Human Tissue Legislation and a New Medical Paradigm: Governing Tissue Engineering in Canada

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Tissue engineering is a promising biotechnology that uses advances in cell science, surgery, and engineering to create products that can be implanted into human patients to replace organs and tissues or to help restore or improve their function. Tissue engineered products contain living cells, scaffolds made from natural or synthetic materials, and chemical signals that help to guide the cells' development. An engineered skin substitute is already approved and on the market, and engineered tracheas, corneas, and blood vessels are entering clinical trials. Tissue engineering raises a number of legal and ethical issues, one of which is considered in this article: to what extent would existing human tissue legislation in Canada apply to the activities and products of this new technology, and what implications would this have? The key terms defining the scope of application of human tissue statutes are examined to see whether and when tissue engineering materials (cells, tissues, and organs donated for use in tissue engineering)

L'ingénierie tissulaire est une biotechnologie prometteuse qui utilise des avancées en biologie cellulaire, chirurgie et ingénierie dans le but de créer des produits pouvant être implantés chez des patients humains afin de remplacer des organes ou tissus ou d'aider la restauration ou l'amélioration de leur fonction. Les produits de l'ingénierie tissulaire contiennent des cellules vivantes, des échafaudages construits à partir de matériaux naturels ou synthétiques, et des signaux chimiques permettant le guidage des cellules en développements. Un substitut cutané produit par ingénierie tissulaire a déjà été approuvé et est actuellement sur le marché, tandis que des trachées, des cornées et des vaisseaux sanguins sont présentement au stade des essais cliniques. L'ingénierie tissulaire soulève plusieurs questions légales et éthiques, et cet article en explore une parmi elles : dans quelle mesure est-ce que la législation canadienne existante concernant les tissus humains s'appliquerait aux activités et produits de cette nouvelle technologie

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and tissue engineered products, along with the processes of procuring material and implanting the final products, will fall within the statutes' scope. The article then considers how the applicability of human tissue legislation in this context might affect the law governing these products and processes, focusing on provisions involving consent to donation and prohibitions on compensation and sale. The analysis reveals that there is considerable uncertainty and variability in the law, which could have a chilling effect on the development of this technology and leave those involved unprepared to deal with legal issues that arise. As human tissue statutes are revisited and reformed across the country, and as larger debates continue about the use of human tissue in biotechnology, it would be useful to work toward greater consistency in key definitions and to consider and clarify how the legislation will apply to tissue engineering and other new technologies.

et quelles implications cela aurait-il? Les mots-clés définissant l'étendue de l'application des lois portant sur les tissus humains sont examinés afin de voir si et quand les matériaux de l'ingénierie tissulaire (cellules, tissus et dons d'organes pour utilisation en ingénierie tissulaire) ainsi que les produits et les processus nécessaires à la fabrication et l'implantation des produits seront assujettis par les lois. Cet article considère ensuite comment l'application de la législation sur les tissus humains dans ce contexte pourrait influencer les lois gouvernant ces produits et ces processus en mettant l'accent sur les articles impliquant le consentement aux dons et la prohibition de la rémunération et de la vente. Cette analyse révèle qu'il existe une importante incertitude et variabilité dans le droit, qui pourrait avoir un effet néfaste sur le développement de ces technologies et laisser les parties impliquées mal préparées pour affronter les questions juridiques qu'elles soulèvent. Alors que les lois sur les tissus humains sont revisitées et réformées à travers le pays, et que se poursuit un débat plus large sur l'usage des tissus humains en biotechnologie, il pourrait être utile de poursuivre une plus grande uniformité dans les définitions clés ainsi que de questionner et de clarifier comment les législations pourront s'appliquer à l'ingénierie tissulaire et aux autres nouvelles technologies.

Introduction

The human body's natural capacity for regeneration is amazing, but limited. For the last few decades, researchers have been making progress in their quest to overcome those limits and devise ways of repairing or replacing organs and tissues that our bodies cannot naturally regenerate. Once the stuff of science fiction, these technologies are finally – though slowly – becoming a reality. Various types of biomaterials, including animal and human bone, teeth, or other tissues, have been used for hundreds of years in attempts to repair or replace parts of the human body, but developments in transplantation surgery and cell science have opened up new possibilities.[1] The United States Food and Drug Administration first approved a tissue engineered product in 1998, and that product, a bi-layered skin substitute made from bovine collagen and human dermal cells, is now used to treat foot and leg ulcers.[2] Within the last 10 years, scientists have been able to create and implant engineered bladders,[3] urethras,[4] and tracheas,[5] and are making progress toward engineering a range of other tissues and organs, including the heart and its valves, lungs, liver, kidneys, pancreas, corneas, intestines, ovaries, blood vessels, bone, tendons, ligaments, cartilage, and nerves.[6] Although to date most of these are still only the subject of labora-

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1 Ulrich Meyer, "The History of Tissue Engineering and Regenerative Medicine in Perspective" in Ulrich Meyer et al, eds, *Fundamentals of Tissue Engineering and Regenerative Medicine* (Berlin: Springer, 2009) 5 at 8-9.

2 Larissa Zaulyanov & Robert S Kirsner, "A Review of a Bi-layered Living Cell Treatment (Apligraf®) in the Treatment of Venous Leg Ulcers and Diabetic Foot Ulcers" (2007) 2:1 Clin Interv Aging 93.

3 Anthony Atala et al, "Tissue-Engineered Autologous Bladders for Patients Needing Cystoplasty" (2006) 367:9518 Lancet 1241.

4 Atlantida Raya-Rivera et al, "Tissue-Engineered Autologous Urethras for Patients Who Need Reconstruction: An Observational Study" (2011) 377:9772 Lancet 1175.

5 Paolo Macchiarini et al, "Clinical Transplantation of a Tissue-Engineered Airway" (2008) 372:9655 Lancet 2023; Philipp Jungebluth et al, "Tracheobronchial Transplantation with a Stem-Cell-Seeded Bioartificial Nanocomposite: A Proof-of-Concept Study" (2011) 378:9808 Lancet 1997; Jonathan M Fishman, Mark Lowdell & Martin A Birchall, "Stem Cell-Based Organ Replacements – Airway and Lung Tissue Engineering" (2014) 23:3 Semin Pediatr Surg 119.

6 See Anthony Atala, "Engineering Tissues, Organs and Cells" (2007) 1:2 J Tissue Eng Regen Med 83; Giuseppe Orlando et al, "Regenerative Medicine as

tory research or at best a few individual or small-scale experimental procedures, a few have already been approved and marketed or are entering clinical trials.[7]

Tissue engineering is an interdisciplinary field that makes use of advances in cell science, surgery, and engineering to create products that can be implanted into patients to replace organs and tissues or to help restore or improve their function. It can be distinguished from previously developed techniques by its use of advanced technologies (incorporating regenerative medicine and advanced materials engineering, including nanotechnology) and by the fact that its products contain living tissue. Tissue engineered products contain three basic components: cells, scaffolds, and signals. The scaffold or matrix provides a structure for the tissue or organ, onto which the cells are seeded and where they will grow, stimulated and guided by signals such as biomolecules (e.g. growth factors) and by the scaffold itself.

There are a number of different options for each of these components. Although it may sometimes be possible to use non-human animal (xenogeneic) cells, in most cases human cells are used. These can be from a human donor (allogeneic) or taken from the patient her- or himself (autologous). Stem cells are particularly useful in tissue engineering because of their potential to differentiate into different cell types.[8] To date, most tissue engineered products have contained adult stem or progenitor cells, but pluripotent cells including human embryonic stem cells (hESCs) and induced pluripotent stem cells (iPSCs), which are produced by reprogramming adult cells, may offer even more promising possibilities.[9] The most common

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Applied to Solid Organ Transplantation: Current Status and Future Challenges" (2011) 24:3 Transpl Int 223 [Orlando et al, "Solid Organ"]; Sean Vincent Murphy & Anthony Atala, "Organ Engineering – Combining Stem Cells, Biomaterials, and Bioreactors to Produce Bioengineered Organs for Transplantation" (2012) 35:3 Bioessays 163; Giuseppe Orlando et al, "Regenerative Medicine as Applied to General Surgery" (2012) 255:5 Ann Surg 867 [Orlando et al, "General Surgery"].

7 See Zaulyanov & Kirsner, *supra* note 2; Michael Eisenstein, "Engineered Tracheas, Corneas and Arteries Begin Clinical Testing" (2014) 32:4 Nat Biotechnol 303.

8 Carole A Heath, "Cells for Tissue Engineering" (2000) 18:1 Trends Biotechnol 17 at 17; Fishman, Lowdell & Birchall, *supra* note 5 at 123.

9 See Mark E Furth & Anthony Atala, "Tissue Engineering: Future Perspectives" in Robert Lanza, Robert Langer & Joseph P Vacanti, eds, *Principles of Tissue*

type of adult stem cells used in tissue engineering is mesenchymal stem (or stromal) cells, which are usually derived from bone marrow.[10] Other cell sources would be donated human embryos (from which hESC lines are derived), fetal tissue, or various tissues from adult or pediatric donors or patients (e.g. skin, muscle, cartilage, or bladder biopsies).[11] One of the reasons that iPSCs are so promising is that they can be derived from the cells either of a donor or of the patient her- or himself, from sources that can easily be obtained, such as a sample of tissue like blood, skin or even cells in hair shafts or urine.[12]

The scaffold component of tissue engineered products can be of human, xenogeneic, or synthetic origin. One technique is to take an organ or tissue from a donor and remove the donor's cells through chemical or physical processing; this "decellularized" tissue can then be used as a scaffold, onto which other cells (e.g. autologous cells from the patient) can be seeded.[13] This is the technique that was used to create the first tissue engineered trachea,[14] and it is also being developed for liver, pancreas, intestine, and kidney engineering.[15] Natural substances such as collagen (human or bovine) or fibrin can be used as scaffold material.[16] A variety of synthetic

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Engineering, 4th ed (Amsterdam: Elsevier, 2013) 83 at 93-104.

10 *Ibid* at 101.

11 *Ibid* at 94.

12 *Ibid* at 94, 99.

13 See e.g. Peter M Crapo, Thomas W Gilbert & Stephen F Badylak, "An Overview of Tissue and Whole Organ Decellularization Processes" (2011) 32:12 Biomaterials 3233; Pedro M Baptista et al, "The Use of Whole Organ Decellularization for the Generation of a Vascularized Liver Organoid" (2011) 53:2 Hepatology 604; Thomas H Petersen et al, "Tissue-Engineered Lungs for In Vivo Implantation" (2010) 329:5991 Science 538.

14 See Macchiarini et al, *supra* note 5 at 2023-27.

15 Pedro M Baptista et al, "Whole Organ Decellularization – A Tool for Bioscaffold Fabrication and Organ Bioengineering" [2009] Conf Proc IEEE Eng Med Biol Soc 6526, cited in Orlando et al, "Solid Organ", *supra* note 6 at 225.

16 See e.g. Murphy & Atala, *supra* note 6 at 166; Pilar de la Puente & Dolores Ludeña, "Cell Culture in Autologous Fibrin Scaffolds for Applications in Tissue Engineering" (2014) 322:1 Exp Cell Res 1.

alternatives, such as polymers,[17] have also been developed, making use of advancements in biomaterials engineering. Some scaffolds are designed to remain intact while others are biodegradable.

Given the multiple possibilities for these components, tissue engineered products are very diverse despite having common elements. Further variability is introduced by the fact that these products and their components are designed to interact with each other and with the living bodies into which they are implanted. Unlike most medical devices, they are dynamic, living products that will both influence and be influenced by their biological environment. As will be apparent from this brief description, tissue engineering is a highly complex technology. It involves a number of different materials and techniques, combined in a "dynamic and continuous process" and presenting "a hitherto unencountered complexity."[18] For this reason, it has been argued that tissue engineering represents a "new medical paradigm."[19]

The need for these new therapies is compelling, as they could offer alternatives for diseases and conditions for which current treatment options are limited or inadequate. For patients needing organ and tissue transplants, the present reality is that demand continues to far exceed supply. For example, in 2012 there were at least 3,404 patients in Canada waiting for organ transplants and 161 who died waiting for transplants.[20] These statistics may underestimate the number of people who could benefit from transplants, since in the case of kidney transplants, for example, many patients

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17 See e.g. Murphy & Atala, *supra* note 6 at 166; Orlando et al, "General Surgery", *supra* note 6 at 874.

18 Leen Trommelmans, Joseph Selling & Kris Dierickx, "Is Tissue Engineering a New Paradigm in Medicine? Consequences for the Ethical Evaluation of Tissue Engineering Research" (2009) 12:4 Med Health Care Philos 459 at 462 [Trommelmans, Selling & Dierickx, "New Paradigm"].

19 *Ibid*.

20 Canadian Institute for Health Information, *e-Statistics Report on Transplant, Waiting List and Donor Statistics* (2012), tables 2A, 2C, online: CIHI <www.cihi.ca/CIHI-ext-portal/internet/en/document/types+of+care/specialized+services/organ+replacements/report_stats2012>. Numbers were even higher the previous year (4660 and 285, respectively): Canadian Institute for Health Information, *e-Statistics Report on Transplant, Waiting List and Donor Statistics* (2011), tables 2A, 2C, online: CIHI <www.cihi.ca/CIHI-ext-portal/internet/en/document/types+of+care/specialized+services/organ+replacements/report_stats2011>.

with serious kidney disease never even reach the waiting list.[21] Average wait times for lung or liver transplants in some provinces can be more than a year, and more than four years for kidneys.[22] There appear to be chronic shortages of tissues such as skin for grafts, heart valves, and corneas.[23] Efforts to increase donation rates and better coordination of organ and tissue donation, recovery, and distribution could make a significant difference,[24] but as demand is expected to increase,[25] these strategies are unlikely to be a complete solution.

