⁵ and the

¹"Brain death" generally refers to the irreversible cessation of brain function(s); see *infra* notes 4, 6, 24. For commentary on the specific criteria relied on by the medical community in diagnosing brain death, see *infra* note 21.

²See e.g. G.B. Young, "Checklist for Brain Death" (1991) 145 *Can. Med. Assoc. J.* 294. But see S. Youngner *et al.*, "Brain Death and Organ Retrieval: A Cross-Sectional Survey of Knowledge and Concepts among Health Professionals" (1989) 261 *J.A.M.A.* 2205.

³*Uniform Human Tissue Donation Act* (1989), ss. 1, 11, in *Consolidation of Uniform Acts* (Fredericton: Uniform Law Conference of Canada, 1991) 22-1 (1992 Supp.) [hereinafter *Donation Act*]. See also *infra* note 24.

⁴Law Reform Commission of Canada, *Criteria for the Determination of Death* (Report 15) (Ottawa: Supply & Services Canada, 1981) [hereinafter Report 15] (defining death as the irreversible cessation of all brain functions). For a dissenting view on the need for brain death legislation, see R.P. Kouri, "Réflexions sur la nécessité d'une définition de la mort" (1983) 13 *R.D.U.S.* 448.

⁵New Jersey Commission on Legal and Ethical Problems in the Delivery of Health Care, *Problems and Approaches in Health Care Decisionmaking: The New Jersey Experience* (New Jersey: The Commission, 1990) at 11 [hereinafter *New Jersey Experience*]. Over half of the U.S. jurisdictions have enacted laws based on a model law of the National Conference of Commissioners on

President's Commission⁶ in the United States and several judicial decisions and bioethical commissions.⁷

But if brain death protocols and laws today enjoy general support and help facilitate the life-saving process of transplanting organs from the deceased into the living, it has not always been so in North America. If we cast our minds back to national and international events of more than a quarter of a century ago, what lessons may be drawn from the development of medico-legal reforms of the definition of death? What, if anything, does this story counsel in terms of the reform of laws and policies on modern tissue transplant and tissue replacement technologies?

In the discussion that follows, these and like questions are examined. Part I explores the origins, cultural rationales and current limits of brain death in North America. Part II suggests a broader perspective on these reforms by comparing them with prior and more recent legal initiatives to facilitate medical uses of the human body.

I. Brain Death: Humankind and Its Machines

Science is committed to the universal. A sign of this is that the more successful a science becomes the broader the agreement about its basic concepts ... As the corollary of science, technology also exhibits the universalizing tendency ... If humans create machines, machines in turn shape their creators.⁸

May it accurately be said of modern medicine that humankind is in the process of disappearing into the machines we have created?⁹ The origins of, need for and consequences of the brain death standard portray something of a modern effort to live outside of and harmoniously with our technological creations.

A. Origins

The origin of the brain death criteria in Canada is a story that probably parallels those experienced by many countries in the 1960s. Then, a series of rather dramatic international events cumulatively forced the medical and legal communities to question, rethink and then propose modifying the traditional standard of death — irreversible heart-lung cessation.

The harbinger of change had entered the medical community decades before the 1960s in the form of an advance in critical care technology to treat severely impaired respiratory function. The mechanical respirator, or what the public would initially call the "iron lung," became part of our early techno-

Uniform State Laws; see the *Uniform Determination of Death Act*, 12 U.L.A. 338 (1991 Supp.).

⁶President'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.: U.S.G.P.O., 1981) [hereinafter *Defining Death*].

⁷See e.g. *supra* note 5 and *infra* notes 25-36.

⁸O.B. Hardison, *Disappearing through the Skylight: Culture and Technology in the 20th Century* (New York: Viking Penguin, 1988) at 142, 143, 144.

⁹See *ibid.* at 347.

logical response to the treatment of disabling or paralytic forms of respiratory failure like polio:

Prolonged mechanical ventilation first became a reality in the midst of the world-wide epidemics of poliomyelitis during the first half of this century. In Europe and the United States, thousands of victims who suffered respiratory paralysis were sustained for months or years with "iron lungs" and other early types of ventilators.¹⁰

How much suffering was alleviated, how many lives were saved by these medical devices, we may never know. By the 1950s, when the advent of safe and effective vaccines helped eliminate polio as a major public health problem, more sophisticated and efficient respirators had made their way into critical care areas such as the emergency units, operating theatres and anaesthesia departments of hospitals. Thus, artificial respiration technology was becoming a modern standard of care when Boston doctors first successfully transplanted a human organ — a kidney — from one twin to his ailing brother in 1954.¹¹

The therapeutic benefits imparted by these machines, however, had already begun to impose clinical and even moral burdens. What, as an eminent theological authority of the day asked, were doctors to do when artificial respiration and mechanical life support seemed to be the true source of life in a severely brain-damaged individual who had been resuscitated?

If the lesion of the brain is so serious that the patient will very probably, and even most certainly, not survive, the anesthesiologist is then led to ask himself the distressing question as to the value and meaning of the resuscitation process ... Out of this situation there arises a question that is fundamental ... When ... has death occurred in patients on whom modern methods of resuscitation have been used?¹²

Doctors turned to the moral authority of the Church for answers to such dilemmas. Pope Pius XII's 1957 response framed the issue, its implications and challenge for decades:

The question of the fact of death and that of verifying the fact itself ... or its legal authenticity ... have ... in the field of morals and of religion, an even greater importance ... [T]he importance of the question extends also to effects in matters of inheritance, marriage and matrimonial process ... and to many other questions of private and social life.

It remains for the doctor ... to give a clear and precise definition of "death" and "the moment of death" of a patient ...¹³

These words reverberated in the early legal controversies over the medical and legal definition of death. One of the first controversies in common law countries arose in 1963 out of a British inquest into the death of John D. Potter, a 32-year-old man who had received extensive brain damage during a fight.¹⁴

¹⁰U.S. Congress, Office of Technology Assessment, *Life Sustaining Technologies and the Elderly* (Washington, D.C.: U.S.G.P.O., 1987) at 207.

¹¹J.P. Merrill *et al.*, "Successful Homotransplantation of the Human Kidney between Identical Twins" (1956) 160 J.A.M.A. 277.

¹²Pope Pius XII, "Prolongation of Life" (1958) 4:4 *The Pope Speaks* 393 at 394-95.

¹³*Ibid.* at 396.

¹⁴*R. v. Potter* (1963), (U.K.) [unreported] [hereinafter *Potter*], discussed in (1963) 2 Brit. Med. J. 394; "The Moment of Death: *Re Potter*" (1963) 31 *Medico-Legal J.* 195; B. Hogan, "A Note on Death" [1972] *Crim. L. Rev.* 80.

Fourteen hours after admission to a hospital, Potter stopped breathing. To preserve the possibility of transplanting his organs, doctors attached Potter to a respirator for a day, secured familial consent and removed a kidney. The doctors thereafter withdrew the respirator and Potter evidenced no signs of spontaneous respiration. Unfortunately, the transplant recipient died within a month, though this was the year in which Boston doctors were to perform one of the first successful kidney transplants between a deceased unrelated donor and a living recipient.¹⁵

In the ensuing inquest, some of the reports adduced as evidence apparently set the time of Potter's death as occurring before the transplant; other reports set the time of death afterwards. Despite such uncertainties, the neurological and pathological medical testimony presented led a coroner's jury to conclude that transplantation had not contributed to death. The jury returned a verdict of manslaughter against Potter's assailant. Thus was first presented what might be called the "Potter defense": namely, an accused's argument that death was caused not by the accused's assault, but by the doctors who removed the victim's kidneys for transplantation or by the doctors who turned off the respirator. Though in this instance the argument had unsuccessfully exploited the divergence between the traditional designation of death and modern medical practices, it still bluntly highlighted the criminal liability concerns for transplant surgeons, neurosurgeons and critical care medical personnel.

