

A Twitch upon a Thread

REGULATION OF HUMAN TISSUE USE IN AUSTRALIA AND THE APPLICATION OF PROPERTY LAW

by

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Submitted in fulfilment of the requirements for the Degree of Doctor of Philosophy (Law)

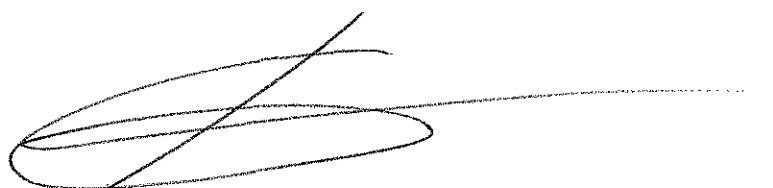
University of Tasmania, November 2004

I caught him with an unseen hook and an invisible line which is long enough to let him wander to the ends of the world and to bring him back with a twitch upon the thread.

as quoted in *Evelyn Waugh*, *Brideshead Revisited*

Declaration of Originality

I declare that this thesis contains no material which has been accepted for a degree or diploma by the University or any other institution, except by way of background information and duly acknowledged in the thesis, and to the best of my knowledge and belief no material previously published or written by another person except where due acknowledgement is made in the text of the thesis.

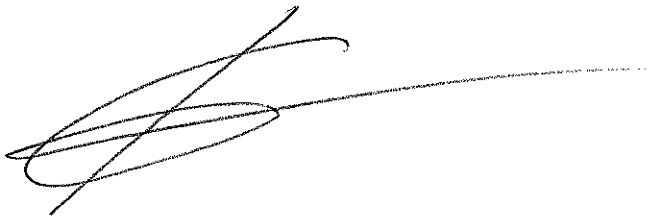
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Imogen Goold

November 2004

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ABSTRACT

Since the days of the body-snatchers, human bodies and their parts have been a valuable resource for science and medicine. They have been used for study, as the raw material for therapeutics and genetic research, as a source of transplant organs and for the creation of artistic works. In effect, human body parts are treated in many respects as items of property for they are possessed, controlled, used, transferred and destroyed. We even use the language of property to express how we experience our bodies – “I broke my arm”, “He donated his kidney”.

However, the Australian legal system has baulked at placing excised human tissue within the ambit of property laws. Mostly a consent approach is taken through legislation and ethical guidelines, with the exception of some case law that has upheld limited property rights in tissue. This situation is problematic in part because these guidelines and legislation cover only some limited uses of tissue, leaving the remainder in a legal vacuum. In the absence of any clear status for tissue having been established, it is not clear how the courts will or should approach alleged misuse of. In addition, the doctrine of consent fails to determine who may hold rights in tissue in a variety of circumstances. As a result, situations may arise where it is unclear how tissue may be used and who may use it. Given the value of tissue for biotechnology and medicine, this should be remedied.

One suggested approach to these problems has been the application of property law to human tissue. Due in part to the intuitive practicality of this approach given the current uses of tissue, and the common law cases upholding such an approach, this issue has generated considerable academic debate. This thesis seeks to examine the foundational issues that affect this debate to determine whether a case can reasonably be made for applying property law to human tissue. In drawing conclusions on the issues that face the debate, this thesis lays the groundwork for developing a comprehensive legal approach to tissue use that will address the current lack of consistency in the Australian legal system’s method of regulating tissue use.

It is concluded that it would be possible to regulate the use of human tissue through the laws of property and that the arguments in favour of doing so outweigh those against.

However, this conclusion is conditioned on the recognition that these rights should be subject to certain limitations.

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For my mother.

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CONTENTS

<i>Introduction</i>	2
<i>Part I: Acquisition and Use of Human Tissue</i>	
INTRODUCTION	18
CHAPTER ONE: <i>Early History</i>	22
CHAPTER TWO: <i>Utilising the Body</i>	44
CHAPTER THREE: <i>Changing Technologies: The Body as Commodity</i>	81
CONCLUSION	106
<i>Part II: Regulating the Body</i>	
INTRODUCTION	109
CHAPTER FOUR: <i>Legislative Regulation: The Human Tissue Acts</i>	110
CHAPTER FIVE: <i>Guidelines</i>	149
CONCLUSION	185
<i>Part III: The Common Law and the Body</i>	
INTRODUCTION	189
CHAPTER SIX: <i>Corpses and the Common Law</i>	192
CHAPTER SEVEN: <i>Modern Uses: Straining at the Confines of the Coffin</i>	208
CONCLUSION	258
<i>Part IV: Human Tissue and the Concept of Property</i>	
INTRODUCTION	262
CHAPTER EIGHT: <i>What is Property?</i>	268
CHAPTER NINE: <i>Can Human Tissue Fit Within the Concept of Property?</i>	280
CHAPTER TEN: <i>Human Tissue and Philosophical Justifications for Property</i>	299
CONCLUSION	321
<i>Part V: Should Human Tissue Be Property?</i>	
INTRODUCTION	325
CHAPTER ELEVEN: <i>Can Property Law Meet the Challenges of Tissue Use?</i>	328
CHAPTER TWELVE: <i>The Commercialisation Debate</i>	373
CONCLUSION	404
<i>Conclusion</i>	406
<i>Bibliography</i>	419

Introduction

Excised human tissue is a unique substance. At one level, like many objects, it can be used in research, stored, transplanted, donated for medical use and in some cases, sold. It is used in medical treatment, tested as part of forensic investigations, used to conduct medical and scientific research, turned into works of art and displayed in museums to educate the community. In Australia, blood samples are also taken from every child at birth for testing, and are later stored in identified form. Consequently, hospitals, pathology and forensic laboratories, military installations and government agencies all hold collections of tissue taken from patients, research volunteers, crime suspects, military personnel and many others.¹

However, unlike other objects, excised human tissue was also once physically part of a person who lived, thought and experienced emotion (or indeed who may often still be alive). Humans have a variety of complex relationships with their bodies, including spiritual and emotional understandings of the body's tissue, and these understandings may or may not change once the tissue is removed. As a result, most communities still regard it as important that excised body parts be treated with a degree of respect that distinguishes those body parts from other objects.

Human tissue is also unique because it almost invariably contains genetic material in the form of DNA that can yield highly personal information about a person's background, health and characteristics. In addition, genetic science and hybridoma technology have enabled scientists to use tissue to manufacture useful bodily substances, and tissue has become the raw material for the production of therapeutics. The commercial nature of the many ventures producing therapeutics meant human tissue also entered the market, as a substance that could be bought, sold and used to generate income.

These unique qualities mean that the use of human tissue in research and other contexts presents complex challenges for legal regulation. The breadth of uses for tissue, which is

¹ A survey in the United Kingdom found that more than 54,300 organs, body parts, still-births and fetuses had been retained by pathology services between 1970 and 1999. In addition, over 800,000 samples had been retained from coronial post-mortems alone in the period between 1970 and 1999. See Department of Health, Department of Education and Employment and the Home Office, *Report of a Census of Organs and Tissues Retained by Pathology Services in England*, HMSO, London, 2000, 1, 4. No national survey has been carried out in Australia, but recent State surveys have revealed lower, but still significant, levels of retention. See, eg, South Australia Solicitor-General, *Report into the Retention of Body Parts after Post-Mortems*, Department of Health Services South Australia, Adelaide, 2001; New South Wales Health Department, *Interim Report into the Retention of Organs following Post-mortems in NSW*, New South Wales Health Department, Sydney, 2001; Crown Solicitor for Western Australia and Commissioner for Health for Western Australia, *Final Report: Removal and Retention of Organs and Tissue Following Post-mortem Examinations*, Department of Health Western Australia, Perth, 2001.

constantly expanding, further complicates the attempts to develop a comprehensive legal framework for regulating tissue. The challenges for regulation include issues of consent and permission; whether it may be transferred; methods of storage; identification and privacy protection and the possibility of benefit sharing between the source of tissue and researchers. They also include larger and more general concerns about the commodification of body parts (and consequently, of people) where tissue is bought and sold, and where the results of research using that tissue are commercialised (such as the patenting of gene sequence information and commercial control of tests developed through research).

The use of human tissue and the particular challenges it presents has garnered considerable attention in recent years, particularly following revelations in the United Kingdom and Australia about the retention of tissue in hospitals. The demands by Australian indigenous groups for the return of Aboriginal remains held in museums around the world have also brought the question of who can claim human tissue into more mainstream debate. Developments in genetics and resulting concerns about privacy and genetic discrimination in employment and insurance have further highlighted the need for an adequate legal framework to regulate how excised tissue is dealt with.

To some degree, the Australian legal system has attempted to respond to the increasingly obvious need for regulation through a variety of methods. In 1977, the Australian Law Reform Commission (ALRC) reported on a range of uses for body parts, particularly transplantation, in its report *Human Tissue Transplants*.² Following this report, each state and territory enacted legislation governing donation and use of tissue in research and medicine (the Human Tissue Acts). The National Health and Medical Research Council (NHMRC) and the Australian Health Ethics Committee (AHEC) have also released a range of guidelines covering research use of tissue. The courts in Australia (as well as in the United Kingdom) have furthermore dealt with a range of diverse cases involving body parts, including the theft of parts. However, debate remains about whether these rather disparate measures are sufficient. In particular, as the majority of relevant legislation was passed before the developments in genetics that allow greater information to be derived from DNA, they may not adequately address the privacy concerns that now attend the widespread use of tissue.

² Australian Law Reform Commission, *Human Tissue Transplants*, ALRC 7, ALRC, Sydney, 1977.

One particular strand of this debate focuses on whether property law provides a suitable legal mechanism for regulating tissue use. This focus has emerged in part because the current treatment of tissue is in many ways analogous to the treatment of property, and the courts in Australia and the United Kingdom have therefore increasingly been forced to consider whether human tissue is a form of legal property. It should be noted that the decisions in these countries are most relevant to this thesis as it examines the Australian law, some of which is based on English precedent. For this reason, the work of writers on these country's laws forms the core of the debate considered in this thesis. United States decisions have no legal force in Australia however in the high profile case of John Moore and the Mo Cell line, United States courts did consider the application of property law to human tissue. As a result, there is also significant and influential academic debate in that country over the property status of tissue, which is hence also examined in this thesis as an input to the debate.

This focus has emerged also because in many ways the current treatment of tissue is analogous to the treatment of property. Further, it is arguable that applying property laws generally to the use of tissue provides a more comprehensive legal framework than the current patchwork of legislation, ethical guidelines and case law, and might also provide an approach more suited to adapting to future uses of tissue in an relatively uniform manner.

This thesis will critically appraise the debate surrounding excised human tissue by examining whether the legal concept of property has the capacity to provide a regulatory solution to the challenges of human tissue use. In addition to this basic research objective, the thesis will address the question of whether property law *should* in fact be the primary approach to regulating human tissue use. Rather than comprehensively outlining the ways in which property law could be applied to excised human tissue, it will address some of the fundamental issues underlying the property law approach to regulating tissue use.

It is outside the scope of this thesis to attempt a full-scale assessment of all possible legal approaches to regulating tissue, outside of property law. Instead, the focus is the legal status of human tissue, specifically whether it feasibly can and should be treated (and regulated) as property. As a result, legal concepts such as equity for example, while not rejected as a workable basis with which to regulate human tissue use, are discussed

only in relation those issues that directly affect the property law approach, which is the focus of the debate under consideration. How this will be achieved is described below in the outline of the thesis structure and methodology. However, it should first be noted that a number of types of tissue, and some areas of law have not been considered in this thesis.

Within this thesis, tissue is defined as all biological materials removed from the body.³ This includes whole organs and body parts but does not extend to waste materials such as urine. Tissue, in the context of this thesis therefore includes blood, skin, hair and parts of organs, small tissue samples (including preserved and blocked tissue), whole organs and limbs. This thesis will not directly consider whole bodies, although they are brought into the discussion to some extent in the examination of the case law. This is because the use and treatment of entire bodies is subject to specific concerns and particular laws in relation to burial, but these are less often 'used' in the contexts on which this thesis focuses, namely research, forensics, and commercial treatment of tissue. Further, this thesis does not exclude tissue on the basis of the context in which it was removed or whether it is identified or not, and issues raised by these differing factors are considered in the course of the analysis.

It should also be noted that this thesis does not engage with arguments about whether the living body is itself property. This issue is not directly relevant to the questions this thesis seeks to answer, although undoubtedly property rights in excised tissue could be derived if the living body is considered property. However, this strand of argument raises a range of questions that are beyond the scope of this thesis. More importantly, this thesis is not specifically concerned with the means of deriving property rights but with whether the legal mechanism of property itself is a feasible means of regulating tissue use.

The right to make decisions about one's own body is one of the key issues that will be examined in the course of this thesis. It is argued that according property rights in tissue

³ For example, Gerald Dworkin and Ian Kennedy define 'human tissue' and 'human biological materials' to mean 'every aspect of a person's being, ranging from body waste (such as urine, faeces, hair, nail clippings), to a list representing an atlas of the human body; for example, blood, skin, bone marrow, organs such as the cornea, liver, heart and kidneys, amputated limbs, foetal tissue, the placenta and other accompanying fluids and membranes (ie the contents of the uterus, other than the foetus resulting from pregnancy), foetal tissue, semen, ova'. See D Dworkin and I Kennedy, 'Human Tissue: Rights in the Body and Its Parts' (1993) 1 *Medical Law Review* 291, 291. Similarly, the Human Tissue Acts define tissue as organs, parts of bodies or any substance extracted from a human body. See, eg, *Human Tissue Act* 1985 (Tas) s 3(1).

is an extension of allowing autonomous control over one's body. Children and those incapable of legally consenting do not have the same legal relationship with their bodies; they are also treated differently by the law in relation to property and contracts for sale. The use and regulation of tissue taken from children or from those who are otherwise not legally capable of consenting to the removal will therefore not be considered in detail, as the property debate is substantially different in relation to these groups.

Human sperm and ova are likewise categories of human tissue that will not be directly considered in the following chapters. Because together sperm and ova have the potential to generate new and distinct bodies, they are distinctly different from other types of tissue. Consequently, as noted by the NHMRC in 1996, donation of reproductive materials raises unique ethical issues.⁴ When donated sperm is used to artificially inseminate a woman, for instance, questions of paternity, legitimacy of children and rights of inheritance all arise, yielding problems which are perhaps better considered in the context of family law, welfare law or the laws of succession. Similar problems surround the donation and use of ova.⁵

While any argument for or against property rights will have a bearing on how these unique tissues are regarded by the law and the status they are accorded, their potential to create life sets them apart as sufficiently different to require special consideration. It is likely that the unique aspects of these tissues mean they are best governed by specific laws that can take account of their particular characteristics. They are excluded from the scope of this thesis because it is beyond its scope to deal with the specific requirements of such laws in sufficient detail. They are also excluded as they are currently regulated by different guidelines to those covering tissue generally and from the Human Tissue Acts, on which this thesis focuses. Foetal tissue and stem cells are similarly excluded because of the particularly complex issues use of these tissues raise, particularly because they raise different, especially difficult ethical and moral concerns that it is beyond the scope of this thesis to consider.⁶

⁴ National Health and Medical Research Council, *Ethical Guidelines on Assisted Reproductive Technology*, NHRMC, Canberra, 1996, 4, note 3.

⁵ Due to advances in cloning technology, it is possible that a new human body might also be created from any human cell. However, due to current prohibitions on this form of reproduction in Australia, this distinction still remains valid to distinguish ova and sperm from other types of tissue.

⁶ In *Human Tissue Transplants*, the ALRC considered it appropriate to consider foetal tissue separately from other tissues. See Australian Law Reform Commission, *Human Tissue Transplants*, 20.

THESIS STRUCTURE AND METHODOLOGY

This thesis takes a five-staged approach to evaluating whether property law provides a mechanism for regulating tissue, and consequently this thesis is structured as five parts.

These are:

- Part I: Acquisition and Use of Tissue
- Part II: Regulating the Body
- Part III: The Common Law and the Body
- Part IV: Human Tissue and the Concept of Property
- Part V: Should Human Tissue Be Property?

At the outset of writing this thesis, it became clear that tissue use and regulation is most often debated in relation to specific types of tissue or in its use in particular contexts. As the major aim of this thesis is to examine whether property law provides a comprehensive solution to tissue regulation across multiple areas of use, the first part of the approach to this question was to develop a clear picture of how tissue is used and acquired in many scenarios. This is covered in Part I, which in three chapters examines a broad range of tissue uses, from dissection and autopsy to medical research, from forensics to genetic testing, and from museum exhibitions and artistic expression.

However, to provide a full picture of how tissue is currently used, and later of the legislation, case law and guidelines that regulate this use, it was also determined that there is a need to give some historical context. To this end, Part I outlines tissue use by tracing the history of use from pre-Christian time, through the emergence of dissection, the 18th and 19th century difficulties with body-snatching, to modern day uses such as research, treatment, testing, forensics and commerce. In doing so, this Part also elucidates some of the changes in the regulation of tissue in response to newer uses and sets the scene for the analysis of the case law stretching from the 16th century to the present.

While this approach to the material does yield a comprehensive picture of tissue use, it also resulted in a vast quantity of examples, which highlighted different issues and which were subject to differing considerations. To manage this material, 18 case studies are used to lend focus to the subsequent discussion of tissue use. Each case study is used to give examples and greater detail about a particular use, and to draw attention to particular issues in tissue use. The case studies cover such uses of tissue as the collection

of Aboriginal remains in museums, newborn screening, the Iceland decode database, the John Moore case, access to tissue for paternity testing and the use of tissue in Orlan's performance art.

Many of these case studies are also drawn from personal interviews, for example with pathology laboratory staff, medical researchers, epidemiologists, genetic testing service staff and one staff member from the John Radcliffe Hospital handling queries about retained organs.⁷ Interviews were conducted in person and written notes taken. At each interview, the subject was informed of the purpose of the research and was given the option of later reviewing material based on the information they had supplied. These interviews were used to develop an understanding of the actualities of tissue use in practice, to supplement the secondary accounts of use in the literature and the case law.⁸ Where a case study is based on such interviews, this is noted in the footnotes.

Similarly, there was a need to impose some order on the range of interests and issues raised by tissue acquisition and use. These interests can be broadly grouped into four classes:

- Individual interests, that is those of the person from whom the tissue is taken and to an extent those of other individuals related to the donor in some way;
- Community interests which may include the interest of indigenous communities in the bodies of their members;
- Research interests encompassing the needs of those who undertake scientific research requiring access to tissue specimens, and the interests of medical practitioners who remove and collect tissue;
- Commercial interests such as those of companies who conduct research and develop products from that research and who may also use tissue in the manufacture of their products; and
- Miscellaneous interests, two examples being those of artists who employ human tissue in the creation of their work, and the non-therapeutic commercial use of tissue as in the case of StarGene, a company that sought to sell celebrity DNA embedded in jewellery and phone-cards to allow consumers to own a piece of their heroes.

⁷ A complete list of interviewees is contained in the bibliography.

⁸ Research travel was also undertaken in 2001. This travel encompassed the United Kingdom and the United States and was aimed at gathering information on tissue use practices in these countries, and to communicate with other researchers in this area. Through this travel, a wider knowledge and a more practical knowledge of the research culture of these countries was gained. In the United States an overview of the legislation governing tissue use in that country was carried out during the author's time as a visiting scholar at the Hastings Centre in New York. This material is used both for comparison with the Australian situation and also to develop a picture of the possible future problems for Australia if its tissue collection and use rises to equivalent levels of those in the United States.

As Part I notes, a range of groups and individuals have valid interests in tissue, and where these intersect problems may arise in who has the right to use tissue. For example, individuals may have interests in protecting the privacy of information contained in their tissue, or in preventing its being used in a way they find objectionable. These interests might conflict with the interest of police in accessing tissue for forensic purposes, or a scientist's need for tissue to use in research. Consequently, in this kind of case, the use of tissue may raise issues about autonomy and privacy.

An effective regulatory system should be capable of managing these intersections and addressing these issues in a way that best promotes both individual and community needs. To assess this throughout the remainder of the thesis, the major interests and issues surrounding tissue use are drawn out in distinct sections in Part I. As many of the case studies highlight particular interests, these sections generally follow on from a case study. Each interest is outlined in a separate section, and then drawn upon when it arises in the context of other uses throughout Part I.

These case studies and interests are then used throughout the subsequent Parts of the thesis to lend both structure and consistency to the analysis. In each Part, the case studies and interests are used as examples by which to measure the effectiveness of the current regulation, the feasibility of applying property law and to highlight how in some instances current practices in the use of tissue are actually analogous to how property is treated under the common law. In particular, legal regulatory measures are examined in relation to the interests in each Part to determine whether they effectively met the needs of individuals, groups, the community and the legal system in the range of instances in which human tissue is used.

Having laid this groundwork, Part II analyses the legislation (Chapter Four) and ethical guidelines (Chapter Five) that regulate tissue use. This second part of the approach to the research question is aimed at providing a clear account of how tissue is governed by the interaction of legislation and guidelines. To fully assess whether property law provides a feasible (and perhaps better) approach to regulating tissue, it was determined necessary to critically appraise the coverage and success of the current legislation and guidelines. In these chapters, the case studies and interests are used in this critical appraisal, particularly to draw attention to uses of tissue that are not regulated either by legislation or guidelines. This Part concludes by summing up the areas in which these

legal regulatory mechanisms fail to respond to some of the issues raised by tissue use, and also to discuss whether they lend themselves to dealing with new uses as they emerge.

Part III examines the case law that has dealt with the use of human tissue and body parts. As there is a relative dearth of cases on this use, and because the Australian common law tradition draws on that of the United Kingdom, decisions from both jurisdictions are considered. This Part addressed one of the same aims as Part II—to critically assess whether the current regulation of tissue is adequate. However, as the courts have over time considered the property status of tissue, it is at this point that the concept of property is first introduced into the analysis.

As noted above, one of the reasons the debate about the regulation of tissue has focused on the use of property law is that the courts have also considered this approach. They have done so because many of the early cases in the 17th, 18th and 19th centuries considered whether there was a rule against property in a corpse, and whether this rule applied to excised parts of bodies. As a result, many of the later decisions, particularly those of the 20th century, have been based around whether the rule exists and whether it should apply in the instant case.

For two reasons, then, this Part focuses on determining whether the case law has developed a clear rule to be applied to tissue, that is, whether tissue has been deemed property. First, it does so to examine the basis of the debate about property and hence enable an assessment of its foundations. Secondly, it does so to consider whether there is anything in the case law that either prohibits or permits deeming human tissue as legal property, and especially to determine what trend the courts have begun to follow. This Part does so through two chapters, which divide the cases both chronologically and by their facts. Chapter Six examines cases dealing with whole corpses, dividing them into cases covering buried corpses, unburied corpses and corpses awaiting burial (as in some instances different rules have been applied to these in the cases). Chapter Seven examines the modern application of the rule against property in corpses, examining cases covering stolen body parts, access to stored materials, police acquisition for testing and a range of miscellaneous decisions. For comparative purposes and because it is one of the major cases in this areas, despite being a United State decision, the chapter also

analyses the decision in *Moore v The Regents of the University of California*.⁹ This Part ends by drawing conclusions about the state of the common law and whether there is a rule for or against allowing property in parts of bodies.

A full analysis of whether the common law in Australia could admit human tissue as property requires more than an assessment of the case law and legislation. A review of the literature demonstrated that for the most part, the general debate about whether human tissue should be property has focused on consequentialist concerns, particularly whether property law would yield the desired results, such as protecting research interests or individual autonomy and privacy. Less often, the debate focuses on the common law concept of property or the philosophical foundations of property law systems. Yet, to properly consider whether the common law can and should admit tissue as property, such a debate should consider these foundational issues.

To this end, Part IV analyses the concept of property at common law. Chapter Eight lays the groundwork for this analysis by outlining the rights-relationships vocabulary developed in the work of Wesley Hohfeld. This vocabulary, which divides legal relationships into four groups of rights and correlatives—rights and duties, privileges and no-rights, powers and liabilities, and immunities and disabilities—aids the later analysis by providing a means of better describing the types of rights provided under property law. The analysis of property rights in Chapter Nine uses this vocabulary to better examine how each right works, the powers, duties and rights each right confers and the types of relationships these rights establish.

Chapter Nine, one of the core chapters of this thesis, analyses whether tissue can fit with the common law notion of property. The chapter is structured around the eleven rights, or ‘incidents’, of property elucidated in the work of A M Honoré. Honoré contends that these incidents encapsulate the rights provided through property law, and together make up the incidents common to ownership in common law systems.¹⁰ Accepting Honoré’s account of property, which has been generally accepted in the literature, this chapter applies examines whether each incident can be applied to human

⁹ (1990) 51 Cal 3d 120.

¹⁰ A M Honoré, ‘Ownership’ in A Guest, (ed.) *Oxford Essays in Jurisprudence*, Clarendon Press, Oxford, 1961, 113ff. For discussion of this list in other works see, eg, L C Becker, *Property Rights: Philosophic Foundations*, Routledge and Kegan Paul, London, 1977, 18–20; J Waldron, ‘What is Private Property?’ (1985) 5 *Oxford Journal of Legal Studies* 313. See also S Hepburn, *Principles of Property Law*, Cavendish, Sydney, 1998, 2–3.

tissue. It does so by asking three questions about each incident in relation to tissue, and answers these with reference to the case studies and interests outlined in Part I. The questions are:

1. Can the incident be applied to human tissue, meaning is it possible to do so effectively and without producing absurdity?
2. Is this incident already reflected in the way human tissue is dealt with?
3. Does the legal system uphold or recognise this incident in relation to human tissue?

These questions were developed to determine whether the debate about property and tissue rests on the reasonable assumption that it would be possible to apply property law to tissue. The first question is clearly directed at considering whether applying property law to tissue would produce unworkability or legal absurdity.

The second and third questions are used to lend depth to the conclusions drawn from the answers to the first question. The second aims to establish whether the accepted treatment of tissue is akin to how property law would allow tissue to be dealt with. If answered in the affirmative, this would suggest that taking a legal property approach to regulating tissue would actually accord with how society and the law consider it reasonable to treat tissue, rather than being wholesale change with possibly unpredictable consequences. An affirmative answer would then support favouring a property approach, and again lend support to both the soundness of the debate and the reasonableness of the case for property rights in tissue. The third question has a similar aim, but takes this analysis a step further to see whether applying property law concepts to tissue would require a significant change in how the legal system deals with tissue.

Chapter Ten concludes Part IV by examining some of the philosophical bases of property law systems. Again, it seeks to consider whether tissue falls within the class of objects and things that it is appropriate to include within the ambit of property. For reasons of scope, it focuses on three major theories that may explain the property law system within the common law, which are first occupancy theory, labour theory and utilitarianism. This Chapter has particular resonance in relation to the tissue as property debate as some arguments in favour of property rights in the literature and the courts have been based on labour theory or utilitarian thinking.

While the foregoing analysis can determine whether it is possible to apply property law

to human tissue, there remains the question of whether it is appropriate to do so. Chapter Eleven, which makes up the whole of Part V, examines this issue and analyses the many arguments for and against applying property law to tissue given in the debate. In particular, there are a number of ethical concerns that might mitigate the desirability of applying property law to human tissue, such as concerns about the adverse implications of commodification and the need to promote altruistic participation in research. Chapter Eleven examines these concerns, and also balances this analysis by examining the range of arguments—legal and ethical—in favour of applying property law to human tissue. These include the need to clarify the status of tissue at law; the need to develop a comprehensive approach to tissue use that will determine how new uses of tissue should be regulated in the interest of consistency; and the need to provide adequate control and legal remedies to those whose tissue is used. This chapter also places particular focus on the issues raised by commercialisation, which form a subset of the general debate about the application of property law to human tissue. Again, this chapter uses the case studies and interests throughout its analysis.

This thesis concludes by examining whether, on balance, there is a sound legal basis to the property debate. It also takes a position on the desirability of applying property law to tissue. This conclusion is not, however, meant to provide a developed account of how property law might be applied to tissue, nor does it suggest solutions to the challenges that doing so might present. Rather, it provides a preliminary suggestion for the basis of such an approach, as the goal of this thesis is to analyse the foundational questions raised by the debate to facilitate further examination of how property law might successfully be applied to tissue if this is deemed appropriate.

Regardless of the position one takes on the issue of applying property law to human tissue, it should be accepted that there is a clear need to address many of the issues raised by tissue use is increasingly pressing. The Human Tissue Acts are long overdue for overhaul in the light of the medical and scientific developments of the 1980s and 1990s. The ‘new’ genetics and the use of tissue in forensics raise privacy concerns that require an effective regulatory framework that is currently lacking. This thesis seeks to assist in addressing this need by providing some basic analytical work on whether there is a case for continuing the debate, and hence assist in reaching some conclusion on whether the property approach deserves further consideration.

Part I

Acquisition and Use of Human Tissue

Contents

INTRODUCTION	17
 <i>Chapter One</i>	
EARLY HISTORY	21
1. Dissecting the Body: The Body in Medicine until the 18 th Century	21
2. Going to Blenheim Steps: Towards Regulation in the 19 th Century	25
3. Acquisition, Retention and the Expansion of Science: Into the 20 th Century	30
3.1 <i>Indigenous Collections</i>	31
3.2 <i>Retention, Research and the Absence of an Adequate Ethical Framework</i>	36
 <i>Chapter Two</i>	
UTILISING THE BODY	43
1. Organ Transplantation and Therapeutic Uses	44
2. Tissue as a Diagnostic Tool and Continued Collection	48
3. Research Uses of Tissue	56
4. Banking of Tissue	60
5. The Advent of Genetics	63
5.1 <i>Genetic Testing</i>	64
5.2 <i>Genetic Research</i>	69
6. Tissue as Forensic Material	72
7. Beyond Medical and Forensic Use	76
 <i>Chapter Three</i>	
CHANGING TECHNOLOGIES: THE BODY AS COMMODITY	80
1. Collections as Commodities	82
2. Tissue and the Generation of Profits	85
2.1 <i>Therapeutic and Manufacturing Uses</i>	94
3. Tissue and Organ Sales	95
4. Full Circle: Tissue as a Medium of Expression	101
CONCLUSION	107

INTRODUCTION

What is happening now across the world is public exposure to medical culture. Two issues must be considered. Firstly, practitioners removing body parts always have the best intentions. By this I mean they are removing the parts for medical research purposes; there is no malice intended. Secondly, the public wants and needs advances in medical science. This cannot occur without body parts for testing.

Bernard Dickens, speaking at the University of Newcastle¹¹

Some uses of human biological materials may be readily apparent, others less so. Most people are aware that organs can be transplanted from one body to another. Fewer may realise that DNA profiles are stored on forensic databases or that stored pathology samples are used in medical research. Developing a picture of how human tissues are acquired and used is fundamental to adequately addressing the issues the use of such tissues raise.¹² In the United States and United Kingdom a variety of government reports have presented information on the amount of tissue held and used;¹³ however until recently such information has been difficult to obtain in Australia.¹⁴ Media reports have regularly portrayed the use of human body parts and tissue as a catalogue of misuse and heartless disregard for the feelings of source individuals and relatives alike.¹⁵

¹¹ University of Newcastle, 'Removing Body Parts: A World Issue' (Press release, Newcastle, 26 March 2001).

¹² The remarkably wide-ranging and in-depth work of Lori Andrews and Dorothy Nelkin in the United States stands apart for this reason. See especially L Andrews and D Nelkin, *Body Bazqaar: The Market for Human Tissue in the Biotechnology Age*, Crown, New York, 2001.