Regenerative medicine, of which tissue engineering is an important component, is seen as one potential solution to these shortages.[26] Furthermore, tissue engineering could help an even larger group of patients who might not be candidates for traditional organ and tissue transplants but for whom "restoration of functional tissue would answer a currently unmet medical need," including those suffering from diabetes, congestive heart

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21 John S Gill et al, "Financial Incentives to Increase Canadian Organ Donation: Quick Fix or Fallacy?" (2014) 63:1 Am J Kidney Dis 133 at 134-35; Canadian Blood Services, *Call to Action: A Strategic Plan to Improve Organ and Tissue Donation and Transplantation Performance for Canadians* (April 2011) at 60, online: CBS Organ & Tissue Donation and Transplantation <www.organsandtissues.ca/s/wp-content/uploads/2012/06/OTDT-INDX-final-C2A.pdf> [Canadian Blood Services, *Call to Action*].

22 *Ibid* at 60, 65.

23 *Ibid* at 128.

24 See *ibid*; National Coordinating Committee on Organ and Tissue Donation and Transplantation, *A Coordinated and Comprehensive Donation and Transplantation Strategy for Canada* (November 1999), online: Health Canada <www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/pubs/transplantation-eng.pdf>.

25 David Baxter & Jim Smerdon, *Donation Matters: Demographics and Organ Transplants in Canada, 2000 to 2040* (Vancouver: The Urban Futures Institute, 2000) at 55, online: London Health Sciences Institute <www.lhsc.on.ca/Patients_Families_Visitors/MOTP/Organ_and_Tissue_Donation/Report46.pdf>; Gill et al, *supra* note 21 at 134. Gill et al, *ibid*, note that demand for kidney transplants seems to be increasing more slowly in Canada than in the United States, but also that selection for wait-listing is more conservative in Canada; consequently, waiting lists may not accurately represent demand.

26 AS Daar, "The Future of Replacement and Restorative Therapies: From Organ Transplantation to Regenerative Medicine" (2013) 45:10 Transplant Proc 3450 at 3450.

failure, Alzheimer's disease, and spinal cord injuries.[27] It is also hoped that it might avoid some of the ethical challenges associated with conventional organ transplantation.[28] Tissue engineering therefore offers enormous promise, but it also raises a range of legal and ethical issues that have yet to be fully appreciated or addressed.

Although there is a substantial and growing literature on the broader field of regenerative medicine, to date there has been relatively little discussion of the legal and ethical issues particular to tissue engineering. There have been, for example, some efforts to analyze the ethical issues relating to the source of cells and consent by donors and recipients,[29] as well as the distinct regulatory challenges that these complex products present.[30] This article focuses on one of the legal questions that will arise as this technology begins to be more commonly used: the extent to which existing legislation governing the donation and transplantation of human tissue would or should apply to tissue engineering. This could have a significant impact on some aspects of the tissue engineering process, such as the rules governing consent to donation of materials and the ability to sell engineered tissues and organs as commercial products. It also provides an opportunity to re-examine

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27 Furth & Atala, *supra* note 9 at 83.

28 See e.g. Anthony Hollander et al, "The First Stem Cell-Based Tissue-Engineered Organ Replacement: Implications for Regenerative Medicine and Society" (2009) 4:2 Regen Med 147 at 147.

29 See e.g. Trommelmans, Selling & Dierickx, "New Paradigm", *supra* note 18; Rob BM de Vries et al, "Ethical Aspects of Tissue Engineering: A Review" (2008) 14:4 Tissue Eng Part B Rev 367; Leen Trommelmans, Joseph Selling & Kris Dierickx, "An Exploratory Survey on the Views of European Tissue Engineers Concerning the Ethical Issues of Tissue Engineering Research" (2009) 15:3 Tissue Eng Part B Rev 241; AJM Oerlemans et al, "Towards a Richer Debate on Tissue Engineering: A Consideration on the Basis of NEST-Ethics" (2013) 19:3 Sci Eng Ethics 963; S Enoch, H Shaaban & KW Dunn, "Informed Consent Should Be Obtained from Patients to Use Products (Skin Substitutes) and Dressings Containing Biological Material" (2005) 31:1 J Med Ethics 2.

30 See e.g. Meredith Lloyd-Evans, "Regulating Tissue Engineering" (2004) 7:5 Mater Today 48; Kiki B Hellman & David Smith, "The Regulation of Engineered Tissues: Emerging Approaches" in John P Fisher, Antonios G Mikos & Joseph D Bronzino, eds, *Tissue Engineering* (Boca Raton, Fla: CRC Press, 2007) 17-1; Barbara von Tigerstrom, "How to Build (and Regulate) a Body Part: Regulating Tissue Engineered Products in Canada" (2011) 19 Health LJ 83.

the legal frameworks for human tissue that exist across Canada, drawing attention to a number of gaps, variations, and outstanding questions.

Human Tissue Legislation

Canadian provinces and territories,[31] like most jurisdictions, have legislation that governs the donation and transplantation of human organs and tissues.[32] The first Canadian legislation regarding human tissue was enacted in the mid-1850s in response to concerns about the availability of human cadavers for use in medical education.[33] A second wave of legislation enacted about a hundred years later provided for the donation of eyes for the purpose of corneal transplants.[34] This legislation "introduced a donation principle" by allowing individuals to authorize the post-mortem use of their eyes, and also allowed next of kin or another person with lawful possession of the body to authorize this donation.[35] Even today, many human tissue

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31 The focus in this article will be on the legislation in Canada's common law jurisdictions. The relevant law in Québec has a different structure, being part of the civil law tradition, and comparison of this distinct legal framework is beyond the scope of this short article.

32 *Human Tissue Gift Act*, RSBC 1996, c 211 [*BC Act*]; *Human Tissue and Organ Donation Act*, SA 2006, c H-14.5 [*AB Act*]; *Human Tissue Gift Act*, RSS 1978, c H-15 [*SK Act*]; *Human Tissue Gift Act*, SM 1987-88, c 39, CCSM c H180 [*MB Act*]; *Trillium Gift of Life Network Act*, RSO 1990, c H.20 [*ON Act*]; *Human Tissue Gift Act*, SNB 2004, c H-12.5 [*NB Act*]; *Human Tissue Gift Act*, RSNS 1989, c 215 [*NS Act (1989)*]; *Human Organ and Tissue Donation Act*, SNS 2010, c 36 (not yet in force) [*NS Act (2010)*]; *Human Tissue Donation Act*, RSPEI 1988, c H-12.1 [*PEI Act*]; *Human Tissue Act*, RSNL 1990, c H-15 [*NL Act*]; *Human Tissue Gift Act*, RSY 2002, c 117 [*YK Act*]; *Human Tissue Act*, RSNWT 1988, c H-6 [*NWT Act*]; *Human Tissue Act*, RSNWT (Nu) 1988, c H-6 [*Nu Act*].

33 Law Reform Commission of Canada, *Procurement and Transfer of Human Tissues and Organs* (Ottawa: Minister of Supply and Services Canada, 1992) at 127-29 [LRCC].

34 *Ibid* at 129-30. See also J-G Castel, "Some Legal Aspects of Human Organ Transplantation in Canada" (1968) 46:3 Can Bar Rev 345 at 393-94.

35 LRCC, *supra* note 33 at 130.

statutes contain specific provisions regarding corneal transplants.[36] The corneal transplant laws were expanded or replaced beginning in the 1960s with more comprehensive legislation covering human tissues.[37] Uniform statutes were adopted by the Conference of Commissioners on Uniformity of Legislation in Canada (now the Uniform Law Conference of Canada) in 1965 (the *Human Tissue Act*),[38] 1971 (the *Human Tissue Gift Act*),[39] and 1989 (the *Human Tissue Donation Act*, revised in 1990).[40]

The 1965 Uniform *Human Tissue Act* is very brief and deals only with post-mortem donation. Only the statutes of the Northwest Territories and Nunavut remain modelled on this original Uniform Act.[41] The subsequent Uniform *Human Tissue Gift Act* in 1971 added provisions on living (*inter vivos*) donations, as well as sections dealing with determination of death, confidentiality of information, protection from civil liability, and a prohibition on the sale of tissue. Most current provincial statutes are based on this

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36 *BC Act*, *supra* note 32, s 7(4); *SK Act*, *supra* note 32, s 8(4); *ON Act*, *supra* note 32, s 7(4); *NS Act (1989)*, *supra* note 32, s 8(4); *NL Act*, *supra* note 32, s 9(3); *YK Act*, *supra* note 32, s 7(4). All of these sections exclude medical practitioners removing eyes for a cornea transplant from the application of provisions regarding determination of death and participation in a transplant.

37 LRCC, *supra* note 33 at 131; Castel, *supra* note 34 at 395.

38 Conference of Commissioners on Uniformity of Legislation in Canada, *Proceedings of the Forty-Seventh Annual Meeting of the Conference of Commissioners on Uniformity of Legislation in Canada* (1965) at 104-06 (Appendix M), online: Uniform Law Conference of Canada <www.ulcc.ca/images/stories/Past_Proceedings_PDF/1965ULCC0047.pdf>.

39 Conference of Commissioners on Uniformity of Legislation in Canada, *Proceedings of the Fifty-Third Annual Meeting of the Conference of Commissioners on Uniformity of Legislation in Canada* (1971) at 152-56 (Appendix I), online: Uniform Law Conference of Canada <www.ulcc.ca/images/stories/Past_Proceedings_PDF/1971ULCC0053.pdf> [*1971 Uniform Act*].

40 Uniform Law Conference of Canada, *Human Tissue Donation Act (1990)*, online: ULCC <www.ulcc.ca/en/uniform-acts-new-order/older-uniform-acts/440-josetta-1-en-gb/uniform-actsa/human-tissue-donation-act/284-human-tissue-donation-act-1990-draft> [*1990 Uniform Act*].

41 *NWT Act*, *supra* note 32; *Nu Act*, *supra* note 32.

1971 Uniform Act,[42] in some cases revised and updated in specific respects.[43] Prince Edward Island adopted the 1990 Uniform *Human Tissue Donation Act*,[44] which contains additional provisions, most notably on donations by minors; a few other provinces have incorporated selected aspects of these or similar provisions without adopting the whole 1990 Uniform Act.[45] Alberta and Nova Scotia have enacted new statutes within the last ten years that are distinct from the other provinces' statutes in some respects; their relevant aspects are noted in the discussion that follows.[46] The Uniform Acts – and indeed all Canadian legislation on this subject – reflect "a general commitment to consent and altruism as the uniform model of tissue donation from living and deceased donors."[47] The "gift ethic" on which the Canadian legal framework is based[48] is reflected in these statutes through a combination of consent requirements and prohibitions on paid donation. In addition, the legislation supplements and extends the common law protection of bodily integrity by requiring consent to any use of a human body or removal of human organs or tissues, both before and after death. Thus, Canadian statutes typically contain provisions dealing with consent to post-mortem donation of the body or body parts as well as, in most cases, living donation of tissues, determination of death, and a prohibition on the sale of human

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42 As of 2006, 10 jurisdictions had adopted the *1971 Uniform Act*. See Uniform Law Conference of Canada, "Table III – 2006: Uniform Acts Adopted before 2000, Showing the Jurisdictions that Have Enacted Them in Whole or in Part, with or without Modifications, or in Which Provisions Similar in Effect Are in Force", online: ULCC <www.ulcc.ca/en/general-info-status/other-implementation-tables/2129-table-iii-pre-2000-uniform-acts-enacted-by-statute> [ULCC, "Table III – 2006"].

43 See e.g. *ON Act*, *supra* note 32; *NB Act*, *supra* note 32; *YK Act*, *supra* note 32.

44 *PEI Act*, *supra* note 32. Prince Edward Island is the only province to have adopted the *1990 Uniform Act*: Timothy C Matthews, "Consent to Donation of Human Tissue in Atlantic Canada" (2012) 31:3 ETPJ 248 at 248; ULCC, "Table III – 2006", *supra* note 42.

45 See *AB Act*, *supra* note 32; *MB Act*, *supra* note 32.

46 *AB Act*, *supra* note 32; *NS Act (2010)*, *supra* note 32. On Alberta's new statute, see Erin Nelson, "Alberta's New Organ and Tissue Donation Law: The Human Tissue and Organ Donation Act" (2010) 18:2 Health L Rev 5.

47 LRCC, *supra* note 33 at 131.

48 Joan M Gilmour, "'Our' Bodies: Property Rights in Human Tissue" (1993) 8:2 CJLS 113 at 116.

bodies or tissues. Consent by the individual or by another person with legal authority is required for the use of a human body or removal of any tissues for transplant, subject to very limited exceptions.[49]

Despite their broad similarity and being modelled on the Uniform Acts, there are many differences between the Canadian human tissue statutes, especially when one begins to examine the statutory language in detail; virtually every statute is distinct in some respect, with the differences ranging from inconsequential details to significant drafting or policy choices. For the purposes of the analysis that follows, the wording of five particular sets of provisions are most relevant. The essential elements of these are reproduced in Table 1. The first are provisions that define the types of human biological material that fall within the scope of the act. For example, almost all of the statutes define the term "tissue" and, in so doing, exclude specific types of tissue (e.g. blood) from that definition or from the scope of the act; there are some small but potentially significant variations in these provisions across Canada. Second, almost all statutes define the term "transplant" or "transplantation." These definitions, which are largely consistent, also affect the scope of application of some substantive provisions, since the living donations to which these statutes apply are donations of tissue for transplantation, while post-mortem donation provisions refer to tissue, bodies, or body parts for therapeutic purposes (which would include transplantation), medical education, or medical research. The third and fourth groups of provisions are those governing living and post-mortem donations, respectively, specifying the consent that is required and in some cases setting limits on the donations that are permissible (for example, through restrictions on living donations by minors or adults without capacity). The final set of provisions studied here are the prohibitions on the sale of tissue, bodies, and body parts that are intended for certain purposes (therapeutic, educational, or research), which can be found in virtually all of the statutes, articulated in similar language.