Some of the broader issues surrounding the Potter defense were explored in an international multidisciplinary symposium on ethics and transplantation in 1966. Was modern society, in fact, working with two definitions of death, the traditional "legal" one and a new "medical" one? Some conference participants remarked that conventional death criteria created clinical and "moral" problems for the termination of mechanical support. Others saw the criteria as impeding transplantation, while still others debated whether five proposed criteria for irreversible brain damage, based on neurological and pathological studies dating from 1959, established "incontrovertible evidence of death."¹⁶

Neither the conference nor the *Potter* case was explicitly mentioned two years later, in the threshold summer of 1968, when an *ad hoc* committee at Harvard University proposed a new definition of death. The proposal spoke to the core concerns raised by the conference two years earlier, by the *Potter* case in 1963 and by the Pope in 1957:

Our primary purpose is to define irreversible comas as a new criterion for death. There are two reasons why there is a need for a definition: (1) Improvements in resuscitative and supportive measures have led to increased efforts to save those who are desperately injured. Sometimes these efforts have only partial success so that they result in an individual whose heart continues to beat but whose brain is irreversibly damaged. The burden is great on patients who suffer permanent loss in intellect, on their families, on the hospitals ... (2) Obsolete criteria for the

¹⁵L.P. Merril *et al.*, "Successful Transplantation of Kidney from a Human Cadaver" (1963) 185 J.A.M.A. 347.

¹⁶See G.E. Wolstenholme & M. O'Connor, eds., *Ethics in Medical Progress: With Special Reference to Transplantation* (London: Churchill, 1966) at 68, 74, 157.

definition of death may lead to controversy in obtaining organs for transplantation ...

*More than medical problems are present. There are moral, ethical, religious and legal issues. Adequate definition here will prepare the way for better insight into all of these matters as well as for better law than is currently applicable. [emphasis added]*¹⁷

The historical import and meaning of the Harvard proposal may be seen in the fuller light of events that made 1968 a milestone year in transplant history. In January, South African surgeon Christiaan Barnard — who had recently startled the world by performing the first successful human heart transplantation — drew further international scrutiny to the transplant community by performing a second one less than two weeks after the death of the first recipient. The first recipient survived 18 days; the second survived over 18 months.¹⁸ In April, France became one of the first countries to give legal effect to a new definition of death by adopting brain death criteria in a ministerial decree.¹⁹ In June and August, two international medical assemblies issued declarations on the role of irreversible cessation of cerebral function(s) as criteria for death and in the selection of transplant donors.²⁰ In November, the Canadian Medical Association endorsed the need for new death criteria based on “cerebral function.”²¹ Hence, while the Harvard criteria were not the first to proclaim a revised standard, nor the first to give brain death legal effect, the criteria proved of such telling effect, in part, because they were so timely; in part, because they spoke authoritatively and cogently for an emerging consensus of experience and thought in the international medical community.

Canada was not immune from the international events and reflection, as evidenced by the 1968 declaration of the Canadian Medical Association. The Canadian medical community performed kidney and then heart transplants through the 1960s. These modern practices and medical technologies eventually combined with man’s ancient combatant rituals to oblige the Canadian legal community to question, study and then reform the definition of death.

A criminal court room in the western province of Manitoba provided the initial forum for change in 1970. In facts similar to those that had arisen seven years earlier in Britain, a man named Page invoked the “Potter defense” to

¹⁷*Ad Hoc* Committee of the Harvard Medical School to Examine the Definition of Brain Death, “A Definition of Irreversible Coma” (1968) 205 J.A.M.A. 337.

¹⁸C.N. Barnard, “Human Cardiac Transplantation: An Evaluation of the First Two Operations Performed at the Groote Schuur Hospital, Cape Town” (1968) 22 Am. J. Cardiol. 584.

¹⁹Circular No. 67 of 24 April 1968 of the Minister of Social Affairs, C. Santé Pub. Ann. VI (Dalloz, 1991), reprinted in “Autopsies and Removal of Organs for Scientific or Therapeutic Purpose: Criteria for Determining Whether Death Has Occurred” (1968) 19 Int’l Dig. Hlth. Legis. 628.

²⁰See Council for International Organizations of Medical Sciences, *CIOMS Round Table (13-14 June 1968): Heart Transplantation* (Liège, Belgium: Desoer, 1969) at 51; “XXII World Medical Assembly” (1968) 15 World Med. J. 131 at 133, 134.

²¹“The Canadian Medical Association Statement on Death, November 1968” (1968) 99 Can. Med. Assoc. J. 1266, later revised by “Guidelines for the Diagnosis of Brain Death” (1987) 136 Can. Med. Assoc. J. 200A. See also Young, *supra* note 2; B. Young, W. Blume & A. Lynch, “Brain Death and the Persistent Vegetative State: Similarities and Contrasts” (1989) 16 Can. J. Neurol. Sci. 388.

refute a charge that he had killed a man whom he had severely beaten.²² Page argued that the hospital treatment of the injured man — specifically, the removal of decedent's kidneys for transplant and the subsequent withdrawal of the respirator — had caused death. The Page jury followed the initial Potter jury and rejected this first invocation of the "Potter defense" in Canada: it returned a conviction for manslaughter.

Due in part to *Page*, the Manitoba Law Reform Commission recommended in 1974 that Manitoba enact a legislative definition of death based on the irreversible cessation of brain function.²³ The Manitoba Legislature heeded the advice in 1975.²⁴ A year later, the highest court of Manitoba upheld a jury's implicit reliance on brain death criteria after the jury rejected the Potter defense the second time when it was raised in a Canadian criminal trial.²⁵ Influenced by the reforms in Manitoba and foreign jurisdictions, the Law Reform Commission of Canada studied the issues in 1979²⁶ and recommended the enactment of a federal statutory definition of death in 1981,²⁷ the same year that the U.S. President's Commission issued its influential report which drew similar conclusions.²⁸

B. Cultural Needs and Consensus

Any narrative of the origins of brain death criteria in Canada and the United States seems unlikely to capture the full story if it fails to speak of the human impact that ambiguity and reform may have on cultural identity. For

²²*R. v. Page* (6 November 1970), (Man. Q.B.) [unreported] [hereinafter *Page*], described in Manitoba Law Reform Commission, *Report on A Statutory Definition of Death* (Winnipeg: Manitoba Law Reform Commission, 1974) at 18-19.

²³*Ibid.*

²⁴*An Act to Amend the Vital Statistics Act*, S.M. 1975, c. 5, s. 1:

When death occurs:

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

²⁵See *R. v. Kitching and Adams*, [1976] 6 W.W.R. 697 at 700-704, 32 C.C.C. (2d) 159 (Man. C.A.) [hereinafter *Kitching* cited to W.W.R.], leave to appeal den'd (1976), 32 C.C.C. (2d) 159 note (S.C.C.) (affirming manslaughter conviction and jury's finding that the appellants' assault — not doctor's subsequent removal of the kidneys from the brain-dead patient — caused death). For more recent Canadian cases, see *R. v. Lenny & Lenny* (6 January 1992), (Alta. Prov. Ct.) [unreported] [hereinafter *Lenny*] (preliminary inquiry ordering alleged assailants of comatose 1-year-old to stand trial for homicide); "Murder Charges against Couple Stayed in Death of Toddler" *The [Toronto] Globe and Mail* (13 February 1992) A6 (homicide charge amended to aggravated assault charge since child victim rendered comatose, but not brain dead); *R. v. Green* (1988), 43 C.C.C. (3d) 413 (B.C.S.C.) [hereinafter *Green*] (rejecting brain death standard). For a critique of *Green*, see Law Reform Commission of Canada, *Procurement and Transfer of Human Tissue* (Working Paper 66) (Ottawa: Supply & Services Canada, 1992) at 98 note 591 [hereinafter Working Paper 66]. For a review of U.S. cases, see D.B. Sweet, "Annotation: Homocide by Causing Victim's Brain-Dead Condition" 42 A.L.R.4th 742 (1985).

²⁶Law Reform Commission of Canada, *Criteria for the Determination of Death* (Working Paper 23) (Ottawa: Supply & Services Canada, 1979) [hereinafter Working Paper 23].

²⁷See Report 15, *supra* note 4 at 10.

