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978-0-521-70954-5 - Human Tissue in Transplantation and Research: A Model Legal and Ethical Donation Framework

David Price

Excerpt

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Introduction

This is a book about policy, aimed at professionals, academics and strategists. It aspires to map out a broad, transferable contemporary ‘model’ framework to govern human organ and tissue donation for transplantation and research. It is my contention that existing systems, whilst well-meaning and considered, often serve – on account of deficiencies and anomalies – to defeat the very objectives which they have set out to achieve; to the detriment of patients, subjects and society in general. Deconstruction is consequently crucial, especially in the light of the controversies surrounding such activities and the ever-increasing challenges presented by them. Of course, differences of view are inevitable in spheres touching so closely upon intimate areas of human activity, but this is a field riven not only by divergence of perspective and emphasis, but also by misconception. These are areas of policy which have invariably developed in pragmatic, customary fashion, being science-, technology- and practice (and hence largely demand-) driven, partly by dint of necessity, but which require in the modern age a sure footing which can survive critical scrutiny.¹ To be sure, legal and ethical principles will inevitably operate in a ‘fuzzy’ way in the real world, but there is nonetheless a need for clear concepts to cut through the increasing ‘noise’. The challenges here are great, but so are the prizes. The need for human organs and tissues is one of the hallmarks of contemporary society and the gateway to interventions of incalculable benefit to mankind, either as forms of therapy or as precursors to the development of preventive, therapeutic and diagnostic strategies.

Whilst there are an increasing number of published works touching on the topics dealt with in this book, and including ethical analyses of the central issues, there are few which attempt to develop a modal framework

¹ In relation to post-mortem practice, the system was said to have operated over the previous thirty years on a ‘custom and practice’ basis; see Chief Medical Officer, *The Removal, Retention and Use of Human Organs and Tissue from Post-mortem Examination*, 2001, at www.doh.gov.uk/orgretentionadvice/orgretcmoadv2.htm. See also V.S. Leith, ‘Consent and nothing but consent? The organ retention scandal’ (2007) 29(7) *Sociology of Health & Illness* 1023 at 1032.

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which cashes out these legal and ethical ‘conclusions’ and translate them into a workable and coherent form able to adequately guide practice. Indeed my own previous book in this sphere fell short of a wholly normative enterprise, being principally analytical in parts.² In this current work some of the areas of detailed discussion in that earlier work are omitted, and it is intended that the present volume ‘build’ upon the earlier one in normative terms.

An ethico-legal skeleton

The book seeks to knit together ethical and legal perspectives relating in particular to autonomy, consent, justice and property. The issue of consent has come to dominate contemporary debates with respect to the donation of human material, albeit without any shared or unifying vision as to what constitutes ‘consent’, or what interests consent is designed to protect. As Brazier notes, ‘Consent is such a simple word’ and is the more beguiling and elusive for that.³ Moreover, it has historically by no means been the norm. The perceived or actual failure to obtain proper consent has been at the heart of many controversies in the transplantation and research spheres, most visibly in the post-mortem organ and tissue retention scandals which have lately arisen around the globe, and in particular in the UK,⁴ and in other analogous

² D. Price, *Legal and Ethical Aspects of Organ Transplantation* (Cambridge University Press, 2000) [Price, *Legal and Ethical Aspects*].

³ M. Brazier, ‘Organ retention and return: Problems of consent’ (2003) 29 *Journal of Medical Ethics* 30 at 30.