One of the legal issues to be addressed with respect to tissue engineering is whether, and to what extent, this legislative framework is relevant to engineered tissue and its components, what effect it might have, and whether any reforms will be needed as this new technology develops. First, it must be determined whether the materials, products, and processes of

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[49] For example, a few statutes contain an exception allowing removal of the pituitary gland for use in treatment of growth hormone deficiency without express consent (though not over a known objection): see *MB Act*, *supra* note 32, s 6; *NL Act*, *supra* note 32, s 16.

tissue engineering could potentially fall within the scope of human tissue statutes, a question that requires consideration of the key terms that define this scope. Then, the two most important types of substantive provisions – those regarding consent for donation and prohibitions on sale or payment of consideration – will be examined to determine whether they could or should apply to tissue engineering. The variations among statutes make it difficult to generalize with respect to both of these questions, but the analysis below will focus on the most common or typical wording that is found in Canadian common law jurisdictions, while noting significant variations where they occur.

A. Key terms and definitions

In order to determine whether the provisions in Canadian human tissue statutes apply to tissue engineering, the legislation's key terms and definitions need to be examined. The statutes define the circumstances in which human tissue can be removed and used for certain purposes and prohibits certain dealings in human tissue. They typically state that transplants are lawful if done in accordance with the statute, but not otherwise,[50] and that certain dealings in human materials are unlawful and void. Under some legislation, procurement of organs for transplantation must be coordinated by a designated agency.[51] Therefore it is important to know whether the creation and implantation of tissue engineered products would fall within their scope.

1. "Tissue" and "body parts"

The first question is whether the cells, tissues, or organs obtained from a donor for use in tissue engineering (collectively, "TE materials") or the final products created from these and implanted into the recipient's body ("TE products") fall within the definition of "tissue" in these statutes, since the substantive provisions refer to "tissue" or sometimes also to a body or

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[50] See e.g. *BC Act*, *supra* note 32, s 2; *SK Act*, *supra* note 32, s 3; *ON Act*, *supra* note 32, s 2; *NB Act*, *supra* note 32, s 2. Alberta has a slightly different provision, which states: "A person's tissue, organs or body may be donated for transplantation, medical education or scientific research only in accordance with this Act" (*AB Act*, *supra* note 32, s 3(1)).

[51] See e.g. *Human Tissue and Organ Donation Regulation*, Alta Reg 196/2009, s 4(2).

body part. If human cells are used as the cellular component of a TE product (rather than xenogeneic cells), they will come either from a donor (referred to as "allogeneic" cells) or from the individual patient her- or himself ("autologous" cells). If embryonic stem cells or fetal cells are used, they would come from a donated embryo or fetus (or a cell line derived from these); otherwise, the cells would be derived from a tissue sample taken from a human donor or patient. It is also possible that the scaffold could contain or be composed of human tissue, such as a decellularized organ or tissue. Depending on the organ or tissue needed, this scaffold source material might come from either a living or a deceased donor. For example, the scaffold used in the first tissue engineered trachea was a decellularized trachea from a deceased donor, onto which were seeded epithelial cells, grown from biopsy samples from the patient's own nose and bronchia, and chondrocytes (cartilage cells) derived from mesenchymal stem cells obtained from bone marrow.[52] The TE product created from these materials would be functionally, and in some cases biologically, similar to a "natural" human tissue or organ, but may contain synthetic materials and would have been generated in a laboratory rather than taken directly from another human body. Should these TE materials or products be considered "tissue" for the purposes of Canadian law?

The most common definition of "tissue" in Canadian legislation states that it "includes an organ, but does not include any skin, bone, blood, blood constituent or other tissue that is replaceable by natural processes of repair."[53] The 1990 Uniform *Human Tissue Donation Act*, used as the basis for the provisions of a few jurisdictions, defines tissue as "part of a living or dead human body," excluding "spermatozoa or ova," "an embryo or fetus," and "blood or blood constituents."[54] More recent statutes in Alberta

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[52] See Macchiarini et al, *supra* note 5.

[53] This wording is from the *1971 Uniform Act*, *supra* note 39, s 1(c), and can be found in: *SK Act*, *supra* note 32, s 2(c); *NB Act*, *supra* note 32, s 1; *NS Act (1989)*, *supra* note 32, s 2(c); *YK Act*, *supra* note 32, s 1. In addition, the *BC Act*, *supra* note 32, s 1, and *NL Act*, *supra* note 32, s 2(g), are virtually identical (merely omitting the word "any").

[54] *1990 Uniform Act*, *supra* note 40, s 1. The *PEI Act*, *supra* note 32, s 1(g), is virtually identical. The *ON Act*, *supra* note 32, s 1, is similar but adds bone marrow to the excluded tissues. The *MB Act*, *supra* note 32, s 1, adapts this provision so that the first clause reads: "[A]n organ, a part of a human body and a substance extracted from the human body or from a part of the human body"; it also excludes "(d) a placenta" from the definition of tissue.

and Nova Scotia use different definitions. The acts of these two provinces define organs and tissues separately, with "organ" including a section, lobe, or part of an organ,[55] and tissue simply meaning "human tissue excluding organs"[56] or "a functional group of human cells, excluding organs."[57] Both of these statutes contain separate provisions excluding "blood or blood constituents" and "zygotes, oocytes, embryos, sperm, semen and ova" from their application;[58] Alberta also excludes "by-products that are used for a purpose other than transplantation."[59]

One of the more significant distinctions between the statutes modelled on the 1971 Uniform *Human Tissue Gift Act* and later enactments is that the former exclude all regenerative tissue – tissue that is "replaceable through natural processes of repair"[60] – from their scope, while the latter do not exclude regenerative tissue generally, but only certain specified types of tissues. Generally, regenerative tissue would include blood and blood constituents, skin, bone, bone marrow, and gametes. The later statutes, however, keep some regenerative tissues within their scope, while specifically excluding others such as blood, and they also draw distinctions between regenerative and non-regenerative tissues in some substantive provisions, such as those addressing living donations by minors.[61]

These provisions thus establish broad definitions of the term "tissue" while excluding reproductive materials, tissues such as blood that regenerate naturally, or both. Consequently, TE materials obtained from a donor might or might not fall within these definitions, depending on the type of tissue and, in some cases, the particular jurisdiction. For example, skin is excluded from the definition of tissue in about half of Canadian jurisdictions,

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55 *AB Act*, *supra* note 32, s 1(*l*); *NS Act (2010)*, *supra* note 32, s 2(r) (not yet in force).

56 *AB Act*, *supra* note 32, s 1(m).

57 *NS Act (2010)*, *supra* note 32, s 2(y) (not yet in force).

58 *AB Act*, *supra* note 32, s 2; *NS Act (2010)*, *supra* note 32, s 3 (not yet in force).

59 *AB Act*, *supra* note 32, s 2(a). A "by-product" is defined as "tissue or an organ that is a waste product of a medical procedure": *ibid*, s 1(b).

60 *1971 Uniform Act*, *supra* note 39, s 1(c). The *1990 Uniform Act*, *supra* note 40, s 1, defines "regenerative tissue" as "tissue that, on injury or removal, replaces itself" in a living body.

61 See note 95 and accompanying text.

while bone marrow would be excluded in most, and blood and blood constituents in all. Other material, such as a whole organ (e.g. a liver or kidney), trachea, or heart valve would be considered "tissue" throughout Canada. Unlike some international documents,[62] no Canadian statute specifically refers to donation of cells (as opposed to tissues or organs). However, it seems likely that even if cells were extracted or derived from a tissue sample for use in tissue engineering, the sample obtained from the donor would be considered "tissue" for the purposes of these statutes (depending, again, on the type of tissue and the scope of the definition in each jurisdiction). In the case of post-mortem donations, many provisions refer to body parts, which could be read to encompass even biological material that would not be considered "tissue" as defined in the legislation, though this is uncertain.[63] It is possible, however, that where the material obtained from the donor is only one of the excluded tissue types or a tissue sample from a biopsy, this would fall outside of the scope of the legislation.

What, then, of a TE product? Should it be considered a "tissue" or "body part" to which the provisions of human tissue legislation would apply? The definitions of the term "tissue" in the relevant statutes are not particularly helpful on this point, given that they tend merely to exclude certain types of tissues from the scope of the statutes, without actually explaining what a tissue is. Only one provides this clarification, stating that tissue means "a functional group of human cells."[64] The accepted contemporary approach to statutory interpretation tells us to consider "the words of an Act … in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act, and the intention of Parliament."[65] In this case, the "ordinary meaning" may not be sufficient to

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62 WHO, *Guiding Principles on Human Cell, Tissue and Organ Transplantation*, WHA Res 63.22 (21 May 2010), online: WHO <http://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_R22-en.pdf>; *Additional Protocol to the Convention on Human Rights and Biomedicine Concerning Transplantation of Organs and Tissues of Human Origin*, 24 January 2002, 2466 UNTS 137, arts 2(2), 15, Eur TS 186 (entered into force 1 May 2001) [*European Transplantation Protocol*].

63 Gilmour, *supra* note 48 at 116-17.

64 *NS Act (2010)*, *supra* note 32, s 2(y) (not yet in force).

65 Elmer Driedger, *Construction of Statutes*, 2d ed (Toronto: Butterworths, 1983) at 87, cited with approval in *Re Rizzo & Rizzo Shoes Ltd*, [1998] 1 SCR 27 at para 21, 36 OR (3d) 418, 154 DLR (4th) 193; *Bell ExpressVu Limited Partnership v Rex*, 2002 SCC 42 at para 26, [2002] 2 SCR 559, 212 DLR (4th) 1; *Bristol-Myers Squibb Co v Canada (AG)*, 2005 SCC 26 at para 37, [2005] 1

resolve the issue. A typical dictionary definition of "tissue" is "the material of which an animal or plant body, or any of its parts or organs, is composed, consisting of an aggregation of specialized cells."[66] A TE product contains biological material, including living cells, and when implanted into the body is intended to perform the function of an organ or tissue; thus, in a certain sense, it could be considered a tissue. It could fit the plain meaning of a tissue as "a functional group of human cells" or an "aggregation of specialized cells" of which body parts or organs are composed.

A TE product could also be considered a "body part" – a term that is used but not defined in the legislation – though this might strain its ordinary meaning. A prosthetic limb, for example, could be called a body part given that it is attached to the body and performs the function of a body part; however, it is doubtful that it was intended to be included in the scope of these provisions, since it contains no human biological material and thus does not raise the concerns of autonomy, bodily integrity, and human dignity that this legislation is commonly understood to address. The same could be said of an artificial organ (i.e., a manufactured medical device that performs the function of an organ). Should engineered tissue be different than a prosthetic limb or artificial organ merely because it contains some biological material? On the other hand, if a TE product is functionally equivalent to a "natural" tissue or body part, should it be excluded merely because it contains synthetic material as well as cells? What if an organic scaffold were used, or the synthetic material were biodegradable, so that after implantation all that remained would be "an aggregation of specialized cells" and the product would be virtually indistinguishable from a "natural" tissue or organ?

There is a general rule or doctrine of statutory interpretation that legislative terms should be given the ordinary meaning they would have had when the legislation was enacted.[67] For the human tissue legislation that dates back to the 1960s and 1970s, the drafters or legislators would not have understood "tissue" and "body parts" to include engineered tissues and organs, since these did not yet exist outside the realm of science fiction. Some statutes are more recent, but even in those cases, tissue engineering

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SCR 533, 253 DLR (4th) 1; *Canada Trustco Mortgage Co v Canada*, 2005 SCC 54 at para 10, [2005] 2 SCR 601, 259 DLR (4th) 193. See also *Canada (Information Commissioner) v Canada (Minister of National Defence)*, 2011 SCC 25 at para 27, [2011] 2 SCR 306, 331 DLR (4th) 513.

66 *Canadian Oxford Dictionary*, 2d ed, *sub verbo* "tissue".

67 *Perka v The Queen*, [1984] 2 SCR 232 at 264-65, 13 DLR (4th) 1 [*Perka*].

was probably not contemplated by the legislature, since even now, it is still not in common use. At any rate, the prohibitions on commercial dealing in tissue – among the most important provisions for tissue engineering – date back, in Canada, to the early 1970s.[68] However, the absence of tissue engineering from the contemplation of the legislators is not necessarily determinative, since the original meaning rule is not absolute. It must be considered along with the general approach of contextual and purposive interpretation, as well as the rules of construction enshrined in provincial legislation, that the law is "always speaking"[69] and an enactment should be given a remedial, "fair, large, and liberal" interpretation that will best attain its objects.[70] The Supreme Court of Canada has held that, notwithstanding the original meaning doctrine, "[b]road statutory categories are often held to include things unknown when the statute was enacted."[71] In the "Harvard Mouse" case involving patenting of higher life forms, the majority in the Federal Court of Appeal and the dissenting judgment in the Supreme Court of Canada specifically rejected the argument that the meaning of the word "invention" in patent legislation should not include a higher life form because at the time of enactment, this could not have been contemplated.[72]

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[68] See *1971 Uniform Act*, *supra* note 39, s 10.

[69] See e.g. *Legislation Act, 2006*, SO 2006, c 21, s 63 [*ON Legislation Act*]; *Interpretation Act*, RSBC 1996, c 238, s 7(1) [*BC Interpretation Act*]; *Interpretation Act*, RSA 2000, c I-8, s 9 [*AB Interpretation Act*].

[70] See e.g. *ON Legislation Act*, *supra* note 69, s 64; *BC Interpretation Act*, *supra* note 69, s 8; *AB Interpretation Act*, *supra* note 69, s 10.

[71] *Perka*, *supra* note 67 at 265.