¹³ National Bioethics Advisory Commission, *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance*, vol I, NBAC, Rockville, MD, 1999; Department of Health (UK) and NHS Department of the Welsh Assembly Government, *Human Bodies, Human Choices: The Law on Human Organs and Tissue in England and Wales—A Consultation Report*, HMSO, London, 2002, especially ch 9, 13–15, 17; Department of Health, Department of Education and Employment and the Home Office, *Report of a Census of Organs and Tissues Retained by Pathology Services in England: Conducted in 2000 by the Chief Medical Officer*, HMSO, London, 2001. An in-depth report into the use of human tissue was also prepared by the Nuffield Council on Bioethics in 1995. See Nuffield Council on Bioethics, *Human Tissue: Ethical and Legal Issues*, Nuffield Council on Bioethics, London, 1995.

¹⁴ Censuses of tissue retained following autopsy have been undertaken in some Australian States. See South Australia Solicitor-General, *Report into the Retention of Body Parts after Post-Mortems*, Department of Health Services South Australia, Adelaide, 2001; New South Wales Health Department, *Interim Report into the Retention of Organs following Post-Mortems in NSW*, New South Wales Health Department, Sydney, 2001; Crown Solicitor for Western Australia and Commissioner for Health for Western Australia, *Final Report: Removal and Retention of Organs and Tissue Following Post-Mortem Examinations*, Department of Health Western Australia, Perth, 2001.

¹⁵ Many news reports of organ retention in both Australia and the United Kingdom used terms such as 'body snatching' and 'organ stripping' to refer to organs removed without consent. These loaded terms play on community fears and heighten the emotional aspect of the situation. See, eg, S Scott, 'Body Snatchers' *Lateline*, ABC Television, 11 October 2000, <www.abc.net.au/lateline/stories/s198380.htm> at 25 October 2004, wherein reporter Sophie Scott stated that organ donation groups stressed that 'body snatching' did not occur, yet then continued to refer to the practice of 'organ-stripping'. See also H Dallis, 'The Body Snatchers' *Sunday*, NineMSN, 18 March 2001, <sunday.ninemsn.com.au/sunday/cover_stories/article_771.asp> at 25 October 2004. *The Times* referred

Public commentary has also fuelled perceptions of tissue use as ‘Frankenstein technology’.¹⁶ But this is only one perspective, and a sensationalised one at that. Instead, concrete examples of problematic and potentially problematic situations should be presented, and these should be placed in context—both historically and with an eye to the particularities of research, medicine and organ transplantation in Australia.

This Part will outline how human tissue is currently used—in medical research; as part of forensic investigations; for the production of therapeutic goods; in diagnosing and treating illness; and in some more esoteric contexts, such as artistic expression. It is not enough, though, to simply take a snapshot of current use. The wider historical background is required to lend resonance to any understanding of current practices in relation to tissue. Hence, rather than simply presenting an overview of tissue uses that occur now, this chapter will trace the history of the use of human tissue from its earliest stages. In doing so, this Part will demonstrate how attitudes to the use of bodies have changed; and how the law has gradually entered the sphere of medicine and research to regulate the use of human tissue. This contextualisation will also explain the social circumstances and scientific discoveries that spurred the development of the legislation and common law rules dealing with tissue. These will be discussed in Parts II and III respectively. However, it bears mentioning here that the Australian legislation that established the current consent-based framework for using tissue was passed in the early 1980s, which, as will be discussed in Chapter Two, was the time when success with transplantation science was making organ and tissue transplantation an increasingly common practice. By contrast, the common law rule against property rights in corpses emerged in the 18th and 19th centuries, in response to the epidemic of body-snatching that will be discussed in Chapter One. An understanding of the contexts of these legal developments will help to illuminate what they were trying to achieve, while the discussion in Chapter Three of scientific and medical progress since will demonstrate why these approaches may no longer be satisfactory.

Originally the body was the focus of almost solely spiritual concerns, but from this

to the retention of organs in British hospitals as ‘a latter-day version of Burke and Hare’s bodysnatching’. See ‘No Consent: Secrecy Not Good Science Has Caused the Liverpool Scandal’ *The Times* (London), 4 December 1999, 23. Dr Trevor Mudge, of the Australian Medical Association, has commented that news stories about organ and tissue retention have played on society’s discomfort and fears about death. See T Mudge, ‘From the Vice-President: Parting With Our Bodies’, 13 *AusMed Online*, 2 April 2001, *Australian Medical Association*, <www.ama.com.au/web.nsf/doc/SHED-5EXGTP> at 23 April 2003.

¹⁶ K Ahmed and G Hinsliff, ‘Human Embryos to be Cloned: Church Fury over “Spare Parts” Research’ *The Observer* (London), 30 July 2000 <www.observer.co.uk/uk_news/story/0,6903,348608,00.html> at 1 September 2003.

position it became the subject of anatomical science, and later anthropological study and collection. In the last century, its parts have become materials for transplantation and the creation of therapeutic goods, and the body gained value for medical research and treatment. Now, as a result of genetic science, human tissues may be used as a source of intimate information about a person. As the raw materials for profitable research and product development, tissue has also become a valuable commodity in the modern market. The growing commercialisation of human tissue will be developed as a theme throughout this and subsequent chapters, as it presents one of the major problems for the current regulatory framework.

This historical approach will elucidate why many of these uses require new and better regulation, and outline emerging challenges not yet dealt with by the legal system. Both present and potential future uses of tissue in Australia will be analysed and case studies will be used to present examples of major uses of tissue. Many of these cases studies are based upon primary research conducted by the author. As noted, one of the failings of much commentary in this field of study is a lack of concrete examples on which assessment of the problems inherent in tissue use is based. This thesis seeks to address this lack by utilising information gathered through interviews with medical and scientific researchers, hospital legal officers, those who administer the return of organs held by hospitals and others who work with and control human tissue samples.

Each study will elucidate particular challenges presented by tissue use for the legal system, and will act as a foundation for examining the issues surrounding the use of human tissue in Australia. Some are examples from the United States,¹⁷ and they are included to throw light on possible future uses and issues which, though they have not yet arisen in Australia, are certainly challenges which must be contemplated in designing a forward-looking legal response.¹⁸

Human tissue sits at the nexus of a multitude of sometimes conflicting interests. The legal system is most required to regulate where these interests conflict. The legal system must balance these interests against one another to develop an equitable and workable

¹⁷ Examples from other countries will be used to give a fuller picture of tissue use, and to demonstrate possible uses and problems that have arisen elsewhere, but may arise in Australia in the future.

¹⁸ One famous example is the case of John Moore, which has been mentioned briefly already. While no similar case has arisen in Australia, and the Australian research culture is less commercialised at present, it is not certain that this will remain the case. The biotechnology industry is growing rapidly in this country and it is possible that a research subject might in future claim some of the profits of research.

solution to the challenges they raise. As each use of human tissue is examined, the varying interests in that tissue will be outlined and analysed—for example, individual interests in privacy; research interests in access to tissue; and police and forensic interests in access to tissue for investigative purposes. As many of these interests arise in different contexts, each will be examined in dedicated sections to enable detailed analysis and avoid repetition. Each case study will also highlight one or more particular interests and potential conflicts between them. Analysis of the interplay of these interests will elucidate the potential problems of each use that any proposed legal reforms must address.

In subsequent chapters, these case studies will be drawn on to examine how effectively the current legal system is dealing with human tissue use, and how it might address future problems that may arise. They will also be used to test proposed solutions. In this way, the same examples will be used both to lend structure to this analysis, and to form consistent test cases both for the current law and possible future legal approaches. Similarly, the interests and conflicts identified in this chapter will also be drawn on each chapter as part of this analysis—for example, to consider how well the legal system currently balances and protects certain interests. This will act as a benchmark of an effective approach to regulating the use of tissue, that is, one which best takes account of the interests different groups have in human tissue and how they need to be balanced.

Chapter One

EARLY HISTORY

Over the last two millennia human bodies have been dissected, their organs taken and studied, their bones placed in museums and their hair used for wigs. Teeth have been taken from the dead and ‘transplanted’ into the jaws of others since Elizabethan times.¹ A foetus has been placed in a jar and exhibited,² while the bodies of children have been stripped of their brains and hearts to be retained for study.³ Though the technological developments of the last two decades have created numerous new and inventive uses for human tissues and corpses, the practice of finding uses for the bodies of the dead can be traced back to well before the emergence of modern science. Our methods have changed, they are more refined and certainly more regulated, but the aims remain the same—to study the body and its workings, and to take from it that of which we, the living, can make use.

1. DISSECTING THE BODY: THE BODY IN MEDICINE UNTIL THE 18TH CENTURY⁴

In the last centuries of the pre-Christian era, the body’s workings and structures were poorly understood, and the major aim of dissection was to uncover the secrets of the body’s processes. In the main, the body had been the site of spiritual, rather than scientific interest before this time. In the Judeo-Christian tradition, interference with the

¹ R Scott, *The Body as Property*, Allen Lane, London, 1980, 180.

² *Doodeward v Spence* (1908) 6 CLR 406.

³ See generally South Australia Solicitor-General, *Report into the Retention of Body Parts*; B Walker, *Inquiry into Matters Arising from the Post-Mortem and Anatomical Practices of the Institute of Forensic Medicine*, New South Wales Department of Health, Sydney, 2001; New South Wales Health Department, *Interim Report into the Retention of Organs*, New South Wales Health Department, *Review of the Human Tissue Act: Organs and Tissue Donation and Use and Post-Mortem Examinations*, New South Wales Department of Health, Sydney, 1999; Crown Solicitor for Western Australia and Commissioner for Health for Western Australia, *Final Report: Removal and Retention of Organs and Tissue*, Independent Review Group on Retention of Organs at Post-Mortem (Scotland), *Final Report*, Scottish Executive Health Department, Edinburgh, 2001; Department of Health, Department of Education and Employment and the Home Office, *Report of a Census of Organs and Tissues Retained by Pathology Services in England: Conducted in 2000 by the Chief Medical Officer*, Department of Health, Department of Education and Employment and the Home Office, *The Removal, Retention and Use of Human Organs and Tissues from Post-Mortem Examinations: Advice from the Chief Medical Officer*, HMSO, London, 2001; Department of Health, *The Report of the Royal Liverpool Children’s Inquiry*, HMSO, London, 2001.

⁴ A good historical account of this period can be found in J Sawday, *The Body Emblazon’d: Dissection and the Human Body in Renaissance Culture*, Routledge, London and New York, 1995. See also D G Jones, *Speaking for the Dead: Cadavers in Biology and Medicine*, Ashgate Publishing, Aldershot, 2000; R Richardson, *Death, Dissection and the Destitute*, Routledge and Kegan Paul, London, 1987 and Scott, *The Body as Property*.

body after death was both an affront to God and to the embodied soul who had once inhabited the body.⁵ With the development of the study of anatomy, the body became the domain of medicine as physicians and scientists came to see dissection as the key to unlocking its mysteries. It became a site of scientific inquiry.

The history of the body in research and medicine begins with the first recorded dissections by Herophilus in the third and fourth centuries BC, mainly using the corpses of criminals.⁶ The practice continued into the time of Galen of Pergamum in the second century AD, whose prolific writings became the accepted texts on the anatomy and workings of the human body for centuries. Galen based much of his work on that of his predecessors, including Herophilus (who may have dissected as many as 600 bodies) as he himself had no access to bodies for dissection, which was not permitted in the Roman Empire. Instead, much of his own work was carried out on animals and based on what he observed as physician to the gladiators.⁷

The study of anatomy through the dissection of corpses lapsed for more than a thousand years following Galen, in part because the scientists of the medieval period took his works as sufficiently authoritative as to preclude the need for more primary investigation.⁸ However, when others came to revive the practice, they met with resistance. Dissection was still regarded as a desecration of the body. It was believed that the body had to be buried whole to ensure salvation, for, as Caroline Walker Bynum has written, 'salvation [was] wholeness, hell [was] decay and partition'.⁹ This perception was based on the prevalent Christian belief that the body should remain whole after death to enable resurrection on the Day of Judgement.¹⁰ However as D Gareth Jones has noted, the process of dismemberment for other purposes was not considered a desecration. In England and France during this time members of the aristocracy would request that if they died abroad, their bodies be boiled and stripped of

⁵ See generally Introduction.

⁶ Jones, *Speaking for the Dead*, 33.

⁷ Ibid, 33–34.

⁸ Ibid, 35.

⁹ C W Bynum, *The Resurrection of the Body in Western Christianity*, Columbia University Press, New York, 1995, 114 as quoted in D Nelkin and L Andrews, 'Do the Dead have Interests? Policy Issues for Research after Life' (1998) 24 *American Journal of Law and Medicine* 261, 262.

¹⁰ Scott, *The Body as Property*, 13. Though there are many strands of belief within what can be called the Judaeo-Christian tradition, William May has in most strands it is believed that there is 'a profound link and identity of the spirit with its somatic existence'. This belief leads to reluctance to allow the body to be tampered with after death. See W F May, 'Religious Justifications for Donating Body Parts,' (1985) 15(1) *Hastings Center Report* 38–42 as quoted in J F Childress, 'Attitudes of Major Western Religious Traditions toward Uses of the Human Body and Its Parts' in D A Knight and P J Paris, (eds), *Justice and the Holy*, Scholars Press, Atlanta, 1989, 216–217.

flesh. The bones were then to be transported back to their home for burial while the flesh could be buried where they had died.¹¹ In the main, though, dissection was not a fate to which many would willingly submit their corpses. In the words of Ruth Richardson, 'in the recesses even of the rational mind, there lurked the fear that mutilation of the corpse might have eschatological implications'.¹²

However, following the efforts of Mondino di Luzzi at the University of Bologna, in the 14th century dissection became an accepted part of the curriculum for Italian medical schools. Di Luzzi's *Anatomica*, written in 1316, became the one of the most widely used anatomical textbooks for the Middle Ages. As in the past, the subjects for dissection were criminals, as desecration of the convicted criminal was of less concern. These dissections were performed in public as an aid to the understanding of Galen's still widely accepted texts. In time, the practice spread across Italy and medical schools began to make observation of a dissection compulsory for students. But while anti-dissection sentiment remained, exceptions were made. For example, Pope Clement VI allowed the bodies of people who had died of the plague to be examined.¹³ Thomas Aquinas' assertion that the mutilation of the body was acceptable when performed for medical, social or political reasons was also highly influential at this time.¹⁴

The medicalisation of the body, so in evidence today, had its beginnings in these early studies of anatomy, which dispersed some of the mystery of internals of the human body. Mimicked, perhaps unintentionally, in Albrecht Durer's 15th century painting, *Artist Drawing a Nude through a Gridded Screen*, the anatomical gaze had pulled the body into its component pieces and this physical deconstruction of the body paved the way for it to be viewed from a mechanistic perspective, and for the regularisation of using the human body as a source of material for study and inquiry.¹⁵

However, with the death of di Luzzi the forces opposing dissection once more gained precedence and the practice he had regarded as a noble and worthy endeavour again slid

¹¹ Jones, *Speaking for the Dead*, 36.

¹² See Richardson, *Death, Dissection and the Destitute*, ch 1, 2.

¹³ Jones, *Speaking for the Dead*, 35.

¹⁴ Aquinas makes this argument in *Summa Theologica*. See further D Gracia, 'Ownership of the Human Body: Some Historical Remarks' in H Ten Have, 'Biomedical Research With Human Body Parts' in H Ten Have and J Welie, (eds) *Ownership of the Human Body: Philosophical Considerations on the Use of the Human Body and its Parts in Healthcare*, Kluwer Academic Publishers, London, 1998), 67, 70.

¹⁵ Robert Romanyshyn has commented that both Durer's image, and the practice of anatomy create a similar attitude of distance and both 'share the same space of separation between spectator and specimen. See R Romanyshyn, 'The Body as Historical Matter and Cultural Symptom' in M Sheets-Johnstone, (ed.) *Giving the Body its Due*, SUNY Press, New York, 1992, 167.

into disfavour. But in time, as medical science continued to develop, the desire to improve understanding of the body by studying corpses began to build. By the 16th century, Andreas Vesalius of Brussels was permitted to perform numerous dissections and revolutionise the study of human anatomy by basing his research on first-hand examination of the structures of the body.¹⁶ The 16th century also saw the emergence of the first British laws dealing with the need for corpses when, in 1506, James IV provided that the body of one executed criminal was to be supplied to the Guild of Barbers and Surgeons every year. Henry VIII made a similar provision in 1540, allowing the United Company of Barbers and Surgeons four bodies per year, a grant that Elizabeth I extended to the College of Physicians in 1564¹⁷ and which Charles II increased to six during his reign in 1663.¹⁸

By the 18th century dissection was a relatively common, if still not widely or overtly admired practice and trade in parts of the body had begun in England.¹⁹ Hair was also taken for wig-making and bones removed to be reassembled for medical specimens, while the budding science of transplantation was developing in the dentist's chair as teeth were taken from the dead to replace those lost by the living.²⁰ To use Ruth Richardson's term, corpses were 'quarried', anything useful being swiftly removed and 'profits were to be made at every stage'.²¹ The commodification of the body has been happening for centuries.

There was, however, no regulated supply of human bodies for anatomical study until the *Murder Act 1752* (UK) (Murder Act). The Act allowed judges sentencing murderers to hang to include the added punishment of either having their bodies rot in a public gibbet or be donated to the Royal Colleges for anatomical study. Despite the Act, supply remained fairly irregular. In addition, having constructed dissection as a punishment, the Act lent little real acceptance to the practice. Dissection may have come to be regarded as desirable in the interests of science by some, but that it was perceived as a fate for the body equal to rotting suggests it was viewed more as a punishment than a noble gift to

¹⁶ Anatomy schools had been established across Italy, and British anatomists came there to study. Vesalius revolutionised the study of anatomy with the publication of *De Humani Corporis Fabrica* (*On the Fabric of the Human Body*) in 1543. His text contained precise and accurate woodcuts of anatomical structures and replaced the inaccurate medieval texts. See further Richardson, *Death, Dissection and the Destitute*, 32.

¹⁷ Scott, *The Body as Property*, 5.

¹⁸ Richardson, *Death, Dissection and the Destitute*, 36.

¹⁹ For a comprehensive history of anatomy and the supply of corpses see Ibid, ch 2, 3.

²⁰ See, eg, P Ducor, 'The Legal Status of Human Materials' (1996) 44 *Drake Law Review* 195, 226.

²¹ R Richardson, 'A Potted History of Specimen-Taking' (2000) 355 *Lancet* 935, 935.

science.²² To dissect a body was still regarded as sacrilegious and degrading, though it was increasingly tolerated in some circles as necessary for the development of medicine and the teaching of students.²³ For others, however, it remained a moral outrage.

2. GOING TO BLENHEIM STEPS: TOWARDS REGULATION IN THE 19TH CENTURY

The body-snatchers, they have come,
And made a snatch at me;
'Tis very hard them kind of men
Won't let a body be.
The cock it crows—I must be gone—
My William, we must part;
But I'll be yours in death although
Sir Astley has my heart.

*Thomas Hood, Mary's Ghost*²⁴

In the 19th century, using the body as an object of study and as a source of materials for research became more usual and began to be legally regulated. Legal sanction was given to dissecting and studying the body, and the language of the law entered into the sphere of medical scientific research. This era in the history of human tissue use can be regarded as a new, second phase as it marks the shift from the ad hoc, unregulated use of bodies in the preceding centuries to the modern phase, when the use of bodies and their parts had become widespread and, in some contexts, highly regulated by the law.

This is also a new, transitional phase because society began to actively address many of the problems raised by the use of bodies and tissue by balancing the need to use tissue in research and medicine with moral and social concerns. This differs from the previous phase when the use of human tissue was mostly outlawed or condemned on religious grounds or due to superstition. In the 19th century, practical concerns began to be balanced against moral and religious concerns to find a middle position on the use of bodies and their parts. By the end of this second phase, using the body had moved from being a practice despised and feared to one that was, at least in some cases, regarded as

²² Ibid.

²³ Nelkin and Andrews, 'Do the Dead have Interests?', 263. Nelkin and Andrews support this by reference, for example, to an American source—an article produced in *Harpers* magazine from 1854 in which the objection to dissection was expressed as: 'Science may prove, ever so clearly, that there is nothing there but carbon, and oxygen, and lime ... but all this can never eradicate the sentiment we are considering. It enters too deeply into our laws of thinking, our laws of speech, our most interior moral and religious emotions': (Editorial, (1853–1854) 8 *Harper's New Monthly Magazine* 690, 690).

²⁴ 'Going to Blenheim Steps' meant going to be dissected or 'resurrected' from one's grave. The phrase refers to an anatomical school located at Blenheim over which the famed surgeon and noted anatomist Sir Astley Cooper presided. See generally *Brewer's Dictionary of Phrase and Fable*, Cassell, London, 1999, 'Going to Blenheim Steps'.

sufficiently important to require legislation of a more comprehensive kind. Consequently, this chapter introduces case studies that demonstrate some of the early modern problems with tissue use—indigenous collections and organ retention—and examines concerns about individual autonomy and the special interests of indigenous communities.

By the beginning of the 19th century, autopsy and the study of corpses was an established aspect of medical science.²⁵ As demand for bodies grew with the rise of the science of anatomy and the increasing numbers of medical schools, the supply of bodies from the gallows proved insufficient and market forces moved in. While the practice had been commonplace since the 1720s,²⁶ the most famous embodiments of these forces were William Burke and William Hare, two of the so-called ‘body-snatchers’ of the early 19th century. Burke and Hare, among others, began to acquire bodies by disinterring newly buried corpses.²⁷ These they delivered to medical schools for study or removed their hair and teeth to be sold. It has been estimated that thousands of corpses were stolen annually, the numbers growing as the body-snatchers became more organised and formed liaisons with anatomists and medical schools.²⁸ Macabre though the practice was, it bears remembering that those with the admirable desire to increase understanding of the human body and improve medical techniques were in a most difficult moral position—striving to learn more about how to cure disease (a morally worthy pursuit), while being prevented from accessing bodies to enable this study, because that practice was morally condemned. In the absence of legal regulation, they also faced an uncertain reception if brought before the courts.

Evidence of how widespread the practice was can be found housed in the Hunterian Museum of the Royal College of Surgeons in London, where almost all the specimens acquired during the period prior to 1832 are believed to have been stolen from graves or otherwise obtained without consent.²⁹ In some instances, corpses and skeletons were

²⁵ Nelkin and Andrews, ‘Do the Dead have Interests?’, 263.

²⁶ Jones, *Speaking for the Dead*, 45. Indeed, body snatching had been occurring in England since the 17th century, and Shakespeare’s own epitaph has been used as evidence for this. It reads:

Good friend, Iesus sake forebeare
To Digge the dust enclosed heare.
Bleste be ye man [that] spares there stones,
And curste be he [that] moves my bones.

as quoted in Richardson, *Death, Dissection and the Destitute*, 54.

²⁷ D E Jeffries, ‘The Body as Commodity: The Use of Organ Markets to Cure the Organ Deficit’ (1998) 5 *Indiana Journal of Global Legal Studies* 621, 621.

²⁸ Jones, *Speaking for the Dead*, 45.

²⁹ Richardson, *Death, Dissection and the Destitute*, 935.

kept because of they were of some unique interest, like the body of the 'Irish Giant', Charles Byrne who died in 1783. Byrne had been a subject of immense curiosity during his lifetime due to his unusual physical size—he was more than seven feet tall³⁰—and on his death the anatomist John Hunter contrived to acquire his corpse. Byrne's body was not only dissected against his express wishes, but is currently subjected to the further ignominy of being displayed in the Hunterian Museum at the Royal College of Surgeons in London³¹—a fate that would no doubt have made him turn in his grave, had he been allowed to rest in one.

By the early part of the 19th century, the age of Mary Shelley's *Frankenstein* with its unsettling tale of a scientist who reanimates a body constructed from parts stolen from charnel houses, the resurrectionists and their trade had become a matter of deep social concern. In 1829, the editor of the *Lancet* declared that '[i]f the horrid traffic in human flesh be not, by some means or other, prevented, the churchyards will not be secure against the shovel of the midnight plunderer, nor the public against the dagger of the midnight assassin'.³² Three years later, in the same journal, the editor argued that it was 'disgusting to talk of anatomy as a science, whilst it [was] cultivated by means of practices which would disgrace a nation of cannibals'.³³ Public dislike of dissection was evidenced when people began to riot at executions to prevent the corpse being used for anatomical study.³⁴ By this time, the wealthy had begun to bury their dead in metal coffins to deter the body-snatchers, and anatomy schools were clamouring for reform as the first conviction was brought against an anatomist for using a corpse which he knew to have been disinterred.³⁵ A Society for the Protection of the Dead was even founded in Scotland.

A Parliamentary Select Committee was established in 1828 to consider the problem and took evidence from retired resurrectionists. One admitted to stealing more than a thousand adult corpses and almost two hundred of children between 1809 and 1813, while the prominent surgeon Sir Astley Cooper reportedly boasted that he could acquire

³⁰ Ibid, 57.

³¹ Byrne had been rightly concerned that in a time of resurrectionism, his body would be a highly prized specimen for the anatomist and most likely would have been swiftly wrested from its grave. Intent on avoiding this fate, he made a large bequest of money to ensure that his body was buried at sea, safe from the hands of any would-be body-snatchers. Despite Byrne's precautions, Hunter managed to bribe the undertaker in possession of the corpse and have it transferred to his dissection rooms.

³² As quoted in Richardson, 'A Potted History of Specimen-Taking', 52.

³³ Taken from an issue of the *Lancet*, 1832 as quoted in Jones, *Speaking for the Dead*, 45.

³⁴ Richardson, *Death, Dissection and the Destitute*, 52–3.

³⁵ Scott, *The Body as Property*, 8.

the corpse of any person 'let his situation in life be what it may'.³⁶ Little action was taken and the first Anatomy Bill, which provided that unclaimed corpses from workhouses and hospitals could be used for anatomical study, was rejected after its introduction into Parliament in 1829. In the main, the bill was rejected because it was thought that it would have the effect of replacing the bodies of murderers with those of the innocent poor.

Only three years earlier, William Burke had been tried when it was discovered that he had gone further than simply stealing the bodies of those already dead, but had also begun to hasten the deaths of others to meet demand.³⁷ Burke was eventually executed on 28 January, 1829 and in a neat and ironic turn of fate, his body was donated to the Edinburgh Medical School for dissection as provided for in the Murder Act, while his skin was allegedly tanned and sold as wallets and tobacco pouches.³⁸ This execution, perhaps in part because it was held in Scotland, did not spur the English Parliament to action. It took the violent death of a fourteen year old boy in 1831 to do so. In November of that year, John Bishop and Thomas Williams murdered Carlo Ferrari and, with their accomplice John May, removed his teeth and sold them for one guinea. They then delivered the body to an anatomist who promised them another nine guineas—more than ten times the weekly wage of an average labourer. But both the dentist and the anatomist were suspicious of the body's source as it was clear that the youth had died violently and that the teeth had been ripped from his jaw. The anatomist called the police and the three were apprehended only hours after the murder.³⁹ Public outcry forced the hand of government, and a choice had to be made between acceptance of the practice of dissection or turning a blind eye to the forces that were meeting the increasing demand. Within ten days of their conviction and execution the Anatomy Bill was re-introduced and this time passed.

This later version of the Bill referred only to unclaimed bodies, which could be handed over for study by those in lawful possession and it did not mention where they were held. The effect, however, was the same and the bodies of those too poor to pay for

³⁶ Ibid.

³⁷ Jones, *Speaking for the Dead*, 46. There were suggestions that Dr Robert Knox, to whom Burke and Hare supplied corpses, had commissioned the murders, but these allegations were not investigated. The two were eventually caught when a guest at Hare's lodging house discovered an ill-concealed corpse and Burke was tried on Christmas Eve, 1828. Hare decided to give evidence for the Crown and was not executed.

³⁸ Ibid, 11. It has also been alleged that portions of the skin were printed with pictures of Burke and Hare and sold as gruesome curios. More than 20,000 people watched the execution and were later allowed to view the results of the dissection.

³⁹ See generally Scott, *The Body as Property*, 11.

their own funerals could be taken for study.⁴⁰ Voluntary donation was also provided for, and anatomy schools were to be licensed and regularly inspected.⁴¹ The effect of this legislation was to last until well into the 20th century and had consequences for Commonwealth countries, like Australia, which inherited English laws.⁴²

Statistics from New Zealand show the effects of colonies following the legislative example of England. With the establishment of the highly respected Otago Medical School in Dunedin in 1875, a supply of cadavers for teaching was needed. The commencement of the *Anatomy Act 1875* (NZ) in the same year, meant these came in very large part from the poor who had died in local public hospitals. The Act authorised the lawful possessor of any body to allow its dissection unless it was known that the deceased had objected during life. However, by 1887 bodies began to be supplied by the Benevolent Institution, a poor house, which by 1900 supplied the majority of corpses for study. After the Benevolent Institutions began to disappear around 1915, the shortfall was made up by the mental hospitals and it was not until the 1950s that consensual donation became the major source of bodies.⁴³

In Australia, following in the legislative example of England, the states enacted Anatomy Acts of a similar form. Concern was voiced at this time from some quarters, for example in relation to the *Anatomy Act 1881* (NSW) that the legislation would render some people more liable to dissection than others, namely those dying without family or friends to ensure the burial of their body.⁴⁴ In South Australia, the *Anatomy Act* of 1884 provided that a party lawfully in possession of a body could authorise its use for

⁴⁰ It has been argued that dread of having one's body dissected after death was so great at this time that the poor would be driven to 'avoid the hospitals and die unattended in the streets'. See M J Durey, 'Bodysnatchers and Benthamites' (1976) 22 *London Journal* as quoted in J Feinberg, 'The Moral Trap of Sentimentality: The Mistreatment of Dead Bodies' (1985) 15(1) *Hastings Center Report* 31, 31. The history of dissection in the United States is relatively similar to that of England, although it differs in some interesting aspects. In particular, the 'profession' of grave-robbing did not develop to any great extent in the United States, nor were many murders committed to obtain bodies for sale. Despite this, the protests against dissection were more vocal than those of England, resulting in rioting in some States. In one instance in 1788, five people were killed during a riot that followed attempts to burn down the Hospital Society building in New York as it was known to contain human specimens. See *Ibid*, 148. This might perhaps be ascribed to the very poor reputation of dissection and medical students, which might itself in part have derived from the fact that the lack of body-snatchers meant doctors and students were forced to do their own 'resurrecting'. There was also a clear resistance to 'fooling with human bodies' as the New York rioters put it. For a more detailed history of dissection in the United States: Jones, *Speaking for the Dead*, 47–54.

⁴¹ This was the same approach which had traditionally been taken on the Continent, where the use of unclaimed bodies for study had been the practice in Italy, France, Germany and Austria for some time, and the problem of body snatching did not arise in these countries. See Scott, *The Body as Property*, 4–5.

⁴² Figures taken from Jones, *Speaking for the Dead*, 51.

⁴³ *Ibid*, 51.

⁴⁴ See, eg, Walker, *Institute of Forensic Medicine Inquiry*, [57]–[59].

anatomical purposes, unless that person was aware that the deceased or a relative had expressed an objection—effectively an ‘opt-out’ system.⁴⁵ This Act has subsequently been amended.

The Anatomy Acts in each country effectively put an end to the trade in cadavers and body-snatching, by providing a regular and adequate source of supply. Though grave-robbing had never been accepted as a legitimate means of acquiring bodies for anatomical study, the passing of these Acts demonstrated a realisation that the need for those bodies was not going to disappear. Acceptance of the medical use of cadavers and the value of such scientific inquiry had progressed by this time to a point where public regulation was preferable to covert black markets. Dissection was gradually becoming the worthy pursuit Mondino di Luzzi had believed it to be, rather than a punishment. The body, meanwhile, was completing its shift into the province of medicine, science and now the law.

3. ACQUISITION, RETENTION AND THE EXPANSION OF SCIENCE: INTO THE 20TH CENTURY

As grave-robbing to supply anatomists decreased, a new phase in the use of human bodies and their parts was beginning. Scientific use of bodies was now legitimated by law, also reflecting changed community attitudes. The body was now accepted as a site of inquiry. This fact, coupled with new scientific developments, led to an extraordinary expansion in the uses for bodies and their parts. From its limited use as an object to be dissected, and sometimes raided for precious materials, the body became a site for wide-scale research.