²⁸See *Defining Death*, *supra* note 6. Compare one of the early leading legal analyses, A. Capron & L. Kass, "A Statutory Definition for Determining Death" (1972) 121 U. Pa. L. Rev. 87.

within the shared customs, beliefs, values and knowledge that help identify the culture of given peoples lie diverse communities and individuals. Even within particular cultures, communities will often subscribe to thinking, customs and attitudes that make them distinct. It is in this sense that the technological imperatives of modern respiratory therapy and transplantation bound diverse communities — patients and their families, nurses and neurologists, theologians and lawyers — in a new, ill-defined technological culture that needed norms, common language and beliefs and more clearly defined roles and expectations, to enable affected individuals and communities to interact more easily and meaningfully.

Indeed, we in the technologically-laden culture of North America still need some minimally common ways of viewing, thinking about and interacting with our neighbour who lies hospitalized and maintained by artificial respirators and circulators with no brain functions. Surely it matters that, under traditional criteria of respiring lungs, circulating blood and a normal body temperature, we would regard her as alive. Surely it also matters that the mechanical support she receives has obscured and eroded the utility of the traditional standards. The questions, suffering and uncertainty provoked by countless such scenarios in hospitals on different continents over the last three decades have helped forge at least four points of consensus on the substance and process of formulating a modern concept of death in the West.

First, death is a religious, moral and legal concept,²⁹ even if the early calls for revised norms were sounded initially by the medical community. An emerging consensus on the clinical need for and scientific basis of revised death criteria made the medical community a leading proponent of change. But Pope Pius the XII's 1957 discourse³⁰ and the Harvard Committee's 1968 proposal³¹ illustrate the early consciousness that these matters transcend the confines of medicine and must include reflection from the theological, ethical and legal communities.

Secondly, the removal of legal ambiguity over the modern life-death line proved to be a major catalyst for law reform. The confusion and challenge raised by the "Potter defense" in Britain in the early 1960s prodded legislatures to enact and courts to adopt or affirm brain death criteria in numerous jurisdictions, including Manitoba and Kansas³² in the 1970s, New York³³ in 1984 and most recently in Minnesota³⁴ in 1989. Beyond the criminal liability concerns, legal reform was needed because the timing and determination of death affects individuals' rights and duties in inheritance, wrongful death, civil liability, fam-

²⁹See *Defining Death*, *ibid.* at 1, 31-36; New York State Task Force on Life and the Law, *The Determination of Death*, 2d ed. (New York: N.Y. State Task Force on Life and the Law, 1989) at 6 [hereinafter *Determination of Death*]; Report 15, *supra* note 4 at 15-16.

³⁰*Supra* note 12.

³¹*Supra* note 17.

³²*An Act Relating to and Defining Death* (1970 Kan. Sess. Laws 378), upheld in *State v. Shaffer*, 574 P.2d 205 (Kan. 1977).

³³*People v. Eulo*, 472 N.E.2d 286 (N.Y. 1984) [hereinafter *Eulo*].

³⁴*State v. Olson*, 435 N.W.2d 530 (Minn. 1989); R. Cranford, "Minnesota Enacts a Brain Death Law" (1989) 72 *Minn. Med.* 717.

ily law matters, and medical examiner and coroner cases.³⁵ Such considerations have persuaded the Law Reform Commission of Canada, the U.S. President's Commission and other public analysts to premise reform on a "unitary concept" of death, which is to say that the revised criteria shall apply uniformly in diverse legal contexts.³⁶

Thirdly, and as something of a corollary to the unitary concept of death, many analysts agreed on the need for fair and neutral principles and procedures in defining and applying the criteria for determining death. One professor critiqued the first brain death statute in North America,³⁷ for example, as being unduly biased towards transplantation, because it might lend the public perception that the law was "being re-written in favour of the potential recipient and against the interests of the moribund donor."³⁸ The concern raises basic issues of bioethical justice and the role of the law in distributing benefits and burdens in the process of reform. These neutrality principles have helped to structure the now routine procedural requirement that doctors involved in determining brain death not be involved with transplant procedures.³⁹ They have also persuaded some legal analysts that while legal reforms might facilitate organ transplantation, transplant concerns alone did not justify modifying the legal definition of death.⁴⁰ Such concerns have more recently persuaded North American analysts to reject amending the definition of death solely to facilitate organ procurement from moribund anencephalic newborns.⁴¹

³⁵See Working Paper 23, *supra* note 26 at 18-22. See also text accompanying note 13.

³⁶See *e.g.* Report 15, *supra* note 4 at 12; *Defining Death*, *supra* note 6 at 60. But see the *New Jersey Declaration of Death Act*, 1991 N.J. Laws 90, §5 (exemption for religious purposes), enacted following the recommendations of the *New Jersey Experience*, *supra* note 5 at 34, 35.

³⁷See *supra* note 32.

³⁸I.M. Kennedy, "The Kansas Statute on Death — An Appraisal" (1971) 285 *New Eng. J. Med.* 946 at 947.

³⁹See *e.g.* *Donation Act*, *supra* note 3, s. 11(2). See also World Health Organization, "Guiding Principles on Human Organ Transplantation" (1991) 337 *Lancet* 1470, Principle 2.

⁴⁰See *Determination of Death*, *supra* note 29 at 6. See also Report 15, *supra* note 4 at 12; *Defining Death*, *supra* note 6 at 1.

⁴¹Proponents of designating moribund anencephalic newborns as legally "dead" tend to ground their proposal on the primacy of saving life and on a view that the mental and medical status of anencephalic newborns disqualifies them from being moral or legal "persons." See M. Harrison, "The Anencephalic Newborn as Organ Donor" (1986) 16:2 *Hastings Centre Rep.* 21. Opponents of designating moribund anencephalic newborns as legally "dead" also place high value on saving life. However, they reject the proposition on the basis of the general unitary and neutrality principles outlined in the text accompanying notes 37-41 above and on the specific grounds of (a) medical uncertainty in the diagnosis of brain death and anencephaly; (b) violating deontological humanitarian ethical injunctions against treating patients as a mere means to an end; (c) slippery slope concerns, or precedential momentum, about designating other severely disabled humans as dead simply to expand the organ donor pool; (d) concerns about discriminating against severely disabled persons; and (e) the alternative of donating non-vital organs or tissues after the infant has, in fact, died. See Working Paper 66, *supra* note 25 at 95-106, 176; *New Jersey Experience*, *supra* note 5 at 21-22. For the most recent North American case, see *In re T.A.C.P.*, 609 S.2d 588 (Fla. 1992) (declining to declare live-born anencephalic infant dead for purposes of vital organ donation). For contrasting perspectives on the transplantation of anencephalic organs from a Canadian donor to a Californian recipient, see G. Annas, "From Canada with Love: Anencephalic Newborns as Organ Donors?" (1987) 17:6 *Hastings Centre Rep.* 36; T. Frewan *et al.*, "Anencephalic Infants and Organ Donation: The Children's Hospital of Western Ontario Experience" (1990) 22 *Transpl.*

Finally, the confluence of medical, legal and theological support for reform owed, in part, to a process that fostered multidisciplinary and intercultural education and consensus-building. The early consensus-building process may not have been conscious or well orchestrated. But the early Papal discourse,⁴² international conferences,⁴³ legal pronouncements⁴⁴ and medical declarations,⁴⁵ helped identify competing views and issues, establish a common language and develop working relations upon which consensus builds. Later recourse to formal public deliberations via bioethical and law reform commissions reveals a purposive consensus-building process for defining revised norms and standards acceptable to the diverse communities affected by our technological culture.

