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Should the law allow sentiment to triumph over science? The retention of body parts

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Discussion Paper Series 210

May 2002

MASSEY UNIVERSITY

SCHOOL OF ACCOUNTANCY

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SHOULD THE LAW ALLOW SENTIMENT TO TRIUMPH OVER SCIENCE? THE RETENTION OF BODY PARTS

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ISSN 1175-2874

Date: 30 May 2002

ABSTRACT

The use of human body material including tissue and organs has been controversial for many centuries. Concerns arose in the eighteenth century about practices used to obtain corpses for dissection. Scientific studies in biotechnology have placed increased value on the body as a source of research material. At the same time there is now a greater emphasis on individual autonomy. Disputes reflect the striking differences between scientific or utilitarian perspectives and the body's social meaning.

This paper considers issues that have arisen in several countries relating to the use of body parts and considers whether the law in New Zealand is sufficient to prevent such problems from arising in New Zealand. The conclusion is that present legal structures are insufficient to keep pace with technological advances. If biotechnology is to advance, it is essential to address the issues of consent while respecting cultural and religious views of the need for respect for the human body.

INTRODUCTION

The body is the site of increasing disputes relating to the collection and distribution of human tissue and organs. The use of human tissue is vital to modern medicine, particularly biotechnology. Human tissue is a group or collection of similar cells and intercellular substance that acts together in the performance of a particular function.¹ These tissues include nerve, fascia, dura, mater, bone marrow, bones, tendons, heart valves, corneas, skin and dedicated stem cell lines. Other body parts such as fat may have use in research by providing stem cells, which have the ability to become anything in the body from nerves to bone and muscle.² The human body has approximately thirty transplantable parts. One body can yield more than 130 pieces of tissue, once the tissue is extracted, sterilised, cut up and packaged.³

The collection and use of human body tissue has evoked concerns, from eighteenth century practices of dissection to twentieth century organ transplantation. Scientific studies in biotechnology have placed increased value on the body as a source of research material. Tissue is also valuable for a variety of purposes, such as ground bone powders used as glue to cement bone grafts and gels and skin-like coverings derived from donated skin that are used in cosmetic surgery. This usefulness may arise for purely commercial reasons, or because the tissue is essential for reconstructive surgery on people who have suffered a disfiguring injury.

The ambiguous legal status of the corpse has been an issue since the seventeenth century.⁴ This ambiguous legal status together with varying cultural and spiritual views of the significance of the dead body has lead to the use of human tissue from the dead for research or medical training continuing to be controversial. Disputes reflect the tension between scientific or utilitarian perspectives and the body's social meaning. These differences are becoming increasingly important with rapid scientific advances in areas such as genetic testing. Pathologists argue that analysis of tissues using molecular methods is helping them understand many diseases.⁵ However, the human body is the subject of strong cultural and emotional values. Society demands general respect for the human body and its parts. At the same time there is considerable public acceptance of advances in medicine and biotechnology involving the use of human tissue in clinical therapy. Examples would be transplant surgery and the interest in genetic research into diseases such as cystic fibrosis and the associated potential for new treatments. Countering this is the outrage expressed by the parents of the dead children involved in the Alder Hey scandal⁶ and in New

¹ The primary tissues are epithelial, connective, skeletal, muscular, glandular and nervous. <u>Tabor's</u> <u>Cyclopedic Medical Dictionary 2000</u> (Clayton et al. eds.1993).

 ² Researchers at the University of California and the University of Pittsburgh claim to have isolated human stem cells from fat sucked out of patients during routine liposuctions. <u>Dominion</u>, Wellington, 11 April 2001.
³ Protection 1 (1001) Human Tisoupa as Median Tractment 65 S. CA I. PEV 445 440.

³ Prottas, J. (1991). Human Tissues as Medical Treatment, 65 <u>S. CA. L. REV</u>. 445, 449.

⁴ Coke E. (1644) Institutes of the Laws of England, 203.

⁵ Herman C. and Schwartz D. (1996), Pathology and Laboratory Medicine. 275 <u>JAMA</u> 1839, 1839, arguing that because the availability of archived tissue specimens can provide a link between emerging infections and past idiopathic illnesses, autopsy is the most important quality assurance indicator for the treatment of the sickest patients.

⁶ <u>The Times,</u> January 30, 2001.

Zealand relating to the actions of Green Lane Hospital⁷, who are intent on reclaiming and reuniting body parts from children who died many years ago.

This paper will consider the differing controversies that have arisen relating to the retention and use of body parts in the United Kingdom, Australia, the United States and New Zealand. It will examine whether New Zealand law is sufficient to ensure that such problems will not arise again in this jurisdiction. Such consideration involves examination of the law relating to property rights in the human body and the legislative provisions presently in place with respect to the use of parts of the body. Ethical issues will be considered with respect to consent, ownership and confidentiality. The paper concludes that the present New Zealand legal framework is spread over a variety of legal sources and, as such, provides insufficient protection of individual autonomy with respect to the use or retention of body parts. Acceptance of such autonomy is reflected in the Code of Health and Disability Services Consumers' Rights ⁸. The paper concludes that further legislation is needed to ensure individuals do not become participants in research without their consent during their life, or the consent of those with a close familial or emotional tie after the participant's death. If the demands of research are permitted to override the concerns of individual autonomy this will lead to a loss of confidence in the ethical standards of researchers and the medical profession in general.

HISTORICAL CONTROVERSIES

During medieval times, the issue of integrity leading to continuity in the after-life dominated considerations of use of the body for research.⁹ It was believed that the integrity of the body was necessary for salvation, and so many people and their families were reluctant to consent to the subjection of corpses to autopsy and research. Certain religious groups continue to hold such beliefs today.¹⁰ By the early nineteenth century anatomical findings as a consequence of autopsies led to increases in medical understanding and the development of the science of pathology. Corpses were in short supply and so they became valuable commodities. Anatomy departments paid between \$10 and \$35 for a cadaver, more than the weekly wage of a skilled worker.

One of the earliest British scandals relating to dead human bodies involved the infamous graverobbers William Burke and William Hare. In the nineteenth century, Edinburgh was one of the major centres of medical education in Europe. Dr Robert Knox of the city's medical school was one of the most popular teachers of anatomy, attracting as many as 500 students per class. Schools were restricted by laws that allowed only the dissection of one body per year, which had to be the body of an executed criminal. Burke and Hare, detecting a commercial opportunity, would dig up the graves of the recently departed in the dead of night, steal the body and sell it to a doctor. Realising that this was taxing work, they devised an easier plan and began murdering hapless victims in

⁷ Dominion, (editorial) March 1, 2002.