The body was now no longer part only of a relationship between doctor and patient, or when dead, between anatomist and corpse. It is in this stage that third parties—biological chemists, anthropologists and later geneticists and pharmaceutical companies—entered into that relationship. And as they did, so also did the law and other means of regulation such as ethical principles. It is at this time that proprietary notions began to enter into discourse on the use of the body, with museums assembling and retaining their collections of specimens. Researchers and anatomists were no longer just examining bodies, they were keeping them.

⁴⁵ *Anatomy Act 1884* (SA) s 8.

3.1 Indigenous Collections

From the middle of the 19th century a practice which has continued up to the present day began, as scientists and anthropologists began not only to dissect, but also to collect and display body parts. The discovery of formalin as a means of preserving specimens spurred collection, and preservation began to occur on a large scale. The turn of the century Australian case *Doodeward v Spence*⁴⁶ is the tale of one such retention, in which the body of a two-headed foetus had been kept not for study, but for display at fairgrounds. Touted as a freak of nature, the corpse was taken around the country suspended in a jar filled with formalin and shown for the amusement of others.

However, these ad hoc 'freak show' collections were more a throwback to previous times. At this time, scientific use of the body was becoming systemised, and museums like the Hunterian began to methodically collect huge quantities of specimens. The experience of the Australian Aborigines is a chilling example of the scale on which this acquisition occurred. During the 19th century, the influence of Charles Darwin's *Origin of Species* fuelled scientific interest in the study of different racial groups and consequently, the desire for specimens to examine.⁴⁷ Researchers saw race as a defining characteristic, and some theorised that Australian Aborigines were a 'primitive' race that formed an evolutionary link between apes and humans.⁴⁸ Robert Knox, who had who studied aboriginal remains, declared aborigines a different species in his 1850 work *The Races of Man*. Notions like these were widely held in England and gave scientists a rationale for collecting Aboriginal remains for study.⁴⁹ For the Victorian student of anthropology Australia was, in the words of Derek Mulvaney, 'a museum of primeval humanity and a storehouse of fossil culture'.⁵⁰ This drove researchers to acquire large quantities of Aboriginal corpses for study, some through grave-robbing but others by murder.⁵¹ It has been estimated that between five and ten thousand Aboriginal graves were plundered

⁴⁶ *Doodeward v Spence*. See generally L Griggs, 'The Ownership of Excised Body Parts: Does and Individual Have the Right to Sell?' (1994) 1 *Journal of Law and Medicine* 223.

⁴⁷ R S Magnusson, 'Proprietary Rights in Tissue' in N Palmer and E McKendrick (eds), *Interests in Goods*, 2nd edn, LLP Reference Publishing, Hong Kong and London, 1998, 38.

⁴⁸ See Jones, *Speaking for the Dead*, 139. See further A Markus, *Governing Savages*, Allen and Unwin, Sydney, 1990.

⁴⁹ Editorial, 'Bringing Truganini Home' *The Age* (Melbourne), 5 January 2002 <www.theage.com.au/opinion/2002/01/05/FFXL0DGU0WC.html> at 1 September 2003.

⁵⁰ D J Mulvaney, 'The Australian Aborigines 1606–1929' in S Janson and S MacIntyre, (eds) *Through White Eyes*, Allen and Unwin, North Sydney, 1990, 24ff, where Mulvaney includes a detailed and illuminating history of anthropological study of Aborigines in the 19th century.

⁵¹ See D Monaghan, 'The Body-Snatchers' *The Bulletin*, (Sydney) 12 November 1991, 30–38; B Sandilands, 'Black Deaths: The Path to Enlightenment' *The Bulletin* (Sydney), 26 November 1991, 50–51 as cited in R S Magnusson, 'Proprietary Rights in Tissue', 38.

for specimens.⁵²

One of these Victorian students, T H Huxley, sought to use Aboriginal remains to support evolutionary theory. In 1863 he had no need to travel to Australia to acquire them, however, but only to visit the Hunterian Museum and examine its comprehensive collection.⁵³ Others had remains brought back to England, including Sir William Turner who had the remains of more than 150 Aborigines to examine following the return of the HMS Challenger after its 1873–6 voyage to Australia.⁵⁴

CASE STUDY 1: COLLECTING ABORIGINAL REMAINS

Truganini, once known as the last Tasmanian Aborigine, feared her body would be put on display after her death, and until just recently she was correct. In 1991 what has been called the 'shameful legacy of trade in Aboriginal body parts' came to public attention⁵⁵ with the return of nine Tasmanian Aboriginal skulls from the University of Edinburgh.⁵⁶ Considerable amounts of skeletal and other remains were and still are held in Australian museums and universities, with the Murray Black collection including more than 1,800 skeletons, many of which were acquired through grave-robbing.⁵⁷ It was estimated in 2000 that there are more than 3000 Aboriginal remains held in more than 100 British museums and other institutions, although agreements are being made to have some of these returned.⁵⁸ The Australian and Torres Strait Islander Commission has asserted that more than 50 institutions in 18 countries admit to holding Aboriginal remains.⁵⁹

⁵² Jones, *Speaking for the Dead*, 120.

⁵³ Mulvaney, 'The Australian Aborigines 1606–1929', 25. Huxley compared the Aboriginal skull to that of a Neanderthal skull discovered in Europe and found great similarities between the two. His work was similar to that of many of his contemporaries who sought to use Aboriginal remains to support theories about the links between humans and apes, with the Aborigine well towards the ape-like end of the spectrum. His work stimulated many others to examine the crania of Australian Aborigines, including Paul Topinard who measured 42 skulls, and Sir William Flower who examined some 50 skulls held at the Royal College of Surgeons Museum in the 1870s.

⁵⁴ Ibid, 30. There are many other similar examples. For instance, Dr William Crowther, the last Premier of the colony of Tasmania stole the body of a Tasmanian aboriginal male, William Lanne, from the Hobart mortuary in 1869, while Joseph Banks, a botanist who travelled with Captain James Cook, presented the Governor of NSW with the preserved head of an aboriginal warrior. See R Glover and D Langsam, 'Day of Reckoning for Darwin's Body Snatchers' *Sydney Morning Herald*, 3 March 1990, 79, 79.

⁵⁵ Magnusson, 'Proprietary Rights in Tissue', 38.

⁵⁶ See Jones, *Speaking for the Dead*, 120.

⁵⁷ Ibid, 138–9. Some have since been returned.

⁵⁸ K Taylor, 'Britain to Return Aboriginal Remains' *The Age* (Melbourne), 6 July 2000, <www.theage.com.au/articles/2002/06/12/1023864297389.html> at 2 August 2004.

⁵⁹ Editorial, 'Bringing Truganini Home'. See also Glover and Langsam, 'Day of Reckoning', 79; P Ruddock, 'Aboriginal Remains Welcomed Home from UK', *Welcome to the Website for the Minister for Immigration and Multicultural and Indigenous Affairs: Minister Assisting the Prime Minister for Reconciliation*, <www.atsia.gov.au/atsia/media/media03/r03025.htm> at 17 April 2003.

Agreements are now being made for the return of some remains. On 4 July 2000, the British and Australian governments released a joint statement agreeing to increase efforts to ensure the repatriation of Aboriginal remains to Australian indigenous communities.⁶⁰ Since that time, a Working Group has been established by the United Kingdom House of Commons to consider the issues surrounding retained Aboriginal remains. The group found that 18 British museums held Aboriginal remains.⁶¹

As a result, the Hunterian Museum of the Royal College of Surgeons in London has agreed to return Aboriginal skulls and bones as well as skin and hair thought to have been taken from the body of Truganini, but as has been pointed out, 'it is acting honourably in so doing.'⁶² The Victorian Museum has also handed back more than 1000 skeletal remains for burial by the Aboriginal community,⁶³ as have the Pitt-Rivers Museum in Oxford, the Peterborough City Museum, Bradford University and the Kelvingrove Museum in Glasgow.⁶⁴

Despite some recent repatriation, Aboriginal groups have pointed out that the bulk of remains returned still rest in museums.⁶⁵ This is in part due to the fact that many museums refuse to return remains. In late 2002, a number of museums in Europe and the United States issued a declaration opposing repatriation. The signatories argue that maintaining large collections that promote culture is more important than the desire of individual countries or racial groups for the return of artefacts.⁶⁶

In Australia, however, museums have been required to return the collected remains of Aborigines⁶⁷ and undertakings have also been made by the Australian government to secure the return of some remains.⁶⁸ All Australian museums have agreed to refrain from displaying any recent skeletal remains.⁶⁹

Three major interests can be seen to conflict in this case study—those of a particular community, those of researchers and museums and the wider community's interest in the cultural and educational value of collections. On the one hand, the Aboriginal community has a deeply spiritual interest in the remains of its ancestors because in Aboriginal culture it is profoundly important that the remains of its members be treated

⁶⁰ 10 Downing Street, *Prime Ministerial Joint Statement on Aboriginal Remains*, (Press release, 4 July 2000), <www.number-10.gov.uk/output/page2829.asp> at 21 August 2003.

⁶¹ In total, 132 of 146 organisations responding to a survey conducted by the Group held remains. See Working Group on Human Remains, *Report*, Department of Culture, Media and Sport, London, 2003, [34]–[35]. The Group reported on 14 November 2003.

⁶² Ibid.

⁶³ Glover and Langsam, 'Day of Reckoning', 79.

⁶⁴ P Huck, 'Bringing Home the Dead' *Australian Financial Review* (Sydney), 24 October 1991, 37, 37.

⁶⁵ Australian Broadcasting Commission, 'Aboriginal Remains to be Returned from the UK' *ABC Radio News*, 7 June 2001.

⁶⁶ P Fray and A Moses, 'Top Museums Unite to Fight Aboriginal Claims' *Sydney Morning Herald*, 11 December 2002, <www.smh.com.au/articles/2002/12/10/1039379839080.html> at 1 September 2003. Among the signatories were the Guggenheim, the Hermitage, the Prado, the New York Metropolitan and the Louvre.

⁶⁷ Jones, *Speaking for the Dead*, 120.

⁶⁸ See, eg, L Tingle, 'PM Gives Word on Aboriginal Remains' *The Age* (Melbourne), 22 June 1997, 1.

⁶⁹ Glover and Langsam, 'Day of Reckoning', 80.

with proper respect. Aboriginal activist Michael Mansell described the damage done by museums retaining remains as 'astronomical', stating '[t]he spirits of our dead are disturbed by being separated from their bodies'.⁷⁰ Another Aboriginal activist, Bob Weatherall, put the matter even more strongly, explaining that Aborigines 'believe that no one has the right to violate the fundamental rights of the dead. Scientists think that when somebody dies it's finished. It's not finished. Because death to us isn't death. It's another phase of life. Life is continuous'.⁷¹

INDIGENOUS COMMUNITY INTEREST

For some communities human tissues and remains have significance for all members of that group, as is the case with Australia's indigenous population. Aboriginal and Torres Strait Islander people make up about 1.5% of the Australian population, but as the only indigenous group and as a people who were originally dispossessed of their country, their views take on even greater importance. As a multicultural society, Australia is home to numerous cultural groups, many of which have different attitudes towards treatment of the dead and their views must be accommodated by legal solutions. That indigenous communities often rely on collective decision-making must also be accommodated.⁷²

As Prue Vines has pointed out, the dominant Protestant/secular culture in Australia 'tends to see the issues relating to dead bodies in psychological rather than religious or cultural terms'⁷³, and thereby fails to take account of specific issues which affect cultural groups. By looking at tissue use from this perspective, the concerns of other groups are often either misunderstood or not given sufficient weight in making legislative and regulatory decisions. This is a tendency which should be avoided where body parts and corpses are concerned.

In many cases, cultural and indigenous groups may also have an interest in research because its wider implications will affect them either directly or indirectly. Often research which focuses on indigenous and cultural groups has other adverse effects for the cultural group. One of the major objections made by such groups to the Human Genome Diversity Project was that it would potentially enable the Western researchers to rewrite their histories and violate cultural beliefs. As one Lakota tribe member stated, 'we never asked science to make a determination as to our origins'.⁷⁴

Research specific to racial or indigenous groups can promote negative racial stereotyping, causing members of that group to be stigmatized, discriminated against in insurance or employment and to suffer the harms of racism.⁷⁵ The

⁷⁰ Ibid, 80.

⁷¹ Huck, 'Bringing Home the Dead', 37.

⁷² A Buchanan, 'An Ethical Framework for Biological Samples Policy' in National Bioethics Advisory Commission, *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance: Commissioned Papers*, vol II, NBAC, Rockville, MD, 1999, B-1, B-26.

⁷³ P Vines, 'Objections to Post-Mortem Examinations: Multiculturalism, Psychology and Legal Decision-making' (2000) 7 *Journal of Law and Medicine* 422, 423. See also P Vines, 'Resting in Peace? A Comparison of the Legal Control of Bodily Remains in Cemeteries and Aboriginal Burial Grounds in Australia' (1998) 20 *Sydney Law Review* 78.

⁷⁴ Andrews and Nelkin, *Body Bazaar*, 75.

⁷⁵ National Bioethics Advisory Commission, *Research Involving Human Biological Materials: Commissioned*

history of racism is almost trite support for this, as is the clear stigma that has been attached to the gay community after observations that HIV rates were higher within their community.⁷⁶ Hence, sensitivity to these possible outcomes necessitates respect be paid to the wishes of the community which is to be the subject of research.

Such research can also amount to treating indigenous groups as research resources, rather than human communities deserving of respect. One leader of an indigenous group summed up the issue: 'you've taken our land, our language, our culture, and even our children. Are you now saying you want to take part of our bodies as well?'⁷⁷

Also, by immortalising their DNA through cell lines, some believed researchers would remove any need to aid the communities in maintaining themselves⁷⁸, while exploiting indigenous people for the benefit of developed countries. Though often cultural groups have been offered the benefits of treatments and test that may result from research performed using their bodily materials, for most the likelihood that they will ever have access to expensive therapeutics from wealthy nations is slim at best.

The early anthropologists, and those who continue their work today, make important scientific discoveries through studying these remains. These discoveries add to the body of the world's knowledge, by giving us a better understanding of our origins. In many cases, museums have refused to return remains because, according to anthropologist Chris Stringer of the Natural History Museum in London, they are still needed to investigate the origins of human variation and evolution. Stringer referred to the 1990 return of remains found at Victoria's Kow Swamp as 'a blow to science and to the study of prehistory in general'.⁷⁹

Those museums opposing repatriation cited the cultural and scientific value for the community of collections of artefacts. In emphasising the community interest in collections, the museums stated that we should acknowledge

that museums serve not just the citizens of one nation but the people of every nation. Museums are agents in the development of culture, whose mission is to foster knowledge by a continuous process of reinterpretation. Each object contributes to that process. To narrow the focus of museums whose collections are diverse and multifaceted would therefore be a disservice to all visitors.⁸⁰

Papers, vol II, 46–47.

⁷⁶ E W Clayton et al., 'Panel Comment: Why the Use of Anonymous Samples for Research Matters' (1995) 23 *Journal of Law, Medicine and Ethics* 375, 376. See also Buchanan, 'An Ethical Framework for Biological Samples Policy', B–7.

⁷⁷ Zef Productions Ltd, 'The Gene Hunters' *BBC and Channel 4*, 1995 as quoted in *ibid*.

⁷⁸ L Andrews and D Nelkin, 'Homo Economicus: Commercialization of Body Tissue in the Biotechnology Age' (1998) 28 *Hastings Center Report* 30, 33.

⁷⁹ *Ibid*.

⁸⁰ *Declaration on the Importance and Value of Universal Museums*, London, December 2002.

The essential problem in this scenario is maintaining respect for the indigenous communities concerned while enabling research to continue and maintaining collections that educate and inform the general public.

3.2 Retention, Research and the Absence of an Adequate Ethical Framework

Early research using human tissue did not occur within a framework of well-defined ethical principles and legal regulation—beyond rules for the acquisition of bodies—nor was consent usually obtained. The culture of research has changed significantly over the past half-century. Ensuring consent has been obtained before tissue is used has only become commonplace in the latter half of the 20th century. Anatomy legislation had been a start, but as the examples presented below will illustrate, scientific use increased without direct legal regulation. These examples detail research practices that would now be regarded as entirely unacceptable.

In one Australian example, between 1957 and 1978 tests were performed on the bones of over one thousand children and infants aged under five years at a Melbourne laboratory. The laboratory was Federally-run and the research directed at determining the effect of nuclear tests at Maralinga and in the Pacific. The bones were supplied by twenty-seven Australian hospitals without obtaining informed consent from the families involved. Attempts are currently being made to identify the parents of these children.⁸¹ In addition, the remains of 6000 children were reduced to ash as part of associated research and later shipped to the United States and the United Kingdom for analysis of Strontium 90 presence as part of a United States program named 'Project Sunshine'.⁸²

It also needs to be remembered that human remains were not always collected with admirable aims in mind. The collection of hair from Nazi prisoners at Auschwitz, Majadenk and Treblinka during the Second World War is one example. Hair was taken from the bodies of people who died in the camps and sometimes from shaving the heads of prisoners still alive, but the harvested hair was not put to any research use. Instead, the hair was cured in lofts above the crematorium chambers and subsequently sold to manufacture rope, carpets and socks, and to stuff mattresses.⁸³ This was not an

⁸¹ M Dunn, 'Secret Tests on Babies Remains' *The Mercury* (Hobart), 13 June 2001, 4, 4.

⁸² See, eg, Australian Broadcasting Commission, 'Child Bodies Used in Nuclear Test' *ABC NewsRadio*, 7 June 2001.

⁸³ T W Ryback, 'Evidence of Evil' *New Yorker*, 15 February, 1993, 68 as cited in D Pergament, 'It's Not Just Hair: Historical and Cultural Considerations for an Emerging Technology' (1999) 75 *Chicago-Kent Law*

action aimed at acquiring material for research, but a deliberate act of dehumanisation and economic exploitation of a grand and grisly scale. The sensitive and complex nature of this hair, which in other contexts might be regarded as waste when left on the hairdresser's floor, is evidenced by the problems faced by the United States Holocaust Memorial Museum which acquired twenty pounds of the hair. Two tons of hair is currently on display in Block IV at Auschwitz, and the United States Museum originally intended to display their collection also. This desire was opposed by members of the museum committee, for the hair was not an object like other relics of the Holocaust, but as Deborah Pergament has described it, 'a signifier of human identity and individuality'.⁸⁴

The Nazi use of body parts is in itself a turning point in the history of regulating tissue use. When the atrocities like this were discovered after the Second World War, and the doctors who had subjected prisoners to horrendous experiments were prosecuted as criminals, the emergence of ethical standards began.⁸⁵ These prosecutions led to the creation of the Nuremberg Code in August 1947, which laid down ethical rules for experimentation involving human subjects. It became the foundation document for later ethical research guidelines, and was based on ten principles, the first and most crucial being that '[t]he voluntary consent of the human subject is absolutely essential'.⁸⁶

The retention of human body parts has continued up to the present day. Most often, body parts have been retained following post-mortem, and in general this has been in accordance with legal provisions.⁸⁷ As the following case study demonstrates, however, revelations about retention have led to widespread public disapproval, and practices have begun to change still further as a result.

CASE STUDY 2: ORGAN AND TISSUE RETENTION FOLLOWING POST-MORTEM

Following the exposure of tissue and organ retention practices in the United Kingdom (see below), scrutiny was directed at Australian institutions. In 1998 Director of the Victorian Institute of Medicine, Stephen Cordner admitted that

Review 41, 49.

⁸⁴ *Ibid*, 51.

⁸⁵ See generally Andrews and Nelkin, *Body Bazaar*, 22.

⁸⁶ *Trials of War Criminals before the Nuremberg Military Tribunals under Control*, Council Law No 10, Vol 2, Nuremberg, October 1946–April 1949; Washington, DC: US Government Printing Office, 1949–1953, Principle 1.

⁸⁷ See Parts II and III.

organs and tissues were removed from bodies during autopsy and later supplied to medical researchers without the consent of the deceased's families.⁸⁸ Allegations of similar removal and retention have been made in Tasmania. Initially denied, it was later established that tissue had been removed and retained without informed consent at the Royal Hobart Hospital until 2000.⁸⁹ Although technically within Tasmanian and Victorian law, these events and revelations about the practices at the Glebe Morgue in New South Wales led to further inquiries. Over the ensuing three years since 1998 investigations into tissue retention have been made in New South Wales, South Australia and Western Australia.⁹⁰

Audits were made of tissue collections in these States. For example, in New South Wales, it was confirmed that as many as 25,000 tissue samples were held, with half collected from post-mortems and bodies donated under the *Anatomy Act 1977* (NSW) and the remainder from surgical procedures. Twenty five percent of tertiary institutions collected material under the same Act and 40% had tissue collections. Between them the Children's Hospital at Westmead and the Sydney Children's Hospital held 900 children's hearts and 4000 tissue samples dating back to 1926, though collection had declined since the 1980s.⁹¹

These inquiries do not cover samples held by all researchers currently in use, but collections kept generally after post-mortem. It should be noted, however, that most of the historical collections held in Australia were acquired prior to the 1990s and there has been a significant decline in collection and retention since the 1980s.⁹²

The incidents in the United Kingdom and at Glebe Morgue bear outlining, to demonstrate that these retentions are not unique, but part of widespread behaviour. In 2001, allegations of mistreatment of body parts taken from autopsied cadavers were made against Associate Professor John Hilton of the Institute of Forensic Medicine at Glebe in New South Wales, specifically that bones and other human biological materials were removed and unauthorised research use was made of them. Some examples of these allegations include: 'the removal of the face of a nun who had drowned after suffering a heart attack while swimming; the removal of a foetus from a pregnant

⁸⁸ S Butcher, 'Scientists Call Halt to Body Tissue Practice' *The Age* (Melbourne), 8 October 1998, 3. Tissue was no longer supplied after July 1998 and Cordner was initially suspended pending investigation.

⁸⁹ M Haley, 'Body Parts Row Erupts' *The Mercury* (Hobart), 1 November 2001, 1, 1.

⁹⁰ At the time of writing, Queensland was preparing to make its own inquiries while the Tasmanian events have thus far led only to Parliamentary debate over hospital procedures, however changes made to hospital guidelines before the events made headlines now ensure that specific consent is obtained for retention. See generally Tasmania, *Parliamentary Debates*, House of Assembly, 20 and 22 March 2001, 31 October 2001 and 1 November 2001. See also reports produced in some States. See Crown Solicitor for Western Australia and Commissioner for Health for Western Australia, *Final Report: Removal and Retention of Organs and Tissue*; New South Wales Health Department, *Interim Report into the Retention of Organs*; South Australia Solicitor-General, *Report into the Retention of Body Parts*.

⁹¹ Details beyond these had not been released at the time of writing. New South Wales Health Department, *Interim Report into the Retention of Organs*, 7–8. See also South Australia Solicitor-General, *Report into the Retention of Body Parts*, ch 3.

⁹² See, eg, New South Wales Health Department, *Interim Report into the Retention of Organs*.

woman and subsequent jokes being made using the foetus as an object; surgeons practising plastic surgery on bodies at the morgue...bodies being stabbed for a senior pathologist's research on stabs and blood splatter patterns; the removal of an entire spine and its subsequent replacement with a broomstick...and the use of a hammer on the head of a donated body to reproduce the injuries of a murder'.⁹³ In some instances Professor Hilton and others were found to have acted unlawfully, and his attitude to the purposes of autopsy was found to be unacceptable and incorrect.

In the United Kingdom, in April 1996 a mother discovered that her child's heart had been retained by the Bristol Royal Infirmary. The heart was returned to her but the event sparked further inquiries and a large number of hearts and other organs were found to have been retained. The information was released to the public in February 1999 and the Infirmary began the process of identification and return. The 'Inquiry into the Management of Care of Children Receiving Complex Heart Surgery at the Bristol Royal Infirmary' was extended to include retention of organs after post-mortem. In March 2000, the British Chief Medical Officer released interim guidelines for National Health Services (NHS) Trusts requiring hospitals to gain consent before retention could be authorised. Following this, a census of the holdings of all NHS Trust hospitals and medical schools was conducted. This census was released in 2001 and reported that in 1999, 54,300 organs, body parts, still-births or foetuses were being held by NHS Trusts and medical schools.⁹⁴

Retained organs and tissue provide material for medical teaching purposes and research. As previously noted, research serves the broad community goal of generating new information, and hence may lead to the development of new treatments and better understanding of the body. But where the organs and tissues of deceased children and adults are used, two other interests are at stake. Media reports have focused on the distress of parents upon learning that their children have not been buried whole. Very often this is highly disturbing and emotionally traumatic, particularly when the organ retained is one with symbolic links to the personality, such as a heart or a brain.⁹⁵ In

⁹³ See generally Walker, *Institute of Forensic Medicine Inquiry*.

⁹⁴ Department of Health, Department of Education and Employment and the Home Office, *The Removal, Retention and Use of Human Organs and Tissues from Post-Mortem Examinations: Advice from the Chief Medical Officer*, 1.

⁹⁵ For example, at the Retained Organs Office of the Oxford Radcliffe Hospital, which by late 2001 had received at least 1300 inquiries, most callers are significantly more emotive where hearts and brains have been held, and much less so where only tissue samples are concerned. See interview with Mary Dorcan, Retained Organs Office, Oxford Radcliffe Hospital, (Personal interview, Radcliffe Infirmary, 25

witness statements taken during the Bristol Royal Infirmary Inquiry parents expressed the extreme distress they experienced on learning that their children's organs had been retained, with one parent stating that the revelations 'made us feel that Bethan [their child] had been violated as a person ... The manner in which it was done, without reference to us, was an assumption that Bethan's body belonged to the Hospital to do with as they wished. Yet to us, Bethan was still our daughter even though she had died'.⁹⁶ In another case, the parent of a child whose organs had been retained said '[w]e were all deceived because what we buried was a shell'.⁹⁷ The interest of families and relatives in such situations should be given consideration and respect.

That people have a profound interest in how their bodies are dealt with is in part due to the emotional significance of that body for their sense of self-identity. People exist as a unified mind and body, but while life, as C Don Keyes states, 'is defined in terms of brain function'⁹⁸ body image and the integrity of that image are vitally important to the mental life.⁹⁹ Empirical studies have demonstrated that external aspects of the body like hair, eyes, hands, legs play an important part in defining and maintaining a person's sense of self.¹⁰⁰

The importance of the body and fundamental beliefs in Western society that an individual should be able to direct what is done to their bodies are bound up in the concept of individual autonomy. In this instance, people may wish to decide what is done with their bodies and body parts after their death or once they have been excised, and the knowledge that their bodies and tissues are protected after death is psychologically important.¹⁰¹ The right to make such determinations should hence be respected. Ensuring informed and valid consent is obtained before parts are taken and used is crucial to the protection of this right.

September 2001).

⁹⁶ 'Witness statement of Paul Bradley, WIT02290001' *Bristol Royal Infirmary Inquiry*, <www.bristol-inquiry.org.uk/evidence/wit/WitSMent/witPBradley.htm> at 25 October 2005, 19.

⁹⁷ S Mann, 'Dead Babies "Treated as Waste"' *The Age* (Melbourne), 1 February 2001.

⁹⁸ C D Keyes, 'Body and Self-Identity' in C D Keyes, (ed.) *New Harvest: Transplanting Body Parts and Reaping the Benefits*, Humana Press, Clifton, New Jersey, 1991, 161.

⁹⁹ The importance of the body to self-identity can be seen in people's reactions to receiving organ donations. Often, on receiving an organ, enlarges the body image of the recipient. Recipients regard the new organ as something external to themselves, despite the fact that it has been placed within their body. For an in-depth consideration of self-identity in the context of organ transplantation see *Ibid*, 161–177.

¹⁰⁰ See C S Campbell, 'Research on Human Tissue: Religious Perspectives' in National Bioethics Advisory Commission, *Research Involving Human Biological Materials*, vol I, C–3.

¹⁰¹ See further Nelkin and Andrews, 'Do the Dead have Interests?'.

INDIVIDUAL AUTONOMY

Autonomy, the right to make free choices about how one's body is treated and its tissues dealt with, is the only defensible starting point for considerations of how that body's tissues should be regulated. To respect and protect the autonomy of all individuals is to uphold what Courtney S Campbell has termed that 'person's full and equal standing in the moral and political community.'¹⁰² It is through ensuring such respect is given that a democratic country ensures each of its citizens is viewed as equal, and equality before the law requires that the legal system protects the autonomy of every person to the same extent.¹⁰³

By respecting autonomous choice, individuals are thereby free to make their choices based on the beliefs that they themselves hold, within the boundaries of what has been permitted by the law. This enables each person to base their decisions on whichever moral, religious or other grounds they so decide, rather than enforcing some majority view.¹⁰⁴ Use of tissue to which the individual from whom it was taken objects constitutes a failure to respect such autonomy.¹⁰⁵

When decisions are to be made about organ retention, there may be tensions between a family's control of how the body is dealt with and the hospital's desire for organs and tissue for research and teaching, in addition to any conflict between the family's wishes as those expressed prior to death by the deceased.¹⁰⁶ There may therefore be control issues in situations of this kind, where there is a need for clear guidance on who has control of, and the power to make decisions about, the fate of a body.

Further, community trust in the medical profession is a vital aspect of ensuring people feel confident in seeking treatment. This issue will be considered in more detail in due course, but in the case of retained organs the faith of the community has clearly been shaken. Legal reforms should be directed at dealing with such disputes, and at repairing the damage done to this trust. However tissues are to be dealt with in these situations, the processes must be transparent to allow the public to see how tissues are treated, that they are used with respect and that people are able to control what is done with their tissues. The process and use must also be in accordance with general community values.

¹⁰² C S Campbell, 'Body, Self and the Property Paradigm' (1992) 22(5) *Hastings Center Report* 34, 38.

¹⁰³ The exceptions to this are children and those deemed incapable of making rational decisions for themselves, such as the mentally ill.

¹⁰⁴ For example, people of Jewish faith may refuse to consent to autopsy of a relation who believed, as many Jewish people do, that autopsy is a desecration of the human body as an image of God.

¹⁰⁵ It has been argued that where the objections of the individual to the use of their tissue are based on 'grossly mistaken assumptions' or 'patently false beliefs' about the consequences of the use of their tissues, those objections should be given less moral weight. See Buchanan, 'An Ethical Framework for Biological Samples Policy', B-8.

¹⁰⁶ The law regulating the removal of organs and tissues after death is outlined in Chapter Four.

What emerges most clearly from the examples and historical events described in this chapter is that the use of human body parts has expanded remarkably over the past few centuries. These examples also highlight our, at times, poor record in dealing with human tissue sensitively, with respect for the wishes of the person from whom it was taken. However, this chapter also describes both a turning point in attitudes towards appropriate use of tissue, and new values that it has acquired. These changes demonstrate the increasing focus on the need to respect individual autonomy and community interests, and the need to find a legal approach to the use of tissue that can account for the varied interests over it. The following chapter traces the results of these changes, examining the continued movement of the body into the medical sphere and the emerging issues of privacy and commercialisation in tissue use.

Chapter Two

UTILISING THE BODY

It is not only the uses for human tissue which have undergone change, but as Bartha Knoppers and Maria Hirtle have noted, 'traditional attitudes whereby individuals had little interest in their removed bodily materials, appear to be changing [also]'.¹ During the Bristol Royal Infirmary Inquiry, consultant pathologist to the Home Office Professor Michael Alan Green remarked on this new trend:

immediately after the passing of the Human Tissue Act it did not make much difference. Then I suppose in the 1970s people started talking about 'informed consent'...the realisation dawned on the profession that fully informed consent involved more than just using the old-fashioned bald one-paragraph consent form.²

This chapter examines the expanding uses of tissue in the latter half of the 20th century. It also explores the shift towards regarding consent to tissue use as morally required. During this period, human tissue acquired a wide range of uses in medicine, and became vital to research in the causes of disease and genetic conditions. Hence, this chapter focuses particularly on research uses and the privacy issues that arise from developments in genetic science.