[72] *President and Fellows of Harvard College v Canada (Commissioner of Patents)*, [2000] 4 FCR 528 (CA) at paras 188-91, 189 DLR (4th) 385; *Harvard College v Canada (Commissioner of Patents)*, 2002 SCC 76 at para 10, [2002] 4 SCR 45, 219 DLR (4th) 577:

> It is true, of course, that in 1869, when the post-Confederation patent act was passed, Parliament did not contemplate genetically engineered "higher life forms" (*Act respecting Patents of Invention*, S.C. 1869, c. 11).… Nor did Parliament in 1869 contemplate moon rockets, antibiotics, telephones, e-mail or handheld computers. The proper question is not whether Parliament intended to include "oncomice" or "higher life forms" or biotechnology generally in patent legislation, but whether Parliament intended to protect "inventions" that were *not* anticipated at the time of enactment of the *Patent Act*, or indeed, at any time before the claimed invention [*ibid*, emphasis in original].

Although the majority of the Supreme Court of Canada reversed the Federal Court of Appeal's decision, this position did not rest on the original meaning of the terms used in the legislation but rather on the majority's understanding of Parliament's intention considering the context and purpose of the legislative scheme.[73] As stated by the Supreme Court in another case, "[t]he words, if clear, will dominate; if not, they yield to an interpretation that best meets the overriding purpose of the statute."[74] That approach seems appropriate here, therefore the purposes of the legislation and its various provisions will be discussed further below.

2. "Transplant"

The next question is whether the process of obtaining tissues from a donor and using them (or cells from them) to make a tissue engineered product which is then implanted into a recipient constitutes a "transplant" within the meaning of these statutes. The emerging field of tissue engineering is closely related to transplantation,[75] but current statutes certainly were not drafted with tissue engineering in mind. Most statutes in Canada define a "transplant" as "the removal of tissue from a human body, whether living or dead, and its implantation in a living human body."[76] Similarly, a typical

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[73] *Ibid* at paras 153-87. For a discussion of the majority's use of the modern approach to statutory interpretation in this case, see Stéphane Beaulac & Pierre-André Côté, "Driedger's 'Modern Principle' at the Supreme Court of Canada: Interpretation, Justification, Legitimization" (2006) 40:1 RJT 131 at 151, 169-71. These authors note (at 151) that the majority and dissenting judgments in this case did not differ in their approach to statutory interpretation, just in their conclusion. On the broader issue of treating patent eligibility as a question of statutory interpretation, see E Richard Gold, "The Reach of Patent Law and Institutional Competence" (2003-2004) 1:1-2 University of Ottawa Law & Technology Journal 263, especially at 268-71.

[74] *Celgene Corp v Canada*, 2011 SCC 1 at para 21, [2011] 1 SCR 3, 327 DLR (4th) 513.

[75] See Giuseppe Orlando et al, "Regenerative Medicine and Organ Transplantation: Past, Present, and Future" (2011) 91:12 Transplantation 1310 at 1310-11.

[76] *BC Act*, *supra* note 32, s 1; *SK Act*, *supra* note 32, s 2(d); *ON Act*, *supra* note 32, s 1; *NB Act*, *supra* note 32, s 1; *NS Act (1989)*, *supra* note 32, s 2(d); *NL Act*, *supra* note 32, s 2(h); *YK Act*, *supra* note 32, s 1. Variations include Manitoba's definition, which is similar except that it says "in another human body" (*MB Act*, *supra* note 32, s 1), and the wording in the *PEI Act*, *supra* note 32, s 1(h):

provision for consent to living donation refers to consent "to the removal forthwith from his body of the tissue specified in the consent and its implantation in the body of another living person."[77] Alberta's 2006 statute defines "transplantation" as "the operation of transferring tissue or an organ from a human donor to a human recipient."[78] Whether an activity is considered to be transplantation is relevant to whether the donation of tissue for TE by a living donor is subject to the legislation, because most of the provisions on living donation specifically refer to removal of tissue *for transplantation* (or implantation into another living body). In the case of post-mortem donation and the prohibition on sale, the legislation refers more broadly to therapeutic purposes (which would include transplantation), medical education, and medical research. Donations of tissue for use in TE might be considered part of a transplant process, as discussed in this section. It likely would also be considered a donation for therapeutic purposes or, if the tissue is to be used in TE research (for example experiments developing new types of TE, or to make TE products for use in clinical trials), for purposes of medical research.

In tissue engineering using human donor cells or tissues, tissue is first removed from a human body and, later, a product containing some or all of that tissue, or cells derived from it, will be implanted into a living human body. However, this scenario does not quite match what we normally think of as a transplant. Transplantation involves two parts: removal from the donor and implantation into the recipient. These two parts are present in tissue engineering, but what is removed (TE materials) is not the same as what is ultimately implanted (the TE product). In ordinary transplants, organs and tissues may be stored or may undergo some processing between removal and implantation, but the plain wording of the definitions suggests that the tissue removed from the donor is what is later implanted, and it is not clear how much processing can take place, nor what length of delay can intervene, before we would consider the implantation of the final product not to be a "transplant" of the original tissue. What type or degree of similarity between the tissue removed and the tissue implanted is necessary, and why?

"[T]he removal of tissue from a human body, whether living or dead, and the implantation of the tissue in a living human body."

77 *1971 Uniform Act*, *supra* note 39, s 3(1); *NS Act (1989)*, *supra* note 32, s 4(1); *SK Act*, *supra* note 32, s 4(1). See also the very similar provisions in, e.g., *BC Act*, *supra* note 32, s 3(1); *ON Act*, *supra* note 32, s 3(1).

78 *AB Act*, *supra* note 32, s 1(n).

Taking these considerations into account, it is conceivable that some uses of donor tissue in tissue engineering might be considered a transplant whereas others would not. For example, if a decellularized trachea from a deceased donor is used as the scaffold of an engineered trachea, this might not seem too different from the transplantation of a donor trachea. However, if stem cells are derived from donated bone marrow or other tissue, are then differentiated, and subsequently are used to form the cellular component of a tissue engineered product, the connection between removal and implantation might seem too remote. If, as will sometimes be the case, the TE product that is implanted contains a mixture of tissue from a donor and from the recipient her- or himself (for example a decellularized organ scaffold seeded with autologous cells), is that a transplant within the meaning of the statute? Again, the ordinary meaning and legislative intent do not seem to provide much guidance here.

To summarize, TE materials from donors may or may not be considered tissue under Canadian human tissue statutes, depending on the particular tissue and the definition used in each jurisdiction. It is not clear whether a TE product would be considered a tissue or body part. Then, it is possible, but by no means certain, that the procurement and implantation processes in tissue engineering will fall within the scope of a transplant as defined by Canadian human tissue statutes, at least in some cases. The donation of TE material would likely be considered a donation for therapeutic (or medical research) purposes, however. The legal position is therefore both variable – that is, potentially different in different jurisdictions within Canada – and uncertain. Where there is uncertainty, looking to the object and scheme of the statute becomes important. The provisions on consent and payment of consideration will therefore be considered in the next section to see whether and how they might apply to tissue engineering, and whether this would be consistent with the statutory purposes.

B. Consent to donation

Most modern human tissue statutes contain provisions governing consent for both post-mortem and living (*inter vivos*) donations of human biological material, and state that transplants are lawful only if done in accordance with those provisions. Post-mortem donations require the consent of the person (if the person is a competent adult)[79] or, where no consent or

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[79] See e.g. *1971 Uniform Act*, *supra* note 39, s 4(1); *ON Act*, *supra* note 32, s 4(1); *BC Act*, *supra* note 32, s 4(1); *MB Act*, *supra* note 32, s 2(1); *AB Act*, *supra* note 32, s 4(1).

objection has been expressed by a person who has died or is near death and no longer able to consent, a family member (spouse, adult child, parent, etc.) or other person lawfully in possession of the body.[80] Consent given in accordance with these provisions is sufficient authority to use the body and remove and use body parts for the purpose or purposes specified in the consent, unless there is reason to believe the person objected or withdrew consent.[81] Other provisions govern the determination of death in the context of post-mortem transplants (i.e. defining how death should be determined and prohibiting physicians associated with the transplant or its recipient from participating in the determination of death).[82]

Generally, the provisions regarding consent to post-mortem donations are broader in scope than those for living donations.[83] As explained above, the post-mortem donation provisions were originally developed to deal with donation of cadavers to be used in medical education, and were later expanded to include donation for transplantation. They generally allow consent to be given to use the body, body parts, or tissues for specified purposes. The purposes mentioned usually include transplantation, but also "medical education," "scientific research," and "therapeutic purposes."[84] Therapeutic

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80 See e.g. *1971 Uniform Act*, *supra* note 39, s 5(1); *ON Act*, *supra* note 32, s 5(2); *BC Act*, *supra* note 32, s 5(1); *MB Act*, *supra* note 32, s 3(1); *AB Act*, *supra* note 32, s 4(2).

81 See e.g. *1971 Uniform Act*, *supra* note 39, ss 4(3), 5(3); *AB Act*, *supra* note 32, s 8; *ON Act*, *supra* note 32, ss 4(3), 5(4); *BC Act*, *supra* note 32, ss 4(3), 5(3)-(4); *MB Act*, *supra* note 32, ss 2(3), 3(5).

82 See e.g. *1971 Uniform Act*, *supra* note 39, s 7; *1990 Uniform Act*, *supra* note 40, s 11; *AB Act*, *supra* note 32, s 6; *ON Act*, *supra* note 32, s 7; *BC Act*, *supra* note 32, s 7; *MB Act*, *supra* note 32, s 8.

83 The exception is legislation modelled on the *1990 Uniform Act*, *supra* note 40, s 3(1), which, for consent by the person him- or herself to post-mortem donation, covers only donation for transplantation into a "living human body," similarly to living donation. See *PEI Act*, *supra* note 32, s 3(1). However, another section of that legislation allows consent to be given to the use of one's body or tissue taken from it for "therapeutic purposes, medical education or scientific research," similarly to other statutes. See *1990 Uniform Act*, *supra* note 40, s 12(1); *PEI Act*, *supra* note 32, s 12.

84 *BC Act*, *supra* note 32, ss 4(1), 5(1); *SK Act*, *supra* note 32, ss 5(1), 6(1); *MB Act*, *supra* note 32, ss 2(1), 3(1); *ON Act*, *supra* note 32, ss 4(1), 5(2); *NS Act (1989)*, *supra* note 32, ss 5(1), 6(2); *NB Act*, *supra* note 32, ss 4(1), 5(1); *NL Act*, *supra* note 32, ss 6(1), 7(1); *YK Act*, *supra* note 32, ss 4(1), 5(1). See the

purposes are not defined in the legislation; they would include transplantation, but could also be interpreted more broadly. Even if tissue engineering would not fall within the definition of a transplant, it certainly could qualify as use for a therapeutic purpose (or as use in scientific research, if part of a research study). However, the two most recent statutes, those of Alberta and Nova Scotia, provide for consent for post-mortem donation of the body or tissues only for transplantation, in addition to education and scientific research, but do not make reference to broader therapeutic purposes.[85] Therefore, it would seem that post-mortem donation of TE materials would not fall within the scope of those statutes unless the tissue engineering process were considered to fall within the definition of "transplantation" or were part of a research study.

Provisions regarding living donations typically deal with consent to removal of tissue from one's body and its implantation into another living person's body[86] – that is, consent to donate tissue for transplantation. A few statutes include provisions for consent by substitute decision makers either on behalf of or in addition to donors who lack capacity to consent or who are under the age of majority or under 16 years of age.[87] These provisions specify whose consent is required and when special procedures, such as an independent assessment, will be required. Of note, they refer specifically to donations for transplants, and so they would not apply to the procurement of TE materials unless the procurement were considered part of a transplant.

Therefore, whether the consent provisions in human tissue legislation would apply to donation of tissue for use in tissue engineering is unclear, and would depend on the particular type of tissue (whether it fell within the scope of the statute), whether the donation were made by a living donor or post-mortem, and whether transplantation were interpreted to include tissue engineering processes. The position may vary from jurisdiction to jurisdiction with the wording of their statutes. Variability and uncertainty in them-

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1971 Uniform Act, *supra* note 39, s 4(1), 5(1).

85 *AB Act*, *supra* note 32, s 4(1); *NS Act (2010)*, *supra* note 32, ss 11.1, 12(2) (not yet in force).

86 See e.g. *1971 Uniform Act*, *supra* note 39, s 3(1); *BC Act*, *supra* note 32, s 3(1); *ON Act*, *supra* note 32, s 3(1).

87 *1990 Uniform Act*, *supra* note 40, ss 5-7; *AB Act*, *supra* note 32, s 5(2); *MB Act*, *supra* note 32, ss 10, 11(1); *NS Act (2010)*, *supra* note 32, ss 7-8; *PEI Act*, *supra* note 32, s 7.

selves can be problematic, but it is also important to consider what practical difference might result from the application of these statutory provisions in the context of tissue engineering. In the case of post-mortem donation of organs and tissues, the scope of application of human tissue statutes is potentially significant, since such statutes have helped to clarify unsettled questions in the common law regarding consent to post-mortem use of bodies and body parts.[88] As we saw above, in most jurisdictions it seems likely that the legislation would apply to post-mortem donation of tissue for use in tissue engineering, since this could be considered a donation for "therapeutic purposes" if not for transplantation. In the two jurisdictions that have most recently reformed their legislation, Alberta and Nova Scotia, the narrower provisions regarding donation for "transplantation" might exclude their application to tissue engineering. It is somewhat ironic that the newest legislation might have the least flexibility in this respect to deal with an emerging technology.

With respect to living donations, the statutes' requirement of consent for the removal of tissue essentially mirrors the common law, in which the tort of battery protects individuals from unwanted interference with their persons, such as medical interventions without consent;[89] this would include any removal of tissue from a living body. Most Canadian jurisdictions now have other statutes outside of the domain of tissue donation that codify and/or supplement the common law on consent, for example with respect to substitute decision making. The scope of human tissue legislation becomes most significant where it might depart from or add to the common law and the generally applicable law on consent. Two possibilities stand out. First, where human tissue statutes contain provisions regarding consent by or on behalf of minors, or on behalf of adults without decision-making capacity, these provisions contain some distinct elements. For example, most Canadian statutes contain a distinct age cut-off (either the age of majority or 16 years) for the ability to consent to donation,[90] a departure from the common

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88 Castel, *supra* note 34 at 378-92.