⁴ See Bristol Royal Infirmary Inquiry Interim Report, 2001, at www.bristol-inquiry.org.uk/interim_report/index.htm (hearts of 170 dead children retained); Redfern Inquiry into the Liverpool Children’s (Alder Hey) NHS Trust, at www.rlcinquiry.org.uk/download/index.htm (organs of 3,500 children retained); HM Inspector of Anatomy, Investigation of events that followed the death of Cyril Mark Isaacs, May 2003, at www.dohc.gov.uk/cmo/isaccsreport/ (24,000 brains in storage in Britain in 2003). A Census in England in 2000 revealed that 54,300 organs, body parts, still-births or foetuses were held following post-mortem examinations carried out since 1970; see Chief Medical Officer, *Report of a Census of Organs and Tissues Retained by Pathology Services in England*, London: The Stationery Office, 2001. See also the Scottish Report, *Final Report of the Independent Review Group on Retention of Organs at Post-Mortem in Scotland*, 2000, and the Northern Ireland, Organ Retention Report, Belfast, 2001. Abroad, see the Madden Report on Post Mortem Practices and Procedures (2006) in Ireland, at www.dohc.ie/publications/pdf/madden.pdf; D. Tilmann, ‘German prosecutor investigates the removal of dead babies’ organs’ (2000) 320 *British Medical Journal* 77; *Organs Retained at Autopsy*, Advice of the Australian Health Ethics Committee, NHMRC, 2001, Commonwealth of Australia, Canberra; U. Jensen, ‘Property, rights, and the body: The Danish context’ in H. Ten Have, J. Welie and S. Spicker (eds.), *Ownership of the Human Body* (Dordrecht: Kluwer Academic Publishers, 1998), 173 at 174 (retention of brains of thousands of psychiatric patients at Aarhus).

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contexts.⁵ The perceived benefits of such activities have often led to practice blinkered to wider ethical perspectives, and the possibility of profit from human body parts has in some other instances been the motivation for the witting or reckless failure to obtain necessary consent for removal and use.⁶ Human bodily resources are increasingly acquiring value and utility either in themselves or as the basis for the development of further biological materials, or merely as sources of biological or genomic information *per se*. This 'value' enhances the vulnerability and prospectability of our bodies and the need for donor, and indeed often community, interests to be properly protected.⁷ By virtue of their nexus to 'self', the retention and use of human material raises profound issues pertaining to the relationship between bodies and personal identity, and generates fundamental questions about who we are and what sort of society we wish to live in.

There is an ever-present tension between the imperative to generate sufficient body parts for societally and ethically crucial goods and the rights of individuals or their families to control the use of such materials. It is argued here that the need to satisfy the relevant demands for body parts cannot entirely justify a donation policy in itself, although it is recognised that a failure to satisfy the needs (of patients and professionals, respectively) is not only a major moral deficiency *per se* but will invariably fuel more and more extreme means of dealing with the deficit; which, in turn, produces a further policy dimension. Whilst a requirement for consent is becoming ubiquitous, different notions of 'consent' prevail in

⁵ Body parts from deceased former workers at nuclear power plants have allegedly been non-consensually retained and tested in both the UK and the US (Los Alamos) over many years; see O. Dyer, 'Inquiry will study claims that Sellafield workers' body parts were removed without families' consent' (2007) 334 *British Medical Journal* 868; *The Times*, 18 April 2007, 19 April 2007, 20 April 2007 and 27 April 2007; L. Andrews and D. Nelkin, *Body Bazaar: The Market for Human Tissue in the Biotechnology Age* (New York: Crown Publishers, 2001), p. 20 [Andrews and Nelkin, *Body Bazaar*]. Body parts have frequently been merely 'retained' post-mortem; see, e.g., C. Abraham, *Possessing Genius: The Bizarre Odyssey of Einstein's Brain* (Cambridge: Icon Books, 2001); N. Stafford, 'German medical schools respond to claim they have stored Namibian skulls from colonial times' (2008) 337 *British Medical Journal* 1047.

⁶ Of course, the exploits of graverobbers and others supplying anatomy schools with whole corpses for profit were the catalyst for the passing of the anatomy legislation in the early nineteenth century. For a contemporary analogue, see <http://news.bbc.co.uk/1/hi/world/africa/3039513.stm>.