C. *Limits and Consequences*

Over the two decades after they were initially proposed, brain death criteria have become a standard that has imparted both beneficial and untoward effects in North America. On the positive side, the reform removes legal uncertainty, helps specify rights and duties and facilitates modern transplant therapy. The legal clarity aids individuals, families, the courts and medical professionals, who may now make difficult decisions about comatose patients on the basis of a medico-legal standard more consonant with the realities of our times.⁴⁶

Despite such benefits, limitations of the standard have meant that legal uncertainty continues in some life-death cases for minors, for some coma patients and even for some brain-dead "cadaver-patients." For example, the continuing lack of certainty in applying the brain death criteria to young children⁴⁷ tends to breed legal conflict over whether some mechanically-sustained children are brain dead, as illustrated by a recent case in which the New York courts reached different conclusions on whether an infant was brain dead.⁴⁸

Nor has a whole brain death standard removed burdensome legal and moral uncertainty about whether to terminate life support for comatose patients who retain lower brain activity, but who may lie indefinitely in a persistent vegetative state (PVS) with no medical likelihood of recovery.⁴⁹ While some

Proc. 1033; Canadian Paediatric Society Bioethics Committee, "Transplantation of Organs from Newborns with Anencephaly" (1990) 142 *Can. Med. Assoc. J.* 715. For a general medical perspective, see the Medical Task Force on Anencephaly, "The Infant with Anencephaly" (1990) 322 *New Eng. J. Med.* 669.

⁴²See *supra* notes 12, 13.

⁴³See *supra* note 20.

⁴⁴See *supra* notes 14, 19, 22.

⁴⁵See *supra* notes 17, 21.

⁴⁶See Working Paper 66, *supra* note 25 at 99.

⁴⁷See D.A. Shewmon, "Commentary on Guidelines for the Determination of Brain Death in Children" (1988) 24 *Annals Neurol.* 789; Task Force for the Determination of Brain Death in Children, "Guidelines for the Determination of Brain Death in Children" (1987) 37 *Neurol.* 1077.

⁴⁸*Alvarado v. City of New York*, 550 N.Y.S.2d 353 (App. Div. 1990) (reversing initial finding that infant was brain dead). See also *Dority v. Sup. Ct. San Bernardino Cnty.*, 193 Cal. Rptr. 287 (Cal. App. 1983).

⁴⁹See 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 *J.A.M.A.* 426.

commentators have suggested that such PVS patients — who have been estimated at some 5,000-10,000 in Canadian and U.S. hospitals⁵⁰ — ought to be considered legally dead,⁵¹ North American public analysts have consistently rejected the proposition.⁵² These circumstances helped to provoke the famous *Quinlan* case⁵³ over the withdrawal of a respirator in 1976 in the United States. They have more recently provoked major “right to die” sequels from the U.S. Supreme Court and the British House of Lords,⁵⁴ as well as some confusion in Canada over whether criminal assault that causes PVS constitutes homicide.⁵⁵

⁵⁰See P. Taylor, “MDs Ponder What to Do with up to 10,000 ‘Living Dead’” *The [Toronto] Globe and Mail* (23 August 1989) A1.

⁵¹See e.g. D.R. Smith, “Legal Recognition of Neocortical Death” (1986) 71 *Cornell L. Rev.* 850.

⁵²See Report 15, *supra* note 4 at 15-16; *New Jersey Experience, supra* note 5 at 13; *Determination of Death, supra* note 29 at 10; *Defining Death, supra* note 6 at 1, 38-40.

⁵³In *Re Quinlan*, 355 A.2d 647 (N.J. 1976), cert. denied 429 U.S. 922 (1976).

⁵⁴See *Airedale NHS Trust v. Bland*, [1993] 1 All E.R. 821 (H.L.) (authorizing withdrawal of feeding tube) and *Cruzan v. Director of Missouri Health Dept.*, 497 U.S. 261 (1990) (patient’s constitutionally protected liberty interest to decline life-sustaining treatment). The *Cruzan* case was reviewed in “Symposium: Medical Decision Making and the Right to Die after *Cruzan*” (1991) 19:1-2 *L. Med. & Hlth. Care* 5. For critical analysis of U.S. right to die case law, see N. Rhoden, “Litigating Life and Death” (1989) 102 *Harv. L. Rev.* 375.

⁵⁵See *Lenny, supra* note 25. The decision in *Lenny* to change the initial charge from homicide to assault seems correct on the facts presented. Variants on the case might initially seem more vexing for the law, however. Should courts, for example, grant an injunction to prevent the termination of life-supporting medical technology for victims who lie in PVS, based on an assailant’s fear that termination of life support would result in death and thereby subject the assailant to homicide charges? Compare D. Brahm, “Delayed Disconnection of Dead Baby from Ventilator” (1992) 340 *Lancet* 1154. The logic behind the consistent rejection by the courts of the “Potter defense” indicates that a motion for such an injunction should be denied. See *Potter, supra* note 14; *Kitching, supra* note 25; *Eulo, supra* note 33. Such cases stand for the proposition that but for the assailant’s assault one would not have suffered injury that “substantially causes” death; see E. Colvin, *Principles of Criminal Law*, 2d ed. (Toronto: Carswell, 1991) at 84-90; D. Stuart, *Canadian Criminal Law*, 2d ed. (Toronto: Carswell, 1987) at 112-13. For purposes of criminal law responsibility, medical (non)treatment of an injury does not generally constitute a supervening cause that breaks the chain of causation flowing from assault to death. In Canada, see *Criminal Code*, R.S.C. 1985, c. C-46, ss. 224-25 [hereinafter *Criminal Code*]; in the United Kingdom, see *R. v. Cheshire*, [1991] 3 All E.R. 670 (C.A.). To grant an injunction, moreover, might authorize nonconsensual invasion of the patient’s person, bodily integrity and autonomy, which are protected by civil law, common law, and *Charter* rights to decline life-supporting medical intervention (see the *Canadian Charter of Rights and Freedoms*, Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (U.K.), 1982, c. 11). See *Nancy B. v. L’Hôtel-Dieu de Québec*, [1992] R.J.Q. 361, 86 D.L.R. (4th) 385 (Sup. Ct.); *Malette v. Shulman* (1990), 67 D.L.R. (4th) 321, 2 C.C.L.T. (2d) 1 (Ont. C.A.); *Fleming v. Reid* (1991), 4 O.R. (3d) 74, 82 D.L.R. (4th) 298 (Ont. C.A.). Such non-consensual invasion exacts the greatest injustice when the evidence indicates no likelihood of recovery and withdrawal is either what the patient would have wanted or is in the patient’s best interests. For many of the same reasons, nor should life-supporting medical technology necessarily immunize criminal assailants from homicide charges, when life support is withdrawn from victims in PVS and results in death more than a year after the initial assault. Criminal defendants might then seek to apply the “year and a day rule,” which traditionally requires death within a year and a day of the instigating event for culpable homicide; in Canada, see *Criminal Code*, s. 227. Modern forensic sciences and life-supporting medical technology have made this 13th century rule an anachronism that warrants abrogation or legislative reform. Some U.S. jurisdictions have in fact abrogated the rule; see *State v. Vance*, 403 S.E. 2d 495 (N.C. 1991). In the meantime, purposive and functional application of the rule should help to avoid miscarriages of justice. See generally,

Finally, brain death criteria have helped to create a new class of mechanically-sustained dead patients, who would seem to require new ethical and legal rules for when they are pregnant,⁵⁶ when they are considered for gamete donation,⁵⁷ when they are used in non-consensual medical research⁵⁸ and when they become the object of dispute between hospitals and families unwilling to consent to donation of the patients' organs.⁵⁹ Such are some of the second generation legal issues presented in North America after decades of reform on the legal definition of death.

II. A Broadened Perspective on Brain Death and Tissue Transfer Regimes: Three Waves of Legal Reform

In many respects the process, merits and principles that guided the development of brain death criteria in North America illustrate many of the dynamics that compel modern medico-legal reforms. A look beyond brain death towards the broader texture of Canadian laws that govern modern therapeutic transfers of human tissues reveals a legal regime largely structured by three waves of legal reform. The reforms began in the anatomy age, accelerated in the transplant age and have continued into the biotechnology age.⁶⁰

A. Anatomy Age

The first wave began three centuries after the Italian medical professor Andreas Vesalius published his 1543 treatise *De Humani Corporis Fabrica*, which ushered in the modern anatomical age:

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

D. Walther, "Taming a Phoenix: The Year-and-Day Rule in Federal Prosecutions for Murder" (1992) 59 U. Chi. L. Rev. 1337.

⁵⁶See A. Tuffs, "Germany: Keeping a Brain-Dead Pregnant Woman 'Alive'" (1992) 340 *Lancet* 1029; D.R. Field *et al.*, "Maternal Brain Death during Pregnancy: Medical and Ethical Issues" (1988) 260 J.A.M.A. 816. See also J.M. Jordan III, "Incubating for the State: The Precarious Autonomy of Persistently Vegetative and Brain-Dead Pregnant Women" (1988) 22 Ga. L. Rev. 1102.