89 See e.g. *Malette v Shulman* (1990), 72 OR (2d) 417 at 423-24, 67 DLR (4th) 321 (CA).

90 Regarding living donations, see e.g. *1971 Uniform Act*, *supra* note 39, s 3(1) (age of majority); *ON Act*, *supra* note 32, s 3(1) (16 years); *BC Act*, *supra* note 32, s 3(1) (19 years); *SK Act*, *supra* note 32, s 4(1) (age of majority); *NB Act*, *supra* note 32, s 3(1) (19 years). Regarding post-mortem donations, see e.g. *1971 Uniform Act*, *supra* note 39, s 4(1) (age of majority); *ON Act*, *supra* note 32, s 4(1) (16 years); *BC Act*, *supra* note 32, s 4(1) (19 years); *SK Act*, *supra*

law position which relies on the individual subject's maturity and mental capacity rather than a set age limit.[91] A minority of the Canadian human tissue donation statutes contain provisions allowing living donations by minors or adults without capacity, under certain conditions. These include requirements for parental consent for donation by a minor, regardless of whether the minor has decision-making capacity[92] – again unlike the common law in Canada[93] – and a specific process for independent assessment in the case of consent by or for a minor.[94] In almost all cases, donations by minors under 16 are limited to regenerative tissues.[95] The limitations found

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note 32, s 5(1) (age of majority); *NB Act*, *supra* note 32, s 4(1) (19 years).

91 See *AC v Manitoba (Director of Child and Family Services)*, 2009 SCC 30 especially at paras 114-16, [2009] 2 SCR 181, 309 DLR (4th) 581 [*AC v Manitoba*]; *JSC v Wren* (1986), 76 AR 115, 35 DLR (4th) 419 (CA).

92 *1990 Uniform Act*, *supra* note 40, s 6(3); *AB Act*, *supra* note 32, s 5(2); *MB Act*, *supra* note 32, ss 10(2)(c), 11(1)(f); *PEI Act*, *supra* note 32, s 7(3). The exception appears to be Nova Scotia's new statute, in which the provisions refer to lack of capacity rather than age: *NS Act (2010)*, *supra* note 32, s 8 (not yet in force).

93 *AC v Manitoba*, *supra* note 91 at paras 114-16; *JSC v Wren*, *supra* note 91 at para 9; *Van Mol (Guardian ad litem of) v Ashmore*, 1999 BCCA 6 at para 75, 168 DLR (4th) 637, 58 BCLR (3d) 305.

94 *1990 Uniform Act*, *supra* note 40, ss 6(4), 7; *AB Act*, *supra* note 32, ss 5(2), 5(5)-(7) (independent assessment committee); *MB Act*, *supra* note 32, s 11(1)(h) (approval by the Court of Queen's Bench required for donation by living minor under 16); *PEI Act*, *supra* note 32, ss 7(4), 8 (independent assessment); *NS Act (2010)*, *supra* note 32, s 8 (not yet in force) (court authorization).

95 *AB Act*, *supra* note 32, s 5(5)(b); *MB Act*, *supra* note 32, s 11(1)(b); *PEI Act*, *supra* note 32, s 7(1). Again *NS Act (2010)*, *supra* note 32 (not yet in force), is the exception, as it does not appear to contain any such explicit restriction, although the type of tissue would be relevant to whether the donation is in the individual's best interests, which is one of the relevant criteria for the court to consider in deciding whether to authorize the donation: s 8(2)(f). Two jurisdictions also restrict living donations by adults when the tissue is non-regenerative. In Manitoba, even competent adults can apparently only consent to the removal of regenerative tissue for medical education or scientific research, whereas they can consent to removal of either regenerative or non-regenerative tissue for therapeutic purposes: *MB Act*, *supra* note 32, s 9(2)-(3). In Prince Edward Island, a transplant of non-regenerative tissue from a living, competent, adult donor is permitted only if authorized by an independent assessment committee: *PEI Act*, *supra* note 32, s 6(3).

in these statutes are distinct from, and apply in addition to, any requirements or other legal restrictions that might exist at common law or in other statutes (e.g. in child welfare legislation or statutes dealing with substitute decision making). The tissue donation provisions represent a deliberate decision by legislatures to impose specific requirements in this context, given the concerns surrounding donations by minors.[96] Donation in these cases is bound up with important and controversial questions about the extent to which either minors or their substitute decision makers should be allowed to consent to procedures that do not appear to be in the minor's best interests – but that rather, in the case of donation for transplants, serve the best interests of the recipient. These questions could arise in the context of tissue engineering in much the same way as in any donation of tissues or organs, and there are probably no unique concerns in this context. What is important is knowing whether the specialized provisions that have been designed to deal with these questions would in fact apply to donation of TE materials.

The second issue is the scope of consent and its effects, which relates to broader questions surrounding the donation and use of human tissue regarding the extent to which the terms of a consent allow a donor to control later uses of the tissue. For example, if it turns out that the tissue obtained is not, in fact, suitable for use in tissue engineering in the way that was contemplated, can it be used for another purpose? Can cells derived from the tissue be retained and used for other additional purposes? Can valid consent to donation be given even if the specific use to which the tissue will be put is not yet known? Most Canadian human tissue statutes have provisions regarding *living* donations that state that "if the tissue specified in the consent is not removed in the circumstances to which the consent relates, the consent is void."[97] This language does not address the situation in which the tissue is removed in the intended circumstances but later cannot be used for the purpose that was originally contemplated; as a result, that question is apparently left to be dealt with under the common law, notwithstanding the

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[96] See e.g. Nelson, *supra* note 46 at paras 25-28; Lainie Freedman Ross & J Richard Thistlethwaite Jr, "Minors as Living Solid-Organ Donors" (2008) 122:2 Pediatrics 454 at 454; *European Transplantation Protocol*, *supra* note 62, art 14.

[97] See e.g. *1971 Uniform Act*, *supra* note 39, s 3(4); *BC Act*, *supra* note 32, s 3(4); *SK Act*, *supra* note 32, s 4(4); *ON Act*, *supra* note 32, s 3(4); *NS Act (1989)*, *supra* note 32, s 4(4).

fact that the common law does not provide much clarity on this point.[98] By contrast, the most common wording regarding post-mortem donations states that if donated tissue cannot be used for the purposes specified in the consent, the tissue must be dealt with as if no consent was given.[99] This would apply whether it became apparent before or after the tissue was removed that it could not be used for its intended purpose: if before, then the tissue would not be removed, and if after, then most likely it would be disposed of. The wording also leaves open the possibility that consent could be given to more than one potential use, in which case the tissue would then be available for any of those purposes (e.g. for transplantation or, failing that, for scientific research). In this vein, the variation that appears in Prince Edward Island's statute, based on the 1990 Uniform Act, specifically provides that if tissue is removed pursuant to a consent under the Act and "cannot for any reason be implanted in a living body," it must be disposed of as if no consent had been given, "unless the donor has consented to the use of the tissue for therapeutic purposes, medical education or scientific research."[100] Alberta also has a general provision stating that no tissue, organ, or body donated under the Act shall be used "except for the purpose for which it was

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98 The extent of control that individuals have over material that has been removed from their bodies has received very little judicial consideration in Canada, leaving the state of the law uncertain. The law of battery protects individuals from incursions on their bodily integrity, including the initial removal of tissues or organs, but does not speak directly to individuals' rights to control these materials *once removed*, except perhaps in limited situations such as where the consent given is vitiated by a deliberate misrepresentation as to the reasons for removal. On the question of misrepresentation vitiating consent (though not specifically in relation to removed tissue), see e.g. *Gerula v Flores* (1995), 126 DLR (4th) 506 at 526-27, 56 ACWS (3d) 996, 83 OAC 128 (ONCA). Broader rights to control use after removal could have a contractual or proprietary basis, but that too is yet to be established in Canadian law. See e.g. *Piljak Estate v Abraham*, 2014 ONSC 2893 at paras 21-29, [2014] OJ No 2665 (QL), which held that excised human tissue could be considered personal property, but that tissue removed for diagnostic purposes was owned by the hospital, subject to a right of access by the patient.

99 See e.g. *1971 Uniform Act*, *supra* note 39, s 8; *BC Act*, *supra* note 32, s 8; *SK Act*, *supra* note 32, s 9; *ON Act*, *supra* note 32, s 8; *NS Act (1989)*, *supra* note 32, s 9. See also the similar provision in *MB Act*, *supra* note 32, s 5(1).

100 *PEI Act*, *supra* note 32, s 10(4). See also *1990 Uniform Act*, *supra* note 40, s 12(2).

donated."[101] It is notable, however, that none of these provisions resolve the question of how broad the scope of consent can be without that breadth undermining the legal and ethical validity of the consent – a live issue that arises in other contexts (such as biobanking) and remains unresolved.[102] The statutory provisions in human tissue legislation make only a very modest contribution to resolving this issue, so in this respect it will not have significant consequences if tissue engineering falls within their scope or not. Nevertheless, the issues surrounding the scope of consent will be important in this context and others, leaving this area in need of clarification, ideally through legislative reform.

C. Commercial dealings in human tissue

Most Canadian legislation on human tissue contains, in addition to consent provisions, a prohibition on the purchase or sale of human bodies, body parts, and tissues.[103] A typical provision states:

> 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.[104]

Note that the prohibition extends to any dealing in tissue, body, or body part, "directly or indirectly, for a valuable consideration," a phrase that would include paying or compensating donors.

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101 *AB Act*, *supra* note 32, s 3(3).

102 See e.g. Timothy Caulfield & Nola M Ries, "Consent, Privacy and Confidentiality in Longitudinal, Population Health Research: The Canadian Legal Context" (2004) 11 Health LJ (Supplement) 1 at 30-31; B Hofmann, "Broadening Consent – and Diluting Ethics?" (2009) 35:2 J Med Ethics 125.

103 The exceptions are the statutes of the Northwest Territories and Nunavut, which are very brief and contain only provisions on post-mortem donation: *NWT Act*, *supra* note 32; *Nu Act*, *supra* note 32. Federal law prohibits the purchase (and offering or advertising for purchase) of gametes, embryos, or other reproductive material, and the sale (or offering or advertising for sale) of embryos: *Assisted Human Reproduction Act*, SC 2004, c 2, s 7.

104 *SK Act*, *supra* note 32, s 11; *ON Act*, *supra* note 32, s 10; *NS Act (1989)*, *supra*

These provisions likely would apply to human organs or tissues donated for use in tissue engineering in most cases. Even if donated TE materials fell outside the definition of "tissue" in these statutes, as discussed above, they would probably be considered to be "part or parts" of a body. As Gilmour has noted, however, it is not clear to what extent material that is not included within the definition of "tissue" would fall within the meaning of "body parts."[105] This term, unlike "tissue," is not defined in any of the statutes. It is also unclear whether cells were intended to be included.[106] In addition, a few statutes expressly refer only to a tissue, organ, or body in these provisions.[107]

The other qualifier in almost all of these provisions is that they apply only to tissues, bodies, or body parts used for particular purposes, in most cases for transplantation, therapeutic purposes, medical education, or scientific research.[108] As noted above, it is not clear whether the use of human tissue in a tissue engineered product that is later implanted in another person would be considered a transplant. However, in most jurisdictions the listed purposes also include "therapeutic purposes," which is broad enough to cover tissue engineering. Again, it is the two most recently enacted statutes (in Alberta and Nova Scotia) that use narrower language, mentioning only "use in transplantation, [medical] education or scientific research."[109] Thus, it is unclear in these jurisdictions whether the ban on purchase and sale of

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note 32, s 11; *YK Act*, *supra* note 32, s 10. See also *1971 Uniform Act*, *supra* note 39, s 10. The *BC Act*, *supra* note 32, ss 10-11; *MB Act*, *supra* note 32, s 15; *NB Act*, *supra* note 32, s 10(1); *NL Act*, *supra* note 32, s 18 are virtually identical.

105 Gilmour, *supra* note 48 at 116-17.

106 LRCC, *supra* note 33 at 135: "That a jurisdiction in the United States has opted to exempt cell lines from its prohibition [on sale] raises a … query – whether the Uniform Act tissues sales ban is intended to apply to cellular or sub-cellular entities."

107 *AB Act*, *supra* note 32, s 3(2); *NS Act (2010)*, *supra* note 32, s 21(1) (not yet in force).

108 Only one jurisdiction (Prince Edward Island) has a broader prohibition that states simply: "No person shall buy, sell or otherwise for remuneration or financial benefit deal in, directly or indirectly, any tissue, body or body part" (*PEI Act*, *supra* note 32, s 15(1)).

109 *AB Act*, *supra* note 32, s 3(2) (including the word "medical"); *NS Act (2010)*, *supra* note 32, s 21(1) (not yet in force) (omitting the word "medical").

tissue would extend to material procured for use in tissue engineering outside of scientific research.

An even more difficult question is whether these provisions would apply to TE *products* that contain human tissue. As described above, a TE product contains live (usually human) cells that are designed to work together as a tissue or organ, along with the other components, which may include synthetic and/or human biological materials (a decellularized donor organ as a scaffold, for example). In some respects, it resembles a "natural" tissue or organ, but in others, it resembles a medical device or other manufactured product. Should these products be considered tissues or body parts within the meaning of these provisions, so that buying, selling, or dealing in these products would be prohibited? As discussed further below, the prohibition on commercial dealings in human tissue is intended to protect important ethical and public policy values. However, prohibiting the sale of TE products could be a significant disincentive to their development. Researchers and companies that develop other biotechnological products, like biologics[110] or medical devices, are able to sell those products and get a return on the investments they have made in research and development. Should those who develop tissue engineered products not be able to sell their products lawfully as well? Given the implications, it is important to consider whether this is, in fact, the effect of our current legislation, and if so, whether that is appropriate.