⁸ See note 59 below.

⁹ Strossen, N. (1997). Religion and Politics : A reply to Justice Antonin Scalia. 24 <u>Fordham Urb. L.J</u>. 427, 472. ¹⁰ Ibid

¹⁰ Ibid.

Edinburgh's Old Town, by way of strangulation. The anatomists do not seem to have been suspicious about this nocturnal supply of bodies resulting from a strangling epidemic, but neighbours of a victim who raised the alarm led to the arrest and trial of the two in 1828. They were only convicted of one murder but were suspected of murdering between 13 and 30 people. Hare gave evidence against Burke, who was found guilty and executed on January 29, 1829 and his body was donated to the Medical School for "useful dissection". The anatomists who bought the bodies were never charged with any crime.¹¹

Disputes over the sources of corpses for medical research arose again following World War I. The increased need for surgeons to remedy the injuries caused to war casualties, led to a need for more corpses on which these doctors could train. The bodies of servicemen killed in the war were ideal subjects for training surgeons, but the families wanted the bodies returned. Although promises were made to treat the bodies respectfully and return all removed body parts to the bodies, this did not happen.¹²

MODERN SCANDALS

The tension between the need for human tissue for diagnostic, research and other purposes and the strong intuitive need of many relatives to have the whole body returned for interment, has led to a series of recent scandals in several countries.

United Kingdom

Some 150 years after the trial of Burke and Hare, on December 3, 1999, a scandal broke in Liverpool relating to the retention and storage of dead children's organs and body parts without parental consent. Initially Alder Hey Hospital admitted having collected the hearts of 2087 children. Later it admitted having discovered, in storage, hundreds of other organs removed during 851 post-mortem examinations.¹³

The report on Alder Hey Hospital by Michael Redfurn, QC, published on January 30, 2001, found that many parents of babies who died at Alder Hey gave consent for "tissue" to be removed, not realising this could include major organs and body parts.¹⁴ During the inquiry, it was discovered that the general practice at Alder Hey was to remove every organ from every child between September 1988 and the end of 1995. This collection was not confined to Alder Hey. Another official inquiry, by Professor Liam Donaldson, involving a census of organ retention found that, at

¹¹ See http://www.tartans.com/articles/graverobbers/.html.

¹² See Bourke J. (1996), *Dismembering the Male: Men's bodies, Britain and the Great War*, 217.

 ¹³ Tim Reid, "Doctor denies storing organs for research", The Times December 4, 1999. http://www.times-archive.co.uk/news/pages/tim/1999/12/04/timnwsnws.
¹⁴ See "Chapter and Provided Party and Provided Party and Part

¹⁴ See "Shocking body parts scandal revealed". <u>The Times</u> January 30 2001. Wysiwyg://66/http://www.thetimes.co.uk/article 0,, 534-76254,00html.

the end of 1999, 210 N.H.S. trusts and medical schools were holding 104,300 organs, body parts and entire bodies of still born babies and foetuses.¹⁵

This scandal was compounded by the revelation that at least three United Kingdom hospitals had sold organs taken from living children without parental consent to the sale. Hospitals routinely removed the thymus gland during heart surgery and sold the glands to drug companies. This process did not harm the children because the thymus, although essential to the development of the immune system of young children, becomes moribund after puberty.¹⁶ This practice is thought to have ended in the early 1990s when the pharmaceutical companies identified a superior material for the production of the drugs. Aventis Paster, a large pharmaceutical company argued that such tissue is, in any event, surgical waste that would otherwise be destroyed. However parental groups expressed outrage.¹⁷

Following the Alder Hey scandal, Salisbury District Hospital admitted selling skin which had been taken from about 240 patients who had breast and abdominal reduction surgery after 1995. The contract was worth £17,000 per annum. The skin was supplied to the Portor Down Laboratory of the Defence Evaluation and Research Agency, for experiments to find ways to protect British soldiers against chemical and biological attack. The patients had signed a consent form, which read; "I agree/disagree to any tissue that is removed in the normal course of the operation being used for medical research." The research was aimed at understanding biological weapons and improving defences against them. The research also related to wound healing, the preparation of an artificial skin and the treatment of burns.¹⁸

One consequence of the ongoing revelations relating to retention of organs and tissue in Britain has been a loss of confidence in the medical profession, resulting in an abrupt drop in organ donations. The process of donation requires considerable confidence in the medical profession on the part of those consenting to donation, and in Britain a drop of up to 50% has been observed.¹⁹ The publicity that has resulted from these issues has led to discussion in the United Kingdom about the nature of informed consent. It has led to the recognition that legislation will be needed to ensure that consent is fully informed and that consent must be actively sought and positively given.²⁰

Australia

Similar problems and controversies have arisen in Australia. It has been reported that up to a third of about 25,000 body parts and organs stored in hospitals, universities and museums in New South

¹⁵ Ibid.

¹⁶ Cobain, I. and Hawkes, N.– "Third Hospital admits selling child organs". <u>The Times</u> January 30, 2001. Wysiwyg//44/http://www.thetimes.co.uk/article/0, 2-75892.00.html.

¹⁷ Ibid.

¹⁸ See http://www.thetimes.co.uk/article/o, 2-81792,00.html.

¹⁹ See David Charter, "Milburn accused of scaring away organ donors". The Times, February 6 2001.

²⁰ Bale, J. "New laws will stop "shocking" organ removal." <u>The Times.</u> January 29, 2001. Wysiwyg://71/http://www.thetimes.co.uk/article/0,534-75049,00.html

Wales were removed from corpses without relatives' consent. Sydney's children's hospitals had among the biggest collections, with most of the samples being children's hearts.²¹ Health officials in Western Australia, South Australia and Tasmania have already set guidelines for the removal and retention of body parts, and legislation is proposed to ban organ removal from corpses during autopsies without the consent of next of kin.²² It has been further alleged that bodies of still born babies and children who died in infancy were sent to the United States from Australian hospitals in the 1950s and 1960s to be used in nuclear experiments.²³ Parents were never asked for permission, nor told what had happened. For a period of over 15 years, hospitals in Australia, Britain, Canada, Hong Kong, the United States and South America provided 6000 bodies. The tests were to measure the effect of fall- out from atom bomb tests. After the tests were completed, the bodies were cremated and radioactivity in the remains was measured.