⁵⁷See K. Nolan, "Live Sperm, Dead Bodies" (1990) 20:1 *Hastings Centre Rep.* 33.

⁵⁸See Working Paper 66, *supra* note 25 at 113-17, 191; J.P. Orlowski, G.A. Kanoti & M.J. Mehlman, "The Ethics of Using Newly Dead Patients for Teaching and Practising Intubation Techniques" (1988) 319 *New Eng. J. Med.* 439; J. La Puma, "Discovery and Disquiet: Research on the Brain-Dead" (1988) 109 *Ann. Intern. Med.* 606; S. Martyn, "Using the Brain Dead for Medical Research" [1986] *Utah L. Rev.* 1.

⁵⁹*Strachan v. John F. Kennedy Memorial Hospital*, 538 A.2d 346 (N.J. 1988), reviewed by G. Annas, "Brain Death and Organ Donation: You Can Have One without the Other" (1988) 18:3 *Hastings Centre Rep.* 28. Legal disputes over the treatment of brain-dead patients, who are identified as transplant "donors," are by no means restricted to North America. See "L'Affaire des prélèvements d'organes abusifs" *Le Monde [Paris]* (20 May 1992) 13 (parental suit, alleging post-mortem theft and violation of sepulchres, against university hospital that procured organs from brain-dead adolescent accident victim).

⁶⁰For a chronological overview of these ages, see the Appendix, below.

calls for solutions... 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. A regulated system of supply would rid the community of grave robbing, body-selling and like black market abuses. Opponents countered that a more appropriate source would be the bodies of criminals, that the proposed legislation would legalize a "traffic in corpses," and make public property of cadavers. The debate resulted in passage of *An Act to regulate and facilitate the study of Anatomy*, in December 1843.⁶¹

This initiative bears striking resemblance to the dynamics and process of reform that led to the enactment of brain death legislation. First, the initiation came from the medical community whose needs and practices were seen as being impeded by existing law. In this instance, an 18th century British common law misdemeanour of indecencies⁶² involving dead bodies applied in Canada and subjected medical practitioners to legal liability.⁶³

Secondly, local and international incidents helped dramatize the need for a public solution. The mid-19th century medical literature reported black market shipments of cadavers between Canada and the United States and between countries of the British Isles.⁶⁴ So-called "grave robbing" incidents in Canada⁶⁵ and the United States⁶⁶ drew local attention to the problem. The conviction of William Burke, for murdering individuals whose bodies he intended to sell to anatomists, in a sensational criminal trial in 19th century Scotland⁶⁷ intensified support for a solution in the United Kingdom.

Thirdly, some consensus on legal remedies began to emerge after study of the problem. In this instance, the model advanced in a British Parliamentary study influenced anatomy laws in Massachusetts in 1830, in Britain in 1832 and in Canada in 1843.⁶⁸ Canada today may thus trace its anatomy acts to the 18th

⁶¹Working Paper 66, *supra* note 25 at 2-3 [citations omitted].

⁶²*R. v. Lynn* (1788), 2 Term Rep. 733, 100 E.R. 394 [hereinafter *Lynn*] (establishing disinterment of the dead, to supply anatomy teachers, as a common law indecency offense); *R. v. Davies* (1828) (Lancaster Assizes) (convicting doctor of possessing, for dissection, cadaver known to have been unlawfully disinterred), described in U.K., H.C., *Report of the Select Committee on Anatomy* at 6,148 (22 July 1828) [hereinafter *Select Committee Report (U.K.)*].

⁶³See F.J. Sheppard, *Reminiscences of Student Days and Dissecting Room* (Montreal: 1919) at 25 [printed for private circulation, available at Osler Library of McGill University Medical School] (fining anatomy professor for "indecencies" involving the receipt of disinterred bodies). This common law misdemeanour appears to have been codified in *Criminal Code*, s. 182(b).

⁶⁴See Erinensis, "On the Exportation of Dead Bodies from Ireland to England and Scotland" (1828-29) 1 *Lancet* 774. See also D.G. Lawrence, "Resurrection and Legislation, or Body Snatching in Relation to the Anatomy Act in the Province of Quebec" (1958) 32 *Bull. Hist. Med.* 408 at 414 ("[T]he 'regular channel' was from the United States where 'plenty of negroes were obtained cheap, packed in casks and passed over the border as provisions, or flour' ...").

⁶⁵See Lawrence, *ibid.*

⁶⁶See F. C. Waite, "Grave Robbing in New England" (1945) 33 *Bull. Med. Libr. Assoc.* 272; F.C. Waite, "The Development of Anatomical Laws in the States of New England" (1945) 233 *New Eng. J. Med.* 716.

⁶⁷W. Roughhead, *Burke and Hare* (Edinburgh: William Hodge, 1921).

⁶⁸For the reports and laws of the respective jurisdictions, see *Report of the Select Committee of the House of Representatives on Legalizing the Study of Anatomy* (Boston: Dutton & Wentworth,

century Paris model adopted in the British Parliamentary study. Fourthly, Canadian debates over whether to use executed criminals or abandoned dead immigrants as a source of anatomical supply, even after a general model of reform had been identified,⁶⁹ again reveal the significant role which the law may play in allocating the benefits and burdens of medico-legal reforms.

B. *Transplant Age*

The technical ability of medical professionals to transfuse blood cells, transplant tissues and implant whole organs generated a second wave of legal reform in Canada beginning in the 1950s. The new transplant technology differed from and paralleled anatomical technology. Both created new medical demand for the human body. But while anatomical demand emanates from the need to study and practice interventions on the dead human body, transplant needs emanate from direct surgical therapy for the living.

The distinction translates into practical, safety, legal and moral consequences. Practically, since transplantation does not require the use of whole human bodies, both deceased or living individuals may provide the transplanted material. With regard to safety, the transfer of human tissues raises concerns both on transmitting disease through transplanted material and on protecting the health and bodily integrity of living donors⁷⁰ and recipients.⁷¹ Legally, transplantation involves the law on dead bodies, on living recipients and on non-traditional patients: donors who undergo medical interventions not for personal illness or injury, but for the benefit of another.⁷² The life saving and health pro-

Printers for the State, 1831); *An Act More Effectively to Protect the Sepulchres of the Dead and to Legalize the Study of Anatomy in Certain Cases*, General Laws of the Commonwealth of Massachusetts, ch. 57 (1831); *Select Committee Report (U.K.)*, *supra* note 62; *Anatomy Act, 1832 (U.K.)*, 2 & 3 Will. 4, c. 75; *Debates of the Legislative Assembly of United Canada (1843)*, vol. 3 (Montreal: Presses de l'École des hautes études commerciales, 1972) at 464-67, 1051, 1207; *An Act to Regulate and Facilitate the Study of Anatomy*, S. Prov. C. 1843, c. 5.

⁶⁹Working Paper 66, *supra* note 25 at 127-29.

⁷⁰See *e.g. Cox v. Saskatoon*, [1942] 2 D.L.R. 412, [1942] 1 W.W.R. 717 (Sask. C.A.) (blood donor injury/infection). As in other areas of medicine involving competent patients, the informed consent doctrine functions partially to help protect the patient-donor from the involuntary assumption of risk. For children, the incompetent, or others who lack the capacity to understand the nature, risks, benefits and consequences of the intervention, rigorous substantive and procedural safeguards must be strictly adhered to. See *E.(Mrs.) v. Eve*, [1986] 2 S.C.R. 388, 31 D.L.R. (4th) 1, 61 Nfld. & P.E.I.R. 273 (rejecting substitute judgment doctrine); *Cayouette et Mathieu*, [1987] R.J.Q. 2230 (Sup. Ct.) (authorizing minor's donation of bone marrow to brother); *Saskatchewan (Minister of Social Services) v. P.(F.)* (1990), 69 D.L.R. (4th) 134, 83 Sask. R. 161 (Prov. Ct.) (upholding parental authority not to consent to liver transplant); *Curran v. Bosze*, 566 N.E.2d 1319 (Ill. 1990) [hereinafter *Bosze*] (finding parentally disputed bone marrow "donation" not in the best interests of 3½-year-old twins); *Donation Act*, *supra* note 3, ss. 4-8; Working Paper 66, *supra* note 25 at 174-75; World Health Organization, *supra* note 39, Principle 4.