The first point to bear in mind is that some statutes explicitly exclude, from the prohibited dealings in human tissue, payment for services associated with a transplant. Thus, for example, Manitoba's statute specifies that a person does not contravene the prohibition

> if the person receives reimbursement for reasonable expenses incurred in, or remuneration for, participating in or performing a service necessarily incidental to the process whereby a transplant of human tissue is effected, or a human body or part or parts of a human body are prepared for use for therapeutic purposes or … scientific research.[111]

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[110] "Biologics," also known as "biological drugs," are products that fall within the definition of drugs but are made from biological material; these products are listed in Schedule D of Canada's *Food and Drugs Act*, RSC 1985, c F-27, and include insulin, vaccines ("immunizing agents"), monoclonal antibodies, and drugs obtained by recombinant DNA procedures.

[111] *MB Act*, *supra* note 32, s 15(2). See also *NB Act*, *supra* note 32, s 10(3).

Nova Scotia's new statute contains a similar exclusion, along with "reimbursement for reasonable expenses associated with the removal, transplantation, implantation, processing, preservation and quality control, and storage of organs or tissue."[112] Arguably, even in those jurisdictions where this exclusion is not specifically provided for, reimbursement or remuneration for services associated with a transplant or other therapeutic use of human tissue should not be considered a sale of or dealing in human tissue, even indirectly,[113] though it has been suggested that it is unclear to what extent reimbursement of expenses is prohibited by the typical Canadian provisions.[114]

Excluding such payments from the prohibition would allow transplant surgeons and other medical professionals involved in tissue engineering to be reimbursed for their work in making and implanting tissue engineered products. This might be the only type of compensation that would be at issue in cases where the product is custom-made for an individual patient, since the main value involved would be the professional services required to design, create, and implant the engineered tissue required by that individual. The more difficult scenario is where a tissue engineered product might be mass-produced and marketed in a way that is similar to other health products, such as medical devices. Obviously, professional services are still important in this case, not least for the implantation of the product, but the scenario would additionally involve transactions that closely resemble an ordinary commercial sale. If tissue engineered products were to be considered tissues or body parts to which the prohibition on purchase and sale applied, these transactions would violate the prohibition. There might also be grey areas in between, such as when products are custom-made but on a larger, more commercial scale.

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112 *NS Act (2010)*, *supra* note 32, s 21(2) (not yet in force).

113 See Bernard M Dickens, "Morals and Legal Markets in Transplantable Organs" (1994) 2 Health LJ 121 at 133.

114 M Sickand et al, "Reimbursing Live Organ Donors for Incurred Non-Medical Expenses: A Global Perspective on Policies and Programs" (2009) 9:12 Am J Transplant 2825 at 2828; see also *ibid* at 2826, 2836 n 22 (citing the language of the former Alberta statute, *Human Tissue Gift Act*, RSA 2000, c H-15, s 10 – "[n]o person shall buy, sell or otherwise deal in, directly or indirectly, for a valuable consideration, any tissue for a transplant …" – as "[a]n example of an unclear clause").

In order to resolve these questions of interpretation and to inform potential legislative reforms, the purposes of these provisions must be considered. What are the purposes of the prohibition on dealing in human tissue, and are they served by preventing the compensation of TE material donors or by disallowing the commercial sale of TE products? There is a huge literature on the purposes and merits of prohibitions on compensation of donors and sale of human biological material, but there has as yet been virtually no discussion of how these relate to tissue engineering.

The moral, ethical, and policy considerations underlying these provisions can be roughly grouped into three broad categories: (1) consequentialist arguments involving the potential effects of allowing compensation or sale, (2) rights-based or fairness arguments about the distribution of benefits from the use of human tissue, and (3) teleological or "Kantian" arguments about the morality of commodifying human biological material. In the first category, proponents of allowing compensation of tissue donors argue that the prohibition may be contributing to the chronic shortages of organs and tissues, to the detriment of those needing transplants.[115] Meanwhile, opponents argue that compensation would undermine altruistic donation, which could potentially *decrease* total numbers of donations.[116] Another argument is that allowing compensation would lead to the exploitation of donors, especially individuals who might be induced to consent due to financial need and, in so doing, accept risks associated with donation.[117] There is also the concern that if donors are unduly influenced by the prospect of receiving compensation, they may be disinclined to report disqualifying factors, thereby compromising the quality and safety of donated tissue.[118] These debates could apply equally to compensating donors of TE materials, but since they

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115 See e.g. LRCC, *supra* note 33 at 58; Michele Goodwin, "Empires of the Flesh: Tissue and Organ Taboos" (2008–2009) 60:5 Ala L Rev 1219; RR Kishore, "Human Organs, Scarcities, and Sale: Morality Revisited" (2005) 31:6 J Med Ethics 362 at 362; Hans J Schlitt, "Paid Non-related Living Organ Donation: Horn of Plenty or Pandora's Box?" (2002) 359:9310 Lancet 906 at 907.

116 See e.g. LRCC, *supra* note 33 at 58; Dickens, *supra* note 113 at 129; Ontario, Legislative Assembly, *Official Report of Debates (Hansard)*, 40th Parl, 2nd Sess, No 115 (20 March 2014) at 5989 (Deborah Matthews).

117 See e.g. LRCC, *supra* note 33 at 82; Gilmour, *supra* note 48 at 130-31; Dickens, *supra* note 113 at 125, 129; Schlitt, *supra* note 115 at 906-07.

118 See e.g. Canada, Commission of Inquiry on the Blood System in Canada, *Final Report*, vol 3 (Ottawa: Commission of Inquiry on the Blood System in Canada, 1997) at 1047 (Commissioner: Horace Krever); LRCC, *supra* note 33 at 82.

involve competing and unresolved claims, they do not suggest any particular conclusion about whether TE material donors should be caught within the scope of the prohibition.

In the second category of considerations, some argue that it is unfair that donors are the only participants in the transplantation process who cannot derive any financial benefit from their contributions to that process,[119] all the more so in situations where the commercialization of a product that was made possible by their donation is very profitable for other parties.[120] To the extent that these arguments are found to be compelling, they would tend to suggest that compensation of TE material donors should be allowed, particularly if TE products can be sold commercially. However, these arguments remain controversial and have not yet persuaded legislators to modify the prohibition. Concerns about the fair allocation of scarce resources tend to support retaining the prohibition, since many fear that allowing commercial dealings in human tissue could lead to access to organs and tissues that is based on individuals' ability to pay rather than on their medical need.[121] These concerns may be less acute in countries like Canada that have a public health care system, but they do not disappear altogether. They clearly could be relevant in the context of tissue engineering, though perhaps to a lesser extent for those TE products that come to be produced on a larger scale and become widely available, much like medical devices or other medical products (and unlike hearts, kidneys, or other organs where there is an absolute scarcity). In the case of more specialized, custom-made TE products devised as a last resort for individual patients, issues of absolute scarcity may still arise, however: "If, as with organs for transplantation, there are not enough cellular sources to meet the demand for any particular

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119 Nuffield Council on Bioethics, *Human Bodies: Donation for Medicine and Research* (London: Nuffield Council on Bioethics, 2011) at 120-21; Charles A Erin & John Harris, "An Ethical Market in Human Organs" (2003) 29:3 J Med Ethics 137 at 137.

120 See e.g. LD de Castro, "Commodification and Exploitation: Arguments in Favour of Compensated Organ Donation" (2003) 29:3 J Med Ethics 142 at 145; Kristy L Williams, "The Hidden Economy of HSC Transplantation Is Inconsistent with Prohibiting the Compensation of HSC Donors" (forthcoming in the Minnesota Journal of Law, Science & Technology) at 28-31, online: SSRN <http://ssrn.com/abstract=2431410>; Sarah Devaney, "Tissue Providers for Stem Cell Research: The Dispossessed" (2010) 2:2 Law, Innovation & Technology 165 at 179-81, 191.

121 See e.g. LRCC, *supra* note 33 at 58, 83; Schlitt, *supra* note 115 at 906-07.

tissue-engineered device, how does one decide who will get the products (on the basis of need, ability to pay)?"[122]

The third category of arguments applies both to compensation of donors and sale of human tissue. They suggest that such transactions are morally wrong because they undermine the dignity of human beings, commodify human life, and attempt to place a commercial value on priceless aspects of humanity.[123] If these arguments are persuasive, they suggest that the prohibition on compensating donors should be maintained, and there does not seem to be any reason why the prohibition should not apply to donors of TE material just as it applies to donors for traditional transplants or other purposes. The same could be said of prohibiting the sale of TE products, although this is perhaps less clear. It could be argued that the processing that is involved in tissue engineering, which may include the integration of synthetic or xenogeneic components, sufficiently distances the final product from its origin so that the sale of that product does not amount to selling and commodifying a human body or its parts.[124] This line of thinking would be analogous to the common law exception that allows human tissue to be owned and sold by those who transform it through their skill and effort.[125] The distinctive additional element in the context of tissue engineering is that the human tissue may also be combined with synthetic or non-human

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122 Bruce J Baum & David J Mooney, "The Impact of Tissue Engineering on Dentistry" (2000) 131:3 J Am Dent Assoc 309 at 317.

123 See e.g. LRCC, *supra* note 33 at 57, 59, 82-83; Dickens, *supra* note 113 at 130; Nuffield Council on Bioethics, *supra* note 119 at 120; Cynthia B Cohen, "Selling Bits and Pieces of Humans to Make Babies: The Gift of the Magi Revisited" (1999) 24:3 J Med Philos 288.

124 For example, Pirnay et al ask whether the processing involved in tissue engineering can "alter the moral status" of the human biological material that is used: Jean-Paul Pirnay et al, "Business Oriented EU Human Cell and Tissue Product Legislation Will Adversely Impact Member States' Health Care Systems" (2013) 14:4 Cell Tissue Bank 525 at 542. In a parallel line of reasoning, Gold suggests that transformation of body components may change the way we value them, giving priority to instrumental value over the intrinsic value of a human body: E Richard Gold, *Body Parts: Property Rights and the Ownership of Human Biological Materials* (Washington, DC: Georgetown University Press, 1996) at 13-14 ("the primary way in which we value [transformed body components] is instrumentally in terms of their effect on increasing human health" at 13).

125 See *Doodeward v Spence* (1908), 6 CLR 406, 15 ALR 105 (HCA); *R v Kelly*, [1998] 3 All ER 741, [1999] QB 621.

material. In Canada, it is a question of interpretation whether these factors would cause a TE product to fall outside the scope of the statutory prohibitions. In some other jurisdictions, an exclusion similar to the common law exception has been codified in legislation.[126]

It has been argued elsewhere that the buying and selling prohibitions may need to be revisited in the context of recent developments in biotechnology, which includes tissue engineering:

> These federal and state statutes effectively banning purchases of human organs were enacted in the mid-1980s in immediate response to the prospect of a widespread trade in these body parts to supply the growing demand for transplant material. The vision of a vendor selling livers and kidneys – or worse, a patient harvesting one of his or her own organs for money [–] clearly hovered over the debate leading to the passage of this legislation. But that vision imagined people selfdismantling for cash; it did not really allow for a trade in renewable body parts, especially cells.[127]

Tissue engineering is just one part of the much larger debate about whether legislative reform is needed in this area,[128] but as it grows in importance, greater attention will have to be paid to how the arguments for and against compensation and sale play out in this new environment. Amending Canadian statutes to provide an explicit exception for products created from human biological material through the application of skill and effort would be a first step towards clarifying the legal position in this country. However, as

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126 See e.g. the United Kingdom's *Human Tissue Act 2004*, c 30, s 32, which pro vides in subsection (9)(c) that "material which is the subject of property because of an application of human skill" is excluded from the prohibition on commercial dealings in controlled material.-

127 Hellman & Smith, *supra* note 30 at 17-13.

128 Witness, for example, the recent controversies surrounding compensation of bone marrow donors in the United States and paid donation of plasma in Ontario. See e.g. *Flynn v Holder*, 684 F (3d) 852 (9th Cir 2012); John A Robertson, "Paid Organ Donations and the Constitutionality of the National Organ Transplant Act" (2013) 40:2 Hastings Const LQ 221; Bill 178, *An Act to ensure that blood and blood constituents are donated freely*, 2nd Sess, 40th Leg, Ontario, 2014; Health Canada, *Round Table Discussion on Payment of Plasma Donors in Canada – Summary Report* (10 April 2013), online: HC <www.hc-sc.gc.ca/dhp-mps/consultation/biolog/plasma-eng.php>.

to TE materials and their donors, there do not seem to be compelling reasons to treat these any differently than other donations of human tissue, therefore any legislative reform to address compensation of donors would require a much wider and more extensive debate.

Conclusion

The legal position of tissue engineering under human tissue legislation is fraught with uncertainty, since the interpretation of key terms and concepts does not provide clear answers as to whether TE materials, products, and processes would be caught within their scope. TE materials will sometimes fall within the definition of "tissue," depending on the type of tissue, and this may vary among Canadian common law jurisdictions according to the specific wording of their provisions. The position of TE products is also uncertain; they may or may not be considered "tissue," since the original meaning of that term understood by legislators would not have included engineered tissue and, furthermore, its current ordinary meaning is inconclusive. TE products could, however, also be considered "body parts," and in that case would usually be caught by certain provisions, such as those prohibiting sale. The process of making and implanting a TE product could fall within the definition of a "transplant," but this is not clear and may vary according to the particular materials and processes used.

We can then put these definitions together to determine whether the provisions regarding consent to donation and payment of consideration would apply in the context of tissue engineering. The provisions regarding consent to post-mortem donation would probably apply to donation of TE materials, since they are usually comparatively broadly phrased to cover donation of material not just for transplantation but also for scientific research and therapeutic purposes. As noted, however, the narrower scope of these provisions in a couple of recent statutes may suggest that they would not apply to donation of TE materials in some cases. The provisions regarding consent to living donation, meanwhile, may or may not apply, since they generally deal only with donation of tissue for transplantation, and the definitions of tissue in the statutes exclude certain types of material (e.g., blood and sometimes skin).