United States

In the United States, the commercialisation of the use of body materials available as a consequence of gratuitous donations has lead to controversy. This controversy revolves around the issue of who should be entitled to share in the financial returns made possible by the demand for human biological materials and, in particular, whether the donors of usable tissue, or their relatives, should receive compensation. Although public support for products and services that make use of human tissue is strong, the prospect of commercialisation of human body components evokes responses ranging from unease to horror.²⁴

In America, the initial donors of solid organs and patients who agree to provide tissue used in medical research act gratuitously for altruistic motives. However, subsequent transfers to transplant programmes, pharmaceutical companies and the like are commercial transactions. The majority of transplantable solid organs are obtained from cadaveric donors. Such donations are made pursuant to the Uniform Anatomical Gift Act,²⁵ a version of which has been enacted in every state. The National Organ Transplant Act²⁶ prohibits payments for any organ to be used in transplantation.²⁷

However, the reality is that the possession of transplantable organs can generate considerable profit. Organ Procurement Organisations, the institutions that procure organs from donors and deliver them to transplant programmes, pursuant to the system established and administered by the

 ²¹ "Thousands of Organs Taken Without Consent", <u>Dominion</u>, Wellington, February 2001. See also, Roger Maynard, "Row over Body Parts erupts in Australia" <u>The Times</u>, February 2, 2001.
²² Soc. New South Walson Interim Policy: on Consent Accessited with Bost Martom Examination

²² See <u>New South Wales Interim Policy on Consent Associated with Post-Mortem Examination</u> www.health.nsw.govt.au/health-public-affairs/publications/policies/interimpolicy.html

²³ "Babies bodies sent to US for "nuclear tests" <u>Dominion</u>, Tuesday June 5, 2001.

 ²⁴ Childress J.F.(1995).Organ and Tissue Procurement: Ethical and Legal Issues Regarding Cadavers. Religious and Humanistic Beliefs, Attitudes and Practices. 4 <u>Encyclopaedia of Bioethics</u> 1854 at 1866. (Warren Thomas Reich ed, 2nd ed.)

²⁵ Uniform Anatomical Gift Act (amended 1987), 8A, ULA 19 (1993)

²⁶ 42, VSC 273-274 (f) (1994)

²⁷ Ibid 274 (e)

United Network for Organ Sharing, receive payment from transplanting hospitals. These payments are often called "acquisition fees".²⁸

The National Organ Transplant Act prohibits the "transfer of any organ for valuable consideration for use in human transplantation, if the transfer affects interstate commerce", but organ procurement organisations are permitted to receive "reasonable payments associated with removal and transportation".²⁹ According to a 1993 study the median "donor acquisition charges" billed to transplant patients ranged from approximately \$12,000 to \$16,000.³⁰

Transplant programmes then provide these organs to patients as part of a comprehensive package of transplant services and in turn are paid considerable amounts for these services by organ recipients and their insurance companies. In 1994, mean charges for the first year following transplantation ranged from \$116,000 for a kidney transplant to \$314,000 for a liver transplant.³¹ Although it can be argued that the organ is not sold and that patients pay only for medical services, the services have no value without the organ and patients cannot acquire organs in a separate transaction.

In the case of tissue used in biotechnology, research, and product development, recent advances have been fuelled by new methods of removing, preserving and transforming human tissue. Much of the tissue used in biotechnology research is obtained in the course of medical treatment and effectively abandoned by the donors who may initially not be aware of the potential value of their medical waste.³² Raw materials for biotechnology research are also acquired by express donations from human sources.

The United States Department of Health and Human Services is reported to be launching an investigation of practices in the human tissue industry, following reports of abuses in the collection and distribution of donated tissue and organs.³³ The concerns relate to the scale of the profits made from the collection, processing and distribution of donated tissue. The two largest for-profit companies in the tissue industry recorded a combined \$142.3m in sales in 1999. The four largest non-profit tissue banks were expected to generate a total of \$261m in sales in 2000.³⁴

 ²⁸ Evans R.W. (1993). Organ Procurement Expenditures and the Role of Financial Incentives, 269 <u>J. Am.</u>
<u>Med. Assn</u>, 3113, 3114.
²⁹ Applied Associate (1994).

²⁹ 42 VSC 274e (1994).

³⁰ See Evans above n. 26 at 3115-16.

³¹ See Milliman and Robertson Inc. Research Report(1996). Cost Implications of Human Organ and Tissue Transplantations, an update: 1996, at 27-28.

³² As in the case of John Moore – see *Moore v Regents of the University of California*, 793 p2d 479, Cal. (1990).

³³ Dorning, M. "Body Parts Trade Faces U.S. Probe". <u>Chicago Tribune</u>, April 10, 2001.

³⁴ Katches, M., Heisel W., and Campbell, R. "Donors don't realise they are fuelling a lucrative business". <u>Orange County Register</u>, April 16, 2000.

Frequently, the families of tissue donors believe donations are a non-profit endeavour for the benefit of the community. They are not aware that the collection, processing and distribution of tissue is a near-billion-dollar nation-wide business. They are also not informed of the ultimate use of the tissue. Although most tissue is used in transplants, it is also used for research by universities and drug companies. A further use is by biotechnology businesses that make medical products. Some of these include ground bone powders used as glues to cement bone grafts and gels and skin-like coverings derived from donated skin and used in cosmetic surgery for such procedures as penis enlargement, the stretching of sagging chins and the puffing of lips.³⁵

There is no federal requirement that tissue banks disclose to families just what will happen to the tissue they collect. The requirements of informed consent vary from state to state. The Food and Drug Administration (FDA) is the federal agency responsible for the regulation of human cellular and tissue based products.³⁶ The FDA derives its regulatory authority from the Public Health Service Act,³⁷ which relates to those regulations necessary to prevent the introduction, transmission or spread of communicable diseases from state to state or from foreign countries into the United States.³⁸ In the late 1980's and early 1990's several examples of transmission of serious illnesses from tissue donors prompted federal government efforts to pass comprehensive legislation regulating human tissue banks.³⁹ The proposed legislation never became law and safety concerns have remained.⁴⁰

COULD IT HAPPEN IN NEW ZEALAND?

Following the overseas disclosures relating to the retention and use of body parts, medical and ethical experts have stated that these issues could not arise in New Zealand. Jane Zucollo, paediatric pathologist at Capital Coast Health, stated that the problem in the United Kingdom arose because; "[sic]...we didn't remember the child was the property of the family..." ⁴¹. However, in spite of the confidence expressed by pathologists and the Wellington Coroner, Garry Evans, that there is no possibility in New Zealand of the unauthorised removal and retention of body parts as happened in Great Britain, the Health Ministry has inquired into the holding of body parts taken by autopsy in New Zealand.⁴² The issues involved had previously arisen in New Zealand in March 1991 over cases of pathologists removing organs from Maori bodies without consulting their families. It was

³⁵ Ibid.