This chapter includes a number of case studies outlining current tissues uses, such as organ transplantation and tissue donation, genetic testing, research, police use of tissue for forensic purposes, and newborn screening card collection. It highlights issues around community and individual interests in altruism, privacy, the community's need for scientific advances and crime prevention, scientists' interests in accessing tissue and concerns about genetic discrimination. In doing so, it explores a range of the complex issues raised by new uses of tissue, and the challenges these may present to the legal system.

Studies on tissue without consent that were once acceptable research practice would

¹ B M Knoppers and M Hirtle, *Banking of Human Materials, Intellectual Property Rights and Ownership Issues: International Policy Positions and Emerging Trends in the Literature*, prepared for Intellectual Property Policy Directorate, Industry Canada, Ottawa, 1995, 3.

² Inquiry into the Management of Care of Children Receiving Complex Heart Surgery at the Bristol Royal Infirmary, *Interim Report, Annex A: An Account of the Evidence to the Inquiry on the Removal and Retention of Human Material at Post-Mortem*, Department of Health, London, 2000, 4.

today be ethically repugnant.³ Obtaining consent is now the norm rather than the exception. However, gaining consent for first-use of tissue or broad consent for future use, as will later be argued, are not catch-all solutions to the myriad problems that surround the use of excised human body parts.

With this shift came a different approach to research using human materials, and it is this shift which delineates current research practices from those of the past. Collection continued, though generally with consent, and tissue became a material that could also be used for diagnostic and forensic testing. Developments in genetics created novel uses for tissue which would occur in this new context of consensual research. Improvements in transplantation techniques meant that by the end of the 20th century, transplantation became a relatively common and successful procedure, creating unprecedented demand for organs and tissue.

The body also came to be regarded as a more materialised, Cartesian construct—that is, as an object that could supply materials and have replacement parts transplanted into it, while the embodied self made autonomous decisions about its fate.⁴

1. ORGAN TRANSPLANTATION AND THERAPEUTIC USES

Human tissue has a variety of therapeutic uses, including the use of blood in transfusions; skin grafts; bone marrow transplants for the treatment of leukaemia and the use of bone and musculoskeletal tissue in reconstructive surgery. Perhaps the most dramatic therapeutic use, however, is organ transplantation. Since the first successful kidney transplant in 1954, organ transplantation has given surgeons the ability to save thousands of lives every year. As well as hearts, lungs, livers and kidneys, a range of other tissues and structures can be transplanted including skin, bone marrow, pancreatic tissue, cartilage, glands (adrenal, thyroid, pituitary and thymus), ear parts and corneas. While most are obtained from cadavers, technological advances have enabled inter vivos transplantation of kidneys, portions of liver, lung lobes, pancreatic tissue and sections of intestine.

³ For example, some early research into the links between tobacco smoking and lung cancer involved tissue samples taken from autopsied bodies without consent. See E Strauss, 'The Tissue Issue: Losing Oneself to Science?' *Science News Online* 27 September 1997, Science News Online, <www.sciencenews.org/sn_arc97/9_20_97/bob1.html> at 21 April 1999.

⁴ See generally on the materialisation of the body in modern Western medicine M Sheets-Johnstone, 'The Materialization of the Body: A History of Western Medicine, A History in Progress' in Sheets-Johnstone, (ed.) *Giving the Body its Due*, 132ff.

This ability, however, is curbed by the shortfall in organ supply and in some countries the market has thrown up a solution of sorts. Traffic in human organs is a worldwide phenomenon. In India organ sales are skyrocketing. Where only 50 organs were sold in 1983, more than 2000 were sold during 1990. Market-like bazaars where one can buy corneas, skin patches and the like have sprung up and people are literally selling off their bodies.⁵ In one scandal of 1989, a kidney transplanted into a private patient at the Human Wellington Hospital in London turned out to have been bought from a Turkish peasant.⁶ Doctors in the United States report that they are having to treat American citizens who have returned from China after paying for organs to be transplanted into their bodies.⁷ More recently, in 1999 a kidney was offered for auction on the eBay, an Internet site.⁸

Widespread organ trafficking has not arisen in Australia, and current legal prohibitions on the sale of organs should prevent it occurring in this country.⁹ Some sale of tissue had occurred in the past, with mortuary technicians receiving payment for the supply of pituitary glands and bone samples from cadavers in some cases,¹⁰ but the passage of the Human Tissue Acts in the late 1970s and early 1980s prohibited the continuation of such practices.¹¹ These Acts were created to address the growing demand for organs and tissue for transplantation, and they took a decisive step towards a clear, consent-based model for the procurement and use of human tissue.¹²

⁵ R Fox and J Swazey, (eds), *Spare Parts: Organ Replacement in American Society* (1992) Oxford University Press, Oxford and New York, 68–9.

⁶ See generally S Wilkinson, 'Commodification Arguments for the Legal Prohibition of Organ Sales' (2000) 8 *Health Care Analysis* 189, 189.

⁷ J Pomfret, 'Rare Chinese Newspaper Exposé Details Prisoner Organ Harvest' *Washington Post*, 31 July 2001, A14.

⁸ Bidding reached \$A8.8 million before the offer was removed. See G Miller, 'Going, Going, Gone: Kidney Sale Axed' (1999) *The Age* (Melbourne), 4 September 1999, A23; 'Dis-organised eBay Pulled Plug on Kidney Sale' *Australian Financial Review* (Sydney), 4 September 1999, 19; '\$9m Bid for a Human Kidney' *The Australian* (Sydney), 4 September 1999, 16.

⁹ See Chapter Four, section 5.

¹⁰ South Australia Solicitor-General, *Report into the Retention of Body Parts*, 18.

¹¹ *Human Tissue Act 1985* (Tas) s 27(1); *Human Tissue Act 1982* (Vic) ss 38, 39; *Human Tissue Act 1983* (NSW) s 32; *Transplantation and Anatomy Act 1983* (SA) s 35; *Transplantation and Anatomy Act 1979* (Qld), *Transplantation and Anatomy Act 1983* (SA) s 35; *Human Tissue and Transplant Act 1982* (WA) s 29; *Transplantation and Anatomy Act 1978* (ACT) s 44; *Human Tissue Transplant Act 1979* (NT) s 24.

¹² The Acts are considered in detail in Chapter Four.

CASE STUDY 3: ORGAN TRANSPLANTATION¹³

Organ donation in Australia is regulated by the Human Tissue Acts in each state and territory, which provide for voluntary donation both after death and in some cases, during life.¹⁴ The Human Tissue Acts specifically prohibit the sale of organs.¹⁵

Potential organ recipients, if they meet the criteria for organ transplantation, are placed on a waiting list. As an example, liver transplants will be made where the recipient is suffering a life-threatening liver disease that is not treatable by means other than transplantation. When a liver becomes available, it will be offered to a transplantation unit capable of handling liver transplants. The unit performing the transplant is responsible for arranging removal of the donor liver either using their own medical staff or by arrangement with another liver unit. Once removed, that unit is also responsible for transporting the liver.

The Australian Organ Donor Registry, where individuals wishing to donate organs can register their intent, also promotes organ donation. Authorised medical practitioners can access information from the registry to facilitate finding a donor. Individuals may also register an intention to donate on their driver's licence. At present, there is no liver donation between live adults in Australia.

As sale of organs is prohibited in Australia, organ donation is a gift made from donor to recipient, generally after the donor has died. That donor may have consented to donation during life, or where no intention or objection is known, their next of kin may consent on their behalf. Here again, the major interest is that of the donor, and their right to decide what is done with their body. This is particularly the case where donations are made by living individuals, as in the case of some kidney donations. However, other interests do come into play. Relatives will wish to see that their relation's body has been treated with respect, and some may object to donation. Where donations are made during life, often the decision to do so is complicated by pressure from families and a sense of duty towards the potential recipient.

There are also the broader interests of the community. There are fewer organs available in Australia for transplant than there are recipients who need them, despite the fact that Australia has a relatively high donation rate. At present, efforts to improve this situation are directed at increasing awareness of donation, rationalisation of registration systems and public awareness programs to encourage people to register. As yet, organ markets

¹³ Case study compiled from Australian National Organ Allocation Protocol, *General Organ Donor Criteria: 2. Liver Protocol*, see Transplantation Society of Australian and New Zealand, *Organ Allocation Protocols*, <www.racp.edu.au/tsanz/oapmain.htm> at 1 October 2000.

¹⁴ See Chapter Four.

¹⁵ There are some exceptions to this prohibition. See Chapter Four.

have not been used in Australia for a number of reasons, both because of the perceived problems with such systems, which will be discussed in Chapter 4, and because the gift relationship is valued.¹⁶ For many, some sense is made out of the tragedy of death by the ability to save the life of another, while this gift relationship promotes unity within the community. This is the notion of altruism as a social good.

ALTRUISM AS A SOCIAL GOOD

Thomas Murray has asserted that '[g]ifts of the body are one of the most significant means that mass societies have to affirm the solidarity, or community, that humans need in order to mature and to flourish as individuals'.¹⁷ By giving to others, people feel part of a community and this has supportive emotional benefits. This applies to both tissue used for transplants and donations of tissue for research which will benefit the community as a whole.¹⁸ How society functions affects how people live, and promoting a gift relationship and charitable acts ensures a sense of security that others will give aid when one is in need. In a society that has become so fragmented and disjointed, such a gift relationship binds a community together and enriches it.¹⁹ It is a gift ethic such as this that runs through the Human Tissue Acts. The Australian Law Reform Commission, which drafted the model bill on which the Acts are based, stated in 1977 that 'the Australian sees his body and its tissues not as an object of commerce but as something to be the subject of voluntary gift'.²⁰ However, this principle is under pressure as the growing biotechnology industry continues to profit from the use of donated tissue.²¹

But while it is accepted that altruism is valuable to the community, there is the interest also of those who are in need of organs to survive. From their perspective there is value also in a means of regulating tissue that ensures efficiency in acquiring organs and promotes supply. It may be, and this will be considered in more detail in Part IV, that a market system would be more efficient providing organs for transplantation. A market system works in direct opposition to a system based on altruism, and here is the real nub of the problem for acquisition and distribution of organs—which of these interests should prevail and how can they best be met by regulatory means of controlling human tissue use? Regardless of which prevails, respect for the interests of the source of the tissue must also be maintained and their right to autonomy protected.

¹⁶ See generally C M Mazzoni, 'Gift Ethics and Organ Donation' in C M Mazzoni, (ed.), *A Legal Framework for Bioethics*, Kluwer Academic Publishers, The Hague, 1998.

¹⁷ T H Murray, 'On the Human Body as Property: The Meaning of Embodiment, Markets, and the Meaning of Strangers' (1987) 20 *Journal of Law Reform* 1055, 1085.

¹⁸ Compare the experience of David Greenberg and others as outlined in Case Study 15: Canavan Disease Research.

¹⁹ E W Clayton et al., 'Panel Comment', 376.

²⁰ Australian Law Reform Commission, *Human Tissue Transplants*, ALRC 7, ALRC, Sydney, 1977, 8. The Human Tissue Acts are based on the recommendations and draft legislation in this report.

²¹ R S Magnusson, 'The Use of Human Tissue Samples in Medical Research: Legal Issues for Human Research Ethics Committees' (2000) 7 *Journal of Law and Medicine* 390, 402.

2. TISSUE AS A DIAGNOSTIC TOOL AND CONTINUED COLLECTION

In Australia tissue is routinely taken for diagnostic purposes and is often stored to allow for later testing and to comply with laboratory accreditation requirements for quality assurance.²² Such tissue is generally held by pathology laboratories and hospitals. For the most part, such samples are stored securely, as evidenced in the following case study.

CASE STUDY 4: HOBART PATHOLOGY²³

Hobart Pathology is the main pathology laboratory servicing the Hobart region. The laboratory performs tests as requested by medical practitioners. Tissue samples for testing are taken by the practitioner and collected for secure transport to Hobart Pathology. Once delivered to the laboratory, each sample is checked and matched to the request form completed by the requesting physician. A code number is allocated to the sample and the form, and from this point onwards the sample is referred to by code number from that time on in read-outs of results. However, the name of the source is also placed on the sample's label.

Samples are retained in accordance with National Pathology Accreditation Advisory Council (NPAAC) requirements and only as long as needed in to carry out further tests or check results. Once there have no further testing use, most samples are destroyed.²⁴ Employees are not given a security check before joining the laboratory, but they are informed that all information stored at the facility is to be kept strictly confidential. Only laboratory staff may access samples.

Results are only released to the physician who requested the tests. Other physicians and the sample provider may obtain results only with the authority of the original physician. The laboratory has never been approached by a patient wishing to regain possession of their sample, but would refuse such a request and any similar request from a third party.

Samples are destroyed by steam-heating while still in their labelled tubes. This process melts the bottles together and their labels to become smudged. Any DNA contained in the samples would very likely be de-natured. The result is a large mass of congealed plastic and tissue—to match a sample to its label or to find a sample in a testable form would be almost beyond possibility.

The use of tissue as a diagnostic tool is one of the primary ways in which human biological materials have become more than mere flesh—they have become a source of information. In addition, advances in genetic science have increased the information

²² In accordance with the National Association of Testing Authorities requirements. These requirements are discussed briefly in Chapter Five, section 3.

²³ This case study was compiled using information gathered from a tour of the Hobart Pathology Laboratory. See also interview with Mr Graham Collins, Director, Hobart Pathology (Personal interview, Hobart Pathology, 28 July 1999).

²⁴ Some types of samples must be retained for up to 50 years in accordance with NPAAC Guidelines. See Chapter Five, section 3.

that can be obtained from a sample.

Individuals who provide material for testing have an interest in its remaining confidential and not being misused. For example, a biopsy may yield information that a person is suffering cancer, a fact that they may not wish others to be aware of. Dorothy Nelkin and Lori Andrews have cited the case of a woman who obtained a sample of her father's blood from the local hospital after his death. After paternity testing, it was clear, as the writers put it, 'that the man she had called Daddy all her life was not her biological father, indicating that her mother had had an affair'.²⁵ Though the mother sued the hospital for invading her privacy, her claim was overruled. Samples and the information they yield must be kept secure. Security is discussed in relation to stored samples in more detail following Case Study 5: Newborn Screening Card Collection.

PRIVACY

Privacy involves concepts such as rights to know and not to know, and control and protection of information. The effects of being given information and having that information supplied to others may be profound. Privacy is experienced on a very personal level and the right to protect it upholds a person's ability to make decisions about what others will know about them.²⁶ Privacy protection includes maintenance of the autonomous ability to make decisions about what others know about one, but also freedom from intrusion, and freedom from violation of one's dignity.²⁷

The Rights to Know and Not to Know: Genetic testing and screening raise issues about whether an individual should be made aware that they are carrying the genes for a genetic condition.²⁸ On one hand, the person may be adversely affected by the knowledge, experiencing distress that they may later suffer the condition, particularly if it cannot be treated. On the other, to know enables one to act accordingly, such as to seek treatment or to live one's life differently knowing that it may be shorter or one may be less able to do the things that one regards as important. The rights to know and not to know refer to a general right to choose what information he or she receives. Knowledge, once acquired, may also be an emotional burden, with decisions to be made about who to tell, whether to inform one's family and where that condition is hereditary, whether to have children. In one sense, there may a case to be made for informing people of their conditions regardless—to give them the ability to refrain from having children both to prevent that child also suffering and to prevent the condition remaining prevalent in the gene pool.

²⁵ L Andrews and D Nelkin, 'Whose Genes Are They, Anyway?' (1999) 45 *Chronicle of Higher Education* B6, B6.

²⁶ S Alpert, 'Privacy and the Analysis of Stored Tissue' in National Bioethics Advisory Commission, *Research Involving Human Biological Materials*, vol II, A-6 – A-7.

²⁷ Ibid, A-7.

²⁸ See, eg, D R C Chalmers, M A Orlowski, D Nicol and L Skene, 'Current Research: Project on the Legal and Ethical Aspects of Genetic Research in Australia' (1995) 3 *Journal of Law and Medicine* 30, 33.

In addition to privacy issues, samples taken for testing also raise the issue of their subsequent use in research. While samples held in pathology laboratories like Hobart Pathology are not supplied to researchers, where they are held in hospitals they sometimes are made available. In some Australian hospitals, pathology samples may be used for research where they have been anonymised and patients have agreed to this procedure.

Additionally, as the United States National Bioethics Advisory Commission reported following its public consultation on human biological materials use, most of the participants who had signed consent forms in the past could not remember if those forms discussed the disposition of tissue.²⁹ Patients, who will often be worried about their treatment or diagnosis, may not take the time to properly read and understand consent forms. This method of gaining consent may not always ensure patients give properly informed and explicit consent to the subsequent use of their tissue. These, and similar examples, highlight some of the issues about obtaining consent, including whether consent obtained for research use in this context is sufficiently informed and how far it can be said to validly cover future uses.

The major issues raised by pathology use of tissue, then, are the privacy of the results that are generated, security of those samples and their related information and consent to subsequent use by the source of the tissue. As with other uses of tissue in research, the need for samples to facilitate research must be weighed against these privacy and autonomy concerns. Tissue should be regulated to ensure use by researchers does not impinge overly on protection of these interests, while the valuable benefits of that research are not stifled by restrictions on access.³⁰

In some cases, tissue is now collected also for screening purposes. The largest screening program in Australia is newborn screening, which is examined in the following case study.

²⁹ 'Appendix A: Beliefs about the Research Use of Human Biological Materials' in National Bioethics Advisory Commission, *Research Involving Human Biological Materials*, vol I, 77.

³⁰ See generally discussion in relation to Case Study 6: Tissue in Australian Research.

CASE STUDY 5: NEWBORN SCREENING CARD COLLECTION (SOUTH AUSTRALIA)³¹

A blood sample is routinely taken each newborn child in Australia, usually between two and five days after birth. These samples are placed on a card and stored as newborn screening cards (previously known as Guthrie cards). Samples are tested to screen for a number of conditions, including phenylketonuria (PKU) and cystic fibrosis.³² Screening identifies inheritable conditions, to inform parent's future reproductive choices and can identify treatable conditions. Practice varies between states, but in general cards are retained indefinitely by the genetics service that performed the tests.³³ The child's name and place and date of birth are retained on the cards, as is the mother's name.

The Adelaide Women's and Children's Hospital conducts screening for South Australia, Tasmania and parts of the Northern Territory. All newborn screening cards dating from May 1980 have been retained.³⁴ Cards are stored permanently for a number of reasons. They may be used to check diagnoses or for retrospective testing if it is found that others in a family suffer from a genetic disorder and the child has died. Newborn screening cards are also regarded as a valuable research resource as they record information about every live birth recorded.

Permission from parents or guardian is sought before research is carried out using cards if that research will produce results which are linked back to the patient. For example, at the time of interview, a study was being carried out into the reliability of diagnostic procedures, which involved linking results back to medical records. Ethics committee approval was obtained.

Newborn screening cards themselves would never be transferred to another facility, only an anonymised section would ever be sent outside the hospital. Where external access is given, a small piece of the card is transferred to the external researcher without any patient information attached to it. Ethics committee approval is always sought before doing so.

³¹ This case study was produced from material gathered during an interview conducted at the Adelaide Women's and Children's Hospital, South Australia. See interview with Professor David Thompson, Adelaide Women's and Children's Hospital, (Personal interview, Adelaide Women's and Children's Hospital, Adelaide, 26 May 2000).

³² Different conditions are screened for in each state and territory, however all screen for PKU, congenital hypothyroidism and cystic fibrosis. See generally National Public Health Partnership, *An Overview of Public Health Surveillance of Genetic Disorders and Mapping of Current Genetic Screening Services in Australia*, NPHP, Canberra, 2002.

³³ Western Australia stores cards for only two years. See Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96, ALRC, Sydney, 2003, [19.15].

³⁴ Most cards taken prior to that date have been destroyed, and the author was unsuccessful in finding the whereabouts of her own newborn screening card, which she was informed had likely been destroyed.

In the history of the hospital, there had been only one incident of a person requesting return or destruction of cards. Following a recent television program that dealt with newborn screening cards and their continued storage, the hospital was contacted by a woman who wished her children's cards to be destroyed. She was informed that NPAAC guidelines required the card be retained for fifty years, but her continued protest led the hospital, reluctantly, to return the card to her. Following this incident, the cards were moved offsite to a secure location, and only the head of chemical haematology has access to them.³⁵

The National Public Health Partnership's 2002 survey of newborn screening card collections and procedures reported that in other states and territories, cards are sometimes released to the Coroner and police for forensic purposes, generally with parental consent.³⁶ In Victoria and New South Wales, screening services have each negotiated a Memorandum of Understanding with the police to lay down procedures for releasing cards.³⁷

In this case study, the first interest in the tissue collected is clearly that of the child from whom it is taken. A blood sample, which could provide information about that child's genetic makeup is held in a public institution, and is at times supplied to third party researchers. Tissue samples are not thought to be protected by privacy legislation in Australia, and hence no privacy protection would be available to the person from whom the blood was taken.³⁸

However, as with previous examples there is also a valid research interest in using such collections. Newborn screening card collections are valuable because they provide a large and comprehensive sample of many individuals. Any researcher using those cards would also be able to gain access only with ethics approval in accordance with NHMRC guidelines that would oblige them to maintain confidentiality.³⁹

Clearly, the example raises similar consent issues to those discussed already. It also raises the more complex issue of consent on behalf of another to the storage of their tissue, which will be stored indefinitely. Problems may arise if the tissue remains stored though the child, when an adult, no longer consents to storage and use. Further, as noted above, the original consent and its scope may be of doubtful validity. When samples are taken

³⁵ One woman's attempts to have her children's Guthrie cards returned has recently been documented. See C Lawson and R Smith, 'Protecting Genetic Materials and Genetic Information—A Case Study of Guthrie Cards in Victoria' (2001) 9 *Journal of Law and Medicine* 215.

³⁶ National Public Health Partnership, *Overview of Public Health Surveillance of Genetic Disorders*, 18.

³⁷ See Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours*, [19.53]–[19.57].

³⁸ The ALRC has recommended that genetic samples be included within the scope of privacy legislation. See generally *Ibid*, ch 8, Recommendations 8–1, 8–2.

³⁹ See Chapter Five, section 2.

from newborns, parents are provided with a brochure that informs them that any samples taken may be used, in anonymised form, in research carried out in the hospital. They are given the option to opt out from having samples used in this fashion. This process relies upon patient's taking the time to read these pamphlets, rather than obtaining specific consent. Elizabeth Thompson, a registered nurse, stated at the 1st International Conference on DNA Sampling and Banking that patients are sometimes asked for their consent in the midst of stressful situations. She cited the example of childbirth, and asserted that 'uninformed dissent' rather than informed consent was obtained, for as she said 'most of them don't get it ... [t]hey don't even remember it'.⁴⁰

Different privacy concerns also arise depending on how a sample is identified. Newborn screening cards are an example of identified samples, where information about the person from whom the tissue was taken is attached or readily linked to the sample. Identified samples raise considerable privacy concerns because once accessed, these samples could be tested and any genetic or other information generated from testing could be directly linked to the person from whom the tissue was taken. For example, it might be possible to test the blood spot on a woman's newborn screening card for a genetic disorder and determine that she carries a condition that could be passed on to her children, or that she suffers from a condition that will eventually affect her ability to do her job. Once this information is linked to her personal details, discrimination and misuse of the information is possible.

Codification of samples as in Case Study 4: Hobart Pathology protects individual privacy to an extent, and therefore may be an effective means to protect privacy in a research context.⁴¹ Other samples may have all identifiers permanently removed. This process is known as 'de-identification' or 'anonymisation'—all personal and coded information is removed from a sample is more effective as it prevents linking of the sample back to the person from whom it was taken. This approach is sometimes used to make it acceptable to perform research on a sample where no consent can be obtained—because the donor has died or cannot be contacted—by removing some of the privacy issues with using the sample. De-identified samples remain useful for many types of research, such as population studies into the prevalence of a genetic mutation that do not require personal information. This approach also removes the ethical

⁴⁰ As quoted in J Lytle, 'Is Informed Consent Possible in the Rapidly Evolving World of DNA Sampling?' (1997) 156(2) *Canadian Medical Association Journal* 257, 258.

⁴¹ See also Case Study 6: Tissue in Australian Research.

dilemma of whether donors should be contacted if information pertinent to his or her health is discovered in the course of research. This approach is widely used and accepted in Australia.⁴²

De-identification removes many privacy concerns. However, it does not address individual concerns about control and use of tissue. For example, while an individual's privacy is protected, their autonomous right not to participate in research is not. This might include research the individual finds offensive, such as a search for genetic causes of homosexuality, or because they find the use of human tissue in research objectionable in itself. It also excludes indigenous community interests in the use of tissue, where tissue may have been obtained from indigenous patients and used in research once de-identified, but this de-identification would not meet the objections of such groups because they are grounded in cultural beliefs about how the body should be treated, not in privacy concerns. Further, samples may not be de-identified for indigenous group. Hence, the concerns of indigenous communities about research into racial traits will not be addressed. De-identification also excludes the person from whom tissue was taken from sharing in any financial or other benefits that may flow from the research.

As noted previously, the community will gain if there are advances in science or medicine that provide new therapies. Public participation in research and allowing researchers access to materials benefits society by improving medical knowledge and aiding the development of treatments. Hence, the community has an interest in ensuring that researchers have access to tissue to enable them to continue their work.

COMMUNITY INTEREST IN SCIENTIFIC ADVANCES

Scientific advances often bring with them new therapies, new understandings of the cause of disease and new uses for tissues, such as forensic use that aids police in capturing criminals. Improvements in health care feed back into the community as benefits by providing means to heal disease, treat pain, restore bodily function and potentially prevent death. Even though not all members of that society benefit, or do not benefit equally, it is still possible to regard the benefits as accruing to the entire community.⁴³ As a group, improved health care means greater productivity within the community work force, and emotional benefits where relatives or friends are cured of distressing conditions. Forensic uses that have come from scientific advances have enabled police to arrest criminals who would otherwise have gone unpunished, enabling the community to enjoy a safer society. Forensics may

⁴² See Chapter Five, section 2.

⁴³ See Buchanan, 'An Ethical Framework for Biological Samples Policy', B-12.

also benefit the community and individuals by helping to prove the innocence of those who are wrongly accused.

As a result, any regulation of tissue use in this area would need to temper protection of privacy with sufficient access to tissue collections for research. Such balancing must occur through weighing the harms to privacy and autonomy of particular research against the availability of other samples of tissue and the utility of the research.

The real problem with newborn screening cards and other collections of this kind, though, is whether they will be released by the hospital for other purposes. Loane Skene has identified a number of possible scenarios in which this might occur, including requests for access from the donor, blood relatives, insurance companies and the police. Skene asserts that neither donors nor relatives have a legal right to access in Australia,⁴⁴ but as she rightly points out, the hospital may simply accede to their requests. This would enable blood relatives access to blood that could possibly be tested for a hereditary genetic condition, revealing sensitive and private information.

Studies have been carried out into whether such requests for access would be granted. One study into United States hospital practices revealed that although most laboratories would balk at releasing identified cards to third parties, many would release them once anonymised.⁴⁵ Of the 53 respondents, two would have released identified cards to insurance companies and three would have released them to employers. More problematic, however, was the fact that they would release cards in certain hypothetical situations. Twenty four were prepared to release cards to a 'physician treating the brother of a deceased child who has an undiagnosed severe metabolic disorder'; one would release to a 'divorced man seeking to resolve a child's paternity' and seventeen would release anonymised cards to a 'researcher conducting studies on racial distribution alleles'.⁴⁶

⁴⁴ See L. Skene, 'Access to and Ownership of Blood Samples for Genetic Tests: Guthrie Spots' (1997) 5 *Journal of Law and Medicine* 137, 140. Blood spots form part of a patient's medical records and following the case of *Breen v Williams* (1996) 186 CLR 71 patients do not have a right to know what is in their records unless it is necessary for their health.

⁴⁵ McEwen and Reilly's study was conceived as a response to concerns that Guthrie cards could be used for genetic testing and 'thus be viewed as inchoate DNA banks'. The study aimed to elicit information from newborn screening laboratories on retention and sharing of Guthrie cards and consisted of a five page questionnaire, with an overall response rate of 100%. See J. McEwen and P. Reilly, 'Stored Guthrie Cards as "DNA Banks"' (1994) 55 *American Journal of Human Genetics* 196.

⁴⁶ *Ibid*, 198.

In each of these cases the privacy and autonomy of the person whose sample is released is violated. In the third, studies into racial discrimination may be offensive to some individuals who would not wish to participate in such studies, while in the second a child's right to know (or not know) about their parentage is interfered with without their consent. In all these cases, the essential issues are privacy and security. Hence, again control is a factor in how tissue is to be used, both in terms of how the testing agency or hospital holding that tissue protects it, and how an individual themselves is to be reassured that their samples are secure.

Centuries ago, the potential misuse of bodies and tissue extended only to desecrating graves and unauthorised use in dissection—something that could occur only where a body was stolen. Unauthorised use of tissue is more possible now, as samples are more often taken from the living and stored. However, what this section shows is that because we now have the ability to extract so much information from tissue samples about the person from whom they have been taken, there is an even greater need to ensure that they are adequately protected from misuse. Genetic developments add a new layer of harms that can be done to the individual if his or her tissue is misused. These range from demonstrating that he or she has a genetic condition that can be passed on or which may lead to discrimination and stigmatisation, to showing that the person's paternity is not what they believed it to be—and each of these harms might occur even if only the tiniest piece of tissue is accessed and misused. These harms demand that in the 21st century, even more so than before, that the legal system develop systems to protect tissue against misuse.

3. RESEARCH USES OF TISSUE

Human tissue provides the basic materials for much research into human disease. In a United States survey during the 1980s, more than half the responding medical schools replied that they used human tissue for research.⁴⁷ The United States National Bioethics Advisory Commission (NBAC) emphasised the vital role human tissue plays in research in its 1999 report, noting a number of past studies utilising tissue that have had profound benefits for society. These included the analysis of autopsied lung tissue taken from smokers, which aided researchers to establish smoking as a cause of lung cancer. The NBAC also cited studies of vaginal tissue samples of precancerous lesions of the uterine cervix, which led to the use of Pap smears becoming routine. The increased use

⁴⁷ L B Andrews, 'My Body, My Property' (1986) 16 *Hastings Center Report* 28, 33.

of such smears has enabled much earlier diagnosis and better treatment of cervical cancer, while other studies of vaginal tissue using identified samples enabled researchers to discover a link between a hormone given to women during pregnancy and cancer. The hormone, diethylstilbestrol was found to be carcinogenic, and this research would have been impossible without the identified samples. The NBAC also noted that in some cases, studies are impossible without human tissue, like research into human brain diseases such as Parkinson's disease and multiple sclerosis.⁴⁸

Other examples of tissue use in research include the use in the United Kingdom of leftover blood from diagnostic tests, which is tested anonymously for HIV to develop a picture of the nationwide status of the disease. In another example, researchers wished to study placental tissue to search for markers of tumour progression and metastasis, while in still another, cell material collected from cervical smears was to be analysed.⁴⁹ In Australia, research proposals have been made to study, amongst other things, faecal and serum samples held at an infectious diseases hospital to sequence the genome of a virus which may be the cause of outbreaks of gastroenteritis.⁵⁰ These are clearly only a very few of the vast numbers of research studies that require the use of human tissue, but they do serve to give some idea of the breadth—and the importance—of the use of tissue in research. Some particular examples are outlined in more detail in the following case study.

CASE STUDY 6: TISSUE IN AUSTRALIAN RESEARCH

This case study covers a number of research projects being carried out in Australia.