⁷ The interests of indigenous populations such as Native American Indians and Aborigines are being increasingly protected, e.g. Native American Graves Protection and Repatriation Act 1990 and the Aboriginal Heritage Act 1988 (South Australia) and the Heritage Conservation Act 1991 (Northern Territory). See R. Tsosie, 'Native American genetic resources and the concept of cultural harm' (2007) 35(3) *Journal of Law, Medicine and Ethics* 396.

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official policies, and widely varying laws, practices and perceptions exist around the world. In particular, presumed consent is a concept which, despite being a widespread legal phenomenon, continues to draw trenchant criticism from various quarters.

The relationship between 'donation' and the allocation or permitted use(s) of organs and tissues to patients or users is a crucial one. Especially contentious is the extent to which the latter should be controlled by donors, professionals, or by society, with issues of justice, equity and utility juxtaposed against individual rights of disposition and control. This again introduces issues pertaining to the relationship between the donor and his or her (separated) body parts. The US President's Council on Bioethics has stated that 'In dramatic ways, the question of who, if anyone, *owns* a part of the body that is brought out of the body's interior and into the light of the laboratory or clinic has become a meaningful one'.⁸ The jurisprudence in common law jurisdictions has been loathe to recognise the existence of private property rights in human materials, especially in tissue sources themselves.⁹ But as Magnusson observes 'To hold categorically that human tissue cannot be the subject of proprietary rights suggests that, in the absence of specific empowering legislation, such tissue could not be gifted, bought or sold, stolen or converted, bailed or patented. In a rapidly developing biotechnological age, a legal vacuum such as this would be very curious indeed.'¹⁰ A lack of a network of property rights emanating initially from the tissue source is unsustainable in the context of a true 'donation' scheme. This by no means necessarily implies a right to trade in such material, however. This is a separate and further matter beyond rights of exclusion, use and transfer *per se*.

There is a perceived conflict between sufficiently protecting donors' interests and the smooth and efficient running of the various services dependent upon the human material emanating from them. This is especially patent in the US jurisprudence relating to the use of human tissue for research but similar tensions can be seen in relation to the secondary use of tissue from living individuals for research across the board, e.g. archived pathology samples, newborn screening cards, etc.¹¹

⁸ President's Council on Bioethics, *On the Body and Transplantation: Philosophical and Legal Context*, Staff Discussion Paper, 2006/7 at 8–9.

⁹ The decision in *Yearworth v. North Bristol NHS Trust* [2009] EWCA Civ 37 (4 February 2009) is a very welcome recent exception.

¹⁰ R. Magnusson, 'Proprietary rights in human tissue', in N. Palmer and E. McKendrick (eds.), *Interests in Goods* (London: Lloyds of London Press, 1993) 237 at 237.

¹¹ Research on pathological specimens has led to important discoveries such as helicobacter pylori bacteria as the cause of peptic ulcers. The distinction between further pathological examination and 'research' is itself blurred. Their conflation has historically been

The post-mortem organ retention scandals in the UK and elsewhere likewise generated the perception of professional and public interests being at odds,¹² but this must be seen in the light of either the professional failure to adhere to contemporary ethical or legal standards or the failure of the prevailing standards to comport with appropriate present-day values.¹³ Whilst in many situations there was a failure to comply with the mandates of the law, in others both law and existing ethical standards supported the retention and subsequent use of tissues removed at post-mortem for various purposes, including research, without proper consent.¹⁴ There was apparently no evidence of any general unwillingness to allow such (research) practices, however, where consent was first obtained. Subject to some necessary accommodations, conflict is not inevitable if openness and transparency exist and a shared, partnership approach is adopted. As the Retained Organs Commission (ROC) remarked ‘If adequate ethical principles govern organ retention enforced by effective laws and regulations, neither medicine nor science should suffer.’¹⁵

Ambit

This book focuses on the use of human material for transplantation and research rather than for ‘treatment’ purposes more broadly. It thus

considered good practice and is to some degree unavoidable. The ability to look back at retained autopsy material has helped to define vCJD, AIDS and the causes of cot death, cerebral palsy and epilepsy.