³⁶ Human Tissue intended for Transplantation, 62 Fed Reg 50, 429, 40, 444 (1997). (Codified at 21 CFR pt 1270 (1999).

³⁷ Section 361,42 U.S.C. @ 264 (1994). ³⁸ 24 CEB at 40, 1270; C2 End Box at 40

³⁸ 21 CFR pts 16, 1270; 62 Fed Reg at 40, 430-31.

³⁹ Wagner, L. Tough Rules urged for tissue banks. <u>Mod Healthcare.</u> Oct 12, 1992 at 17.

⁴⁰ FDA must improve Human Tissue Oversight GAO says. <u>Andrews Health L. Lutig. Rep</u>. 15 (Jan. 1998).

⁴¹ Aldridge, V. "Bodies of Evidence" <u>Dominion</u>, Wellington, March 15, 2001.

⁴² "Ministry inquiry into keeping of body parts". Dominion, Wellington, March 15, 2001.

alleged that in many cases the removals were not necessary to determine the cause of death and they broke sacred tapus, which breached Maori cultural sensitivity.⁴³

In March 2002 it was admitted by Auckland's Green Lane Hospital that more than 1000 babies' hearts have been retained, and in many of these cases the retention was without parental consent. The practice had continued until late 2001 and the hearts used for research and teaching.⁴⁴ Subsequently, 310 body parts were discovered in an old laboratory at Green lane Hospital. It was stated by the Auckland District health Board chief executive that it is most likely that these are surgical specimens or sections of specimens removed during operations and sent to histology for testing.⁴⁵

The law relating to cadaveric body parts is contained in the Human Tissue Act 1964, the Health Department Code of Practice,⁴⁶ the Coroners Act 1988 and the Code of Health and Disability Services Consumers Rights, together with the common law.

The Human Tissue Act 1964 (the HTA) covers the use of the body or any specified part of the body for therapeutic purposes or for purposes of medical education or research.⁴⁷ Post-mortem examinations are authorised under section 4 of the HTA and the Coroners Act 1988. Post-mortems must be carried out by, or in accordance with, the instructions of a medical practitioner. No post-mortem other than one authorised by a coroner or other competent legal authority shall be carried out without the authority of the person lawfully in possession of the body.⁴⁸

If the coroner has authorised the post-mortem, the coroner must as soon as practicable take all reasonable steps to notify a member of the immediate family that the examination has been authorised, the reasons for it and that any member of the family may obtain a copy of the post-mortem report.⁴⁹ If authorisation for a post-mortem is not given by the coroner, or in certain circumstances by the High Court, then authority must be given by the person lawfully in possession of the body.⁵⁰ (This does not include the person lawfully in possession of the body of the purpose only of its interment or cremation.⁵¹) If the deceased is on hospital premises the person lawfully in possession of the body is the person in charge of the hospital.⁵² However this provision is stated to not limit the rights, powers or duties of any person entitled under any rule of law to the possession of any body.⁵³ This would indicate that the common law possessory rights of the relatives in the intact remains of the deceased still exist.

⁴³ Pahl, S. Removal of body parts: the Legal Position [1993] <u>NZLJ</u> 144.

⁴⁴ <u>Dominion</u>, March 1, 2002.

⁴⁰ <u>Dominion</u>, March 28, 2002.

⁴⁶ A Code of Practice for Transplantation of Cadaveric Organs, Department of Health, Wellington 1987.

⁴ HTA, s3.

⁴⁸ That authority must be given in accord with HTA, ss 3(2),(5) and (6).

⁴⁹ Coroners Act 1988, s11.

⁵⁰ HTA s4(2).

⁵¹ HTA s3(6).

⁵² HTA s2.

⁵³ HTA s2.

If the body is to be used after death for therapeutic purposes or medical education or research, the person may either in writing at any time, or orally in the presence of two or more witnesses during that person's last illness, have expressed a request that the body be so used. The person lawfully in possession of the body may then authorise the use of the body in accordance with the request.⁵⁴ If the person has not made such a request, the person lawfully in possession of the body must make such reasonable inquiry as may be practical, to ensure that the deceased had not expressed an objection to such use of the body, or that the surviving spouse or any surviving relative does not object.⁵⁵

The Health Department Code of Practice adds that, in practice, it is desirable to approach relatives wherever practicable and explain to them that the deceased requested that his or her organs be used to benefit others. If despite that request, the relatives are opposed to the removal of any part of the body, the person lawfully in possession of the body may decline to authorise the removal. The Working Party which prepared the Code may have recognised the reluctance of doctors to take body parts in the face of opposition from relatives, even with the legal right to do so, in light of the distressing altercations which could result from such an action. In addition the multicultural nature of the New Zealand population may mean that within one extended family more than one culture might be represented. Thus the Code indicates a preference for respecting the mores of the living even if this results in disregarding the expressed request of the deceased. The request may, in any event, not be followed in situations where the body is unsuitable for the requested purpose, such as the organs being diseased or otherwise unsuitable for transplantation, or no suitable recipient being found within the tight time constraints that apply.

If the wishes of the deceased are unknown, then the person lawfully in possession of the body must make such reasonable inquiry as may be practicable to discover whether the deceased person has expressed an objection, or whether the surviving spouse or any surviving relative of the deceased person objects to the proposed use of the body.⁵⁶ This appears an onerous condition that theoretically allows the objection of any relative however distant to be determinative. It has been suggested that in practice only those relatives already known to the hospital authorities need to be consulted.⁵⁷ The Health Department Code of Practice states that;

"in most instances it will be sufficient to discuss the matter with any one relative who has been in close contact with the deceased, asking him his own views, the views of the deceased and also if he has any reason to believe that any other relative would be likely to object. There is no need actually to establish a lack of objection from all relatives before authorising the removal of organs, or to make inquiries which are unreasonable or impracticable."⁵⁸

⁵⁴ HTA,s3(1).

⁵⁵ HTA,s3(2).

⁵⁶ HTA,s3(2).

⁵⁷ Montgomery, J. <u>Health Care Law</u>. (1997). Oxford University Press at p. 430.

⁵⁸ Above, n.40 at 4.