1. Immunology Research using Human Thymus Tissue: Dr Stephane Vandenabeele, Walter and Eliza Hall Institute, Melbourne⁵¹

Human thymus tissue in newborns has regenerative qualities and regrows after partial or full removal. It is a rich source of dendritic cells and this project examines the populations of such cells in tissue to study autoimmune disease. Thymus tissue is often removed during cardiac surgery on newborns to enable the surgeon to reach the heart. This tissue is generally discarded, however the Walter and Eliza Hall Institute (WEHI) has an agreement with the Royal Melbourne

⁴⁸ Ibid, 20.

⁴⁹ H Zwart, 'Biomedical Research with Human Body "Parts"' in Ten Have and Welie, (eds) *Ownership of the Human Body: Philosophical Considerations on the Use of the Human Body and its Parts in Healthcare*, 47, 55.

⁵⁰ R S Magnusson, 'Confidentiality and Consent in Medical Research' (1995) 17 *Sydney Law Review* 549, 551ff.

⁵¹ Interview with Dr Stephane Vandenabeele, (Personal interview, Walter and Eliza Hall Institute, Melbourne, 28 August 2000).

Children's Hospital for the supply of discarded tissue for this research project. When a sample is required for research, the hospital is contacted and a portion of tissue removed for surgical purposes will be retained. No monetary or other compensation is exchanged. There is no other way for the researchers to gain tissue of this kind for their research. Consent procedures are completed at the hospital and the sample is anonymised. Once the research on the tissue is completed, the sample is destroyed as a biohazard in compliance with the Institute's procedures.

2. Dermal Therapeutics and Research into Psoriasis: Dr Chris Wraight, Murdoch Children's Research Institute, Melbourne⁵²

Dr Wraight's research into skin disease with a focus on psoriasis involves taking skin samples which are then maintained in the laboratory for a few days. Skin for this research is acquired from a number of sources:

- (a) Normal skin from consenting laboratory workers. This tissue is stored by labelling it with the initials of the donor, which are held in a database and are linked to donor information.
- (b) Normal skin discarded during surgery. Skin tissue which would otherwise be discarded is sometimes supplied to the researchers. Samples are anonymised.
- (c) Skin afflicted with psoriasis from consenting volunteers. Volunteers usually contact the project following advertisement of the research. Information is provided to donors on a consent forms and subjects are required to discuss the project with the laboratory dermatologist. Samples are coded with the initials of the subject as above.
- (d) Samples provided by a pathology laboratory. These samples are coded by the pathology laboratory before supply and could only be identified with access to the pathology laboratory's database. They are returned to the pathology laboratory after research is completed, with the laboratory asserting that they have a right to possession and need the samples in case future testing is required.
- (e) Skin samples from the Victorian Institute of Forensic Medicine in the form of wax blocks of tissue kept from the margin of incisions made at autopsy. These are identified by age and sex only.

This case study demonstrates some of the sources of tissue that is used in research, and they are clearly wide-ranging, from tissue discarded during surgery, to pathology samples, to voluntarily donated tissue. It also raises again the variety of interests in this tissue—the privacy and autonomy interests of the person from whom it was taken; the research interests of researchers who need access to tissue to undertake their work; and the community interest in the development of new treatments.

However, as discussed previously, protection of individual interests must be balanced against research need to have access to tissue for the development of tests and

⁵² Interview with Dr Christopher Wraight, Murdoch Children's Research Institute, (Personal interview, Murdoch Children's Research Institute, Melbourne, 30 August 2000). Ethics approval from all relevant Institutional Ethics Committees was obtained for all research projects outlined in this case study.

treatments for disease. While having emphasised the importance of obtaining informed consent to tissue use throughout this chapter, it bears noting at this point that doing so may be an onerous burden on researchers and individuals. Angela Holder and Robert Levine argue that to require consent for the use of all portions of tissue removed during surgery or after autopsy is excessive and unnecessary.⁵³ They have a point, for if researchers are required to complete excessive paperwork and recontact all sources in all situations, the burdens on research both of time and money may impede that research.

Similarly, excessive checking for consent may disincline individuals to participate. As F J Engelfinger has argued,

the patient, asked to sign countless releases or consents, may respond with a blanket refusal or with a pro forma signature. The physician, immersed in a profusion of unimportant detail, will lose sight of, and respect for, the important issues. Perhaps he will feel compelled to practice defensive ethics—no more honourable than defensive medicine. For medical ethics, in short, trivialization is self-defeating.⁵⁴

This overstates the case, but it does point to the need to balance both concerns, so that respect for patient autonomy is maintained without stifling research.

These problems are potentially most acute where samples may be used for multiple purposes and shared between collaborating researchers and commercial bodies.⁵⁵ It may be difficult to foresee these uses when samples are taken and thus the patient may not always be informed of the use to which their tissue will be put when the initial consent is given, while to contact all people whose tissue is stored in large collections may be too onerous a task. Where individuals cannot be contacted, respecting their right to control tissue may prevent the use of valuable material altogether. Consequently, new treatments, drugs and diagnostics may not be developed to cure diseases and disorders, a cost which will be borne by the entire community.

ACCESS TO HUMAN TISSUE FOR RESEARCH

Demand for tissue is currently supplied by tissue taken from autopsies, surgery and volunteers. It is generally transferred via agreements with hospitals, or where researchers have recruited subjects themselves. Were these avenues for tissue acquisition to disappear, much medical research

⁵³ Ibid.

⁵⁴ F J Engelfinger, 'The Unethical in Medical Ethics' (1975) 83 *Annals of Internal Medicine* 264–269 as cited in A R Holder and R J Levine, 'Informed Consent for Research on Specimens Obtained at Autopsy or Surgery: A Case Study in the Overprotection of Human Subjects' (1976) 24 *Clinical Research* 68, 68.

⁵⁵ World Health Organization, *Proposed International Guidelines on Ethical Issues in Medical Genetics and Genetic Services—Report of a WHO Meeting on Ethical Issues in Medical Genetics*, Geneva, 15–16 December 1997, WHO/HGN/GL/ETH/98.1, 20.

would be impossible. However, at present controls on access mean that some research may not be undertaken because of supply reasons or ethical restraints on the use of tissue. Hence, in some cases, more relaxed consent requirements and strong ethical controls might result in increased research. While there are clearly good reasons for these controls, it bears remembering that some important research—research on embryos is a good case in point—may be constrained by concerns for individual interests.

4. BANKING OF TISSUE

Tissue is stored for numerous reasons. In a hospital dealing with 10,000s of samples every year, up to 25,000 blocks and 40,000 slides will be generated. Many of these will be kept for quality assurance and future testing. Tissue leftover from donations made to research projects are also frequently stored and, depending on the initial consent obtained, may be used in further research.⁵⁶

In some instances, tissue is specifically donated to be stored and used in research. In the Netherlands, tissue is more commonly stored than destroyed, while the use of tissue for purposes other than that which it was taken is regarded as so common as to be normal practice.⁵⁷ Stored tissue has enabled researchers to study the course of diseases of long periods of time. In one recent study, examination of tissue retained from a patient who died in Manchester of unexplained causes in 1959 revealed that he had in fact died of AIDS, evidence that the virus has existed for at least forty years.⁵⁸

An example of tissue stored for research purposes from the United Kingdom is the new United Kingdom BioBank. The BioBank is intended to be a research resource, containing blood samples, medical records and lifestyle information for hundreds of thousands of Britons.⁵⁹ By linking this information with samples, researchers will be able to search for the genetic causes of disease on an unprecedented scale. Samples and information are donated by volunteers and managed by the Coordinating Centre.⁶⁰ The collection is overseen by the Wellcome Trust and the Medical Research Council of the United Kingdom. The issues associated with such collections are discussed below in

⁵⁶ M Hirtle and B Knoppers, 'Banking of Human Materials, Intellectual Property Rights and Ownership Issues' (1997) 6 *Law and Human Genome Review* 63, 72.

⁵⁷ H Zwart, 'Biomedical Research with Human Body "Parts"', 52.

⁵⁸ Ibid, 55.

⁵⁹ See, eg, R McKie and P Wintour, 'Mass Gene Bank Launched' *The Observer* (London), 13 February 2000, <www.guardian.co.uk/genes/article/0,2763,191901,00.html> at 1 September 2003.

⁶⁰ Wellcome Trust, Medical Research Council and Department of Health (UK), 'Welcome to the UK BioBank' *UK BioBank: A Study of Genes, Environment and Health*, <www.ukbiobank.ac.uk> at 25 July 2003.

Section 3 in relation to the Icelandic Health Sector Database and Case Study 12: Iceland and deCODE.

In Australia, as in other countries, some types of tissue banks also store donated and discarded body tissue so that it may be used for therapy—such as blood banks holding blood for transfusions—and sometimes for research. These banks differ from collections of samples maintained as part of research or pathology collections held by laboratories and hospitals because their prime purpose is to retain material for later use in therapy. Research use is usually secondary, and they do not retain material for diagnostic purposes. An example is given in the following case study.

CASE STUDY 7: DONOR TISSUE BANK OF VICTORIA⁶¹

The Donor Tissue Bank of Victoria is the largest tissue bank in Australia and is a division of the Victorian Institute of Forensic Medicine. The bank collects, stores and processes tissue donated from people who have died. The bank collects four major types of tissue—bone and musculoskeletal tissue, which is used in reconstruction surgery; heart valves, which are often used to repair congenital heart defects in newborns; corneas, which are transplanted; skin tissue used as tissue grafts for burn victims.

The bank obtains tissue by contacting the relatives of a recently deceased person. Tissue is retrieved from the deceased's body by the bank's staff, and the body is then reconstructed and the tissue stored. For example, retrieved heart valves are individually stored in liquid nitrogen for up to five years. These valves are then supplied for transplant Australia-wide. In 2002, more than 70 heart valves obtained by the bank were transplanted.⁶² Approval for retrieval and use is obtained from the bank's ethics committee.

The most obvious interest to be considered is that of the donor—how their autonomy may be respected, even in death, by using parts of their body in accordance with any expressed wishes. As the tissue is stored, privacy and security issues may also arise. Familial interests are also highly important, given the emotional stress that agreeing to donation places on a deceased person's relatives—those who remain behind may be severely affected by the treatment of the deceased's body and its parts. Those who obtain donated tissue as part of their treatment have an interest in there being a supply of donated tissue, as does the community in general.

⁶¹ This case study is drawn from the Donor Tissue Bank of Victoria website, Victorian Institute of Forensic Medicine, *Donor Tissue Bank of Victoria*, <<ftp.vifp.monash.edu.au/n135.html>> at 25 July 2003.

⁶² Victorian Institute of Forensic Medicine, 'Cardiac Tissue Supplied by the DTBV', <<ftp.vifp.monash.edu.au/n479.html>> at 25 July 2003.

These issues have been previously discussed in the context of organ donation. Where this case study differs is in the storage of tissue. Some tissue will remain at the bank for up to five years and it may be identified in some way. As a result, other interests may arise. For example, relatives may later seek access to tissue because they wish it to be buried—for example, if the donor if was part of an indigenous community, its members or other relatives who did not consent to the donation may object to storage. Researchers may also have an interest in accessing tissue. In Australia some donor tissue banks do supply tissue for research. In its recent report, the Australian Law Reform Commission gave the example of the Perth Bone and Tissue Bank, which supplies bone from failed allografts for research; and also the example of the Red Cross Blood Bank which occasionally supplies expired blood for research.⁶³ The wishes of relatives and the desires of researchers may also conflict in this type of situation.

Some tissue is also commercially stored for personal use. As yet this appears to be a mainly American phenomenon, however commercial storage facilities are now being established in Australia. With technological developments has come the discovery that blood from the placenta and umbilical cord is a rich source of haematopoietic stem cells which may be a possible replacement for bone marrow transplants.⁶⁴ As a result, placental blood is being banked both publicly, where it is donated and used for those who need it⁶⁵ and by commercial ventures where parents can store placental blood for their own child's use—for example, by the Australian firm Cryosite.⁶⁶ What was once waste is now viewed, like many other tissues, as a valuable resource or in the words of one advertisement for private banking: 'cord blood, once discarded as useless, can now be described as priceless'.⁶⁷

Commercial storage of tissue may bring familial interests into conflict. Banked cells can be used by other family members which raises the issue of who has the best claim to stored tissue, and how this will be determined. Also while placental blood banking is sold as a form of 'biological insurance', where there is no history of blood disease there is only a one in 20,000 chance that the child will have any use for their banked tissue.

⁶³ Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours*, [19.18].

⁶⁴ G J Annas, 'Waste and Longing—The Legal Status of Placental—Blood Banking' (1999) 340 *New England Journal of Medicine* 1521, 1521.

⁶⁵ S R Kirshenbaum, 'Banking on Discord—Property Conflicts in the Transplantation of Umbilical Stem Cells' (1997) 39 *Arizona Law Review* 1391, 1418

⁶⁶ See Cryosite, 'Australian Cord Blood Service', <cordblood.cryosite.com> at 25 July 2003.

⁶⁷ See Kirshenbaum, 'Banking on Discord', 1398.

Tissue which could have been stored publicly and made available for the use of other children in need.⁶⁸ This form of personal storage, control and use of tissue, which may be wasted, may put individual interests in direct conflict with public interests in the general health of the community.

5. THE ADVENT OF GENETICS

...the most important scientific breakthrough of this century may be seen in time, to be neither nuclear fission, nor interplanetary flight, nor even informatics, but the fundamental and basal molecular biology which permits the human species to look into itself and find, at last, the basic building blocks of human and other life.

*Hon. Justice Michael Kirby*⁶⁹

With the development of modern genetic science a new meanings entered the language used to speak about the body. It has variously been described as a 'book' to be read, a 'library', and a 'wilderness' to be mapped.⁷⁰ Tissue has become information. Samples of blood, skin and other biological materials can be used to extract DNA, which can be tested to tell us about whether the person suffers from a variety of genetic conditions and predispositions. Research on DNA can be directed at examining the molecular alterations that cause genetic diseases and population diversity.⁷¹ DNA can be used to determine whether a woman will be susceptible to breast cancer or show that a foetus will suffer from cystic fibrosis. In the words of Arthur C Upton, '[f]ew developments are likely to affect human beings more profoundly in the long run than the discoveries resulting from advances in modern genetics'.⁷²

5.1 Genetic Testing

Genetic conditions may be caused either by a single faulty gene or a group of genes (multifactorial disorders) which will often interact with the environment and lifestyle of

⁶⁸ Annas, 'Waste and Longing', 1522. Other banks in the United States include Safe-T-Child and Child Trail, which store tissue to enable identification of missing or kidnapped children and BioBank which offers to store various tissues from individuals in case they have need of it in the future. See Andrews and Nelkin, 'Homo Economicus', 30.

⁶⁹ M Kirby, 'Legal Problems: Human Genome Project' (1993) 67 *Australian Law Journal* 894 as quoted in Chalmers, Otlowski, Nicol and Skene, 'Project on the Legal and Ethical Aspects of Genetic Research in Australia', 31.

⁷⁰ M Rosner and T R Johnson, 'Telling Stories: Metaphors of the Human Genome Project' (1995) 10(4) *Hypathia* 104-129 as cited in C S Campbell, 'Research on Human Tissue: Religious Perspectives' in National Bioethics Advisory Commission, *Research Involving Human Biological Materials*, vol I, C-4.

⁷¹ American College of Medical Genetics Storage of Genetics Materials Committee, 'Statement on Storage and Use of Genetic Materials' (1995) 57 *American Journal of Human Genetics* 1499, 1499.

⁷² M A Rothstein, (ed.) *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era*, Yale University Press, New Haven and London, 1997, xi.

a person to produce a condition. These conditions can be detected through tests that analyse human DNA and its genetic sequences, such as Huntington's disease.

Tests may be performed presymptomatically, where a disease is suspected. Most often, such tests will be performed on people whose families carry a genetic mutation—the test determines whether the person has inherited the mutation and will develop the condition. A person may also be tested for carrier status, to see if they carry a mutation but do not have the condition it may cause. Other tests may be predictive and results may point only to a predisposition to develop a condition. For example, a person may be predisposed to heart disease and some cancers, meaning they will have a higher risk of developing the disease, but it is not certain that they will do so. These predispositions will often be affected by environmental factors, rendering their onset less predictable. Tests may also be performed where symptoms are already in evidence to confirm diagnosis. Prenatal testing involves taking tissue from foetuses in utero for predictive testing. The following case study describes the operation of a service providing genetic testing.

CASE STUDY 8: SOUTH AUSTRALIAN CLINICAL GENETICS SERVICE⁷³

The South Australian Clinical Genetics Service provides diagnostic genetic testing and specialist counselling. Specific consent is not always obtained for each genetic test, as general consent to testing to determine the cause of a condition may be regarded as sufficient. For example, where a patient is suspected of suffering from β -thalassaemia both genetic and indirect tests may be used. In other instances a request for diagnosis may be regarded as tacit consent to any necessary tests. Samples collected by the service may also be used for research. Written consent is required before samples are taken.

Examples of tests provided by the service are presymptomatic molecular genetic tests for types of familial cancers. The patient is advised of the purpose for which the test is being done and the consequences of the test⁷⁴ The patient is also informed that the test may have implications for family members and that it is not known whether the test result could affect the patients' or their children's ability to obtain insurance or employment now or in the future.

⁷³ This case study was developed from interviews conducted at the South Australian Women's and Children's Hospital. See interview with Associate Professor Eric Haan, South Australian Clinical Genetics Service, Women's and Children's Hospital (Personal interview, Women's and Children's Hospital, Adelaide, 25 May 2000); interview with Professor Grant Sutherland, Women's and Children's Hospital (Personal interview, Women's and Children's Hospital, Adelaide, 24 May, 2000).

⁷⁴ South Australian Familial Cancer Service, *Consent Form: Presymptomatic Molecular Test for Familial Cancer*, South Australia Clinical Genetics Service, Adelaide, 2000.

Blood samples are stored in labelled tubes, identified by a number which links the tube to the patient information stored in the laboratory database. Anyone working at the laboratory with access to the database can connect a sample with the patient's personal information. Access to the database is available only to those who can establish their credentials when contacting the laboratory. All workers at the genetic registry are required to sign a confidentiality agreement before commencing work. Laboratory workers, however, are not formally bound to keep confidentiality, but to do so is regarded as understood by all who are employed. Samples are usually retained indefinitely.

Consent forms for testing include provisions for consent to 'the DNA and other relevant information being used on an anonymous basis for research studies which have been approved by an Institutional Ethics Committee.'⁷⁵ All patients are informed that they may opt out of having their tissue used for research by deleting this provision from the consent form. They are not, however, recontacted if the tissue is to be used unless ethics approval requires it. Samples are transferred on an ad hoc basis for research purposes and are retained by the receiving facility.

Individuals who are tested for genetic conditions will clearly have an interest in knowing the results of those tests and the information they yield. It will affect their future life choices and health care decisions and perhaps even their self-identity. Family members, too, may have an interest where the results may indicate something about their genetic status. The sensitivity of the information generated by tests creates a need to protect the confidentiality of results and to keep samples and results secure. Hence, there will be considerable privacy concerns.

If an individual is shown to have an inheritable condition, this may reveal information about the genetic status of other family members. For example, if a daughter is shown to have the gene for Huntington's disease, a late onset disorder, then one of her parents must also have the gene to have passed it on, and other siblings may have received the gene as well. Their health status, and a future suffering from a debilitating disorder will be revealed. They may not wish to know this, and hence testing of one person may affect another's right not to know as much as their own right to know. The Human Genome Organisation Ethics Committee has suggested that in such instances, there may be justification for the individual's wishes to be overruled by those of relatives. The Committee found that such a situation would arise where the relative faced a high risk of having, or being able to transmit, a serious disorder and treatment or prevention was available.⁷⁶

⁷⁵ Ibid.

⁷⁶ Human Genome Organisation Ethics Committee, *Statement on DNA Sampling: Access and Control*,

Where children are involved, the issues around genetic testing become even more complex still as parents may wish to have children undergo predictive testing for disorders. While parents may have control of the child, that child's right to make autonomous decisions will be affected if their wishes are not respected. Their competency may also be at issue.⁷⁷ Privacy as a means of controlling what we know and what is known about us, and consequently the security of samples and confidentiality of results, then, are crucial issues when tests are performed.

Where samples are later used in research, as noted in Case Study 8: South Australian Clinical Genetics Service, rights to know and not to know also come into play. If the researcher discovers that the person from whom the tissue was taken is suffering from a treatable genetic condition, there may be some duty on them to inform the individual. There may be a similar duty where the individual is the carrier of a disease which they might pass on to any children. These possible duties, however, need to be balanced against the individual's right not to be informed which protects them from unwanted distress at being given knowledge about themselves that they have not sought to generate.

Finally, individuals have an interest in protecting information about them derived from genetic tests because their genetic status may affect their ability to find employment or acquire insurance—they may be stigmatised or discriminated against on the basis of their condition. Again, privacy and confidentiality are the major concerns. Confidentiality of information is crucial in instances where it may be used in a discriminatory fashion. Individuals have an interest in being treated fairly and not being discriminated against on the basis of genetic test results where there is not justifiable reason for doing so. Where the individual is already aware of a test result, they may be placed under pressure to reveal the results when applying for employment, and will be required to do so if applying for life insurance. They may also be required to undergo testing to apply for work or insurance, which places on them the added burden of undertaking a test the results of which they may prefer not to know about.

February 1998.

⁷⁷ See generally J Savulescu, 'Predictive Genetic Testing in Children' (2001) 175 *Medical Journal of Australia* 379.

GENETIC DISCRIMINATION

Genetic discrimination occurs when a person is treated differently, and often adversely, on the basis of some genetic characteristic or condition. Employment and insurance are two major areas in which genetic discrimination may potentially occur.

Employment: Discrimination in an employment context may occur in a number of ways—by basing decisions to employ on existing genetic conditions or predispositions; by screening current employees or by monitoring the effects of employment by testing during employment.⁷⁸ Employers may argue that certain genetic conditions will affect an individual's ability to do a job or that they will be more susceptible to harms inherent in their employment duties. Screening for such susceptibility has what Margaret Otłowski has described as 'a strong exclusionary focus, namely, to identify those who are susceptible with a view to denying them employment opportunities and benefits'.⁷⁹ It is uncertain as yet how this issue will be dealt with in Australia, nor whether Disability Discrimination legislation will apply.⁸⁰ There is currently no legal prohibition on genetic testing in the workplace nor on the use of genetic information.

Discrimination on the basis of genetics has already been detected in Australia. Studies conducted by Kristine Barlow-Stewart and David Keays found three alleged cases of employment discrimination, where discrimination was defined as less favourable or adverse treatment on the basis of a positive genetic test result. In each of these cases asymptomatic individuals, that is individuals who had either a predisposition or a condition but in neither case were yet suffering symptoms, were predisposed to later-onset neurological diseases. In one case, the person concerned was fired; in the remaining two the individuals were demoted.⁸¹ Barlow-Stewart and Keays concluded that individuals were deterred from undergoing genetic tests.⁸²

Insurance: Genetic information can adversely affect a person's ability to obtain insurance. The essential purpose of insurance is to protect, financially,

⁷⁸ See generally Australian Law Reform Commission and Australian Health Ethics Committee, *Protection of Human Genetic Information*, IP 26, ALRC, Sydney, 2001, [10.6]–[10.11]. The use of medical information in employment has been occurring for more than a century. For example, in the United States, Sears Roebuck and Company began testing applicants and employees for tuberculosis in 1909, and these persons were then isolated. See generally M A Rothstein, 'The Law of Medical and Genetic Privacy in the Workplace' in Rothstein, (ed.) *Genetic Secrets*, 281.

⁷⁹ M Otłowski, 'Implications of Genetic Testing for Australian Employment Law and Practice' (2001) 2 *Centre for Law and Genetics Occasional Paper Series* 1, 9.

⁸⁰ The *Disability Discrimination Act 1992* (Cth) requires that individuals be treated in the same manner unless different treatment may be justified by their circumstances being sufficiently 'materially different'. See *Disability Discrimination Act 1992* (Cth) s 5. It may be that genetic conditions could satisfy this requirement. See generally *ibid*. Racial and sex discrimination legislation also operates in Australia and may be relevant in the context of genetic testing, for example where a predisposition is linked to gender such as cervical cancer predisposition. See further *Sex Discrimination Act 1984* (Cth); *Racial Discrimination Act 1975* (Cth). See generally Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours*, ch 30.

⁸¹ K Barlow-Stewart and D Keays, 'Genetic Discrimination in Australia' (2001) 8 *Journal of Law and Medicine* 250, Appendix A, cases 24, 27 and 33. In the case of termination, the individual was diagnosed with familial early onset Alzheimer's disease and the employer believed he or she would be unable to continue in their duties (case 24). In cases 27 and 33, each individual had been diagnosed with Huntington's disease, with one individual being demoted to lighter duties and consequently reduced pay while the other resigned after being placed on light duties.

⁸² *Ibid*, 254–5.

in the case of loss being suffered. By paying premiums, the individual's risk of loss is placed on the insurer, who must compensate them in the event of that loss occurring.⁸³ Where the risks are greater, higher premiums may have to be paid. Insurance may be provided in the form of life insurance or health insurance. In Australia, health insurance providers are prohibited from excluding individuals from cover on the basis of health and must charge the same premiums.⁸⁴ Life insurance providers, however, increase premium rates on the basis of risks to health. Those applying for insurance are required to disclose all relevant information, and insurance companies may take genetic test results into consideration, but may not use them in an unjustifiably discriminatory manner.⁸⁵

The Barlow-Stewart and Keays studies discovered forty-five instances of discrimination by insurers on the basis of genetic information.⁸⁶ Two of these cases were discrimination by health insurers in the form of longer waiting periods.⁸⁷ This imposition is an allowable action by a health insurer where the individual applying for insurance has a pre-existing condition.⁸⁸ This may only be done where the individual has signs of symptoms of the disease, but as Keays and Barlow-Stewart point out positive genetic test results are being viewed as such pre-existing conditions even where no symptoms have been displayed.⁸⁹ The implications of being denied insurance in these situations can have a large financial impact on sufferers who will have to pay for their own treatment where not covered by Medicare, and the fear of discrimination may deter them and their families from seeking future tests, thus jeopardising their future health.

Discrimination in other contexts: It is feasible that if genetic science becomes able to point to genetic origins of characteristics these may also become a basis for discrimination. For example, genetic disposition to violence or criminal behaviour could easily, if detectable, be used to influence sentencing in criminal proceedings, which might be considered discriminatory. If a person's intelligence could be measured through genetic testing, it is possible that children may be discriminated against in the classroom by teachers either under- or overestimating their abilities. However, where genetic causes of learning disabilities may be detected this could allow schools to discriminate positively to provide remedial help for disadvantaged students. A similar approach could be taken where behavioural problems can be attributed to genetic causes. Discrimination is not always negative in effect.⁹⁰

⁸³ M Otlowski, 'Implications of Genetic Testing for Australian Insurance Law and Practice' (2001) 1 *Centre for Law and Genetics Occasional Paper Series* 1, 8.

⁸⁴ Australia health insurance providers may only carry on business if registered under the *National Health Act 1953* (Cth), of which s 73(2A) prohibits registration of insurers who refuse cover on the basis of health status. See Ibid, 9 and see generally on the principle of community rating and its effect on contribution rates.

⁸⁵ See generally Ibid, 11–16.

⁸⁶ Ibid, Appendix A.

⁸⁷ Barlow-Stewart and Keays, 'Genetic Discrimination in Australia', 256.

⁸⁸ *National Health Act 1953* (Cth), Schedule 1, [bc]. Insurers can impose a waiting period of one year for such conditions.

⁸⁹ Barlow-Stewart and Keays, 'Genetic Discrimination in Australia', 256.

⁹⁰ See generally L F Rothstein, 'Genetic Information in Schools' in Rothstein, (ed.) *Genetic Secrets*, 317. Laura Rothstein also points out that schools form a perfect environment for carrying out screening program.

It is conceivable also that genetic testing might be used to discriminate against people applying to immigrate to Australia, those with unwanted conditions being refused entry to prevent the spread of such diseases into the Australian gene pool. This could be included as part of the immigration health requirement.⁹¹

It is apparent, then, that tissue samples have the potential, with the development of genetic testing, to produce harmful results if tested or used inappropriately. The use of these samples, both in research and testing for diagnostic purposes needs to be carefully controlled, while access by third parties must occur only with the consent of the source individual. Physical security must also be maintained, as the situation where persons who have access to such tissues and the information they can generate taking and using that information can be envisaged. Misappropriation of samples or their unauthorised supply to those who would extract private, stigmatising or discriminatory information is not so unthinkable to preclude protection from this eventuality.

5.2 Genetic Research

At the forefront of genetic research in the past years has been the Human Genome Project, a worldwide collaborative effort to map the genetic sequence of human DNA.⁹² By doing so, scientists will have the basic material for determining the location, and eventually the function of the genes which code for all aspects of the human body, including physical characteristics and bodily function. Such discoveries also enable scientists to discover genes that cause disorders, understand mutations that cause health problems and better comprehend the interplay between genetic and environmental forces.

Genetic research also takes the form of population studies, which may search for the frequency of mutations or for links between lifestyle, genetics and diseases. These are carried out on a large scale, using samples from hundreds or even thousands of

⁹¹ Potential migrants must undergo medical examinations on application for residency. This requirement aims to ensure that 'risks to public health in the Australian community are minimised; public expenditure on health and community services is contained, and Australian residents have access to health and other community services'. Decisions are based on whether the individual poses a public health risk, and if not; on whether the 'potential cost and impact on the Australian community resulting from the possible use of medical and related services'. Specific provisions apply to HIV, tuberculosis and hepatitis but as yet not to genetic conditions. Therefore, it is unclear how genetic conditions will affect an individual's ability to gain residency in this country. See Department of Immigration Multicultural and Indigenous Affairs, *Fact Sheet 22—The Health Requirement*, Commonwealth of Australia, Canberra, revised 25 March 2002, <www.dima.gov.au/facts/22health.htm> at 6 April 2002.

⁹² The Human Genome Project made a joint announcement with Celera Genomics in June 2000 that the draft version of the genome was almost completed. Material was subsequently published by the Public Sequencing Consortium of the Human Genome Project in February 2001.

participants. Often, genetic databases containing samples, medical records, and health and lifestyle information are compiled to enable such studies. These are discussed further below.

CASE STUDY 9: MENZIES CENTRE FOR POPULATION RESEARCH⁹³

The Menzies Centre for Population Health Research conducts research to identify and commercialise genes that are important in determining susceptibility to common human diseases. The Centre conducts research into the genetic aspects of glaucoma, prostate cancer, osteoarthritis, multiple sclerosis and diabetes mellitus.

Research participants⁹⁴ supply a sample of blood or saliva for DNA testing, a detailed family tree and information about whether other family members have suffered the condition. Before samples are taken, participants must complete a written consent form that includes an acknowledgment that information will be kept confidential and that the participant understands the nature and effects of the study. No forms address whether the subject may reclaim their sample. The participant is informed that the sample will be stored and that it will not be used for any purpose other than that stated in the consent form. Participants are also advised that their samples may be used in other related studies, but not for any other purposes unless they give specific consent to those uses.

Once consent has been given, two duplicate samples are taken through blood collection or buccal mucosa swab. The samples are taken by registered nurses and then transported to Menzies Centre laboratory where they are logged and stored. Samples are stored at the Centre, but duplicates are sometimes sent to other centres conducting research in conjunction with Genetic Epidemiology Unit. DNA is extracted from the blood or buccal swab taken, analysed and the results used, with the family and medical information supplied, to research genetic disease.

Samples never leave the Centre labelled with any identifying information other than a code. These codes are also the only identification used in family trees that leave the Centre. Hence, contacting the Centre to match the code to the participant's file is the only means of identifying the sample, though coded family relationships will be clear in genealogical tables. As yet, the Menzies Centre has not disposed of any genetic samples.