⁷¹See *e.g. Nesom v. Tri Hawk*, 985 F.2d 208 (5th Cir. 1993) (internationally contaminated tissue used in reconstructive brain surgery); R. Simonds *et al.*, "Transmission of Human Immunodeficiency Virus Type I from a Seronegative Organ and Tissue Donor" (1992) 326 *New Eng. J. Med.* 726 (3 transplant recipient deaths owing to AIDS).

⁷²See L. R. Shaw *et al.*, "Ethics of Lung Transplantation with Live Donors" (1991) 338 *Lancet* 677. In the legal context, Canadian society must reconcile the physician's traditional legal responsibilities to ensure that patients reasonably "benefit" from surgical interventions, with the modern

moting goals of transplantation also tend to endow these interventions with particular moral force in societies that rank human life high in the hierarchy of public values. Could the added needs and dimensions of these new therapeutic practices be accommodated by the anatomy acts?

In Canada, the new needs inspired new law. As transplant successes moved from simple tissues to more complex organs, the law evolved. To facilitate the supply of cadaveric tissue, the Uniform Law Conference of Canada proposed model corneal grafting legislation in 1959, seven years after Britain did so.⁷³ The law, *inter alia*, incorporated principles from the Anatomy Acts and proposed a modern tissue transfer principle whereby individuals might henceforth bequeath their eye tissue for transplant purposes. Six years later, by the time kidney transplants had joined corneal transplants as relatively routine therapies, the Uniform Law Conference of Canada proposed a model human tissue act.⁷⁴ It expanded the bequeathal principle into the concept of giving tissue from either deceased or living donors, which has become the express consent model of donation. The 1971 revision of the Act further entrenched the "gift of life ethic" for tissue transfers by generally prohibiting the sale of tissue.⁷⁵ The 1989 revision continues this ethic and expressly adopts the brain death concept.⁷⁶

C. *Biotechnology Age*

Advances in cell fusion, cell culture and genetic engineering technologies in the last 20 years have begun to prompt a third wave of legal reform aimed at accommodating the advent of biotechnology. Several features of these new tissue transfer and replacement technologies distinguish them from those of the transplant and anatomical ages: (1) they are typically derived, by dint of substantial research and development, from human tissues or bodily substances and genetic material; (2) they may often be preserved or "banked" indefinitely; (3) they may yield increased quantities of natural human substances like hormones,

reality that kidney, partial lung or liver and bone marrow donors undergo varying risks and invasions of their bodies with no physical benefit. See *Civil Code of Québec*, S.Q. 1991, c. 64, art. 19. See also *Criminal Code*, ss. 14, 45, 268, 269, discussed in Working Paper 66, *supra* note 25 at 87-94 and by M. A. Somerville, "Medical Interventions and the Criminal Law: Lawful or Excusable Wounding?" (1980) 26 McGill L.J. 82. Compare *Bosze*, *supra* note 70 (applying psychological benefit theory for intra-familial tissue donation).

⁷³Compare the *Uniform Cornea Transplant Act* in Uniform Law Conference of Canada, *Proceedings of the 41st Annual Meeting of the Conference of Commissioners on Uniformity of Legislation in Canada* (Victoria, B.C.: The Conference of Commissioners on Uniformity of Legislation in Canada, 1959) at 77 and the *Corneal Grafting Act, 1952* (U.K.), 15 & 16 Geo. 6 & 1 Eliz. 2, c. 28 [hereinafter *Corneal Grafting Act*]. See also J.-G. Castel, "Some Legal Aspects of Organ Transplantation in Canada" (1968) 46 Can. Bar Rev. 345 at 393-94.

⁷⁴*Human Tissue Act* (1965) in Uniform Law Conference of Canada, *Proceedings of the 47th Annual Meeting of the Conference of Commissioners on Uniformity of Legislation in Canada* (Niagara Falls, Ont.: The Conference of Commissioners on Uniformity of Legislation in Canada, 1965) at 31, 104.

⁷⁵*Uniform Human Tissue Gift Act* (revised 1971), s. 10, in Uniform Law Conference of Canada, *Proceedings of the 53rd Annual Meeting of the Conference of Commissioners on Uniformity of Legislation in Canada* (Jasper, Alta.: The Conference of Commissioners on Uniformity of Legislation in Canada, 1971) at 76, 152.

⁷⁶See *Donation Act*, *supra* note 3, s. 15.

which naturally occur in small quantities; and (4) as a result of the potential therapeutic supply and initial research and development, they may prove financially lucrative and more closely associated with commerce.⁷⁷

These and other features of biotechnology have already begun to generate therapeutic advances, scrutiny and reform of the law. Consider the recent licensure in North America of genetically engineered human growth hormone (HGH), which is used to treat childhood growth disorders.⁷⁸ Genetically engineered HGH yields purer and larger quantities of the hormone. Indeed, reports in the international literature that cadaveric HGH was contaminated with a lethal virus, prompted Canada and other nations to expedite the availability of genetically engineered HGH.⁷⁹ Its availability tends to make obsolete those provisions in North American tissue transfer laws that have traditionally facilitated the procurement of cadaveric pituitaries for distilling HGH.⁸⁰ The advance is not unique. Biotechnology companies have developed or are developing genetically engineered insulin for treating diabetes,⁸¹ blood factors for treating haemophilia,⁸² biosynthetic skin for burn therapy,⁸³ genetically altered animals to produce human tissue constituents⁸⁴ and cultivated human bone⁸⁵ for therapeutic grafts and reconstructive surgery.

While such technological advances may help meet the modern therapeutic demand for human tissues and bodily substances, they may also raise novel legal questions. Four contexts convey the flavour of novelty. First, for instance, who shall have predominant rights over banked human tissue? Prodded in part

⁷⁷See Working Paper 66, *supra* note 25 at 16-18, 22, 25, 121-24; U.S. Congress, Office of Technology Assessment, *Biotechnology in a Global Economy* (Washington, D.C.: U.S.G.P.O., 1991) at 73-96 [hereinafter *Biotechnology*]. For a discussion of some early legal responses to biotechnological concerns, including moratoria on genetic engineering research, see "Symposium: Biotechnology and the Law: Recombinant DNA and the Control of Scientific Research" (1978) 51 S. Cal. L. Rev. 969.

⁷⁸See *Genentech v. Bowen*, 676 F. Supp. 301 (D.D.C. 1987).

⁷⁹H.J. Dean & H.G. Friesen, "Growth Hormone Treatment in Canada: End of One Era and Beginning of Another" (1986) 153 Can. Med. Assoc. J. 297-301. For international commentary on contaminated cadaveric HGH and the litigation it has prompted, see J.E. Fradkin *et al.*, "Creutzfeldt-Jakob Disease in Pituitary Growth Hormone Recipients in the United States" (1991) 265 J.A.M.A. 880; C. Dyer, "Families of Creutzfeldt-Jakob Disease to Sue Government" (1992) 305 Br. Med. J. 73.

⁸⁰See *e.g.* *An Act to Amend the Coroners Act, 1972*, S.O. 1978, c. 95, s. 1, codified in *Coroners Act*, R.S.O. 1990, c. C.37, s. 29; *An Act to Amend the Public Health Law in Relation to Removal of Pituitary Gland Tissue for the Extraction of Growth Hormone*, c. 242, 1981 McKinneys Session Laws (codified at New York Public Health Law, §4222).

⁸¹See *Biotechnology*, *supra* note 77 at 77-78.

⁸²See *Scripps Clinic v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

⁸³E. Bell & M. Rosenberg, "The Commercial Use of Cultivated Human Cells" (1990) 22 Transpl. Proc. 971; L.M. Fisher, "3 Companies Speed Artificial Skin" *The New York Times* (12 September 1990) D1.