This Code of Practice was written in 1987 and attitudes have moved substantially since then. In particular, since the National Women's Inquiry and the Cartwright report, leading to the Code of Health and Disability Services Consumer's Rights made under the Health and Disability Commissioner Act 1994.⁵⁹ This has lead to the development of a doctrine of informed consent for "health care consumers"60 and succests that a prudent doctor would take active steps to contact a number of members of the family of the person before deciding to remove organs or tissue. The HTA does not define the boundaries of spouse or family ⁶¹ and so the position of a spouse in a de facto or same sex relationship is unclear. Similarly the Act gives no recognition to the close bonds of friendship which may exist outside the family relationship. A close friend may have a much more accurate idea of the views of the deceased than family, with whom the deceased has had minimal contact. Tension must exist between the need to make a rapid decision if organs are to be used for transplantation and the need to consult, resulting in delays while enquiries are made. In addition, the HTA provides no way of ranking relatives, thus potentially an objection from a more distant relative would carry as much weight as the views of a sibling. The Act refers to "the surviving spouse or any surviving relative" which suggests priority should be given to the wishes of the spouse.⁶² This is in contrast to the Coroners Act 1988 which refers to the "immediate family" as including de-facto spouse, step child, step parent, step brother or step sister.⁶³

In the case of bodies lawfully in the possession of the coroner pursuant to the Coroners Act 1988, the Code states that the coroner's consent needs to be sought for removal or organs where an inquest or post mortem may be required.⁶⁴ The circumstances in which these may be required are set out in section 4 of the Coroners Act 1988. These include deaths on the operating table and deaths whilst under the effect of anaesthetic. Post-mortems can only be carried out as directed or requested by a coroner or any other competent legal authority, or by the authority of the person lawfully in possession of the body.⁶⁵ The coroner has the right to remove organs and tissue to determine the cause of death. The authorisation of a post-mortem "does not of itself provide authorisation for the removal and use of parts unrelated to the post-mortem."

In deciding whether to authorise a post-mortem, the Coroner must have regard to the factors set out in section 8 of the Coroners Act 1988. These include, whether the death was unnatural, or violent, or due to the action or inaction of other persons.⁶⁷ The factors to be considered include the desirability of minimising the causing of distress to persons who, by reason of their ethic origins,

⁵⁹ Code of Health and Disability Services Consumers' Rights, www.knowledge-basket.co.nz/hdc/welcome. html

⁶⁰ Ibid, Right 7.

⁶¹ The provisions of the Relationship (Property) Act 1976 recognise de facto relationships and same sex relationships. The Act also gives rights to previous relationship partners. By analogy, such relationship partners may need to be consulted with respect to retention of human tissue or organs.

⁶² HTA s3(2).

⁶³ Coroners Act 1988 s2.

⁶⁴ Ibid at n.40.

⁶⁵ HTA, s4(2).

 ⁶⁶ Skegg, P.D.G. (1991). The use of corpses for medical education and research: the legal requirements. <u>31</u>
<u>Med. Sc. L.</u> 345 at 350.
⁶⁷ Corport At 1088 as(a)

⁶⁷ Coroners Act 1988, s8(c).

social attitudes or customs, or spiritual beliefs, customarily require bodies to be available to family members as soon as possible after death,⁶⁸ or persons in the above categories who find postmortem examination of bodies offensive.⁶⁹ Also relevant is whether or not members of the immediate family want there to a post-mortem.⁷⁰ The Coroner may also take into consideration any other relevant matters.⁷¹ In section 14 there is a requirement that once the coroner is satisfied that it is no longer necessary to withhold a body from family members, the coroner shall forthwith authorise its disposal. Disposal means burial, cremation and all other lawful modes of disposing of a body.⁷² A body is defined in part as any part of a person without which no person can live.⁷³ Thus tissue which is not essential to life such as bone and skin may not fall within the definition if the quantity is such that a person could live without it. There is no specific provision within the Coroner's Act requiring the Coroner to inform families that organ and tissue have been removed. If the body parts are removed to determine the cause of death there is no specific statutory requirement to inform families. However it is likely that the tissue must be retained for purposes implicit in the authorisation of the post-mortem itself, such as the preservation of evidence for a criminal trial. The law does not specify who has a right to possession of retained body parts.

ETHICAL ISSUES

The various controversies arising in different countries indicate a variety of ethical issues which arise in this area including:⁷⁴

- 1. Informed Consent: To what extent should donors or their families be made aware of the use to which organs or tissue are to be put? If this changes, should additional consent be required? (For example, if a heart is to be found unsuitable for transplantation but is used for another purpose). If biomedical storage is allowed, must the donor give consent for such preservation and any subsequent use? (For example, must the donor consent be secured for every different use of the donor's tissue even years after the donation?) If material such as residual tissue from surgery that would otherwise be treated as waste is to be used for research purposes, should the donor be required to consent?
- 2. Property: Who is the owner of the biomaterial? The person who donated the tissue, the research institution, the individual researcher or society as a whole? Alternatively, should human tissue even be considered as property at all?

⁶⁸ Ibid s8(e).

⁶⁹ Ibid s8(e).

⁷⁰ Ibid s8(g).

⁷¹ Ibid s8(h).

⁷² Ibid s2.

⁷³ Ibid s2(a).

⁴ Nielson , L. (1995). Legal and Ethical Aspects of Further Use of Human Tissue, <u>20 Eur. J, Health L</u>. 109-110, 112.

3. Confidentiality: To what extent should the protection of the donor's autonomy, privacy, and human dignity be balanced against the fundamental societal interests of freedom of research and efficiency of medical care? Does the donor have the right to know of any information about genetic profile and future health and relevant medical information affecting the donor's biological family?

It is essential to recognise that dead bodies do have significant value to individuals and families and the use of dead bodies without familial consent may violate personal or religious beliefs and social understandings.⁷⁵ The distress of the parents of the children involved in the Alder Hey and Green Lane Hospital scandals relate to an instinctive repugnance to their children's body parts being retained without their consent. When the decedent's religious and personal interests are not respected, or where the body is treated without respect, families may suffer emotional distress as a result.⁷⁶ Such cavalier attitudes towards the dead may damage the opportunities for research and reduce the willingness of the public to make altruistic donations of bodies or tissue. (In Britain it has been suggested that donations have dropped as a direct result of the result of the publicity from Alder Hey).⁷⁷

The research goals of advancing scientific understanding and curing diseases are laudable but research should never be a matter of conscription. People must be able to refuse to participate in research even if it involves no risk to them and enormous potential benefit to the community.⁷⁸

ARCHIVING OF TISSUE

Archiving involves retaining material. It may occur following an operation while a patient is alive, or following a medically requested post-mortem.