⁹³ This case study was developed from an interview at the Menzies Centre for Population Research. See interview with Dr Michèle Sale, Director, Genetic Epidemiology Unit, Menzies Centre for Population Research (Personal interview, Menzies Centre for Population Research, Hobart, 9 August 1999) and the information sheets and consent forms provided to subjects.

⁹⁴ Usually participants are identified through contact with medical practitioners, publicity generated about a study and information provided at treatment centres. For example, for the Diabetes Mellitus Family Study, the names of possible participants are obtained from clinics and diabetes nurses. The Tasmanian Insulin-Treated Diabetes Registry also provides the names of subjects for the Centre. The Registry is a collaborative project run by the Menzies Centre and the International Diabetes Institute in Melbourne, and aims to study the cause, prevention and treatment of diabetes. Registration is voluntary and members are informed that the information they provide to the registry will be used in research.

Participation in research as an identifiable subject, as undertaken by the Menzies Centre in the case study above, is voluntary. This reflects the currently accepted view in Australia that the decision to participate in research should be informed and voluntary. In addition, individuals also have an interest in the privacy of the information they supply for population research, for as discussed above, the individual may not wish others to know certain facts about them.

However, an individual's interest in privacy is somewhat more complicated in relation to research that involves making linkages between family members and their genetic status. The linkages made in population research of this kind generate new information. For example, depending on the genetics of a condition, by examining a family tree a researcher might be able to deduce that other members of the family will suffer the condition, although they themselves may not be aware of this.

In providing a family history to the Centre, an individual may reveal information about his or her family in general and about specific family members. The privacy interests of each of these family members needs to be balanced against the other interests involved in research—the participant's interest in research outcomes that may be relevant to his or her health; the community's interest in the benefits that may arise from the research and the Centre's interest in having access to samples and information to conduct research. In addition, as the study may generate information about a participant's condition, or that of a family member described to the researchers, each of these individuals may have an interest in knowing their genetic status. By contrast, some may wish not to be informed as they prefer not to know about their condition. Finally, this case study highlights a more general community interest in being involved in research and benefiting from discoveries made through the research.

COMMUNITY INVOLVEMENT IN MEDICAL RESEARCH

When members of the community donate tissue to develop cures and advance science, the general community is linked to scientific community in the pursuit of the same worthy goal. The community is involved in the process of scientific discovery, and the scientific sphere of endeavour is less alienated from the wider population. This maintains the altruistic relationship between individuals and researchers, and between community members.

Studies such as those conducted at the Menzies Centre are an example of this. In a small community such as Tasmania, the studies are visible and the community is aware that they are being carried out. Often families are involved in studies together where the

disease studied has familial linkages. By being involved the community is more aware of scientific developments, and potentially general distrust of science is reduced. Where the scientific and medical research is visible, the value of promoting and funding such research is more apparent, hence greater public support for research may be inspired.

6. TISSUE AS FORENSIC MATERIAL

It's a two-edged sword. If you are guilty of a crime, DNA is probably your worst enemy. On the other hand, if you're innocent, it's your greatest friend.

*Dr Paul Ferrara, Director, Virginia Division of Genetic Science*⁹⁵

The unique genetic material in every cell of a person's body makes all tissue samples potentially identifiable. This aspect of tissue has made it a tool for forensic investigations, mainly for the purpose of identifying victims, suspects and corpses. By examining the DNA in cells left behind at a crime scene and comparing them with samples taken from known sources, forensic scientists can search for matches to determine to whom the unidentified sample may belong. Samples can be compared to those of suspects to place them at the scene of a crime, or to support a connection with an offence.

The development of DNA databases, storing large quantities of identified DNA profiles (a series of numbers generated from examining portions of DNA from a sample) has enabled police to match samples found at crime scenes with stored profiles from convicted offenders. This allows the police to make what are known as 'cold hits', when a profile taken from a sample found at a crime scene matches a profile held in a database.⁹⁶

Forensic use of human tissue has possibilities far beyond that of mere fingerprinting or eye witness statements. It is a source of information about the person from whom they were taken and might be able to be tested to determine, for example, the colour of their eyes or whether they carry a genetic mutation that causes a disease. This information could be used to better track suspects. However, while DNA samples taken for forensic

⁹⁵ PBS Broadcasting, 'Strands of Justice: Do DNA Databanks Infringe on Defendants' Rights?' *NewsHour Online Forum*, 17 July 1998, <www.pbs.org/newshour/forum/july98/dna_databanks.html> at 16 February 1999.

⁹⁶ In Australia, a national database of DNA profiles is operated by CrimTrac under the *Crimes Amendment (Forensic Procedures) Act 2001* (Cth), while the states and territories operate their own databases, sharing information and allowing matching with one another.

purposes are not tested for genetic susceptibilities, this genetic material could be used to reveal far more about a person than the patterns made by the whorls on their fingers. And once obtained, these possible uses may present problems, from using samples for research into possible genetic bases for criminal behaviour, to planting genetic material at the scene of the crime, to discrimination if they are transferred to other parties like employers or prisons.

CASE STUDY 10: FORENSIC DNA TESTING⁹⁷

Developments in genetic science have had a vast impact on the science of forensics, with investigators now able to take samples from suspects and use DNA testing to match them to samples of skin, hair, blood and other tissues found at crime scenes. With these developments has come the advent of the DNA database, where profiles previously obtained are retained to identify possible criminals and the bodies of the deceased.

In Australia, DNA forensic testing is governed at the Federal level by the *Crimes Act 1914* (Cth) and in the States and territories by the relevant criminal code or act. These acts provide for the collection, use, storage and destruction of forensic material. Recent amendments to the Commonwealth Act have not only expanded provisions relating to sample collection, but have provided for the establishment of a national DNA Database known as the National Criminal Investigation DNA Database (NCIDD), which is administered by an executive agency, CrimTrac. These changes were effected by the *Crimes Amendment (Forensic Procedures) Act 2001* (Cth) which came into force on 20 June 2001.⁹⁸

The database will eventually hold DNA profiles, generated from tissue samples, and it has been estimated that these holdings will amount to nearly 25,000 profiles by June 2002.⁹⁹ Samples will be obtained from volunteers, crime scenes, unidentified corpses, missing persons, suspects and serious offenders. Samples may be obtained using 'reasonable force' but must be acquired without cruelty or degradation of the individual.¹⁰⁰ CrimTrac will not hold the actual tissue sample taken, this will remain with the laboratory where it was analysed. CrimTrac will possess only a DNA profile and various coded identifying material.

Profiles are stored in a number of indices based on the source of the sample. Those taken from volunteers will be held on a volunteer index divided into two sections: limited and unlimited purposes. The former will contain samples that may only be used in the investigation for which they were provided.

⁹⁷ This case study is drawn from Australian Law Reform Commission and Australian Health Ethics Committee, *Protection of Human Genetic Information*, IP 26, ALRC, Sydney, 2001, ch 13.

⁹⁸ Ibid, [13.1]–[13.11].

⁹⁹ Senator the Hon Christopher Ellison (Minister for Justice and Customs), 'CrimTrac's New Crime Fighting Systems Switched On' (Media Release, 2001) cited in Ibid, [13.10].

¹⁰⁰ *Crimes Act 1914* (Cth) ss 23 XJ(1), 23XK. See generally Ibid, [13.23]–[13.24].

No samples or profiles will be destroyed as physical destruction is not required by the Act.¹⁰¹ Rather, samples will be de-identified. When and if this will happen is dependant on the individual from whom it was taken, with volunteers having the option of choosing a date on which their sample and profile is de-identified.¹⁰² It has been noted by the Australian Law Reform Commission, however, that the Act does not provide for clear procedures to govern such agreements.¹⁰³ Samples taken from suspects will be de-identified within twelve months or as soon as possible following their acquittal.¹⁰⁴ Material taken from convicted offenders is not destroyed unless the conviction is later overturned,¹⁰⁵ while material from crime scenes and from the deceased or missing is retained indefinitely.

This case study demonstrates three sometimes conflicting interests: community interest in safety and crime prevention; police interest in being able to conduct investigations effectively and individual interests in privacy and control of their body parts. Clearly, the prevention of crime is socially important to ensure community safety and to protect social institutions.

CRIME PREVENTION

The prevention of crime promotes both personal security and order in society. It is crucial to ensuring that the social institutions of law and government are upheld, and also provides individuals with the psychological benefit of knowing they are safe. By catching and punishing criminals, it is hoped that crime is also deterred. To do so, the police force must be able to identify suspected criminals, the bodies of victims and trace human tissue evidence found at crime scenes. The police, therefore, have an interest in technologies that enable them to do so, and the developing science of DNA identification is becoming one of the most important tools police have to find the perpetrators of crime.

However, there are also drawbacks to invading the privacy of individuals. As discussed previously, privacy is valuable to many people for its own sake, but living in a surveillance society may also have detrimental social effects such as eroding the trust relationship between police and the general community and a devaluation of the principle of 'innocence until proven guilty'. In the United Kingdom, plans to expand the

¹⁰¹ *Crimes Act 1914* (Cth) ss 3ZK, 23WA(5). The act provides that 'destruction' of a sample merely requires destroying 'any means of identifying the forensic material or information with the person from whom it was taken or to whom it relates'.

¹⁰² *Crimes Act 1914* (Cth) s 23YQ(1).

¹⁰³ Australian Law Reform Commission and Australian Health Ethics Committee, *Protection of Human Genetic Information*, [13.3].

¹⁰⁴ *Crimes Act 1914* (Cth) ss 23YD(2), (3)(b). This period may be affected by the lodging of an appeal or the decision of a magistrate after an application has been made by the Director of Public Prosecutions or a police constable. See s 23YD(5).

¹⁰⁵ *Crimes Act 1914* (Cth) s 23YDAA.

national DNA database were criticised as an invasion of privacy,¹⁰⁶ and as having the potential to decrease public trust of police and hence reduce community cooperation with law enforcement.¹⁰⁷

Another concern raised by the use of tissue for forensic purposes is the possibility of 'function creep', that is, the gradual expansion of the uses to which samples and profiles are put once they have been obtained. This might include performing research into links between genetics and crime by linking criminal records with stored profiles or by examining crime scene samples. Were genetic causes of criminal behaviour found, use in forensics and criminal proceedings might also extend to testing samples taken from alleged offenders to be used as part of the individual's trial, such as to demonstrate a tendency to violence. Such function creep is a method of increasing surveillance of a community and expanding the power of law enforcement agencies. As Dorothy Nelkin and Lori Andrews have rightly pointed out, '[m]ore than just a source of identification, DNA databanks are also subject to abuse for political or economic ends'.¹⁰⁸

The United Kingdom Human Genetics Commission noted its concern about the storage of tissue samples for forensic purposes that might in the future be used for reasons other than those for which they were collected. In its 2002 report, *Inside Information*, the Commission pointed out that under current British law, volunteers providing samples are asked to sign a non-revokable consent form that allows the indefinite storage of samples. The Commission noted that such retention runs counter to accepted practice in both medicine and research.¹⁰⁹ The use of human tissue in this context to generate genetic profiles is already a topic of debate, and future developments in genetic science could see forensic samples used in many potentially problematic ways.¹¹⁰

¹⁰⁶ BBC News, 'DNA Database Warning' *BBC News Online*, 1 September 2000, <news.bbc.co.uk/2/hi/uk_news/politics/906849.stm> at 25 April 2003.

¹⁰⁷ BBC News, 'Rights Fears over DNA Plan' *BBC News Online*, 30 July 1999, <news.bbc.co.uk/2/hi/uk_news/408097.stm> at 25 April 2003.

¹⁰⁸ D Nelkin and L Andrews, 'DNA Identification and Surveillance Creep' (1999) 21(5) *Sociology of Health and Illness* 689, 689.

¹⁰⁹ Human Genetics Commission, *Inside Information: Balancing Interests in the Use of Personal Genetic Data*, London, 2002, 148, 150–152.

¹¹⁰ See generally on the privacy and other concerns raised by forensic use and banking of DNA A de Gorgey, 'The Advent of DNA Databanks: Implications for Information Privacy' (1990) 16(3) *American Journal of Law and Medicine* 381; J E McEwen, 'DNA Databanks' in Rothstein, (ed.) *Genetic Secrets*, 231.

7. BEYOND MEDICAL AND FORENSIC USE

New scientific techniques, which have rapidly become less costly and more accessible to the community, have broadened the use of tissue beyond the medical and forensic spheres. For example, sections of tissue can now be used to accurately check a child's parentage. In the United Kingdom, biotechnology company Sciona Ltd offers genetic testing of samples to provide personalised advice about diet, alcohol intake and drug reactions.¹¹¹ Other firms market sample storage kits for parents to take tissue samples from their children. These samples are retained in case a child goes missing to provide samples for forensic matching.¹¹² Immigration departments also use DNA samples to check the identity of, and relationships between, potential immigrants.¹¹³ In Tasmania, it was suggested that DNA testing might be used to substantiate asserted Aboriginality during debate over the proposed Aboriginal and Torres Strait Islander electoral role, where only people of Aboriginal descent were given voting rights.¹¹⁴ These non-medical uses of tissue have brought the use of samples out of the hospital and into the hands of the community, and as a consequence produced new interactions of interests—between family members, individuals and commercial organisations. One of these, the use of tissue for parentage testing and the tensions this creates between family members, is outlined in the following case study.

¹¹¹ Sciona Ltd, 'Product Range', <www.sciona.com/coresite/products.htm> at 23 April 2003. Once testing is completed, samples are destroyed.

¹¹² See, eg, Just About Me, 'Child ID and Fingerprint Kits', <www.justaboutme.com/WebPages/homepage_fil_jam.htm> at 23 April 2003. In the United States, the Virginia government currently supplies free storage kits as part of its Kidsafe Initiative, through the Virginia Automobile Dealers Association. See Governor's Office for Substance Abuse Prevention (Virginia), 'Kidsafe Virginia', <www.gosap.state.va.us/kidsafeva.htm> at 23 April 2003.

¹¹³ For a good coverage of the uses of tissue samples in immigration and the issues this raises see Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours*, ch 37.

¹¹⁴ A Darby, 'Blood Lines Called into Question' *Sydney Morning Herald*, 26 August 2002 <www.smh.com.au/articles/2002/08/25/1030053009287.html> at 25 October 2004; R Flanagan, 'Tension in Tasmania over who is an Aborigine' *Sydney Morning Herald*, 17 October 2002 <smh.com.au/articles/2002/10/16/1034561211169.html> at 25 October 2004.

CASE STUDY 11: *ROCHE V DOUGLAS*

In 2000, the Western Australian Supreme Court was called upon to determine the status of stored tissue samples in the case of *Roche v Douglas*.¹¹⁵ The case involved a claim for maintenance from the estate of Edward Rowan by Susan Roche, a woman who asserted that he was her natural father. The defendant Ronald Douglas, administrator of Rowan's estate, disputed the alleged relationship. Roche sought access to a sample of Rowan's tissue for paternity testing to prove the alleged relationship to support her claim. The court then had to decide whether the sample could be acquired for the purpose of testing.¹¹⁶

In this case study, the major interests are those of the individual from whom the tissue was taken, the family members who seek access to it for testing and the laboratory holding the sample. It demonstrates that in many cases, the information contained in a sample may have importance for other people, and also beyond medical and scientific uses. That information is not merely clinical information, it is also social information, as it may reveal the nature of a relationship.

It is arguable whether the law recognises privacy rights of deceased persons, but were the sample to belong to a person who was still alive, that person would have interests in both maintaining the privacy of the information in the sample and controlling access to it. That person might not wish to know the nature of their relationship, yet this 'right not to know' must be balanced against the interest of the person seeking access in gaining information that relates to them as much as to the person whose tissue it is. This begs the question of which factors should determine who may control access to tissue, and whether being the source of the tissue is sufficient right to prevent others accessing the information it contains where it is highly relevant to their own life.

Consider, for example, if instead of seeking access to the sample to test for parentage testing, Roche needed access to identify the particular genetic mutation carried by her family members that causes a life threatening disorder. Testing for many mutations may be possible, but by knowing the exact mutation considerable time and expense might be saved and her condition identified more rapidly. Would such a need outweigh the privacy interest of the sample's source? Or imagine that she knows her family to carry the mutation that causes Huntington's disease. She feels she would not wish to be tested, but could cope with knowing whether she had a fifty percent chance of suffering

¹¹⁵ [2000] WASC 146.

¹¹⁶ The details of this claim, including the complicated background to Roche's relationship with Rowan, are discussed in Chapter 7, section 3.

the disease or no chance at all. She knows that her maternal grandmother carried the mutation, and her forty year old mother has refused to be tested. Would her interest in accessing a sample taken from her mother for testing outweigh that of her mother's interest in privacy and not knowing her own disease risk? Issues of this kind may affect the kinds of control people should be able to have over their own tissue, as those rights will determine who may access tissue, when and for what purposes.

FAMILIAL INTERESTS

In its *Statement on DNA Sampling: Control and Access*, the Human Genome Organisation Ethics Committee described the family as 'the nexus of a variety of relationships (legal, moral, social and biological),'¹¹⁷ pointing out that interests in DNA extend to those who are intimately connected with the individual from whom it was retrieved. Tissue samples, and the information they can yield, can have a huge impact on members of a source individual's family. For one, they may reveal a genetic disorder in the individual which points to other members of the family either being carriers or affected by it. Where used for paternity testing, tissue may show that a father is not the biological parent of a child. Also, results from tissue testing may have emotional effects, where relatives learn that a family member is terminally ill. In some of these cases, family members may wish to have access to tissue samples to discover these facts, in others they may wish not to know. The risk of informing those who do not wish to know, and the desire for access to tissue raise moral and ethical dilemmas, as well as legal ones which must be determined by balancing these wider interests against those of the individual.

This shift in the use of tissue from outside the traditional environments of medicine, scientific research and more recently, forensic investigations, into use by the wider community has brought with it new complexities for regulating how tissue may be used and its legal status. The genetic component of tissue further complicates these issues, for tissue has moved from being solely related to the person from whom it was taken, to containing intimate information about that person's parents, siblings and wider family. The uses of tissue have also become more complex, as tissue is no longer solely used to produce individual benefits—by aiding diagnosis or tracing missing persons—or generalised community benefits—such as scientific advances or aiding in the prevention of crime. Now, tissue can be used to reveal information that affects personal relationships—by showing that a child is not the biological offspring of a father, and hence perhaps demonstrating that a wife has been adulterous. Tissue testing can also be a tool used in tests that are marketed directly at individuals rather than filtered through the controls of medical practitioners. These incursions of commerce into the use of tissue, such as commercial paternity testing, are part of the broader shift that is now

¹¹⁷ Human Genome Organisation Ethics Committee, *Statement on DNA Sampling: Access and Control*.

beginning to occur, that of the market entering into the medical and scientific sphere, as tissue becomes a commodity in the modern marketplace.

Chapter Three

CHANGING TECHNOLOGIES: THE BODY AS COMMODITY

The impact of biotechnology on the way we value the human body is not limited to simply causing us to recalibrate the ways in which we value the body; the advent of biotechnology creates a setting in which to value the body and its components as commodities. The products of biotechnology from genetic therapies, to hormones, to pharmaceuticals are things that we buy, sell, and trade. The body itself, when understood as the mine from which we extract these products, is similarly valuable as a commodity.

*E Richard Gold*¹

This is the new gold of the future.

*Andrew Kimbrell*²

The past twenty years have witnessed emerging perceptions of the body as a 'natural resource'.³ As our ability to isolate medically useful substances has increased, so has the value of tissue from which they are obtained. According to Dorothy Nelkin and Lori Andrews, 'the body in the biotechnology age is speaking to us in new ways'.⁴ There are numerous reasons for this. First is the expansion in uses for bodily materials, particularly in a research context. 'Every part of the body will interest a researcher somewhere,' asserts Russell Scott, 'whether that part be from a living person, a corpse or an aborted foetus, or whether it be a necessary part of the body, as vital as the brain or the heart, or only waste like sweat, urine, or cut hair'.⁵ This chapter examines the growing commercialisation of the body and its parts and the incursion of commerce into medical science. It concludes by outlining some of the ways the body is now used that go beyond research, such as paternity testing and the use of body parts in artistic works. It

¹ E R Gold, *Body Parts: Property Rights and the Ownership of Human Biological Materials*, Georgetown University Press, Washington DC, 1996, 2.

² 'The new great wealth of the world is no longer the soil of the earth, the ores or the past, of the industrial age. But the new value we are seeking is new genetic material, new biodiversity, new genes of microbes, animals and humans. This is the new gold of the future and we are seeing a mass gold rush to try and find those valuable genes that when patented could bring billions of dollars of profit to those corporations'. See A Kimbrell, International Centre for Technology Assessment, Washington DC speaking on CBC Canada Radio, 'Who Own's Life—Part Two', *CBC Radio Canada*, 21 March 2000.

³ Knoppers and Hirtle, *Banking of Human Materials*, 1.

⁴ D Nelkin and L B Andrews, 'The Body, Economic Power and Social Control' (1999) 75 *Chicago-Kent Law Review* 3, 4.

⁵ Scott, *The Body as Property*, 15.

includes case studies on research leading to patenting of tissue-based inventions, the sale of human DNA as souvenirs, Orlan's use of tissue in her artwork and the renowned case of John Moore. It focuses on familial interests in tissue and DNA, the interests of investors in research, the community's interest in access to affordable therapeutics, and the cultural value of artistic expression using human bodily substances.

Financial gain is made from human tissue in a variety of ways, with profits being potentially generated at many stages along the path from tissue removal to product delivery. This can be demonstrated by considering the process of conducting research and developing a treatment. First, tissue is removed from the body. This might be altruistically donated for research purposes and be used by researchers searching for the genetic basis of a condition. But in some instances, mainly in the United States, this tissue might have been obtained from a commercial tissue processing company that acquires tissue donated for research from hospitals, processes it and on-sells it to researchers. Having made a breakthrough in their work, the researchers may develop a patentable invention from the research utilising the tissue. Profit is made from licensing the rights to use or manufacture this invention. The invention might be a test, a treatment or perhaps a drug. If it is a drug, tissue might be used in the testing phase that precedes marketing the drug to the general population, making tissue an integral part of getting the product to market and hence making financial returns for investors. It might be a test or a therapy, in which case it might contain genetic material or other tissues. When such a product is sold, again tissue is commercialised.

From another perspective, human tissue collections and databases have become commodities because linked together, they form a unique research tool. Access to these samples is sometimes restricted, and researches must pay for access. However, the commercialisation of human body parts is most blatant when organs and tissue are sold for transplant. In that case, body parts are sold like any other good in the marketplace. The company StarGene, which sold tiny amounts of DNA from celebrities embedded in jewellery and pens is the ultimate example of such direct commercialisation. Each of these situations will be considered in the course of this chapter.

Changing conceptions of the body have attended these developments, with a movement towards perceiving the body as a resource. As Courtney S Campbell has observed, there is a trend in the scientific literature to deem the body 'merely a natural resource' for 'gene prospectors' to 'map' or 'mine'; to make 'claims' establishing property rights or

patents over; and to use in creating commercial products'.⁶ This he has aptly described as the 'resource paradigm' in the understanding of the body.⁷

1. COLLECTIONS AS COMMODITIES

Developments in the field of genetic science have leant new meaning to collections of human tissue, whether they have been obtained for testing or retained after their use in pathology and diagnosis. Specimen collections dating back many years enable researchers to perform studies into genetic changes,⁸ and to trace hereditary conditions. Other studies for which collections are highly useful include association studies into the correlation between genetic changes and disease with no clear pattern of inheritance; linkage studies that seek to identify gene sequences that are thought to be linked to genetic diseases; epidemiological studies into the interaction between genes and the environment; and pharmacogenetic studies that examine links between drug reactions and genetic makeup.⁹ One example of the use of collections for large scale genetic research is the Icelandic Health Sector Database project overseen by the company deCODE, which is outlined in the following case study.

CASE STUDY 12: ICELAND AND deCODE

The majority of Iceland's population is descended from a small group of settlers who came to the country in the 9th century, and there has been little immigration since that time. As a result, Iceland has a highly homogenous population and has also maintained extensive genealogical and medical records which extend back past the Second World War.¹⁰ Tissue samples have also been taken and stored from a large portion of the population during that period.¹¹ Such characteristics are thought to make Iceland's population useful in the study of genetic conditions, as there is less genetic variation between members of the population, which makes it easier to isolate the genetic causes of some diseases.¹² In 1996 the company deCODE Genetics was formed to utilise these unique aspects of the Icelandic population to conduct research into the causes of genetic disease.

⁶ C S Campbell, 'Research on Human Tissue: Religious Perspectives' in National Bioethics Advisory Commission, *Research Involving Human Biological Materials*, vol II, C-5.

⁷ C S Campbell, 'Religion and the Body in Medical Research' (1998) 8(3) *Kennedy Institute of Ethics Journal* 275, 282.

⁸ National Bioethics Advisory Commission, *Research Involving Human Biological Materials*, vol I, 20-21.

⁹ Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours*, [18.12].

¹⁰ S Boyles, 'Government Approves Plan to Sell Iceland's DNA' Editorial, *World Disease Weekly Plus*, 1 February 1999.

¹¹ R Chadwick, 'The Icelandic Database—Do Modern Times Need Modern Sagas?' (1999) 319 *British Medical Journal* 441, 442.

¹² See generally H Rose, *The Commodification of Bioinformation: The Icelandic Health Sector Database* (2001) Wellcome Trust, London, 12.

On 17 December 1998, the Icelandic parliament passed a bill allowing the Minister of Health and Social Security to grant an exclusive license to deCODE for the compilation of a database from Icelandic health care records taken from hospitals. A Governing Committee was appointed 24 February 1999, in accordance with the bill, to oversee the establishment and operation of the database and on 22 January 2000 a license was granted to deCODE subsidiary Íslensk erfðagreining ehf providing exclusive rights to establish and run the database for the next twelve years. As a result research conducted by deCODE does not have to pass through review by the bioethics and data protection committee that regulate research.¹³

DeCODE collects research material through two main methods. First, through collaboration with medical practitioners, the company collects DNA samples from individuals affected by certain genetic conditions. Secondly, the company is constructing what is known as Icelandic Health Sector Database, a database of health information on the constructed from 'selected, non-personally identifiable information from patient records'¹⁴. Information is collected from a variety of medical records and other collections with presumed consent—individuals may opt out from having their information collected. Tissue samples, however, are collected through medical practitioners with informed consent.¹⁵ All data and samples held are encrypted, but not anonymised. To retrieve personally identified information from the encrypted database is illegal.¹⁶

The company has four major aims for these databases and the material it has gathered: to discover the genetic causes of some diseases and identify drug targets for these conditions; to allow subscription to the DCDP for gene discovery and drug target validation; to collaborate with pharmaceutical companies to perform research into pharmacogenomics; and to form links with pharmaceutical and biotechnology companies to develop therapeutics to treat genetic conditions. As a spin-off of the company's work in encrypting the databases, it will also offer various types of privacy and encryption software for medical and biotechnology company use. Since its inception, the project has produced at least one buyer for the results of deCODE's research with one company having paid \$US200 million for access.¹⁷

Community efforts to aid scientific advances arise from two interests—the altruistic spirit of those who contribute, and their own interest in improved treatments that may result. Both individuals and the community have an interest in such mass efforts to assist scientific progress. As the case study above highlights, in some instances these interests go hand in hand with commercial interest—in the profits to be made from

¹³ B Anderson and E Arnason, 'Iceland's Database is Ethically Questionable' (1999) 318 *British Medical Journal* 1565, 1565.

¹⁴ DeCODE Genetics, 'The Icelandic Health Sector Database', <www.decode.com/database/main.html> at 31 May 2000.

¹⁵ J Kaye and P Martin, 'Safeguards for Research Using Large Scale DNA collections' (2000) 321 *British Medical Journal* 1146.

¹⁶ DeCODE Genetics, 'The Icelandic Health Sector Database'.

¹⁷ R Kunzig, 'Blood of the Vikings' (1998) 19 *Discover* 90, 90–99 as cited in Andrews and Nelkin, *Body Bazaar*, 4. See also W Henderson, 'Government Approves Plan to Sell Iceland's DNA' *World Disease Weekly Plus*, 1 February 1999.

manufacturing and marketing drugs and treatments that result from research—and broader government interest in improving health in the community.

These interests can converge with success where the costs and benefits are evenly distributed, for example with treatments being passed on to the participating community at affordable prices. However, the tension between them can potentially lead to considerable problems. DeCODE is a good example of these problems, as the methods used to encourage widespread participation are unacceptable to some community members. Interests may also conflict if participants in research, like the Icelandic population, learn that researchers are making financial profits from their research using the participants' altruistically donated tissue. Conflict may arise if participants wish to share in these profits. Further, individual and community interests in affordable therapeutics, which they pursue by participating freely in research, may conflict with commercial profit motives that may increase the price of treatments.

The deCODE project also underscores the possible problems that arise from storing large quantities of linked information and samples. The main concerns raised by tissue banking of this kind are the protection of the privacy and confidentiality of the information and samples held. Although the samples and information are coded, the small Icelandic population and the potential for backwards linking of coded material means there is still the potential for re-identification and subsequent misuse—through discriminatory use or disclosure of sensitive or possibly stigmatising information. Ensuring that informed consent for the storage and use of samples has been obtained is also an area for potential problems.¹⁸ Consent, confidentiality and privacy concerns result from the tension between researcher's need for access to detailed information and samples, and individual interests in having their bodies used as they determine and protecting the privacy of their personal information. These concerns are all the more real given the lack of external mechanisms for the ethical scrutiny of deCODE's research.

Finally, this case study introduces the emerging role of the profit motive in research. DeCODE is a commercial venture investing money in the development of this collection in the hope that it will generate profit-making discoveries. While the Icelandic government is also involved in the project, and many of the benefits will flow to the

¹⁸ See generally Chadwick, 'The Icelandic Database', 442–443.

Icelandic people, deCODE's investment is not purely altruistic. As Chapter Two concluded, and as demonstrated by this case study, human tissue, once collected, has considerable value. This is a theme that will be expanded in the following sections by providing more modern examples of how tissue is increasingly gaining a commercial value.

2. TISSUE AND THE GENERATION OF PROFITS

Human tissue has become a money-making object, however to date this has largely been a United States phenomenon. In that country, commercial organisations such as Ardaïs have begun acquiring samples from hospitals, which are processed and sold to researchers.¹⁹ The Australian research culture is significantly different to that of the United States,²⁰ and there are few purely commercial ventures in human biotechnology in this country, most being linked with public bodies like universities.

The Australian research environment is now characterised by what are known as Co-operative Research Centres (CRCs).²¹ The CRC program was launched in May 1990 by the Federal Government and its aim is to bring together 'researchers from universities, CSIRO and other government laboratories, and private industry or public sector agencies, in long-term collaborative arrangements that support research and development and education activities that achieve real outcomes of national economic and social significance'.²² These Centres receive Federal government funding,²³ but commercial ventures within a CRC have first right to commercialisation of research outcomes. Most, if not all research using human tissue is conducted at CRCs rather than

¹⁹ See, for example, Ardaïs, 'Tissue Samples', <www.ardais.com/products_tissues.asp> at 26 July 2003.

²⁰ In the United States, legislative changes in the 1980s generated a sharp increase in the number biotechnology companies as tax incentives were provided to companies investing in academic research and universities were allowed to apply for patents on federally-funded research. Academic researchers entered agreements with commercial ventures as a result. This can be seen in the results of a survey of published papers in biotechnology fields, in which 34% of the authors stood to make a profit from the results of their research. See generally Andrews and Nelkin, 'Homo Economicus', 31ff.