⁸⁴See P.J. Hiltz, "Gene-Altered Pigs Produce Key Part of Human Blood: Search for Substitute" *The New York Times* (16 June 1991) 1; B.J. Feder, "'The Pharmers' Who Breed Cows that Can Make Drugs" *The New York Times* (9 February 1992) 3:9 (transgenic pigs that produce human haemoglobin).

⁸⁵E.L. Andrews, "Next: Artificial Bone to Repair Fractures" *The New York Times* (24 October 1990) D10.

by lawsuits in the United States⁸⁶ and France⁸⁷ over the control and transfer of banked reproductive tissues, some tissue banks have begun to specify more rights and duties under different eventualities in their informed consent forms for tissue donors and depositors.⁸⁸ Secondly, what legal standards shall govern physician and patient rights and duties in an era when physicians may cultivate the therapeutically excised tissue or cells of their patients into patented "bio-tech" drugs or similarly commercial therapeutic agents?⁸⁹ If reform analysts tend to agree on the need for consent⁹⁰ to protect a patient's bodily integrity, autonomy and dignity in this context, they tend to disagree over whether express⁹¹ or implied⁹² consent standards should govern. Thirdly, is processed human eye tissue — procured from a cadaver, purified, frozen and cut for implantation into needy recipients as a "living contact lens" — to be considered natural tissue or an implantable medical device,⁹³ for purposes of national safety standards? The same may be asked about some 250 cadaveric human heart valves, which were procured in Canada between 1988-1992, processed and frozen in the United States and then shipped back to Canada for use in reconstructive heart surgery.⁹⁴ Such questions recently prompted proposed reforms in Canada⁹⁵ and regulations in the United States.⁹⁶ Finally, what of a \$500.00 fee charged by a company that specializes in processing such tissue? Does the fee

⁸⁶*York v. Jones Institute*, 717 F. Supp. 421 (E.D. Va. 1989) (parental litigation to compel the transfer of frozen embryo from one fertility clinic to another).

⁸⁷Trib. gr. inst. Créteil, 1 August 1984, *Parpalaix v. CECOS*, Gaz. Pal. 1984, 2e Sem. Jur.560 [hereinafter *Parpalaix*] (ordering restitution of deceased husband's frozen sperm to widow), reviewed by D.J. Jones, "Artificial Procreation, Societal Reconceptions: Legal Insight from France" (1988) 36 Am. J. Comp. L. 525.

⁸⁸Trib. gr. inst. Toulouse, 26 March 1991, *Gallon v. CECOS*, J.C.P. 1992.II.21807 (Annot. P. Pédrot). In this sequel to *Parpalaix*, *ibid.*, the French sperm bank successfully argued that the informed consent form provisions instituted after *Parpalaix*, and agreed to by the sperm depositor, precluded post-mortem restitution of the deceased depositor's sperm to his widow.

⁸⁹See *Moore v. University of California*, 793 P.2d 479 (Cal. 1990) [hereinafter *Moore*]; W.J. Curran, "Scientific and Commercial Development of Human Cell Lines: Issues of Property, Ethics and Conflict of Interest" (1991) 324 New Eng. J. Med. 998. See also United States Congress, Office of Technology Assessment, *New Developments in Biotechnology: Ownership of Human Tissues and Cells* (Washington, D.C.: U.S.G.P.O., 1987); C.S. Campbell, "Body, Self & the Property Paradigm" (1992) 22:5 Hastings Centre Rep. 34.

⁹⁰See *Civil Code of Québec*, *supra* note 72, arts. 11, 22.

⁹¹*Moore*, *supra* note 89 at 483-84. See also Working Paper 66, *supra* note 25 at 188-99.

⁹²Comité consultatif national d'Éthique pour les sciences de la vie et de la santé, *Éthique et recherche biomédicale: Rapport 1987* (Paris: La Documentation Française, 1988) at 18-21.

⁹³See *Medical Devices Regulations*, C.R.C., c. 871, as amended, adopted under the *Food and Drug Act*, R.S.C. 1985, c. F-27, ss. 2, 30. For U.S. commentary, see generally A.L. Schwartz, "Annotation" 3 A.L.R. Fed. 843 (1970).

⁹⁴Communication with Health and Welfare Canada and the Canadian Organ Replacement Register. The heart valves were shipped to and processed at Cryolife, Inc., a U.S. company that specializes in tissue preservation techniques and technologies. See E. Andrews, "Patents: Preserving Tissue in Deep Freeze" *The New York Times* (21 December 1992) D2.

⁹⁵Working Paper 66, *supra* note 25 at 183-84.

⁹⁶56 Fed. Reg. 29177 (1991) and 57 Fed. Reg. 29001 (1992), which delay the effective date of 21 C.F.R. §870.3925. Tissue banks in the United States have instituted litigation to challenge the new regulations. *Alabama Tissue Centre of University of Alabama v. Sullivan*, 975 F.2d 373 (7th Cir. 1992) (upholding government view that processed human cadaveric heart valves constitute implants/medical devices, subject to federal safety regulations).

constitute a "sale" of human tissue in violation of Canadian⁹⁷ and U.S.⁹⁸ law, or are we satisfied that the monetary exchange is a legitimate fee for medical services? The State of Minnesota recently attempted to reconcile such new technological developments with existing tissue transfer law by exempting the sale of cell lines from its tissue sales prohibition.⁹⁹ Such examples indicate that biotechnological advances may generate legal uncertainty, potential for conflict and eventual reform by blurring the definitions and standards of existing legal regimes that govern tissue transfer and replacement technologies.

Conclusion

From the broadened perspective of laws adopted in the anatomy, transplant and biotechnology ages, brain death laws and criteria stand as a fundamental pillar that North America has erected in a legal regime that governs the therapeutic transfer of human tissues and tissue replacement technology. This regime is, perforce, structured with pillars and imbued with lessons from the three ages. Indeed, the recent biotechnology case of *Moore*,¹⁰⁰ the decades old brain death case of *Potter*¹⁰¹ and the centuries old grave robbing case of *Lynn*¹⁰² collectively indicate that societal tensions and uncertainties associated with medical advances in a particular age may erupt into legal controversies that tellingly symbolize the need for clarity and reforms in that age. In this way, advances in medicine regularly prod the legal regime to evolve. Changes in societal thought and attitudes help restructure and refine the regime.

It is, thus, not surprising that nearly a quarter of a century after some of the first jurisdictions in the West gave legal effect to a new definition of death, proposals and reforms again are under way to clarify the ethico-legal status of the human body in medicine. Much of the current activity to regulate modern tissue transfer and replacement technologies centres, *inter alia*, on refining familiar notions of consent, defining the precise role of the family in the transplant process and addressing bodily property issues, commerce and safety, human rights and biotechnological implications.¹⁰³

As medicine continues its creative therapeutic use of the human body, what legal rules and public policies shall structure the natural, artificial and bio-prosthetic tissue replacement technologies of the future? While a precise answer obviously cannot be known, the lessons and broader context of the brain death reforms suggest at least three insights about emerging and future regimes.

⁹⁷ *Uniform Human Tissue Gift Act*, *supra* note 75 at s. 10 (adopted in most Canadian provinces), as revised by s. 15 of the *Donation Act*, *supra* note 3.

⁹⁸ *National Organ Transplantation Act of 1984*, 42 U.S.C.A. §274e, as amended (West 1991).

⁹⁹ Minn. Stat. Ann. §145.422 (West Supp. 1988).

¹⁰⁰ *Supra* note 89.

¹⁰¹ *Supra* note 14.

¹⁰² *Supra* note 62.

¹⁰³ See *e.g.* World Health Organization, *supra* note 39, the development of which is described by World Health Organization, "Human Organ Transplantation: A Report on Developments under the Auspices of WHO (1987-91)" (1991) 42 Int'l Dig. Hlth. Legis. 389; Working Paper 66, *supra* note 25; *Donation Act*, *supra* note 3.