With respect to a living person, this is most likely to occur as a consequence of the removal of tissue during an operation or other medical procedure. The Code of Health and Disability Services, Consumer's Rights provides that "every consumer has the right to make a decision about the return or disposal of any body parts or bodily substances removed or obtained in the course of a health core procedure."⁷⁹ The Code further states that such body parts or bodily substances may be stored, preserved or utilised only with the informed consent of the consumer.⁸⁰ This would appear to include the situation where the tissue has been removed with consent but the original purpose has subsequently become exhausted and the tissue is to put to some other use.

⁷⁵ Childress, J.F. (1995).Organ and Tissue Procurement: Ethical and Legal Issues Regarding Cadavers: Religious and Humanistic Beliefs, Attitudes and Practices, 4 *Encyclopedia of Bioethics* 1854, 1863 (Warren Thomas Reich ed., 2nd ed.)

⁷⁶ Andrews, L. B. (1986). My Body, My Property" <u>Hastings Centre Rep</u>, Oct 1986, 28 at p. 30.

⁷⁷ Hawkes, N. "Minister tackles organ donor scare." <u>The Times</u>, February 5, 2001.

⁷⁸ The Nuremberg Code states "the voluntary consent of the human subject is absolutely essential". The Nuremberg Code reprinted in *The Nazi Doctors and the Nuremberg Code: Human Rights in the Human Experimentation* 2 (George J Annas and Michael A Groden ed.s 1992).

⁷⁹ Right 7(9).

⁸⁰ Right 7(10).

Before giving consent, the consumer has the right to the information that a reasonable consumer in that consumer's circumstances needs to make an informed choice or give informed consent.⁸¹ The consent must be given in writing if the consumer is to participate in any research or the procedure is experimental. The Health and Disability Commissioner Act 1994 provides for the code to be made as a regulation under the Act.⁸² Section 20 provides that the code must contain provisions relating to the principle that no health care procedure shall be carried out without informed consent.

Clause 3 of the code provides that a provider is not in breach of the code if the provider can prove it took reasonable action in the circumstances to comply with the code. Such circumstances include all the relevant circumstances and the providers' resource constraints.

The Act and the code together create a form of civil liability, but the majority of complaints are resolved without proceedings being instituted.⁸³ The Act requires a complaint to be investigated by the Commissioner.⁸⁴ The matter may be referred to an advocate to attempt a resolution by agreement between the parties. The Act provides a wide range of actions that the Commissioner may take if a breach of the Code is determined.⁸⁵ These include reporting the Commissioner's opinion,⁸⁶ making a complaint to a health professional body⁸⁷ and referring the matter to the Director of Proceedings.⁸⁸ The Director may, following an investigation under the Act, institute civil proceedings before the Complaints Review Tribunal.⁸⁹ If the Tribunal is satisfied on the balance of probabilities that any action of the defendant is in breach of the code, it may grant the statutory remedies, which include a declaration, a restraining order or an order that the defendant perform certain acts. If the action of the defendant has been "in flagrant disregard of the rights of the aggrieved person" and in certain other circumstances, damages may be awarded against the defendant.⁹⁰

This assumed ability to complain would, of course presuppose a person's awareness that circumstances have changed since their initial consent for the use of their organs was given. The problem of the entitlement to any profits that might result from the sale of tissue or profits from biotechnological advances resulting from research on the tissue is not resolved.

With respect to the archiving of tissue or organs from the dead, neither coroners nor pathologists have an express statutory right to the possession of the body or body parts of the deceased. The Coroners Act does not require coroners or pathologists to notify family members that a body part

⁸⁴ S50(g).

⁸¹ Right 6(2).

⁸² Ss20 and 74(1).

⁸³ http://www.hdc.org.nz

⁸⁵ Ss36(i)(b)and 42.

⁸⁶ S45.

⁸⁷ S45(d).

^{°°} S45(e).

⁸⁹ S52.

⁹⁰ See the reports on the Commissioner's website, above n. 81.

has been retained. Neither does the Act address the question of who has the right to possession of retained body parts. Pathologists as a matter of practice take and retain microscopic samples from many organs of a deceased person. They state that generally there is no need to retain major body organs.⁹¹ The Law Commission has recommended that the Coroners Act be amended to provide that the deceased must be returned to the deceased's family as soon as possible. Before release, the coroner must ensure that any body parts retained for further testing are placed back into the body or otherwise dealt with by direction of the family.⁹² The Commission recommended that "body parts" or "tissue" should exclude microscopic samples which pathologists retain as a matter of practice.⁹³

Currently legislation does not prevent archiving of tissue following a post-mortem. Consequently it is necessary to consider whether the common law permits the retention and possible sale of the tissue. This raises questions as to whether there are property rights in dead bodies.

PROPERTY RIGHTS IN BODIES

Any discussion of the possession or commercialisation of human body parts raises the question of the fundamental premise of the existence of property rights in the human body.⁹⁴ In order to sell body parts, people would need some recognised ownership, or property rights, in their own bodies and their component parts. If a commercial arrangement to harvest organs and tissue after death was permitted, the contracting party would need to have proprietary rights over the body. The common law has presumed there are no property rights in a dead body, but only the quasi-property rights of the executor or administrator to claim a corpse for burial purposes.

Living bodies

At common law, living bodies were often categorised as property. Under English common law, a debtor could be attached to act as payment for a debt.⁹⁵ A woman's body was the property of her husband. Consequently, a man who raped a woman was tried for a property crime against her husband.

Courts and legislatures have accepted that renewable body parts can be the subject of ownership. Blood is commonly sold in America and is deemed to be full-fledged property – a "product" whose sale constituted "income" under the tax code, while the "business expenses" incurred by the seller in creating this "product" are deductible for the purposes of tax.⁹⁶ There has been recognition of

⁹¹ Law Commission Report, <u>Coroner's Report 62</u>, August 2000, Wellington, New Zealand, at para 202.

⁹² Ibid recommendation 20 at p.78.

⁹³ Ibid recommendation 21 at p.80.

⁹⁴ The discussion that follows, relating to property rights in bodies, is an extract from Thomas, C. (2001). Commercialisation of the Supply of Organs for Transplantation. <u>Massey University School of Accountancy Discussion Paper Series</u> No 207, 10 May 2001.

⁹⁵ United States v Garber. 607 F. 2d, 92, 97 (5th Gr. 1979).

⁹⁶ Matthews, P. (1983). Whose body? People as Property. 36 <u>Current Legal Problems</u>, 193.

property in hair, urine and bone marrow. These, together with the existence of sperm banks, all indicate that individuals can have proprietary rights over their body.