¹² The majority apparently support the retention of organs and tissue for research post-mortem provided informed consent had been obtained; see Retained Organs Commission, *Qualitative Research to Explore Public Perceptions Regarding Retention of Organs and Tissue for Medical Practice, Teaching and Research*, Research Report, London, 2002.

¹³ Whilst in some instances such practices were lawful, ‘staying within the law is not enough – practice needs to reflect what the community regards as acceptable in the environment in which autopsies are now performed’; see Australian Health Ministers’ Advisory Council, *The National Code of Ethical Autopsy Practice*, Australian Department of Human Services, 2002 at 5.

¹⁴ The Chief Medical Officer’s Report remarked that ‘The law governing organ retention is unclear, ambiguous and ageing. It was poorly understood and, as a result, not well applied’; see Chief Medical Officer, *The Removal, Retention and Use of Human Organs and Tissue from Post-Mortem Examinations*, Stationery Office, London, 2001. By contrast, in various jurisdictions, including many Australian States and Territories, consent for hospital post-mortem examination was by law explicitly stated to be sufficient to permit the retention and use of body parts for transplantation or research, e.g. section 28, *Transplantation and Anatomy Act 1983* (South Australia). See also *Report Into the Retention of Body Parts After Post-Mortems*, Solicitor General South Australia, August 2001, Adelaide; and *Interim Report into the Retention of Tissue and Organs Following Post-Mortems in NSW*, New South Wales Health Department, February 2001, Sydney.

¹⁵ Retained Organs Commission, *Remembering the Past, Looking to the Future*, NHS, 2004, para.1.19.

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excludes the use of substances of human origin as aspects of medicinal products or *in-vitro* diagnostic devices. The rationale for such exclusion hangs on the need to focus attention on core common issues and avoid the need to consider discrete and specific areas of regulatory activity.¹⁶ The use of organs and tissues from animals for transplantation ('xenotransplantation') or research are not considered here either, in view of the broader issues they raise and the fact that the former is not yet generally even considered to be an experimental therapy (principally on account of issues relating to physiology, disease transmission and public health).¹⁷ They require detailed scrutiny in their own right which cannot be afforded here.

At first glance, to focus solely upon transplantation and research may seem arbitrary and selective. Human biological materials have a plethora of other uses, such as forensic purposes, education and training, cadaver identification, infertility treatment, etc. However, quite apart from constraints of space, both of these chosen activities may be broadly seen as part of the 'therapeutic endeavour'. Although the UK Organ Donation Taskforce Supplement Report remarked as regards transplantation that 'Rarely in health is there such a direct and rapid link between the action to address a problem and its resolution to save lives',¹⁸ medical research has been appropriately dubbed 'indirectly therapeutic',¹⁹ focusing on better and more accurate diagnoses, development of new therapies, better understanding of disease, etc. Sanner's research found that both autopsy and anatomical dissection are regarded by individuals as beneficent activities in the longer term, although not regarded as altruistic acts in the same way as organ donation, which has a direct immediate, potentially life-saving consequence.²⁰

Moreover, they are not discrete spheres. Organs and tissue not suitable for transplantation – which takes priority – may be used instead for

¹⁶ Medicines are governed by a discrete regulatory regime under the Medicines Act 1968 and *in-vitro* medical devices by the Medical Devices Regulations 2002 SI 2002 No. 618 as amended.

¹⁷ It is anticipated that xenotransplant trials will be initiated in the UK in the near future. Lord Winston has announced that pig organs could be available for transplantation within ten years; see *The Times*, 7 November 2008. See also www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_06307. See generally S. McLean and L. Williamson, 'The demise of UKXIRA and the regulation of solid-organ xenotransplantation in the UK' (2008) 34 *Journal of Medical Ethics* 373.