²¹ One example of a CRC is the CRC for Discovery of Genes for Common Human Diseases, which includes Cerylid Biosciences Ltd (the centre agent and commercial partner of the CRC), the Walter and Eliza Hall Institute of Medical Research; the Menzies Centre for Population Health Research, the Murdoch Children's Research Institute, the Queensland Institute of Medical Research and the Institute for Molecular Bioscience at the University of Queensland. Established in 1997, the Gene CRC works to utilise 'several of Australia's strategic genetic resources to identify disease susceptibility genes in a range of areas, including cancer, metabolic disorders, immunological disorders, women's health and public health'. The CRC also acts as 'a platform for a high level of debate in the community regarding human genetics'. See CRC for the Discovery of Genes for Common Human Diseases, 'About the Gene CRC', <www.genecrc.org/site/gc/gc2.htm> at 26 February 2002.

²² Department of Education Science and Training, 'Cooperative Research Centres', <www.crc.gov.au> at 25 February 2002.

²³ The Federal Government contributes around \$145 million per annum to the Centres. See *Ibid.*

by commercial ventures alone, and most genetics research in Australia is conducted at CRCs.²⁴ This has the effect of keeping research linked to public bodies such as universities, an effect that will be considered in greater detail in the context of the property rights debate. As such, most research will also be linked to NHMRC funding which is contingent on adherence to the NHMRC's ethical guidelines. This issue will be considered in more detail in Chapter Five. Research using human tissue conducted by the CRC is undertaken solely by the public research institutes within the centre. No tissue is used by the commercial partner, nor can it gain access to samples.²⁵ CRCs in Australia produce a research culture that is neither entirely public nor private. In many cases, it is most likely that a commercial venture not part of a CRC would approach academic researchers to conduct research for them on areas where they seek to develop products.²⁶

Other examples of commercial utilisation of tissue can also be found in the United States and United Kingdom. Despite laws banning commercial sale of tissue, reports have emerged from the United States that bodies donated to medicine are harvested for material used in cosmetic surgery. While some of the tissue removed is used to mend sports injuries and to treat damaged jaws, more than 20,000 bodies allegedly supplied fat and other tissue to fill out the wrinkles of cosmetic surgery patients. As Arthur Caplan comments, '[p]eople who donate have no idea that their tissue is being processed into products that, per gram or per ounce, are in the price range of diamonds'.²⁷

In England, the United Kingdom government recently admitted that skin and heart valves not required by the NHS are sometimes exported to overseas medical institutions on a 'cost recovery basis', despite the fact that commercial dealing in human tissue is banned by the *Human Organs Transplant Act 1989* (UK).²⁸ Skin samples were also sold to the Defence Evaluation and Research Agency by the Salisbury Health Care Trust between 1995 and 2000. Patients were not informed that their tissue would be used for defence development.²⁹

²⁴ Interview with Andrea Douglas, Business Manager, CRC for the Discover of Genes for Common Human Diseases, (Personal interview, Cerylid Biosciences, Melbourne, 1 September 2000).

²⁵ Ibid.

²⁶ Ibid.

²⁷ G Lean, 'Body Sellers Help You to Gain that Stiff Upper Lip' *The Independent* (London), 7 May 2000, 1.

²⁸ This was admitted by the Junior Health Minister, Lord Hunt of King's Heath. See 'Tissue Exported for Cash' *Birmingham Post*, 8 June 2000, <static.highbeam.com/t/thebirminghampostengland/june082000/tissueexportedforcashnews/index.html> at 1 September 2003. The United Kingdom human tissue legislation is currently under review.

²⁹ While no weapons have been developed at DERA since the 1950s, the skin was used to test how

As noted previously, tissue is not only bought and sold, it is also used in research which itself generates profits, in the form of valuable intellectual property such as patents on tests and treatments. One example is the Australian company Bionomics, which is examined in the following case study.

CASE STUDY 13: BIONOMICS³⁰

Bionomics is an Australian gene discovery company based in Adelaide. Its work focuses particularly on discovery of genes responsible for breast cancer, epilepsy and angiogenesis and the company seeks to commercialise gene discoveries and develop their potential into new treatments. Research into gene discovery is carried out under contractual agreement on behalf of Bionomics at the Women's and Children's Hospital in Adelaide. Tissue samples held by the hospitals and university centres linked to Bionomics are used for research, but only researchers employed by those hospitals and universities perform this research. Hence, this research is still covered by hospital and university ethics requirements. These tissue samples are obtained from autopsies and from material discarded following surgery. All patients will have been required to sign consent forms which inform them that their tissue may be used in research.

As an example, for Bionomics' breast cancer research, tumours are usually obtained from the Flinders Medical Centre, while cell lines created from breast cancer tissue are mostly purchased from overseas tissue banks. In other cases, where only a single sample is required, these may be obtained from the hospital pathology laboratory with consent and ethics approval.

Bionomics owns all intellectual property generated by the research and is free to develop products using the information and knowledge generated by the research. In patenting these results, Bionomics protects these results to allow commercial development and marketing of resulting tests and treatments.

As with all other research on tissue samples, individuals from whom the tissue is taken have a variety of interests in that tissue, including privacy, control and autonomy, and indigenous community interests. However, this case study has been included to highlight the commercial aspect of research that involves human tissue. In this instance, scientists and companies seek access to tissue to undertake research that they hope will result in discoveries and inventions that can be turned into profits—either through selling or licensing the rights to exploit patented technologies, or to make tests and treatments based on those technologies themselves. Such researchers and companies

chemicals which might have been used against the British army are absorbed by the body. See C Dyer, 'Skin Sold for Chemical Warfare Research' (2001) 322 *British Medical Journal* 384, 384.

³⁰ Interview conducted with Professor Grant Sutherland, Director of the Department of Cytogenetics and Molecular Genetics at the Women's and Children's Hospital, Adelaide and Co-chair of Bionomics Scientific Advisory Board (Personal interview, Women's and Children's Hospital, Adelaide, 25 May 2000).

have a clear commercial interest in being able to access and use human tissue samples, which will obviously need to be balanced against the individual interests noted above.

In addition, consideration must be given to the community interest in the provision of new and better treatments. Where these result from research that is partially commercially funded, if the profit motive for conducting such research is removed or too greatly reduced, it may be that companies choose not to invest. It is in the community's interest that the viability of investing in research is maintained.

VIABILITY OF INVESTMENT IN RESEARCH AND PRODUCT MANUFACTURE

Pharmaceutical companies and commercial research organisations rely on access to tissue samples on which to test their products, use in their research and use in the development of treatments and tests. If research is to attract commercial investment it must be economically viable. Restrictive laws on the use of such samples would drive up prices on samples, or make it more difficult for firms to find research subjects. These price increases would in turn be passed on to the consumer, thus affecting the community interest also. Higher costs would form a disincentive to private investment, slowing research and product development, both of which are vital in the effort to treat conditions. For the same reason the patent system is in place, it is necessary for the law to take account of the need to encourage private investment in medical research. The profit motive is great in such a market where demand is relatively inelastic, and thus this interest must be played upon to ensure patients may receive the best treatments we can develop.

Commercial links with research using tissue also raises the issue of benefit sharing, and whether people from whom tissue is taken and developed for financial gain should share in those profits. The issue of benefit sharing is considered in more detail in the following section, which examines the now famous case of John Moore.

CASE STUDY 14: JOHN MOORE'S SPLEEN

The United States case of *Moore v Regents of University of California and Ors*³¹ has generated vast amounts of commentary over the past decade and as the facts are generally well known, only a relatively brief overview of them will be given here.³² John Moore suffered from hairy cell leukaemia and as a result his spleen was removed in 1976 by Dr David Golde. Golde, with his assistant Shirley Quan, used

³¹ *Moore v The Regents of the University of California and others* (1990) 51 Cal 3d 120.

³² For more detailed discussions of the *Moore* case see variously Andrews and Nelkin, *Body Bazaar*, 27–34; D Mortimer, 'Proprietary Rights in Body Parts: The Relevance of Moore's Case in Australia' (1993) 19 *Monash University Law Review* 217, 217–234 and Gold, *Body Parts*.

part of Moore's spleen to continue research that they had been conducting prior to treating Moore. Moore was not made aware of their intentions, although he did sign a routine consent form.

Despite having cured Moore's condition, they continued to have him visit their California laboratory where they took blood, skin, bone marrow and sperm samples between 1976 and 1983. Golde and Quan had discovered Moore's blood contained unusual viral antibodies. Due to their malignant nature, his T-lymphocyte cells over-produced a type of lymphokine. This made his cells highly valuable as they would assist the researchers to identify the genetic material which produced the lymphokines more easily.³³ These lymphokines could be used in the treatment of blood diseases, cancers and immune system deficiencies.³⁴ In 1979, Golde managed to establish a cell-line from Moore's cells. He had already been publishing papers on his research using the cells,³⁵ and subsequently patented the cell-line, known as the Mo-cell line, in 1981. Its value was later estimated more than \$US3billion.³⁶

In 1983 Moore was asked to sign a consent form to allow continuing research into his cells. The form gave Golde rights to use Moore's body products in research, and in signing it Moore purportedly waived any rights he might have in cell-lines or products developed from his body materials in favour of the University of California. The form required Moore to select whether he would or would not consent to this by circling the appropriate response. He chose not to consent and when Golde questioned him on this, Moore became suspicious. His lawyer discovered the patent and evidence of Golde's previous publications and Moore sued Golde, Quan, the University of California Board, the Genetics Institute and Sandoz, a company with whom Golde had a commercial agreement in relation to the products of the cell-line.

The Moore case is rightly famous because it is one of the most blatant examples of profits being generated from exploitation of human tissue. The conflicting interests are many. First and foremost, is Moore's interest in determining what was done with his excised body parts. Moore's own statements about how the incident made him feel are telling about the complex psychological and emotional relationship individuals have with their physical body. Moore commented that he had felt 'raped' by his treatment, and that he had been 'violated for dollars'.³⁷

Moore also had an interest in receiving trustworthy treatment from his physician. In some instances, a treating physician will also be a medical researcher or have links with a

³³ Mortimer, 'Proprietary Rights in Body Parts', 218.

³⁴ Appellant's Operating Brief, 5, *Moore v Regents of the University of California*, App No. B021195 (Cal. Ct. App., Aug 1987) as cited in M T Danforth, 'Cells, Sales, and Royalties: The Patient's Right to a Portion of the Profits' (1988) 6 *Yale Law and Policy Review* 179, note 1.

³⁵ Andrews and Nelkin, *Body Bazaar*, 28.

³⁶ Gold, *Body Parts*, 24.

³⁷ Andrews and Nelkin, *Body Bazaar*, 28.

research group.³⁸ The physician is faced with a potential conflict of interests, because he or she is under a duty to provide the best possible care to the patient, while he or she may also wish to undertake research using samples or information acquired in the course of treatment. This case study is an example of the potential problems that may arise when such a conflict occurs. Dr Golde clearly had ulterior motives in requesting Moore return for further treatment, because he sought access to more samples of Moore's tissue. In effect, Dr Golde allowed his own financial and research interests to override his duty as a physician and to conflict with Moore's interest in having his physician treat him with the best possible care.

TRUST AND THE DOCTOR/PATIENT RELATIONSHIP

It is important that the community has trust in the medical profession, hospitals, the police and the government. For medicine, individuals are more likely to seek treatment and be fully open with medical practitioners if they trust them, which enhances their doctor's capacity to diagnose and treat them. Community trust in the police force means people are more likely to assist police in their investigations and work better in conjunction with police when required. This aids effective policing, consequently helping to reduce crime and to promote social stability and community security.

In the case of tissue use, where that use occurs in a manner that is acceptable to the public then trust in the bodies to whom tissue is transferred is maintained. Reports of misuse, as in the case of tissue retention by hospitals, erode this trust. A recent report, *Public Perceptions of the Collection of Human Biological Samples*, found that people's cynicism about the motives and trustworthiness of doctors has declined, in part in response to the retention of tissue. As one person surveyed commented '[i]t [Alder Hey] has made me a bit more suspicious. You don't necessarily believe what the GP is telling you...I am just a bit sceptical now.'³⁹

If individuals become aware that their samples, or those of others, have been used, even anonymously, without their consent as Moore did, both their trust in the health care system and the desire to participate in research projects could be adversely affected.⁴⁰ They may be wary of seeking treatment if they believe the physician has ulterior motives or is not acting solely in the interests of caring for their health.

As discussed previously, there is obviously a community interest in promoting research, and hence in enabling researchers to access needed tissue samples. As in some cases these will be sought in the context of the doctor/patient relationship, the conflict outlined above will inevitably sometimes occur. In such cases, each of these interests

³⁸ See also Case Study 9: The Menzies Centre for Population Research.

³⁹ Cragg Ross Dawson, *Public Perceptions of the Collection of Human Biological Samples*, Wellcome Trust, London, 2000, 19–20.

⁴⁰ E W Clayton et al., 'Panel Comment', 375.

needs to be carefully balanced, and regulated to prevent unacceptable infringement of the patient's interests and erosion of community trust in the medical profession.

This case study contrasts with the previous study—Case Study 13: Bionomics—because it demonstrates the problems that may develop when commercial interests are allowed to override the interests of patients and a physician's duty of care. It also highlights further the issue raised in relation to organ sales—because human tissue can be used to generate financial gain, then should the person from whom it is taken be allowed to share in that gain. From one perspective, the unique nature of Moore's tissue made it an integral aspect of the research that produced the valuable cell line, without which Golde and Quan could not have developed it nor made their profits. From another, Moore's contribution was very small compared to the years of research and investment poured into developing the cell line. Added to this are the drawbacks of allowing individuals to sell their tissue to researchers or to contract for a share of profits. Doing so may drive up the cost of conducting research, and hence the price of any tests or treatments generated, disadvantaging the community. It may also create a barrier to some research being able to be performed—for example where an individual with unique tissue asks for a very high price or profit share, or where so many samples must be bought that the researcher cannot afford to acquire them. These issues will be considered in more detail in Part V, however what this case study demonstrates most clearly is the multiplicity of complex, intersecting issues that arise when human tissue becomes, as it has, a commodity.

A related situation is examined in the following case study, but in addition to the issues considered above, this example focuses more on issues of control and what happens when tissue is misused.

CASE STUDY 15: CANAVAN DISEASE RESEARCH⁴¹

Canavan disease is a fatal, currently incurable recessive genetic disorder that appears to have higher rate of incidence among the Ashkenazi Jewish community. Carriers of the genetic mutation that causes the disease will not be sufferers, but if they have a child with another carrier there is a 25% chance that their child will have the disease.

⁴¹ Most of the information on which this case study is based is taken from *Greenberg v Miami Children's Hospital Research Institute* (No. OOC 6779) *Proceedings filed in ND III Oct 30, 2000*. The action was filed at the Federal District Court in Chicago on 30 October 2000.

In 1987, genetic carrier testing for the condition was not available. In the United States, David Greenberg—the father of two children suffering from the disease and founder of the Chicago chapter of National Tay-Sachs and Allied Diseases Association (NTSAD)—along with Dor Yeshorim⁴² and later the Canavan Foundation⁴³ approached Reuben Matalon to research Canavan disease. These groups identified and recruited parents of children with the disease to acquire medical histories, pedigrees, and blood, urine and autopsy samples, which were subsequently supplied to Matalon as the materials on which to base his research.⁴⁴

All samples and personal information were provided on the understanding that they would be used for the specific purpose of identifying the genetic mutation responsible for the disease to enable carrier detection among the donor families and the wider population and on the understanding that Matalon's research would remain in the public domain.⁴⁵ Matalon isolated the Canavan disease gene in 1993 and a few years later a screening test was made available by the Canavan Foundation free of charge.

However, unbeknown to the donor families and organisations working with Matalon, he had been recruited by the Miami Children's Hospital Research Institute (MCHRI) which applied for a patent on the disease gene and related applications, including carrier and prenatal testing.⁴⁶ The patent was awarded in October 1997 and the Miami Children's Hospital (MCH) attempted to restrict the number of laboratories providing carrier testing through exclusive licensing agreements and caps on the number of tests that could be provided. Each laboratory was required to pay royalty and licensing fees to the MCH for use of the test.

⁴² A not-for-profit institute providing counselling and information about the disease and carrier status to at-risk populations.

⁴³ Founded in 1992 by parents and friends of children with the disease to support research and education.

⁴⁴ Greenberg even provided samples from his own son Jonathan's brain upon his death in 1992. An Australian couple even flew to the United States as part of the project to provide autopsy samples from two of their sons, both of whom had died of the disease. See J Gillis, 'The Human Blueprint: Patenting Life? Gene Research Spurs Profit Debate' *Washington Post*, 30 December 2000, <www.canavanfoundation.org/news/newswp.html> at 25 October 2004.

⁴⁵ *Greenberg v Miami Children's Hospital Research Institute*, 9.

⁴⁶ Matalon has stated that his employment contract with the MCHRI provided that 'every invention I [made] would be theirs, and that's it. I am not in the inventing business. I am a research person. If they make money on me, I don't care'. See G Kolata, 'Sharing of Profits is Debated as the Value of Tissue Rises; Patients Increasingly Ask, What About Me?: Who Owns Your Genes?' *New York Times*, 15 May 2000, A1.

Greenberg and other parents, Dor Yeshorim, the Canavan Foundation and the NTSAD subsequently brought an action against the MHC, MCHRI and Matalon himself. They assert that they did not consent to the patenting of the gene or restricted access to the results of the research. They also assert that the defendants misused the samples by putting them to purposes other than those for which they were supplied, namely by obtaining exclusive economic benefit from them when they were donated to produce good for the public at large. Recently, the United States District Court for the Southern District of Florida, Miami Division let stand the plaintiff's claim of unjust enrichment.⁴⁷ The case has since been settled.⁴⁸

Many of the interests and issues that are raised in this example are the same as those raised in the previous case study—autonomy and control, conflicting research and commercial agendas, trust relationships and the need to promote research. However, where the conflict in Moore arose from the use of his tissue without fully informed consent, in this example the participants were fully aware of the purpose of donation. This case study highlights potential misuse of tissue and the fact that in some instances, the donor of that tissue may have few avenues open to them to prevent that misuse or claim compensation.

This case study also emphasises the community interest in research, and how this must be balanced against both the interests of participants, researchers and investors to ensure wide access to tests and treatment and the encouragement of research. It demonstrates that in some cases where commercial interests are able to override other interests, individuals and the community may suffer as prices of tests increase or where access to tests is restricted.

ACCESS TO AFFORDABLE THERAPEUTICS

Individuals have an interest in having access to therapeutics and tests to meet their health needs. High prices and other restrictions on access (such as limited licences for testing) may conflict with this interest. Improved population health also potentially decreases health costs for the state, particularly in the case of diseases that would previously have required long and expensive treatment. Therefore, the community generally has an interest in access to affordable treatments.

⁴⁷ Gorner, P, 'Court Allows Suit on Use of Dead Kids' DNA for Patent' *Chicago Tribune*, 8 June 2003, <www.dmdoptions.com/research_1244.html> at 25 October 2004.

⁴⁸ Canavan Foundation, 'Joint Press Release' (Press release, <www.canavanfoundation.org/news/09-03_miami.php>, 29 September 2003).

2.1 Therapeutic and Manufacturing Uses

Tissue has become the raw material from which therapeutic products can be manufactured, such as diagnostic testing kits. Some products used in human treatment are in fact bodily compounds: hormones, insulin, immunological agents. For example, the urine of menopausal women is used as a source of human chorion gonadotrophin that may have a role in the treatment of AIDS-related Kaposi's Sarcoma.⁴⁹ Advances in genetic technology have enabled scientists to place human DNA in bacteria which is then able to produce proteins for which that DNA codes. In this way, large supplies of human substances such as insulin can be manufactured,⁵⁰ while therapeutic substances can be manufactured from umbilical cord blood to treat blood cancers and research into stem cells may enable the treatment of Parkinson's disease. Factor VIII, used in the treatment of haemophilia, is derived from fractioning human blood plasma.

Most human cells will eventually die after being removed from the body, however hybridoma technology is now used to create sources of cells that will can grow and survive long-term in culture known as 'cell lines'.⁵¹ Using these cell lines, scientists are able to study the cells for extended periods of time. The cells produced are significantly different from the original cells, most having extra chromosomes within their nuclei.⁵² Once established, cell lines can be used to test drugs, create cells for transplantation in therapy, supply genetic material and proteins and to produce useful substances. Due to their altered genetic make-up these substances can sometimes be produced in much greater quantities. This enables scientists to use cell lines to 'manufacture' naturally occurring substances, for example lymphokines, in far larger amounts than through other processes.⁵³ Lymphokines cannot be produced in quantities sufficient for study through other processes and hybridoma technology provides a means to produce usable quantities.⁵⁴

⁴⁹ H Zwart, 'Biomedical Research with Human Body "Parts"', 52.

⁵⁰ *Hearing before the Subcommittee on Investigations and Oversight of the Committee on Science and Technology, House of Representatives*, 99th Congress, 1st Session, October 29 1985, US Government Printing Office, Washington, 1986, 30.

⁵¹ Congress of the United States, Office of Technology Assessment, *New Developments in Biotechnology: Ownership of Human Tissues and Cells*—Special Report—OTA-BA-337, US Government Printing Office, Washington DC, 1987, 3, note 1 as quoted in C Erin, 'Who Owns Mo? Using Historical Entitlement Theory to Decide the Ownership of Human Derived Cell Lines' in A Dyson and J Harris, *Ethics and Biotechnology*, Routledge, London and New York, 1994, 157.

⁵² See, eg, J Lavoie, 'Ownership of Human Tissue: Life after *Moore v Regents of the University of California*' (1989) 75 *Virginia Law Review* 1365, 1367–8.

⁵³ *Ibid*, 1368.

⁵⁴ H Horsley, 'Reconsidering Inalienability for Commercially Valuable Biological Materials' (1992) 29 *Harvard Journal on Legislation* 223, 225, note 7.

In each example, human tissue has value as one of the raw materials for producing valuable treatments. It is a resource, like pipettes and reagents, and intellectual property such as a patented invention, which goes into the production of a product that will generally be sold. In some cases, as will be examined in the following section, this tissue will have been bought rather than donated for research or therapy.

3. TISSUE AND ORGAN SALES

The sale of organs is prohibited in Australia and in most other countries, but this has not stopped the development of a black market in organs around the world. Grisly and tragic accounts of organ sales—some voluntary, some not—abound in the media. Reports of organ sales have emerged from Hungary, the Middle East, the Philippines, and most often, India. One report from the *Los Angeles Times* estimated that more than a thousand kidneys are sold in the Middle East and India each year, and asserted that individuals also offer eyes and skin in return for money. According to the report, one of the most infamous areas for organ sale in Madras—Second Street, Villivakkam in India—is informally known as ‘Kidney Street’.⁵⁵ Such sales are not limited to poorer, Third World countries. In 2002, in the United Kingdom, Dr Bhagat Singh Makkar was found guilty of offering to arrange a kidney transplant from a live donor for a fee, and was consequently struck off the British Medical Register.⁵⁶ These instances demonstrate that commercial trading in body parts is not a 19th century phenomenon; it continues in some countries to the present day.

In other instances, discarded tissue or that donated for research with consent, is transferred for monetary compensation. For example, In the United Kingdom, the NHS occasionally exported unwanted skin and heart valve to overseas institutions on a cost recovery basis.⁵⁷ In the United Kingdom it was also discovered that more than 360 tons of placental material was collected and sold by the Merieux company to companies in France, where it was used in drug production.⁵⁸ Russian companies buy testicles that are then used to create cosmetics.⁵⁹

In the United States, partnerships have been formed between a number of hospitals and biotechnology companies to supply tissue for research uses. For example, as part of its

⁵⁵ C Wallace, ‘For Sale: Body Parts of the Poor’ *Los Angeles Times*, 27 August 1992, A11, A11.

⁵⁶ C Dyer, ‘GP Struck Off after Offering to “Fix” Kidney Sale’ (2002) 325 *British Medical Journal* 510, 510.

⁵⁷ ‘Tissue Exported for Cash’ *Birmingham Post*.

⁵⁸ S Lonsdale, ‘A Placenta’s Life After Death’ *The Independent* (London), 3 April 1994, 54

⁵⁹ Annas, ‘Waste and Longing’, 1521.

National Clinical Genomics Initiative, the Ardaïs company has agreements for the supply of tissue with numerous hospitals, including Harvard University's Beth Israel Deaconess Medical Centre and Duke University Medical Centre. Patients are asked to consent to the transfer of their tissue to the company, and to its subsequent use in research. Tissue is linked to clinical information about the patient, and these are coded to ensure confidentiality. The company has developed a catalogue of tissue that it will make available to researchers for a fee.⁶⁰ Australia has yet to follow suit, and still maintains non-commercial tissue repositories only.

The major concerns raised by such commercial tissue storage and supply are the privacy of individuals, for although material is coded, it is not completely de-identified. Stored information and samples could still be linked back to the person who supplied them, revealing potentially sensitive health data and other information. As with the other examples given in this section, concern about treating human body parts as commodities has also been voiced.⁶¹

While in some cases, organs and tissue may be sold by choice, in others, tissue is sold without the consent of the person from whom it is taken or the next of kin. Discarded skin removed during plastic surgery has been sold by the NHS Salisbury Health Care Trust to the British Defence Evaluation and Research Agency for use in chemical warfare research. This trade occurred without patient consent or knowledge.⁶² In Hungary, allegations were made that the Semmelweis Hospital in Miskolc, among others, systematically removed tissue from bodies and sold it to hospitals in Europe and the United States for research and medical uses.⁶³ Allegations have been levelled at the Chinese government for similar actions, including assertions that organs are regularly removed from prisoners and in some cases sold. Dr Wang Guoqi told a hearing of the United States subcommittee on International Relations and Human Rights that during his work for the Paramilitary Police Tianjin General Brigade Hospital, he had been required to 'remove skin and corneas from the corpses of over 100 executed prisoners' which was supplied to wealthy patients.⁶⁴ In some cases, however, commercial interests

⁶⁰ See Ardaïs, 'National Initiative: Overview', <www.ardais.com/national_initiative/index.html> at 25 April 2003.

⁶¹ See, eg, D Josefson, 'US Hospitals to Ask Patients for Right to Sell their Tissue' (2000) 321 *British Medical Journal* 653, 653.

⁶² C Dyer, 'Skin Sold for Chemical Warfare Research' (2001) 322 *British Medical Journal* 384, 384. This trade has since ceased and been condemned by the United Kingdom Department of Health.

⁶³ C Kovac, 'Tissue Trade in Hungary is Investigated' (1998) 316 *British Medical Journal* 645, 645.

⁶⁴ F Charatan, 'Doctor Testifies to China's Reuse of Prisoners Organs' (2001) 323 *British Medical Journal*

and individual interests can operate together successfully, as demonstrated in the following case study.

CASE STUDY 16: TED SLAVIN AND DIAGNOSING HEPATITIS

Ted Slavin's contribution to medical research is a relatively unique blend of canny business sense and altruism. Slavin was a haemophiliac who contracted hepatitis B during the course of his treatment after he received a blood transfusion contaminated with the virus. Later, it became apparent that his blood had an unusual characteristic – it contained high levels of antibodies against hepatitis. As such, it could form the basis for a diagnostic test for the virus.

Slavin proceeded to sell his blood to a company that used it to produce such tests, and put the proceeds towards the cost of his medical treatment. But, having discovered that his body produced a unique and sought after resource, Slavin chose not to exploit this fact solely for profit. Instead, he also donated blood to scientist Baruch Blumberg who, with his collaborators, developed a vaccine for hepatitis B from it.⁶⁵

The case of Ted Slavin is included here as an example of a successful commercial relationship between an individual and a commercial entity in which tissue is exchanged for compensation. One of the questions often raised in debates about the use of the human body is that allowing people to sell their tissue will spell the end of altruism. It is then argued that altruism is a valuable part of medical research and a community good. It unites the efforts of scientists with those of the wider population in pursuit of a single goal— improved health and hence the saving of lives. The Ted Slavin example reinforces that while the body has become a resource and a commodity, commercialism and altruism are not always mutually exclusive.

Further, Slavin was demonstrably capable of making informed and considered decisions about how he wished his body parts to be used, while the research and commercial interests in developing tests and a vaccine were both upheld through organised agreements about the cost of the blood and how it might be used. One of the major tensions in this instance is between the level of individual autonomy acceptable to society—how far we allow people to do as they wish with their own bodies, even if this includes hurting themselves—and the view that the law should protect people from harming themselves.

69, 69.

⁶⁵ Andrews and Nelkin, *Body Bazaar*, 24.

On the one hand, if we are to support individual autonomy and the right to choose what we do with our own bodies, we might believe that people should be allowed to sell parts of themselves if they choose to take on this risk to their health. We allow people to take on dangerous employment for increased salaries, such as working in mines and as stunt performers. We also generally accept that people should be able to make decisions about their own healthcare, even if these decisions are irrational or may not be in the best interests of their own health, such as requiring doctors to respect a Jehovah's Witness's decision to refuse a blood transfusion. There is little difference between these positions and allowing a person to make a considered decision to sell an organ they can do without to acquire money, where they consider the risk to their health less important than the gains to be made from the money—being able to pay debts; funding a child's education; or paying for other medical treatments that they would otherwise have had to forego. Further, as Julian Savulescu has argued, why should we be allowed to risk our own health for pleasure, such as smoking or skiing, yet not for money to acquire other things we desire?⁶⁶ If the individual chooses to make an agreement to accept money during life for the transfer of organs after his or her death, there seems to be even less problem as there is no risk to life or health.

There are a number of countervailing considerations. First, concerns are often raised that the sale of organs from living people can never be done with freely given consent, that the decision cannot be fully rational or free from coercion. A second is that if individuals may sell organs, then these will be transferred only to those able to pay, creating a division between rich and poor and basing the distribution of life-saving organs on ability to pay rather than medical need. Finally, it is often argued that allowing organ sale will undermine the system of altruistic donation, which as discussed above, is a vital binding force within the community.⁶⁷ However, these considerations must then be weighed against the need to increase organ supply, and whether they outweigh the need to acquire organs to save lives. These issues, and the possibility of an ethically justifiable market in organs such as the monopsony model posited by Charles Erin and John Harris,⁶⁸ will be considered in greater detail in Part V.

Beyond organ sales, a United States company has taken commodification of body tissue to a new level. StarGene, a company marketing portions of preserved celebrity DNA, is

⁶⁶ J Savulescu, 'Is the Sale of Body Parts Wrong?' (2003) 29 *Journal of Medical Ethics* 138.

⁶⁷ See Section 1.3 and Case Study 2: Organ Retention.

⁶⁸ See J Harris, and C Erin, 'An Ethically Defensible Market in Organs' (2002) 325 *British Medical Journal* 114.

examined in the case study below.

CASE STUDY 17: STARGENE

DNA and genetic technology has captured the public imagination and as ever the market system throws up a diversity of products which play on that imagination. In 1997 an American company tapped into this sense of curiosity and fascination by producing jewellery and other articles that contain the DNA of the famous. The company, StarGene, was established by Nobel Prize recipient Kary Mullis and used DNA cloning techniques to amplify and replicate genetic material from celebrities, athletes and those it terms 'heroes.' This replicated DNA is then embedded in clear plastic and fashioned into earrings, phone cards and pens. The phone cards, for example, 'display a wafer-thin, gem-like amulet, containing the subject's unique DNA.'⁶⁹ Other products, known as Genestones, are comprised of an artificial gemstone casing which houses the DNA.

StarGene approached the estates of Marilyn Monroe and Elvis Presley for DNA samples to replicate and market. Both refused, reportedly on the grounds that the idea was 'distasteful' and could lead to numerous assertions of paternity in the case of Presley.⁷⁰ The company has, however, managed to acquire a strand of Abraham Lincoln's hair from which it created the Lincoln Pen. The pen sold for more than \$US1, 600.

Despite this success, StarGene is no longer trading as the majority of living celebrities were less than comfortable with having their DNA preserved and sold.