The issues arising are demonstrated by the Californian case *Moore v Regents of the University of California*⁹⁷. The plaintiff, John Moore, sought treatment at the Medical Centre of the University of California for hairy-cell leukaemia. Dr David Golde examined Moore and determined that his spleen had to be removed as a necessary part of his treatment. Dr Golde, together with a medical researcher and UCLA employee decided that Moore's spleen cells were unique and of great commercial value. Moore's spleen was removed and genetic engineering used to develop a cell-line with an estimated commercial value of three billion dollars. Moore had not been informed nor had he consented to this use of his spleen. For seven years he returned to UCLA for what he believed was treatment of his condition. During these visits, samples of Moore's blood, blood serum, skin, bone marrow aspirate and sperm were taken for research. Moore was never informed of the value of his tissue. He was told that it had no commercial or financial value. He signed a form consenting to the removal of his tissue but he expressly denied the rights to his cell-line. However they continued to commercially exploit his cell-line and responded to Moore's refusal by altering the name of the cell-line to avoid detection. When Moore eventually discovered all this he sued, seeking damages for conversion of his spleen.

The Californian Court of Appeal held that Moore's spleen was an item over which he had "an unrestricted right to ... use, enjoyment and disposition and thus it fit under the traditional legal provisions of property."⁹⁸ The Court held that Moore could claim that the defendants had converted his tissue and denied that Moore had abandoned his spleen.⁹⁹ The Court noted that the potentially "intense moral, religious and ethical concerns" which could accompany the use for sale of a person's body or body part without consent made an inference of abandonment, even with a diseased organ, "inappropriate".

However, the California Supreme Court¹⁰⁰ found that unlike blood, spleen cells are not considered to be the property of the person from whose body they are withdrawn. Spleen cells may become the property of the scientists who harvest them and transform them into a valuable cell-line, once the government issues a patent, thereby conferring a proprietary interest. Moore's tort claims for breach of fiduciary duty and lack of informed consent for removal of his spleen were allowed by the Californian Supreme Court but not his claim for conversion of his personal property. Thus he was denied a right to recoup a share of the profit made from the valuable cell-line derived from his spleen.

⁹⁷ 202 Cal. App. 3d 1230 Cal. Reptr. 494 (Cal. Ct. App.) 252 Cal. Reptr, 816, 763, P.2d, 479 (1988).

⁹⁸ 202 Cal. App. 3d 1245, 249 Cal. Reptr at 504.

⁹⁹ Ibid at p 510.

¹⁰⁰ 793, P. 2d, 479, 479-97 (Cal. 1990).

Moore affirms the individual's right to exclude others from taking his spleen from his body while it simultaneously protects the researcher's rights in the resultant cell-lines.

Radhika Rao¹⁰¹ argues that *Moore* is capable of at least three different constructions:

- 1. The Court's refusal of Moore's conversion claim was recognition that body parts cannot be property so long as they are contained in a living human being. Rao states that in the case the Court could have recognised Moore's ownership of his spleen at the point it was detached from his body, without making his whole person a form of property.
- 2. Even if the spleen was initially Moore's property, its "owner", for whom the diseased organ was valueless, and so was available to be used by another, had abandoned it.
- 3. The Court may have implied that body parts once removed, return to the public commons available to all and become a form of communal property available for "capture" by the first person who recognises their commercial potential and puts them to productive use.

Moore's case demonstrates the need to develop policy and legislation to keep pace with rapid technological developments. Common law views of property may be inadequate in light of such developments.

Dead Bodies

Legislation has long provided that a person may make provision by way of a will for the disposal of their property following death. ¹⁰²Although a request relating to the disposal of the body may be included in the will, such a request is not binding on the executor. The manner of burial is in the discretion of the executor.¹⁰³

The issue as to whether property rights exist in a dead body has been in question since the seventeenth century.¹⁰⁴ Sir Edward Coke suggested that as the burial of a corpse is "nullius in bonis" - "in the goods of no one" there could exist no property rights in them. This statement was recognised in common law cases and led to the general rule that human body parts cannot be propertv.¹⁰⁵ As stated in Clerk and Lindsell¹⁰⁶, the executors or administrators or other persons charged by the law with the duty of interring the body have a right to the custody and possession of

¹⁰¹ Property, Privacy, and the Human Body<u>. 80 B.U.L. Rev</u> 359 (2000) at 374.

¹⁰² Wills Act (UK) 1837 as amended.

¹⁰³ Murdoch v Rhind [1945] NZLR 425; [1945] GLR 263.

¹⁰⁴ Edward Coke, Institutes of the Laws of England, 203 (1644).

¹⁰⁵ Boulier W.(1993). Sperm, Spleens and other Valuables: the need to recognise property rights in human body parts. 23 HOFSTRA L. Rev. 693, See also Williams v Williams (1882) 20 Ch D 659, at 662-663 and ¹⁰⁶ Clerk and Lindsell on Torts (17th ed. 1995) p. 653 para 13-50. Ibid. n. 30.

it until it is properly buried. There are other persons charged by the law with the duty of interring the body, such as the parent of an infant child who dies where the parents have the means to provide for burial.¹⁰⁷ There does not appear to be such a duty on next-of-kin as such.¹⁰⁸ If there is no duty, there is no legal right to possession of a corpse.

However, once a body has undergone a process or other application of human skill, stuffing or embalming, it seems it can be the subject of property in the ordinary way. The proposition is based on the case of *Doodeward v Spence*.¹⁰⁹ That Australian case involved the preserved foetus of a two-headed child, stillborn 40 years previously, which the appellant had purchased. He sought to recover it from the police so that he could exhibit it for gain. He succeeded in an action for detinue. In the High Court of Australia, Griffith C J stated that it was not unlawful to possess a mummy or a prepared skeleton or a skull or other parts of the human body. He referred to the many collections of anatomical and pathological specimens formed and maintained by scientific bodies.¹¹⁰

He stated "... so far as it constitutes property, a human body, or a portion of a human body, is capable by law of becoming the subject of property."¹¹¹ He added; "when a person has by the lawful exercise of work or skill so dealt with a human body or part of a human body in his lawful possession that it has acquired some attributes differentiating it from a mere corpse awaiting burial, he acquires a right to retain possession of it, at least as against any person not entitled to have it delivered to him for the purpose of burial..."