¹⁸ *Organs for Transplant: A Report from the Organ Donation Taskforce: Supplement Report*, Department of Health, 2008 at 6 [Supplement Report].

¹⁹ Nuffield Council on Bioethics Working Party Report, *Human Tissue: Ethical and Legal Issues*, 1995, Nuffield Council, at para. 6 [Nuffield Council].

²⁰ M. Sanner, 'People's attitudes and reactions to organ donation' (2006) 11(2) *Mortality* 133 at 143.

research, e.g. livers converted to liver hepatocytes for drug function tests, etc. Transplant organ and tissue donor retrieval teams work alongside research tissue retrieval teams in many healthcare institutions.²¹ Moreover, research on human tissue is the very source of many developments in transplantation therapies.²² Most importantly, though, the ethical and conceptual underpinnings have very significant commonality, so that whilst they are usually considered discretely the discussion is better informed by considering issues as between them. Indeed, this work centres on *donation* policy rather than broader aspects of either transplantation or research.²³ This is not, however, to deny the very significant contemporary importance of some of these other matters, e.g. the treatment of the potential donor prior to death and non-heart-beating donation, etc.²⁴

Replacement therapies

At present there are generally no substitute ‘permanent’ therapies to transplantation available for end-stage organ failure. Research is continuing apace to develop stem cell and tissue engineering techniques to ‘grow’ tissues for replacement,²⁵ either from pluripotent/totipotent stem cells or from adult cells.²⁶ Whilst the use of human totipotent embryonic stem cells as a source for transplantation is being investigated to replace diseased or damaged tissue,²⁷ it is estimated that in order to avoid graft rejection from poor tissue (HLA) compatibility, a bank of at

²¹ Some forms of tissue to be used for transplantation are actually removed by pathologists at post-mortem examination.
²² Although it has been alleged that research in Britain is being unnecessarily hindered by bureaucracy, including Lord Winston’s research on growing replacement organs inside genetically modified pigs (which was allegedly moved to the US as a result); see ‘Organ research being hindered by red tape, says professor’, *Guardian*, 11 September 2007.
²³ My previous book considered transplantation in slightly broader fashion. See, e.g., Price, *Legal and Ethical Aspects*, chapters 4, 5 and 10.
²⁴ See *Organs for Transplant: A Report from the Organ Donation Taskforce*, Department of Health, 2008, at 33 [*Organs for Transplant*].
²⁵ EU Regulation (EC) No. 1394/2007 governing tissue engineered products which have potential therapeutic application to humans has been issued. Currently some of these products fall outside the definition of either medicinal products or medical devices.
²⁶ Such as the use of artificial livers to provide pieces of liver to repair damaged livers and potentially entire liver transplants (see ‘British scientists grow human liver in a laboratory’, at www.thisislondon.co.uk/news/article-23372701-details/British+scientists+grow). Work is also ongoing to re-grow damaged bones and cartilage using patients’ stem cells; see *The Times*, 18 February 2008.
²⁷ In somatic cell nuclear transfer a nucleus from an adult cell is inserted into a recipient egg cell from which its own nucleus has been removed. At present, however, its efficiency for stem cell derivation is very low.

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least 150 HLA-typed human embryonic stem cells would be required in order to generate an acceptable match for the large majority of patients.²⁸ Cloned embryos created by using cell nuclear transfer, on the other hand, are likely to be immunologically compatible with the donor. However, quite apart from the scientific challenges, research using embryos (which will thereafter be destroyed) is highly controversial, and under attack from the Roman Catholic Church in particular.²⁹ The news that it may be feasible to generate induced pluripotent stem cells from skin cells rather than embryos is therefore highly significant.³⁰ However, much of this research is still at a very early, unrealised stage, and the potential of such therapies has been subject to much overblown hype and misinformation.³¹ In theory, in so far as these are 'master' cells, stem cells could be caused to differentiate into any of the tissues or organs of the body. They are also self-renewing, so that the entire demand for such materials could be theoretically met. However, due to their anatomical and functional complexity renewing human organs is only a longer-term potential reality. Nonetheless, stem cells can already be induced to form the insulin-producing cells of the pancreas and it is anticipated that heart valves and muscles might soon be grown by such methods.³² Patients' stem cells may also be used to re-grow damaged tissue where a scaffold can be formed using donated tissue.³³ A patient recently had a windpipe transplanted in Barcelona which had been constructed using the patient's own re-engineered bone marrow stem cells.³⁴