Looking to the purposes of these provisions can be of assistance in interpreting them and considering where revisions might be needed. Generally, it would be consistent with the purposes of consent provisions to recognize that donation of TE material falls within their scope, and there would

be no significantly different considerations here as compared to other tissue donations. The provisions do not appear to substantially change the position that would exist at common law, except in relation to post-mortem donation and, to some extent, consent to donation by or on behalf of minors. Other issues that may arise – notably questions involving the scope of consent – are not unique to tissue engineering and, in any case, are not resolved by the statutory provisions that currently exist. Certainly this is an area where some clarification would be desirable, either through legislative amendment or through the development of the common law. Legislative reform would be preferable, given the uncertainty of these questions at common law and the time it might take for clarification to be obtained through litigation of the issues, but a consensus position that reconciles the diverse interests in this context may be difficult to formulate.

Finally, the prohibition on payment of consideration would probably apply to donated TE materials in most cases, since these may be "tissue" (unless the particular type of tissue falls into one of the excluded categories) or, alternatively, could be considered "body parts" to which the prohibition also applies. In most Canadian jurisdictions, the prohibition applies to material for transplants or therapeutic purposes in most cases, and therefore would be broad enough to capture TE materials. Consequentialist arguments for and against allowing compensation of donors are probably equally applicable to donation of TE materials, but these debates remain unresolved and do not provide much guidance as to whether the prohibition is appropriate in the context of tissue engineering. The most that can be said is that the arguments on both sides could apply to donation of TE materials, no more or less than to donation in other contexts. However, the argument that it is unfair that donors cannot benefit financially may be more compelling if or when TE products become commercially marketed and profitable. This would create a different dynamic in tissue engineering as compared to other transplantation scenarios, and could lend weight to arguments that donors should be allowed to be rewarded for their contributions to a successful product. Such an argument would likely be especially persuasive if the TE product made from the donors' material could itself be bought and sold.

The status of TE products is also uncertain. It is less important for custom-made TE products whether the prohibition on sale of tissue and body parts would apply to them, since it would usually be adequate to provide that those involved can be compensated for their services. In the case of TE products that are produced and marketed on a larger scale, however, the question of whether they can be lawfully bought and sold is not merely academic but could affect the viability of the products. It could be argued that

moral or philosophical concerns about commodifying the human body and its parts are less relevant where donated human material is transformed into a manufactured product (especially if that product is partly synthetic). This would suggest that allowing TE products to be bought and sold would not undermine human dignity in the way that buying or selling natural organs and tissues might. A legislative amendment, excluding from the prohibition any tissues that have been transformed through the application of human skill, would help to clarify the legal position for TE products.

This analysis has revealed that there is considerable uncertainty and variability in interpreting and applying human tissue statutes across Canadian common law jurisdictions. This is hardly an ideal environment for the development of a promising biotechnology; although the current legal framework may not actually present specific barriers to the evolution and adoption of tissue engineering, legal complexity and uncertainty can have a chilling effect on technological development, and those involved – patients, researchers, health care providers and institutions, and companies – could find themselves facing legal issues for which they are not prepared. As human tissue statutes are revisited and reformed across the country, it would be desirable to work toward greater consistency in key definitions, and to consider and clarify how the legislation will apply to tissue engineering and other new technologies.

Many of the questions raised here are not entirely new or unique to tissue engineering, though they will become more pressing as this technology begins to be more widely used. They form part of a larger ongoing debate about uses of human biological material in modern medical research and treatment. Given that the prevailing model of human tissue legislation in Canada was established almost half a century ago, a comprehensive review of our legal framework is long overdue. Canada is not alone in needing this review; while a jurisdiction like the United Kingdom that has enacted more comprehensive and modern human tissue legislation in recent years[129] would be in a better position to address the range of issues arising from emerging technologies, it is unlikely that any jurisdiction is fully prepared to deal with the new medical paradigm of engineered tissue. As that larger project moves forward, the specific questions raised here in relation to tissue engineering will require further attention, in Canada and elsewhere.

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[129] *Human Tissue Act 2004* (UK), *supra* note 126.

Table 1. Relevant Statutes (excerpts)

(a) Canadian provincial statutes (in force or pending entry into force)

	British Columbia *Human Tissue Gift Act*, RSBC 1996, c 211
Definition of tissue/organ; exclusions	**"tissue"** includes an organ, but does not include skin, bone, blood, blood constituent or other tissue that is replaceable by natural processes of repair; [s 1]
Definition of transplant/ transplantation	**"transplant"** means the removal of tissue from a human body, whether living or dead, and its implantation in a living human body; [s 1]
***Inter vivos* donation**	A person who has reached age 19, is mentally competent to consent, and is able to make a free and informed decision, may sign a consent to the removal at once from the person's body of the tissue specified in the consent and its implantation in the body of another living person. [s 3(1)]
Post-mortem donation	A person who has reached age 19 may consent … that the person's body or parts of it specified in the consent be used after the person's death for therapeutic purposes, medical education or scientific research. [s 4(1)] If a person of any age who has not given a consent under section 4 dies, or in the opinion of a medical practitioner is incapable of giving a consent by reason of injury or disease and the person's death is imminent, [the person's spouse, other relative, or person lawfully in possession of the body] … may consent … to the body or the parts of it specified in the consent being used after death for therapeutic purposes, medical education or scientific research. [s 5(1)]
Prohibition on sale	A person must not buy, sell or otherwise deal in, directly or indirectly, for a valuable consideration, any tissue for a transplant, or any body or parts other than blood or a blood constituent, for therapeutic purposes, medical education or scientific research. [s 10]

Table 1(a), continued

	Alberta *Human Tissue and Organ Donation Act*, SA 2006, c H-14.5
Definition of tissue/organ; exclusions	"organ" means a human organ whether whole or in sections, lobes or parts; [s 1(l)] "tissue" means human tissue excluding organs; [s 1(m)] This Act does not apply to the following: (a) by-products that are used for a purpose other than transplantation; (b) blood or blood constituents; (c) zygotes, oocytes, embryos, sperm, semen and ova. [s 2]
Definition of transplant/ transplanta-tion	"transplantation" means the operation of transferring tissue or an organ from a human donor to a human recipient. [s 1(n)]
***Inter vivos* donation**	An adult's by-products, tissue or organs from the adult's living body may be donated for transplantation (a) if the adult gives a consent … [s 5(1)] Subject to subsection (3), a minor's tissues or organs may be donated from the minor's living body for transplantation if the donation is approved by an independent assessment committee and a guardian gives a consent. [s 5(2)] Before approving a donation under this section, the independent assessment committee must ensure that … (b) if the minor is under 16 years of age, only regenerative tissue or organs are to be donated, [s 5(5)]
Post-mortem donation	A person's tissue, organs or body may be donated for transplantation, medical education or scientific research from his or her deceased body if a consent is given (a) where that person is an adult, by the adult, or (b) by a person in accordance with subsection (2). [s 4(1)]
Prohibition on sale	No person shall offer, give or receive any reward or benefit for any tissue, organ or body for use in transplantation, medical education or scientific research. [s 3(2)]

Table 1(a), continued

	Saskatchewan *Human Tissue Gift Act*, RSS 1978, c H-15
Definition of tissue/organ; exclusions	"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; [s 2(c)]
Definition of transplant/ transplantation	"transplant" as a noun means the removal of tissue from a human body, whether living or dead, and its implantation in a living human body, and in its other forms it has corresponding meanings; [s 2(d)]
***Inter vivos* donation**	Any person who has attained the age of majority, is mentally competent to consent, and is able to make a free and informed decision, may, in a writing signed by him, consent to the removal forthwith from his body of the tissue specified in the consent and its implantation in the body of another living person. [s 4(1)]
Post-mortem donation	Any person who has attained the age of majority may consent … that his body or the part or parts thereof specified in the consent be used after his death for therapeutic purposes, medical education or scientific research. [s 5(1)] Where a person of any age who has not given a consent under section 5 dies, or in the opinion of a physician is incapable of giving a consent by reason of injury or disease and his death is imminent … [the person's spouse, other relative, or person lawfully in possession of the body] … may consent … to the body or the part or parts thereof specified in the consent being used after death for therapeutic purposes, medical education or scientific research. [s 6(1)]
Prohibition on sale	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. [s 11]

Table 1(a), continued

	Manitoba *Human Tissue Gift Act*, CCSM c H180
Definition of tissue/organ; exclusions	**"non-regenerative tissue"** means tissue other than regenerative tissue; **"regenerative tissue"** means tissue that, after injury within or removal from the body of a living person, is replaced in the person's body by natural processes; **"tissue"** includes an organ, a part of a human body and a substance extracted from the human body or from a part of the human body, but does not include (a) spermatozoa or ova, or (b) an embryo or a fetus or a part of an embryo or a fetus, or (c) blood or blood constituent, or (d) a placenta; [s 1]
Definition of transplant/ transplantation	**"transplant"** means the removal of tissue from a human body, whether living or dead, and its implantation in another human body; **"therapeutic purposes"** includes transplant purposes; [s 1]
***Inter vivos* donation**	A person who is (a) 18 years of age or over; and (b) able to make a free and informed decision; may, subject to subsections (2), (3) and (4), consent to the removal of tissue specified in the consent, from the person's own body while living, for therapeutic purposes or for purposes of medical education or scientific research, as the consent may specify. [s 9(1)] A consent under subsection (1) for the removal and use of tissue for therapeutic purposes may be given in the case of both regenerative and non-regenerative tissue. [s 9(2)] A consent under subsection (1) for the removal and use of tissue for medical education or scientific research may be given only in the case of regenerative tissue. [s 9(3)] A person who is under the age of 18 years but not under the age of 16 years may, subject to subsection (2), consent to the transplant of tissue specified in the consent from the person's own body while living to the body of another living person. [s 10(1)] In the case of a person who is under the age of 16 years, tissue from the body of the person while living may be transplanted to the body of another living person where, but only where, (a) the person from whose body the tissue is to be removed consents thereto; (b) the tissue is regenerative tissue; (c) the proposed recipient of the tissue would likely die without the transplant; (d) the risk to the life and health of the person giving the consent is relatively insubstantial; (e) the person giving the consent is a member of the immediate family of the proposed recipient of the tissue;

Table 1(a), continued

	(Manitoba, continued)
***Inter vivos* donation (cont'd)**	(f) a parent or legal guardian of the person giving the consent consents to the transplant of the tissue; (g) the transplant is recommended by a physician who does not have and has never had an association with the proposed recipient of the tissue; and (h) the transplant is approved by the Court of Queen's Bench upon an application therefor. [s 11(1)]
Post-mortem donation	A person who is 18 years of age or over may direct that the whole body of the person, or any tissue or specified tissue from the body, may be used after the person's death for therapeutic purposes or for purposes of medical education or scientific research. [s 2(1)] Where a person who dies (a) has not made a direction under section 2; (b) has made a direction under section 2 that by virtue of clause 2(3)(b) cannot be acted upon; or (c) is under 16 years of age; a person described in subsection (1.1) may direct that the deceased person's whole body, or any tissue or specified tissue from the deceased person's body, may be used for therapeutic purposes or for purposes of medical education or scientific research. [s 3(1)] Where a physician is of the opinion that a person (a) who has not made a direction under section 2; or (b) who has made a direction under section 2 that by virtue of clause 2(3)(b) cannot be acted upon; is incapable of making a direction under section 2 and that the person's death is imminent and inevitable, a person described in subsection (3.1) may direct that the dying person's whole body, or any tissue or specified tissue from the dying person's body, may be used after death for therapeutic purposes or for purposes of medical education or scientific research. [s 3(3)]
Prohibition on sale	No person shall buy, sell, or otherwise deal in, directly or indirectly, for valuable consideration, any tissue for a transplant, or any body or parts of it other than blood or a blood constituent, for therapeutic purposes or for purposes of medical education or scientific research, and any such dealing is invalid as being contrary to public policy. [s 15(1)] No person contravenes subsection (1) if the person receives reimbursement for reasonable expenses incurred in, or remuneration for, participating in or performing a service necessarily incidental to the process whereby a transplant of human tissue is effected, or a human body or part or parts of a human body are prepared for use for therapeutic purposes or for purposes of medical education or scientific research. [s 15(2)] 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 carrying out a direction or complying with a consent under this Act. [s 15(4)]

Table 1(a), continued

	Ontario *Trillium Gift of Life Network Act*, RSO 1990, c H.20
Definition of tissue/organ; exclusions	"tissue" means a part of a living or dead human body and includes an organ but, unless otherwise prescribed by the Lieutenant Governor in Council, does not include bone marrow, spermatozoa, an ovum, an embryo, a foetus, blood or blood constituents; [s 1]
Definition of transplant/ transplantation	"transplant" as a noun means the removal of tissue from a human body, whether living or dead, and its implantation in a living human body, and in its other forms it has corresponding meanings; [s 1]
***Inter vivos* donation**	Any person who has attained the age of sixteen years, is mentally competent to consent, and is able to make a free and informed decision may in a writing signed by the person consent to the removal forthwith from his or her body of the tissue specified in the consent and its implantation in the body of another living person. [s 3(1)]
Post-mortem donation	Any person who has attained the age of sixteen years may consent … that the person's body or the part or parts thereof specified in the consent be used after the person's death for therapeutic purposes, medical education or scientific research. [s 4(1)] Where a person who has not given or cannot give a consent under section dies, or in the opinion of a physician is incapable of giving a consent by reason of injury or disease and the person's death is imminent, [the person's spouse, other relative, or person lawfully in possession of the body] … may consent … to the body or the part or parts thereof specified in the consent being used after death for therapeutic purposes, medical education or scientific research. [s 5(2)]
Prohibition on sale	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. [s 10]