First, the merits of particular reforms shall depend on an ability to define, articulate and rank the public principles and values that shall guide reform. Secondly, public deliberations shall prove more effective if they are cultivated through a process that consciously attempts to identify the conflicts, ambiguities, language and cultural underpinnings of reform options. Such a process has facilitated multidisciplinary and transcultural understanding in the brain death reforms in North America. Indeed, the process has helped to structure problem-solving and consensus-building models relied on today for addressing other pressing bioethical issues before society. Finally, future reforms promise more success if they unfold with a sensitivity to the role of the law in establishing new medico-legal norms — its strengths and limits; its hand in clarifying and allocating rights and duties; its ability to regulate, facilitate or impede the healing arts.

Appendix

Corpus Humanum: Chronology

Anatomy Age (Circa 1540 – 1950)

- 1540 Act authorizing Barbers and Surgeons Guild of London to receive four executed felons annually for dissection and anatomical study.¹⁰⁴
- 1543 *De Humani Corporis Fabrica*: The father of modern anatomy Andreas Vesalius' anatomical treatise formed the basis of anatomical study in Europe for some two centuries. The treatise on which modern anatomy is founded.
- 1746 Dr. William Hunter establishes first British anatomical and dissecting school.
- 1752 Act authorizing bodies of all murderers executed in London and Middlesex to be given to Hall of Surgeons for dissection and anatomical study.¹⁰⁵
- 1788 *R. v. Lynn*, established common law criminal misdemeanour for disinterring bodies for dissection: though exhumation for purposes of dissection is not explicitly forbidden by the felony prohibition on exhuming cadavers for witchcraft, such practice is still highly indecent, "contra bonos mores," and an indictable offence.¹⁰⁶
- 1815 Massachusetts *Act to Protect Sepulchres of the Dead*: \$1000 fine or one year imprisonment for exhuming or knowingly and wilfully receiving or concealing exhumed dead bodies.¹⁰⁷

¹⁰⁴For *Barbers & Surgeons* (U.K.), 32 Hen. 8, c. 42.

¹⁰⁵An *Act for Better Preventing the Horrid Crime of Murder* (U.K.), 25 Geo. 2, c. 37.

¹⁰⁶*Supra* note 62.

¹⁰⁷General Laws of the Commonwealth of Massachusetts, ch. 174 (1815).

- 1824-29 Montreal Medical Institution integrates into McGill University to become first university medical school in Canada.
- 1828 *R. v. Davies* (Lancaster Assizes) involving common law criminal misdemeanour for receiving and possessing corpses known to have been illegally disinterred.¹⁰⁸
- 1829 The conviction and execution of William Burke for murdering individuals for the sake of selling their bodies to Edinburgh anatomists (whence the verb "to burke," to suffocate, to dispose of in a disguised manner).
- 1831 Massachusetts Anatomy Act, amending 1815 Act, to authorize cadavers to be used for medical study.¹⁰⁹
- 1832 British *Anatomy Act*.¹¹⁰
- 1843 Province of Canada Anatomy Act.¹¹¹
- 1867 Canadian Confederation.
- 1870s McGill University Medical School Demonstrator of Anatomy fined \$50 for receiving dead bodies, as "offenses against decency." Bodies often obtained from Côte-des-Neiges Cemetery in exchange for \$30-\$50.
- 1882 *Williams v. Williams*, regarded as establishing no property in corpse rule.¹¹²
- 1892 *Criminal Code of Canada* enacted.¹¹³ Section 206 (currently s. 182) criminalizes misconduct respecting dead human bodies and remains.

Transplant Age (Circa 1950 – 2000+)

- 1950 Corneal transplant era begins.
- 1952 British *Corneal Grafting Act*.¹¹⁴
- 1954 First successful organ (kidney) transplant performed in Boston between twins, some seven years after the introduction of the artificial kidney.
- 1955 First Canadian Eye Bank established in Toronto.
- 1959 Uniform Law Conference of Canada proposes *Uniform Cornea Transplant Act*.¹¹⁵

¹⁰⁸*Supra* note 62.

¹⁰⁹*An Act More Effectively to Protect the Sepulchres of the Dead and to Legalize the Study of Anatomy in Certain Cases*, *supra* note 68.

¹¹⁰*Anatomy Act, 1832*, *supra* note 68.

¹¹¹*An Act to Regulate and Facilitate the Study of Anatomy*, *supra* note 68.

¹¹²(1882), 20 Ch. D. 659, [1881-5] All E.R. Rep. 840.

¹¹³*An Act Respecting Procedure in Criminal Cases and Other Matters Relating to Criminal Law*, S.C. 1869, c. 29; *An Act Respecting the Criminal Law*, S.C. 1892, c. 29.

¹¹⁴*Supra* note 73.

¹¹⁵See *supra* note 73.

- 1961 British *Human Tissue Act*¹¹⁶ repeals *Corneal Grafting Act*.¹¹⁷
- 1963-65 Ontario, Nova Scotia, New Brunswick enact legislation similar to the British *Human Tissue Act*.¹¹⁸
- 1965 Uniform Law Conference of Canada, *Human Tissue Act*¹¹⁹ repeals *Uniform Cornea Transplant Act*.¹²⁰
- 1967 First successful heart transplant performed in South Africa. Recipient survives 18 days.
- 1968 (1) *Uniform Anatomical Gift Act* proposed in U.S.
(2) Harvard University *ad hoc* Committee proposes "brain death" criteria of death, which will facilitate organ donation.
- 1970 Kansas becomes first North American jurisdiction to enact brain death legislation, which the Kansas Supreme Court would uphold six years later.¹²¹
- 1971 Revised *Uniform Human Tissue Gift Act* of Canada.¹²²
- 1975 Manitoba legislates brain-death definition of death.¹²³
- 1976 Multi-centre organ retrieval system established between Ontario hospitals.
- 1981 (1) First Canadian adult liver transplants undertaken. Heart transplant renaissance, following general worldwide moratorium in the 1970s.
(2) Law Reform Commission of Canada proposes brain death legislation for all federal laws in Canada.
- 1982 Cyclosporin, an anti-rejection drug, dramatically increases survival rates for transplants.

Biotechnology Age (Circa 1980 – 2000+)

- 1984 Six years after one of the first medical biotechnology companies is founded (Genentech), a California cancer patient institutes suit against the company and his doctor, alleging that they misappropriated his cells and patented derivative elements thereof (a cell line) without his knowledge or consent. The California Supreme Court would issue its landmark ruling in the case six years later, *Moore v. University of California*.¹²⁴

¹¹⁶*Human Tissue Act, 1961* (U.K.), 9 & 10 Eliz. 2, c. 54.

¹¹⁷*Supra* note 73.

¹¹⁸*Supra* note 116. See Castel, *supra* note 73.

¹¹⁹*Supra* note 74.

¹²⁰*Supra* note 73.

¹²¹*Supra* note 32.

¹²²*Supra* note 75.

¹²³*Supra* note 24.

¹²⁴*Supra* note 89.

- 1985
- (1) First Canadian paediatric liver transplant performed.
 - (2) Canadian patent office grants patent application for human cell lines.
 - (3) Genetically-engineered human growth hormone receives federal licensure, replacing human growth hormone derived from cadaver pituitaries.
- 1989
- Uniform Law Conference of Canada revises *Uniform Human Tissue Donation Act*.¹²⁵
- 1990
- (1) Biotechnology companies begin clinical trials on genetically engineered blood products, skin equivalents and cell growth factors.
 - (2) Following a major ruling of the Canadian Supreme Court,¹²⁶ the Canadian Manual of Patent Office Practice is amended to recognize, officially, that cell lines and other new microbial life forms may be patentable subject. The amendment comes nearly 15 years after the Canadian Patent Office granted one of its first patents for human cell lines (#999, 546 of 9 Nov. 1976).
- 1991
- (1) World Health Organization adopts Guiding Principles for Human Organ Transplants.
 - (2) A U.S. biotechnology company successfully breeds a transgenic pig to produce human blood products, and applies for patent protection for the process.

¹²⁵*Supra* note 3.

¹²⁶*Pioneer Hi-bred Ltd. v. Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623, 60 D.L.R. (4th) 223.