²⁸ C. Taylor *et al.*, 'Banking on human embryonic stem cells: Estimating the number of donor cell lines needed for HLA matching' (2005) 366 *The Lancet* 2019.

²⁹ See *The Times*, 26 November 2007. In the US, embryonic stem cells have apparently been produced by stimulating unfertilised eggs, see www.medicalnewstoday.com/articles/75700.php. Embryonic stem cells have also been produced in mice without destroying embryos in the process.

³⁰ See *The Times*, 21 November 2007 and 1 December 2007.

³¹ The scandal surrounding Dr Hwang's false claims regarding the creation of human embryonic stem cell lines from somatic cell nuclear transfer in South Korea led to much re-appraisal and even a US Congressional Hearing. See <http://olpa.od.nih.gov/hearings/109/session2/testimonies/koreaclone2.asp>.

³² See *The Times*, 11 April and 3 September 2007. Whilst the growth of whole replacement organs still remains a distant vision, injections of stem cells into organs may, with nature doing the rest, allow repair *in situ*, e.g. heart attack patients' own stem cells being injected to repair organ damage; see *The Times*, 8 November 2006. President Obama has recently lifted restrictions upon federal funding of the therapeutic use of stem cells.

³³ Tissue may also be created from existing material. Bladders, cartilage and skin (from foetal skin tissue) have already been grown, the latter for the use of paediatric patients with burns; see J. Hohlfield *et al.*, 'Tissue engineered fetal skin constructs for pediatric burns' (2005) 366 *The Lancet* 840.

³⁴ See *The Times*, 19 November 2008.

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Despite the overwhelming attention of clinicians, the media and politicians upon *organ* transplantation, tissue transplantation occurs on an even larger scale, although deceased patients are assessed less routinely. In some instances, these are equally as ‘life-saving’ as some forms of organ transplantation, e.g. heart valve replacement procedures, although they are generally life-enhancing rather than life-saving.³⁵ Heart valves, tendons, cartilage and bone, skin, corneas and other tissues have been routinely transplanted for many years – some, such as skin and corneas, even longer than organs. Tissue donors need not always be as healthy as organ donors, and in so far as such tissue is avascular, the compatibility of donor and recipient is less important. There is also typically less urgency with the transplantation of tissue, such as skin, corneas and tendons, than with organs, as there is no need for the heart to be still beating at retrieval, and thus continued ventilation is unnecessary (retrieval may take place several hours or even longer after a death has been certified).³⁶ There are specific psychological issues which attach to certain types of tissue transplantation. For instance, *composite* tissue, such as hand and face, transplants generate particular issues relating to ‘self’ and personal identity. Isabelle Dinoire, the first face transplant patient, has spoken of the ‘other woman inside her’, and the difficulty of living with her new ‘features’.³⁷ This book does not consider the specific issues raised here for reasons of space.³⁸

As with much tissue that is used for research, tissue intended for transplantation is typically ‘banked’, where it is cleaned, sterilised and tested for certain types of infection, by contrast with most forms of organ transplantation where any substantial storage period remains elusive. It is this longer-term storage of tissue and the routine intermediate processing of

³⁵ This alters the ethical calculus, as health risks generated by immunosuppression therapy need to be outweighed by the benefits which attach exclusively to improved quality of life.