Table 1(a), continued

	New Brunswick *Human Tissue Gift Act*, SNB 2004, c H-12.5
Definition of tissue/organ; exclusions	"tissue" includes an organ, but does not include any skin, bone, blood, blood constituent or other tissue that is replaceable by natural process of repair. [s 1]
Definition of transplant/ transplantation	"transplant" means the removal of tissue from a human body and its implantation in a living human body. [s 1]
***Inter vivos* donation**	Any person who has attained the age of 19 years, is mentally competent to consent, and is able to make a free and informed decision may consent in writing, signed by him or her, to the removal from his or her body of tissue specified in the consent and its implantation in the body of another living person. [s 3(1)]
Post-mortem donation	Any person who has attained the age of 19 years may consent … that his or her body or a specified part or parts of his or her body be used after his or her death for therapeutic purposes, or for the purposes of medical education or scientific research. [s 4(1)] Where a person of any age who has not given a consent under section 4 dies or, in the opinion of a medical practitioner, is incapable of giving a consent by reason of injury or disease and the person's death is imminent, [the person's spouse, other relative, or person lawfully in possession of the body] … may consent in writing, or orally in the presence of at least 2 witnesses, to the use of the body of the person or any specified part or parts of the body after death for therapeutic purposes, or for the purposes of medical education or scientific research. [s 5(1)]
Prohibition on sale	No person shall buy, sell or otherwise deal in, directly or indirectly, for a valuable consideration, any human tissue for a transplant or any human body or part of any human body, other than blood or a blood constituent, for therapeutic purposes or for the purposes of medical education or scientific research. [s 10(1)] No person commits an offence under subsection (2) where that person, for a valuable consideration, participates in, or performs a service necessarily incidental to, the process whereby a transplant of human tissue is effected or a human body or part of the body is prepared for use for therapeutic purposes or for the purposes of medical education or scientific research. [s 10(3)]

Table 1(a), continued

	Nova Scotia – *current* *Human Tissue Gift Act*, RSNS 1989, c 215
Definition of tissue/organ; exclusions	"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; [s 2(c)]
Definition of transplant/ transplantation	"transplant" means the removal of tissue from a human body, whether living or dead, and its implantation in a living human body; [s 2(d)]
***Inter vivos* donation**	Any person who (a) has attained the age of majority; (b) is mentally competent to consent; and (c) is able to make a free and informed decision, may in a writing signed by him consent to the removal forthwith from his body of the tissue specified in the consent and its implantation in the body of another living person. [s 4(1)]
Post-mortem donation	Any person who has attained the age of majority may consent … that his body or the part of parts thereof specified in the consent be used after his death for therapeutic purposes, medical education or scientific research. [s 5(1)] Where a person of any age, who has not given a consent under section 5, dies or, in the opinion of a physician, is incapable of giving a consent by reason of injury or disease and his death is imminent, [the person's spouse, other relative, or person lawfully in possession of the body] … may consent … to the body or the part or parts thereof specified in the consent being used after death for therapeutic purposes, medical education or scientific research. [s 6(2)]
Prohibition on sale	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. [s 11]

Table 1(a), continued

	Nova Scotia – *not yet in force* *Human Organ and Tissue Donation Act*, SNS 2010, c 36 **(not yet in force)**
Definition of tissue/organ; exclusions	"organ" means an organ, whether whole or in sections, lobes or parts; [s 2(r)] "tissue" means a functional group of human cells, excluding organs; [s 2(y)] This Act does not apply to (a) blood or blood constituents; or (b) zygotes, oocytes, embryos, sperm, semen or ova. [s 3]
Definition of transplant/ transplantation	"transplantation" means the operation of transferring organs or tissues from a donor, whether living or dead, to a living human recipient; [s 2 (aa)]
***Inter vivos* donation**	Any capable individual may, in a writing signed by the individual, consent to donate specific organs or tissues from the individual's living body. [s 6(1)] Where an individual lacks the capacity to give a valid consent and the individual has a valid personal directive setting out clear instructions or expressions of wishes that the individual would want to consent to living donation, a person authorized to give consent pursuant to clause 3(1)(b) or section 14 of the Personal Directives Act who gives voluntary and informed consent may, in a writing signed by that person, consent to the living donation of organs for transplantation on behalf of the individual. [s 7(1)] Where an individual lacks the capacity to give a valid consent, and the criteria set out in section 7 are not met, the individual's organs may not be donated from the individual's living body for transplantation without court authorization. [s 8(1)]
Post-mortem donation	Any individual who gives voluntary consent may consent … to donate the individual's body or specified organs or tissue after the individual's death for transplantation, education or scientific research. [s 11(1)] Where an individual of any age who has not given a consent under section 11 dies or, in the opinion of a physician, is incapable of giving a consent by reason of injury or disease and the individual's death is imminent, a substitute decision maker for the individual who, except in the case of a minor spouse or a minor parent, is of the age of majority and who gives voluntary consent, may consent … to donate the individual's body or specified organs or tissue after death for transplantation, education or scientific research. [s 12(2)]
Prohibition on sale	Subject to subsections (2) and (3), no person shall buy, sell or otherwise deal in, directly or indirectly, for valuable consideration, any human organs, tissue or body for use in transplantation, education or scientific research. [s 21(1)] Valuable consideration does not include reimbursement for reasonable expenses associated with the removal, transplantation, implantation, processing, preservation and quality control, and storage of organs or tissue or remuneration received for participating in or performing a service necessarily incidental to the process whereby a transplant of human tissue is effected or a human body or part of the body is prepared for use for therapeutic purposes or for the purpose of education or scientific research. [s 21(2)] Parties who conduct, fund or participate in research involving human organs or tissue donated under this Act may receive payments for products or processes developed for therapeutic purposes as a result of such scientific research. [s 21(3)]

Table 1(a), continued

	Prince Edward Island *Human Tissue Donation Act*, RSPEI 1988, c H-12.1
Definition of tissue/organ; exclusions	"tissue" means any part of a living or dead human body, but does not include (i) spermatozoa or ova, (ii) an embryo or fetus, or (iii) blood or blood constituents; [s 1(g)] "non-regenerative tissue" means tissue other than regenerative tissue; [s 1(c)] "regenerative tissue", in a living human body, means tissue that, on injury or removal, replaces itself; [s 1(e)]
Definition of transplant/ transplanta-tion	"transplant" means the removal of tissue from a human body, whether living or dead, and the implantation of the tissue in a living human body. [s 1(h)]
***Inter vivos* donation**	A person who is sixteen 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. [s 6(1)] 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 8 indicate that the transplant should be carried out. [s 6(3)] A person who is under sixteen 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. [s 7(1)] Notwithstanding subsection (1), bone marrow may be removed from a person who is under sixteen 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 person. [s 7(2)]
Post-mortem donation	A person who is sixteen 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 tissue or such tissue as may be specified in the consent from his or her body after death for the purpose of implanting the tissue in a living human body. [s 3(1)]

Table 1(a), continued

	(Prince Edward Island, continued)
Post-mortem donation (cont'd)	After the death of a person who has not given a consent under section 3, who is under sixteen 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 tissue or such tissue as may be 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. [s 5(1)] Notwithstanding anything in this Act, a person who is sixteen years of age or over and understands the nature and consequences of such a decision may consent to the use of his or her body or tissue from his or her body specified in the consent after death for therapeutic purposes, medical education or scientific research. [s 12]
Prohibition on sale	No person shall buy, sell or otherwise for remuneration or other financial benefit deal in, directly or indirectly, any tissue, body or body part. [s 15(1)]

Table 1(a), continued

	Newfoundland and Labrador *Human Tissue Act*, RSNL 1990, c H-15
Definition of tissue/organ; exclusions	"tissue" includes an organ, but does not include skin, bone, blood constituent or other tissue that is replaceable by natural processes of repair; [s 2(g)]
Definition of transplant/ transplantation	"transplant" as a noun means the removal of tissue from a human body, whether living or dead, and its implantation in a living human body, and in its other forms it has corresponding meanings; [s 2(h)]
Inter vivos **donation**	A person who has reached the age of 19 years, is mentally competent to consent, and is able to make a free and informed decision may, in writing signed by him or her, consent to the removal from his or her body of the tissue specified in the consent and its implantation in the body of another living person. [s 4(1)]
Post-mortem donation	A person who has reached the age of 19 years may consent … that his or her body or the part of the body specified in the consent be used after his or her death for therapeutic purposes, medical education or scientific research. [s 6(1)] Where a person of whatever age who has not given a consent under section 6 dies, or in the opinion of a legally qualified medical practitioner is incapable of giving a consent because of injury or disease and that person's death is imminent [the person's spouse, other relative, or person lawfully in possession of the body] … may consent … to the body or the part of the body specified in the consent being used after death for therapeutic purposes, medical education or scientific research. [s 7(1)]
Prohibition on sale	A person shall not buy, sell or otherwise deal in, directly or indirectly, for a valuable consideration, tissue for a transplant or a body or part of a body, other than blood or a blood constituent for therapeutic purposes, medical education or scientific research. [s 18]

Table 1(a), continued

	Yukon *Human Tissue Gift Act*, RSY 2002, c 117
Definition of tissue/organ; exclusions	"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; [s 1]
Definition of transplant/ transplantation	"transplant" means the removal of tissue from a human body, whether living or dead, and its implantation in a living human body; [s 1]
Inter vivos **donation**	Subject to section 3.1, any person may in a writing signed by them consent to the immediate removal forthwith from their body of the tissue specified in the consent and its implantation in the body of another living person. [s 3(1)]
Post-mortem donation	Any person who has reached the age of majority may consent … that the person's body or the part or parts thereof specified in the consent be used after their death for therapeutic purposes, medical education, or scientific research. [s 4(1)] If a person of any age who has not given a consent under section 4 dies, or in the opinion of a medical practitioner or nurse practitioner is incapable of giving a consent because of injury or disease and their death is imminent, [the person's spouse, other relative, or person lawfully in possession of the body] … may consent … to the body or the part or parts thereof specified in the consent being used after death for therapeutic purposes, medical education, or scientific research. [s 5(1)]
Prohibition on sale	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. [s 10]

Table 1(a), continued

	Northwest Territories *Human Tissue Act*, RSNWT 1988, c H-6	**Nunavut** *Human Tissue Act*, RSNWT (Nu) 1988, c H-6
Definition of tissue/organ; exclusions		
Definition of transplant/ transplantation		
***Inter vivos* donation**		
Post-mortem donation	A person who is 19 years of age or over may … direct that his or her body or any specified part or parts of it be used after his or her death for (c) therapeutic purposes, (d) purposes of medical education, or (e) purposes of medical research. [s 1(1)] Where a person, other than a person who has given a direction under section 1, dies [the person's spouse, other relative, or person lawfully in possession of the body] … may direct that the body or any specified part or parts of the body may be used for (f) therapeutic purposes, (g) purposes of medical education, or (h) purposes of medical research. [s 2(2)]	A person who is 19 years of age or over may … direct that his or her body or any specified part or parts of it be used after his or her death for (c) therapeutic purposes, (d) purposes of medical education, or (e) purposes of medical research. [s 1(1)] Where a person, other than a person who has given a direction under section 1, dies [the person's spouse, other relative, or person lawfully in possession of the body] … may direct that the body or any specified part or parts of the body may be used for (f) therapeutic purposes, (g) purposes of medical education, or (h) purposes of medical research. [s 2(2)]
Prohibition on sale		

(b) Uniform Acts

	1965 Uniform ***Human Tissue Act***	**1971 Uniform** ***Human Tissue Gift Act***
Definition of tissue/organ; exclusions		"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; [s 1(c)]
Definition of transplant/ transplantation		"transplant" as a noun means the removal of tissue from a human body, whether living or dead, and its implantation in a living human body, and in its other forms it has corresponding meanings; [s 1(d)]
***Inter vivos* donation**		Any person who has attained the age of majority, is mentally competent to consent, and is able to make a free and informed decision may in a writing signed by him consent to the removal forthwith from his body of the tissue specified in the consent and its implantation in the body of another living person. [s 3(1)]
Post-mortem donation	A person eighteen years of age or over may … direct that his body or any specified part or parts thereof be used after his death for therapeutic purposes or for purposes of medical education or for purposes of medical research. [s 1(1)] Where a person other than a person who has made a direction under section 1 dies, [his spouse, other relative, or person lawfully in possession of the body] may direct that the body or any specified part or parts thereof may be used for therapeutic purposes or for purposes of medical education or for purposes of medical research. [s 2(1)]	Any person who has attained the age of majority may consent … that his body or the part or parts thereof specified in the consent be used after his death for therapeutic purposes, medical education or scientific research. [s 4(1)] Where a person who has not given a consent under section 4 dies, or in the opinion of a physician is incapable of giving a consent by reason of injury or disease and his death is imminent, [his spouse, other relative, or person lawfully in possession of the body] may consent … to the body or the part or parts thereof specified in the consent being used after death for therapeutic purposes, medical education or scientific research. [s 5(1)]
Prohibition on sale		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 purpose, medical education or scientific research, and any such dealing is invalid as being contrary to public policy. [s 10]

Table 1(b), continued

	1990 Uniform *Human Tissue Donation Act*
Definition of tissue/organ; exclusions	"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. [s 1] "non-regenerative tissue" means tissue other than regenerative tissue; [s 1] "regenerative tissue", in a living human body, means tissue that, on injury or removal, replaces itself; [s 1]
Definition of transplant/ transplantation	"transplant" means the removal of tissue from a human body and the implantation of the tissue in the living human body of another. [s 1]
***Inter vivos* donation**	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. [s 5(1)] 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. [s 5(3)] 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. [s 6(1)] 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. [s 6(2)] 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. [s 6(3)] 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. [s 6(4)]

Table 1(b), continued

	(1990 Uniform *Human Tissue Donation Act*, continued)
Post-mortem donation	A person who is [16] year 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. [s 3(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). [s 4(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. [s 12(1)]
Prohibition on sale	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. [s 15(1)]