Although Barton J reinforced the general rule that an unburied corpse was not the subject of property, Higgins J dissented; being of the view that no one could have property in another human being alive or dead. He stated "A right to keep possession of a human corpse seems to me to be just the thing which the British law and therefore the New South Wales law, declines to recognise."112

In Dobson and another v North Tyneside Health Authority and another,¹¹³ the English Court of Appeal considered the issue in a case where the next of kin of a woman who had died of a braintumour were contemplating legal action on the grounds of negligent misdiagnosis. They wanted the hospital to produce the brain, which had been removed at post mortem but not sectioned for histology. The hospital could not do so. The Court held that while it was "arguable" that a body or body part that had been embalmed or fixed might become property, a brain held in storage but later lost or destroyed was not. The Court did not wish to impose on hospitals a duty to retain tissue removed at post mortem just in case it was required for any future litigation.

¹⁰⁷ Clark v London General Omnibus Co Ltd [1906] 2 K.B.648 at 659.

¹⁰⁸ Dobson and Another v North Tyneside Health Authority and Another [1996] 4 All ER 474 at 478.

¹⁰⁹ (1908) 6 CLR 406.

¹¹⁰ Ibid at p. 413.

¹¹¹ Ibid at p. 414.

¹¹² Ibid at p. 424.

¹¹³ Ibid. n. 106.

The issue arose again in another context in R v Kelly, R v Lindsay¹¹⁴, a case where the body parts were "stolen" from the Royal College of Surgeons in London to be used for artistic purposes. It was argued on appeal that the trial judge had been wrong to say that these preserved body parts were property in the *Doodewood* sense. It was argued that the Royal College might have been custodian of the parts, but since they were not property it could not own them so they could not be stolen. Lord Justice Rose stated that, however questionable the historical origins of the principle, it has now been the common law for 150 years at least that neither a corpse nor parts of a corpse are in themselves capable of being properly protected by rights. However if they have acquired different attributes by virtue of the application of skill, such as dissection or preservation techniques for exhibition or teaching purposes, they are capable of becoming property. He went on to add that the common law does not stand still, so the courts might in the future hold that body parts are capable of being property, even without the acquisition of different attributes, if they have a use or significance beyond their mere existence. He stated, as examples, where they are intended for use in an organ transplant operation, for the extraction of DNA, or as an exhibit in a trial. Thus the legal position remains unclear.

The uses for human tissues and body parts are rapidly increasing with the remarkable advances in modern medicine. Scientists seeking unimpeded access to human tissue argue that restraints on their ability to gain access to, manipulate and commercialise tissue obstruct the progress of research and deprive society of useful medical advances¹¹⁵. However, the corpse is more than a utilitarian object; it is the subject of conflicting beliefs and to many cultures has a sacred meaning.

CHANGE OF PURPOSE

It would seem that in New Zealand, a living person would have to give informed consent to each activity involving their body parts or tissue.¹¹⁶ However in the case of a deceased person the situation could arise where the relatives have given consent for the removal of the deceased person's organs for one purpose and circumstances change so they are used for another purpose. In the United States, hearts that are not good enough for use as transplants are sold by tissue banks to one of several tissue banks and companies, including Cryolife of Atlanta, for about \$1500.¹¹⁷

A family may have given the required approved under the Human Tissue Act¹¹⁸ for the removal of a relative's kidneys for transplant, but the intended recipient dies before the transplant can occur. If

¹¹⁴ Times Law Report, 21 May 1998.

¹¹⁵ The Official Report on the Alder Hey hospital by Michael Redfern Q.C., published January 30 2001, states that since 1970, 6,500 open-heart operations have been carried out on children at Alder Hev. The mortality rate fell from 20% in 1970 to 3.6% in 1999. In operations on babies, mortality fell from 75% to 6%. The report states that not all of this improvement was the result of the heart collection yet there can be no doubt that pioneering positive developments have resulted directly from work undertaken surrounding the heart collection. See wysiwyg://81/http://www.thetimes.co.uk/article/0,2-76381,00.html

¹¹⁶ See Rights 6 and 7, ibid n. 81.

¹¹⁷ Hegdes S.J. and Gaines W., "Donor bodies milled into growing profits" <u>Chicago Tribune</u> April 10, 2001.

¹¹⁸ S3.

there are no other compatible recipients, would the hospital be obliged to return the kidneys or seek further consent if they were to be used for a different purpose? Section 3(7) of the HTA provides that "nothing in this section shall be construed as rendering unlawful any dealing with or with any part of, the body of a deceased person which is lawful apart from this Act."

This suggests that if retention of the tissue for an alternative use is lawful under the common law then the fact that it is not specifically authorised under the Human Tissue Act is irrelevant. As the rights of possession at common law are most likely to be with the hospital, it is unlikely that an offence will have been committed.

Bereaved families who struggle with the initial decision to donate may experience renewed distress if required to give further consent should the initial plans for the deceased change. However, if they believed they were giving the gift of life to a recipient and later discover the body of the deceased was used to make products of a different nature, they may feel they have been misled.

CONCLUSION

The development and application of technologies will arguably be the driving force for the evolution of the world society over the next few decades. However there is apprehension about the potential risks of new technologies. Present legal concepts, procedures and structures are insufficient to keep pace with technological advances. It is essential that the law develops to ensure that technology serves as many people as possible and disadvantages as few as possible. Such discourse involves consideration of societal rights as contrasted with individual rights. The protection of an individual's autonomy, privacy, and human dignity must be balanced against the fundamental societal interests of freedom of research and efficiency of medical care.¹¹⁹

Irrespective of notions of property rights in human bodies, many individuals and family members believe they have an interest in the uses to which body parts may be put. It is essential to grapple with the complex area of consent, in particular to consider the level of detail it is necessary to provide before informed consent can be given. Arguably even more difficult is the issue of the need to obtain further consent should the original plans change. Many people will give consent in the hope that they may benefit others, but others may wish that consent to be limited to certain types of procedures and may not consent to others, such as cosmetic procedures or commercial uses. Consent should specify the period of time for which it is agreed the body part may be retained, as well as the use to which it may be put.

¹¹⁹ Indech ,B. (2000) The International Harmonization of Human Tissue Regulation: Regulatory Control Over Human Tissue Use and Tissue Banking in Select Countries and the Current State of International Harmonization Efforts. <u>55 Food Drug L.J.</u> 343.

Other people may refuse consent for personal cultural or religious reasons. The ethical issues considered in this paper demonstrate a gulf between the attitudes of medical professionals towards the human body and those of many members of the public. Clinician's assumptions that their interests in research and the like override other considerations may have diminished in recent years, but these assumptions have not disappeared. The fact that society may gain benefits and lives may have been saved does not excuse actions that are ethically unsound.

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