³⁶ For more detail, see B. Kent, ‘Tissue donation and the attitudes of health care professionals’, in M. Sque and S. Payne (eds.), *Organ and Tissue Donation: An Evidence Base for Practice* (Maidenhead: Open University Press, 2007) 102 [Sque and Payne (eds.), *Organ and Tissue Donation*]. Organs are also removed from non-heart-beating donors for transplantation in many instances, although removal must take place very soon after pronouncement of death.

³⁷ ‘Face transplant “made me human again”’, *The Times*, 7 July 2007; ‘Face patient tells of “the woman inside her”’, *The Times*, 1 October 2007. See generally R. Hartman, ‘Face value: Challenges of transplant technology’ (2005) 31 *American Journal of Law and Medicine* 7.

³⁸ See D. Dickenson and G. Widdershoven, ‘Ethical issues in limb transplants’ (2001) 15 *Bioethics* 110. The first hand transplant was performed in Lyon, France, but was removed in 2001 as the patient could not psychologically adjust to it and stopped taking his immunosuppression.

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such material (and potential vending of such end-products) which distinguish it from organ transplantation. Tissue banks are proliferating. As well as specific disease-based banks and registries (e.g. the UK Children's Cancer Study Group tumour bank; the Canavan disease registry, etc.) and small hospital-based collections typically linked to one type of tissue (such as bone or eye banks), much more extensive multi-tissue banks supplying research as well as therapeutic needs have come into being, at arm's length from treatment providers.³⁹ In addition to sperm and brain banks, we have witnessed the recent growth of public and private peripheral cord blood banks containing stem cells able to be used in the treatment of leukaemias and anaemias, etc.⁴⁰ In addition, 'purpose-built' or converted 'biobanks' or 'genebanks' are being created to facilitate population-based disease research, for instance in Estonia, Iceland and the UK (UK Biobank), consisting of biological samples linked to personal data relating to health, lifestyle, etc.⁴¹ Such tissue bank repositories are vital to satisfy the needs of clinicians, researchers, biotechnology and pharmaceutical companies, academic institutions, etc.

A pound of flesh

Both profit and not-for-profit enterprises play a part in the process of transition from donated to transplantable tissue and tissue suitable for research. In the US, tissue transplantation is a billion-dollar industry.⁴² Since the Nuffield Council on Bioethics advocated the growth of non-profit medical intermediaries in tissue collection and distribution – to connect the market and non-market structures – commercial tissue banks have proliferated around the world.⁴³ There is also a trend toward the commercialisation of existing public tissue collections.⁴⁴ The

³⁹ The United Kingdom Human Tissue Bank based at De Montfort University is one such example in the research arena.

⁴⁰ In the UK the public Kingscord cord blood bank has been established. A two-year-old with leukaemia recovered after receiving a transplant from a donor who was discovered from tracing umbilical cord blood frozen in Tokyo; see *The Times*, 6 February 2008.

⁴¹ UK Biobank hopes to collect blood and urine samples from 500,000 individuals; see www.ukbiobank.ac.uk/about/what.php. Generation Scotland is another UK-based genetic database.

⁴² See R. Katz, 'The re-gift of life: Who should capture the value of transplanted human tissue?' (2006) 18(4) *The Health Lawyer* 14. He notes that the government makes little or no attempt to stop intermediaries earning 'super-normal' profits, at 15.

⁴³ Nuffield Council, at paras. 6.38–6.40. For-profit enterprises process such tissue to produce materials such as bone and hips for therapeutic application.

⁴⁴ See G. Lewis, 'Tissue collection and the pharmaceutical industry', in R. Tutton and O. Corrigan (eds.), *Genetic Databases: Socio-Ethical Issues in the Collection and Use of DNA* (Oxford: Routledge, 2004) 181 at 191 [Tutton and Corrigan (eds.), *Genetic Databases*].