The criticisms levelled at StarGene provide examples of the issues this case study highlights. One such criticism was that to duplicate and sell the DNA of another person, particularly one who is dead and cannot give or withhold consent, is an invasion of privacy, as it might be possible for the DNA segment in the product could be tested and used to discover information about the celebrity or hero from whom it was taken.⁷¹

Another possible criticism of commercial dealings with human tissue is that it commodifies human beings. In the example above, DNA, to some the 'essence' of humanity, is taken and actively processed into a form which makes it marketable for no other reason than that people wish to have a piece of another person's physical form. As Mullis himself remarked, the company's hope is that 'teenagers might pay a little money to get a piece of jewellery containing the actual piece of amplified DNA of

⁶⁹ StarGene, *StarGenes: Genetic Essence Collector Phone Cards*, <www.timeforamerica.com/stargenes> at February 2002. DNA is replicated using the polymerase chain reaction (PCR) process developed by Mullis.

⁷⁰ M Honigsbaum, 'The Price of Life' *Guardian Newspaper* (London), 21 October 1997. The type of DNA used in the products was useless for determining paternity or for cloning, according to Joanne Gaffra, a former StarGene executive.

⁷¹ This criticism was also made by the estate of Marilyn Monroe. See Ibid.

somebody like a rock star'.⁷²

In another, more gruesome example, a trade in preserved fetuses was recently uncovered in the United Kingdom. Collectors buy and sell the aborted and stillborn fetuses as 'curios', particularly prizing those with deformities. One seller, Alexis Turner, a dealer in antique natural history from Surrey, informed the press that a medical institution had offered him 'a crate from some kind It contains all sorts of stuff: pickled fetuses, deformities ...'.⁷³ While the practice has been condemned, new human tissue legislation introduced in the United Kingdom will not make the practice illegal as long as specimens are more than one hundred years old, which are exempt from the consent provisions of the new Act.⁷⁴ In some ways, commodification of the body has evolved very little since the days of William Burke.

There are also a range of arguments that suggest commodification of human beings and commercial trade in body parts have deleterious effects on individuals and the community. Individual interests in protecting the privacy of information about them and to do as they will with their own bodies should be balanced with concerns about protecting people from themselves and the problematic effects of commercialising body parts. These effects will be considered in Part V, however what can be said is that this case study, and the other examples given in this section, demonstrate that commercialisation of human tissue is a live issue.

⁷² 'Kary Mullis' (1992) April *Omni Magazine* 60 as quoted in Andrews and Nelkin, 'Homo Economicus', 30.

⁷³ 'Fetuses as Curios', *Sydney Morning Herald*, 3 August 2004, <smh.com.au/articles/2004/08/02/109143210751.html> at 3 August 2004.

⁷⁴ The legality in Australia of this kind of trade is discussed in Parts II and III.

4. FULL CIRCLE: TISSUE AS A MEDIUM OF EXPRESSION

...my art supply shop, the yellow pages...

*Jenny Holtzer, on being asked where she acquired bones used in her artistic work*⁷⁵

Lori Andrews and Dorothy Nelkin have noted that artists use tissue to explore 'ways to define the fragile boundaries of the self'.⁷⁶ Artist Jenny Holtzer employed real human remains in her work *Lustmord*—femurs, ribs, teeth—which observers were encouraged to pick up and feel. Holtzer deliberately placed labels with text too small to read on each bone on display as an incentive to hold them closely to read what is there and to feel the texture of what makes up their own bodies. Others have used foetal remains to create earrings which were subsequently displayed in a London gallery. The owner of the gallery was later convicted of outraging public decency,⁷⁷ while the Hayward Gallery was criticised for displaying preserved foetuses and scalped heads.⁷⁸ Mark Quinn, the creator of *Self*, a model of his head made from nine litres of his own congealed blood, also uses his own faeces as paint. His work has been received with shock and revulsion.

Having constructed the body as a sacred space, then object of study, something to be collected, something to be tested to acquire information about ourselves, and lastly, as a source of material to be sold, now uses of the body have in a sense come full circle. Where initially the body was a medium of spiritual expression, now artists have taken the physical parts of the body itself to express reactions to use of human tissues and treatment of bodies as people. As Mark Quinn has asked in relation to his own work, 'Do we only know what the natural is because we've found it through science?'⁷⁹

Others have sought to blend the artistic with the educational, of whom the most publicised is probably Professor Gunther von Hagens. In 2002, Von Hagens carried out the first public autopsy in Britain since the 19th century. Described as a 'scientist-cum-showman', von Hagens avowed that he wished to dispel the mysteries of the internal body, and thereby encourage organ donation and consent to autopsy.⁸⁰ Von Hagens also

⁷⁵ Quotation from Artist's Week, Adelaide Festival, 9–13 March 1998, reported by Teri Hosken. See T Hosken, '12.3.98 Grief Becomes You' *Electronic Writing Research Ensemble*, <www.ensemble.va.com.au/column/ti/text/lustmord.html> at 26 July 2003.

⁷⁶ Andrews and Nelkin, 'Homo Economicus', 137.

⁷⁷ Jones, *Speaking for the Dead*, 24.

⁷⁸ D Alberge, 'Art Gallery to Display Human Body Parts' *The Times* (London), 15 September 2000.

⁷⁹ *Incarnate* Exhibition Catalogue as cited in Andrews and Nelkin, *Body Bazaar*, 137.

⁸⁰ P Fray, 'Slab Show Alley' *Sydney Morning Herald*, 22 November 2002, 14.

perfected the art of plastination—a process of impregnating body parts with a reactive polymer that preserves them in almost lifelike form—and created a travelling roadshow of anatomical specimens open for public viewing.⁸¹ In these exhibitions, von Hagens combines art and science to both comment on our reactions to the body and to educate. For some, the exhibitions have been fascinating; for others they fly in the face of human dignity and the special respect to be given the bodies of the dead.⁸² The following case study examines one example of an artist using tissue in her work to express and to educate.

CASE STUDY 18: ORLAN AND MANIPULATION OF THE FLESH

Orlan, famed for her work in undergoing plastic surgery as a form of conceptual performance art sells pieces of her own tissue. Following her cosmetic operations, Orlan retains portions of the excised skin. From these, she creates what she terms 'reliquaries', skin and gauze containing images of her face.

Her work explores what can be done with, and to, the body through science and medicine, examining the boundaries of both.⁸³ The reliquaries and the operations serve to point both to the place science makes for the body and the nature of that body as part of the self, while questioning medical manipulation. 'My work and its ideas,' she has said, 'incarnated in my flesh, interrogate the status of the body in our society and its evolution in future generations via new technologies and upcoming genetic manipulation.'⁸⁴

In speaking of her exploration of the body, Orlan has said that her art 'puts the naked body in the spaces opened up through scientific discovery.' Her work challenges religious denials of the body as a site of pleasure by placing the body instead in the context of science, stripping it back to expose it as mere flesh and blood, not the mysterious receptacle of the religious view of soul. Orlan recalls the body back into the conception of self, praising it for itself and its place as part of the self:

*I can observe my own body cut open, without suffering! ... I see myself all the way down to my entrails; a new mirror stage. I can see to the heart of my lover; his splendid design has nothing to do with sickly sentimentalities'—Darling, I love your spleen; I love your liver; I adore your pancreas, and the line of your femur excites me.*⁸⁵

⁸¹ Examples can be seen at the *Body Worlds* website. See G von Hagens, 'Gunther von Hagens' Body Worlds: The Anatomical Exhibition of Real Bodies', <www.bodyworlds.com/en/pages/home.asp> at 25 April 2003.

⁸² See generally Jones, *Speaking for the Dead*, 26.

⁸³ Andrews and Nelkin give an informative account of the use of bodily materials in art in *Body Bazaar*. As they note, some artists employ such materials to comment on the nature of the body, and for Quinn the fact that his head sculpture will melt outside its refrigerated container is in itself a representation of the fragility of the body. See generally Andrews and Nelkin, *Body Bazaar*, 135-139.

⁸⁴ Orlan, interviewed in P Phelan and J Lane, (eds) *The Ends of Performance*, New York University Press, New York, 1998, 319 as quoted in *Ibid*, 136.

⁸⁵ Orlan, 'Carnal Art Manifesto', *Orlan Homepage*, <www.cicv.fr/creation_artistique/online/orlan/manifeste/carnal.html> at 4 April 2002. Orlan has said of her operation-performances: 'At the beginning of all my performance-operations, I read this excerpt

This case study raises fundamental questions about attitudes towards dealing with bodies. Orlan processes and sells her own tissue, but she does so outside the context of medicine and science. Should she be entitled to deal with her own flesh in this way? Does taking the use of tissue entirely out of the medical context alter what we can accept as justifiable uses? Does it make a difference that it is she, rather than someone else who takes and uses her tissue? And if we accept that tissue use to produces benefits to society is acceptable, do we define those benefits broadly enough to encompass wider cultural benefits or are they limited to medical treatment and scientific progress.

This also raises issues of whether what Orlan does constitutes self-harm and whether there a policy grounds for legally prohibiting her use of tissue in this way. The raises issue is one of autonomy—how free should we be to take apart our own bodies? And if we do not condone people self-harming to sell their organs, shouldn't we then not condone Orlan's artistic processes? It is at this juncture that the balance between socially acceptable use of bodies, individual autonomy and the need to protect and preserve the dignity of the body is once more called into question.

CULTURAL VALUE OF ARTISTIC EXPRESSION

Humans produce works of artistic expression to tell the world of how they feel and what they think. Art is a medium which allows the artist to share these thoughts and feelings with others, and it is culturally important to ensure that freedom of expression through art is not censored or curtailed.

For each of us, our bodies are the centre of our own world and they are of complex and fundamental importance to our understanding of that world and ourselves. Bodies and their parts have enormous significance for human experience, and it is not in the least surprising then that artists have focussed on the body in an attempt to comment upon, and respond to, that human experience. Such artists have a need for access to tissue for expression, and a need to be allowed to use the products of their own bodies as they choose. Though offensive to some, the community itself has an interest in this tissue and the promotion of access to it, as unfettered artistic expression enriches our community's cultural and helps us to better comprehend the world in which we find ourselves.

It is not surprising that artists have begun to use parts of the body as a medium of expression in the late 20th century and early 21st centuries. The body and its parts have

from my book, *La Robe*: 'Skin is deceiving ... in life, one only has one's skin ... there is a bad exchange in human relations because one never is what one has ... I have the skin of an angel, but I am a jackal ... the skin of a crocodile, but I am a puppy, the skin of a black person, but I am white, the skin of a woman, but I am a man; I never have the skin of what I am. There is no exception to the rule because I am never what I have'.

moved beyond being the physical embodiment of an individual, through being the material for studying the workings of life, and finally into being a commodity within the marketplace of biotechnology innovation. How we view our bodies has changed, how we treat them has changed, and in many ways those changes say much about how the world itself has developed over the past few thousand years. We must now determine how we will deal with these changes, where we will site the body within the legal system and how we will regulate its use to best balance all the myriad interests that are held in that body.

CONCLUSION

The wide and varied uses the modern world has found for excised human tissue have placed it at the intersection of a multiplicity of interests. In some instances, these interests share concordant objectives. In others, these interests may be at odds. The legal system has developed an approach to some of these uses, and has some mechanisms in place to deal with conflicting interests and problematic situations. Having outlined how tissue is acquired and used, the following Parts will analyse how these uses are currently governed under Australian laws and guidelines and whether the current regime is working effectively. Part II considers legislative controls and ethical guidance, while Part III examines the approach the common law has taken to the use of human tissue. These chapters will demonstrate that the ever-expanding uses to be made of human body parts present a significant challenge to the current law.

Part II

Regulating the Body

Contents

INTRODUCTION	109
 Chapter Four	
LEGISLATIVE REGULATION: THE HUMAN TISSUE ACTS	110
1. Definitions and Scope	114
1.1 'Regenerative' and 'Non-regenerative' Tissue	114
1.2 Exclusion of Sperm, Ova and Foetal Tissue	116
1.3 Exclusion of Tissue Removed during Surgery	117
1.4 Previously Collected Tissue	121
2. Donations from Living Adults	122
2.1 Regenerative Tissue	123
2.2 Non-regenerative Tissue	129
2.3 Blood	130
3. Donations from Deceased Adults	130
3.1 Donations after Death	130
3.2 Post-Mortems	132
3.3 Anatomical Use of Bodies	138
4. Prohibition against Trade in Tissue	139
4.1 Ministerial Approval Exception	139
4.2 Processing Exception	140
5. Confidentiality Provisions	142
5.1 Privacy Protection in Australia	143
6. Overall Effectiveness of the Human Tissue Acts	146
 Chapter Five	
GUIDELINES	149
1. Legal Effect of Guidelines	150
2. National Health and Medical Research Council Guidelines	151
2.1 National Statement on Ethical Conduct in Research Involving Humans	156
2.2 Guidelines for Genetic Registers and Associated Material	168
2.3 Privacy Guidelines	172
3. Laboratory Practice Guidelines	174
4. Human Genetics Society of Australasia Policies	178
4.1 Guidelines for Human DNA Banking	178
4.2 Newborn Screening Policy Statements	180
5. Conclusion	183
 CONCLUSION	 185

INTRODUCTION

Human tissue use in Australia is regulated through a collection of legislative instruments and ethical and practice guidelines. This Part considers both these regulatory mechanisms and also how they may work together to protect and promote the interests of individuals, families, the community and researchers. Chapter Four examines the legislative framework, focusing on the major legislation regulating tissue use, the Human Tissue Acts. Chapter Five examines the range of ethical and practice guidelines, including those produced by the National Health and Medical Research Council and the National Pathology Accreditation Advisory Council. The framework is outlined and some of its strengths and weaknesses in each area are considered, to demonstrate both how the framework is effective and where there are gaps that require either additional regulation to fill them, or should be reformed. In doing so, it lays the groundwork for later Parts that consider the efficacy of using property law to address these concerns.

Chapter Four

LEGISLATIVE REGULATION: THE HUMAN TISSUE ACTS

Having outlined many of the uses of human tissue, and the issues they raise, this chapter examines the legislative scheme that has been developed to regulate some of these uses. It analyses the scope and effect of the current legislative provisions, and considers how effective that are in regulating the now myriad uses of human tissue.

Chapter Two noted that the growing success of medical transplantations in the 1970s created an unprecedented demand for tissue and organ donations. Such widespread need for donated tissue had barely been conceived of a decade before, and some form of legally sanctioned and regulated supply for transplantation became increasingly necessary. In response, at the instigation of the Federal government, the Australian Law Reform Commission (ALRC) undertook an extensive inquiry into the issues surrounding organ transplantation specifically, and tissue donation and use generally. A brief account of this inquiry and its recommendations gives an indication of both the general ambit of the current legislation, and the thinking on which it was based.

In 1977, the ALRC released a series of recommendations based on its inquiries, and as a result each state and territory enacted legislation to deal with the donation and use of human tissue.³²⁷ The acts, referred to collectively as the 'Human Tissue Acts', followed the same general form and approach as that recommended by the ALRC, and attempted to provide a regulatory framework for organ and tissue donation based on a consent model.³²⁸ They also provide criminal sanctions, including imprisonment, for misuse of tissue and unauthorised disclosure of information under the Acts.³²⁹

³²⁷ Australian Law Reform Commission, *Human Tissue Transplants*, ALRC 7, ALRC, Sydney, 1977, 9.

³²⁸ See *Human Tissue Act 1985* (Tas); *Human Tissue Act 1982* (Vic); *Human Tissue Act 1983* (NSW); *Transplantation and Anatomy Act 1983* (SA); *Transplantation and Anatomy Act 1979* (Qld); *Human Tissue and Transplantation Act 1982* (WA); *Transplantation and Anatomy Act 1978* (ACT) and *Human Tissue Transplant Act 1979* (NT). Human tissue use is a State matter, and as such there is no Commonwealth legislation that specifically regulates its use.

³²⁹ *Human Tissue Act 1985* (Tas) ss 30, 31; *Human Tissue Act 1982* (Vic) ss 44, 45; *Human Tissue Act 1983* (NSW) ss 36, 37; *Transplantation and Anatomy Act 1983* (SA) ss 38, 38a, 39; *Transplantation and Anatomy Act 1979* (Qld) ss 38, 38a, 39; *Human Tissue and Transplantation Act 1982* (WA) ss 33, 34; *Transplantation and Anatomy Act 1978* (ACT) ss 48, 39 and *Human Tissue Transplant Act 1979* (NT) ss 27, 28.

In some states and territories, legislation had been in place to deal with some tissue transplants at the time of the ALRC inquiry. Most of this legislation was directed at tissue transplants from the deceased, and was based on the *Corneal Grafting Act 1952* (UK). For example, New South Wales had previously enacted the *Corneal and Tissue Transplant Act 1955* (NSW) and the *Tissue Grafting and Processing Act 1966* (NSW).³³⁰ Between states and territories, the legislation varied greatly in scope and the stringency of its consent requirements for donation. The ALRC recommended uniformity, but made the further departure of recommending that legislative measures be introduced to allow donation of tissue and organs from living adults. Prior to the enactment of the Human Tissue Acts, there had been no legislation in Australia to regulate live donations—the new acts legalised the practice.³³¹

The ALRC also considered whether there was a need to clarify the status of human tissue, particularly in the light of moves in the United States to commercialise blood donation. It concluded that tissue had no legal status and should continue so, because there were no uses of tissue that required it to have legal status.³³² In addition, the ALRC considered that the commercial aspects of tissue use were minimal, as in Australia tissue donation was regarded as a gift, rather than a transfer for financial gain. For this reason, it was not considered necessary to recommend provisions to regulate commercial dealings with tissue.³³³

The ALRC's recommendations were clearly a turning point in the regulation of human tissue and organs in Australia. Although some specific uses of tissue are subject to other legislation. For the most part the Human Tissue Acts that grew out of the ALRC's recommendations remain the major legislation dealing with tissue use, twenty-five years after they were created. For this reason, both this chapter and this thesis generally will focus on these acts. Although the law may have stayed relatively static, Part I demonstrated that organ and tissue use has done precisely the opposite. This chapter examines whether this ageing legislation can adequately cope with the new challenges this use now presents the legal system.

³³⁰ Further examples include *Tissue Grafting and Processing Act 1955* (Qld), *Transplantation of Human Tissue Act 1974* (Tas), *Medical (Organ Transplants) Act 1968* (WA) and *Tissue Grafting and Processing Act 1936–1966* (WA).

³³¹ Australian Law Reform Commission, *Human Tissue Transplants*, [106].

³³² *Ibid*, [13].

³³³ *Ibid*, [13].

It should be noted, however, that New South Wales has recently conducted a comprehensive inquiry into the operation of the *Human Tissue Act 1983* (NSW) (NSW Human Tissue Act).³³⁴ As a result, the *Human Tissue and Anatomy Legislation Amendment Act 2003* (NSW) was passed, substantially amending the NSW Human Tissue Act. This chapter will comment on these amendments as appropriate. It will be apparent when comparing the legislative provisions, that the New South Wales amendments are based on a more modern conception of the rights of individuals over their excised tissue, as they have reduced the scope for unauthorised tissue removal and use.

Each of the Human Tissue Acts defines tissue and excludes certain bodily materials from its scope. Each act is divided based on distinctions between donations from living and dead donors, adult donors and children, and between tissues termed 'regenerative' and 'non-regenerative'. This chapter will examine the reasoning and efficacy of these distinctions. In the interests of clarity, it will also be structured around these distinctions to follow the general structure of the Acts. This chapter will take the *Human Tissue Act 1985* (Tas) (Tasmanian Human Tissue Act) as the model Act where necessary, as it closely follows the draft provisions produced by the ALRC, and mirrors the Acts in most states and territories. Relevant differences in other Acts will also be noted.

Following a general outline and analysis of each aspect of the Human Tissue Acts, the case studies will be used to further analyse the effectiveness of the legislation in dealing with current use. As donations from the dead include tissue taken during post-mortem, consent and authorisation requirements for such procedures will also be examined. Some states and territories have regulated coronial and anatomical use through legislation other than the Human Tissue Acts, and therefore the various state and territory Coroners Acts and Anatomy Acts will be considered where relevant. Provisions regulating tissue taken from children will not be considered because, as discussed in the main introduction, the issues child donation raises are beyond the scope of this thesis.

The case studies will be used particularly to highlight the types of tissue transfers, use, storage and destruction that are not covered by the major legislation. How effectively the present legislation protects and promotes the varying interests in tissue will also be considered at this point, for the legislation must do more than regulate—it must regulate

³³⁴ See B Walker, *Inquiry into Matters Arising from the Post-mortem and Anatomical Practices of the Institute of Forensic Medicine*, New South Wales Department of Health, Sydney, 2001; New South Wales Health Department, *Review of the Human Tissue Act: Organs and Tissue Donation and Use and Post-Mortem Examinations*, New South Wales Department of Health, Sydney, 1999.

in keeping with the needs of society and the ethical standards that society has set.

It is worth recapping these issues and interests at this point to highlight the areas that the Acts should regulate. The major interests in tissue outlined in Part I were individual interests in control and privacy and related concerns about discrimination; familial interests in access to tissue for testing; community interests in research; the development of new treatments and altruism; indigenous community interests in the fate of removed body parts; and researcher interests in access to tissue for research.

A particular concern these interests raise is the potential conflict between ensuring individuals have adequate control over the use of their tissue to respect their autonomy and privacy and the need to acquire organs and tissue for research to produce treatments, for transplantation and for teaching purposes. Another was how to balance the interests of families in accessing tissue with those of the individual. Part I raised issues around the commercialisation of tissue and an individual's interest in selling their tissue for financial gain, which should be balanced against the community interests in altruism and access to affordable therapeutics. Part I also raised the more esoteric issue of the use of tissue in art, demonstrating that there are ever-widening uses for tissue that may not be contemplated by current legislative schemes. A challenge for the Human Tissue Acts is to balance these various interests effectively.

In the course of this analysis, the chapter will also briefly examine some of the other legislation that may be relevant to human tissue use and donation in Australia, particularly privacy legislation. The chapter will conclude by assessing the successes and failures of the legislative framework, with particular regard to the issues identified in Part I. It will identify areas in which that framework does not adequately address the challenges tissue use now presents, and examine how the framework succeeds or fails in balancing the varied interests in tissue highlighted in Part I.

1. DEFINITIONS AND SCOPE

1.1 'Regenerative' and 'Non-regenerative' Tissue

The Human Tissue Acts define 'tissue' to include 'an organ, or part, of a human body or a substance extracted from, or from part of, the human body'.³³⁵ Tissue is then divided into two main categories for the purposes of the legislation:

- *regenerative tissue*, defined as 'tissue, that after injury or removal, is replaced in the body a living person by natural processes of growth or repair'; and
- *non-regenerative tissue*, defined as 'tissue other than regenerative tissue'.³³⁶

This distinction only applies to donations of tissue by living persons. In its report, the ALRC explained that this distinction should be made to account for the effects of removing different tissue might have on a donor and hence the conditions and restrictions that should be placed on donations. It made the point that the removal of some regenerative tissue, such as bone marrow, could have serious implications for the donor (including pain and the potential complications associated with general anaesthesia). In other instances, such as blood donation, the effects will be minor. The ALRC also suggested that the conditions to be placed on donations of non-regenerative tissue should not be manifestly different from those on regenerative tissue.³³⁷

However, the ALRC did recommend that differing consent requirements and other restrictions apply to the two types of tissue.³³⁸ Regenerative tissue was regarded as suitable for donation for therapeutic, scientific and medical uses as well as transplantation, while non-regenerative tissue could be donated only for transplantation. The ALRC further considered that donations of regenerative tissue could be made upon consent, while non-regenerative tissue donations should occur only after a twenty-four hour cooling off period after consent had been given. The ALRC did not, however,

³³⁵ *Human Tissue Act 1985* (Tas) s 3(1). See also *Human Tissue Act 1982* (Vic) s 3(1); *Human Tissue Act 1983* (NSW) s 4(1); *Transplantation and Anatomy Act 1983* (SA) s 5(1); *Transplantation and Anatomy Act 1979* (Qld) s 5(1); *Human Tissue and Transplantation Act 1982* (WA) s 3(1); *Transplantation and Anatomy Act 1978* (ACT) s 4(1) and *Human Tissue Transplant Act 1979* (NT) s 4(1).

³³⁶ *Human Tissue Act 1985* (Tas) s 3(1). See also *Human Tissue Act 1982* (Vic) s 3(1); *Human Tissue Act 1983* (NSW) s 4(1); *Transplantation and Anatomy Act 1983* (SA) s 5(1); *Transplantation and Anatomy Act 1979* (Qld) s 5(1); *Human Tissue and Transplantation Act 1982* (WA) s 4(1); *Transplantation and Anatomy Act 1978* (ACT) s 4(1) and *Human Tissue Transplant Act 1979* (NT) s 4(1).

³³⁷ Australian Law Reform Commission, *Human Tissue Transplants*, 14–16.

³³⁸ Blood donation was excluded from these recommendations because the practice of blood donation was regarded as sufficiently well-established to require different provisions. See *Ibid*, 16–17.

explain the reasoning behind these differing conditions.³³⁹ It is likely, though, given the ALRC's explanation of the distinction that these conditions were applied due to the greater seriousness of donating non-regenerative tissue.

A distinction based on these criteria is no longer readily applicable to tissue as it is removed and used today. For the purpose of the Acts, the distinction remains useful because the division to which it applies deals only with live donations of tissue. In this context, harm to the donor is relevant to whether tissue may be donated and for what purposes. However, the distinction highlights one of the first major problems with the structure and approach of the Acts—the distinction is based on a division that is only relevant where tissue is voluntarily removed solely for donation. The distinction is not relevant where tissue has been removed for another purpose, such as during surgery, where the decision to remove it is determined by medical necessity.

As will be discussed below, tissue removed for purposes other than donation, post-mortem or anatomical study is excluded from the Acts.³⁴⁰ The issue is, however, that because the provisions for live donations are based on this distinction, the structure of the Act cannot easily be expanded to encompass donations of tissue removed in other contexts without these donations being subject to the same restrictions. For example, if the exclusion of tissue removed during surgery were repealed, and donations of this kind of tissue brought within the general live donation provisions, the same restrictions based on the distinction would apply. Imagine James has an operation in which some skin tissue (regenerative) and a portion of his lung (non-regenerative) are removed. Applying the distinction, the tissue could be donated for research purposes upon consent. The lung portion, however, could only be donated for transplantation and only after a cooling off period. The reason for the distinction—to restrict harmful donations of non-regenerative tissue except for the necessity of transplant—is irrelevant, because James is not harmed by the removal, in fact it has helped him overcome an illness. Yet, because of this distinction the lung tissue cannot be used for research. Clearly, the distinction would make expanding the ambit of the Act difficult because there might be many such instances in which it would unreasonably restrict current practice in the donation and use of tissue.

³³⁹ Ibid, 50.

³⁴⁰ See further sections 1.2–1.4. This exclusion does not apply in New South Wales, where tissue removed during surgery, dental treatment or therapy is also covered by the Human Tissue Act. See further section 1.3.

A second criticism of the distinction is that in the light of new technologies, it is no longer always a useful distinction. To the law, this is the fundamental distinction that is to be made between tissues, as it is fundamental to the working of the Human Tissue Acts. However, distinctions based on the use the tissue may be put to, the privacy concerns the use raises, and future storage and transfer are also relevant to consent for donation. For example, adult stem cells have uses that cells without their capacity to reproduce and divide into new types of cells do not, and hence the uses to which stem cells can and should be put are different. Those different uses in turn can have different ethical and legal consequences, and might therefore be relevant to consent for donation. Despite this, based on the legislative division this difference has no bearing on how that tissue may be donated. In effect, the division between tissues that can and cannot regenerate is not sophisticated enough to deal with the ways tissue is used and viewed at present. In retaining the distinction in the legislation, the Acts do not easily allow more developed conceptions of tissue to be included.

Finally, the distinction perpetuates the legislative focus on the process of donation and how it is to be authorised, rather than on the later use, storage and transfer of tissue. This focus will be considered in more detail in later in this chapter. At this point, however, it suffices to say that the distinction is one of the aspects of the legislation that support the Acts' concentration on processes of consensual donation instead of on the now more practical problem of what may later happen to the tissue once removed.

1.2 Exclusion of Sperm, Ova and Foetal Tissue

Sperm, ova and foetal tissue are excluded from the part of the Human Tissue Acts covering donations of tissue from living adults.³⁴¹ These exclusions are noted to clarify the ambit of the legislation, but they will not be considered in detail as these tissues are not within the scope of this thesis's analysis. The ALRC's report recommended that these materials be excluded from the Acts because their use and transplantation raised specific, complex issues that could not be dealt with adequately in legislation to regulate transplantation generally.³⁴² Their use is covered by a range of other legislation.³⁴³

³⁴¹ *Human Tissue Act 1985* (Tas) s 5; *Human Tissue Act 1982* (Vic) s 5; *Human Tissue Act 1983* (NSW) s 6; *Transplantation and Anatomy Act 1983* (SA) s 7; *Transplantation and Anatomy Act 1979* (Qld) s 7; *Human Tissue and Transplantation Act 1982* (WA) s 6; *Transplantation and Anatomy Act 1978* (ACT) s 6 and *Human Tissue Transplant Act 1979* (NT) s 6.

³⁴² Australian Law Reform Commission, *Human Tissue Transplants*, 18–19.

³⁴³ See, eg, *Infertility Treatment Act 1995* (Vic) (s 12 regulates the use of donated sperm and ova); *Human Cloning and Other Prohibited Practices Act 2003* (NSW) (s 18 prohibits trading in sperm or ova). The NSW Human Tissue Act does regulate businesses supplying sperm from living donations. See *Human Tissue Act 1983* (NSW) Pt 3B.

1.3 Exclusion of Tissue Removed during Surgery

Tissue removed during surgery ‘or otherwise in the possession of a doctor or hospital’ was specifically excluded from the terms of the ALRC’s terms of reference.³⁴⁴ Amputated limbs and placentae were given as examples of such tissue, and were deemed to have no status in law. The ALRC perceived no need for to recommendation regulation of tissue obtained in this way, stating ‘the creation of procedures for the lawful giving for transplant and other therapeutic use, of tissue taken from living and dead persons, should be sufficient in the Australian community [at that time]’. This view rested on ‘the conclusion that, in the context of medical therapy, the Australian sees his body and its tissues not as an object of commerce but as something to be the subject of a voluntary gift’.³⁴⁵ From these statements it is clear that the ALRC did not think that tissue removed during surgery other than for donation as transplantation material or therapy, presented significant problems that required regulation.

This view should be considered in context. One of the most important developments in medical research, as has been discussed already in this thesis, is genetic science and the ability to map and comprehend the human genome. But these developments came some time after the ALRC’s report and the issues they raise—for example, the privacy of samples, the commercialisation of the products of research on a large scale and the possibility of genetic discrimination—were not yet issues in 1977.

As a result, all of the Human Tissue Acts (excepted the amended New South Wales Act) explicitly exclude tissue removed by registered medical practitioners from the body of a person during medical treatment to which either express or implied consent has been given, or where that treatment is necessary for the preservation of life from their ambit.³⁴⁶ This exclusion covers the removal of tissue, the uses to which it may be put and its disposal. Under the Acts, treatment is any procedure or operation carried out in the interests of the health of the person treated. Therefore, any tissue removed during surgery, amputated body parts and any sample taken for diagnostic testing is excluded. The exclusion also explicitly includes tissue removed during embalming or the

³⁴⁴ Australian Law Reform Commission, *Human Tissue Transplants*, [13].

³⁴⁵ *Ibid*, [13].

³⁴⁶ *Human Tissue Act 1985* (Tas) s 28(1)(a), (b); *Human Tissue Act 1982* (Vic) s 32(1)(a), (b); *Transplantation and Anatomy Act 1983* (SA) s 37(1)(a), (b); *Transplantation and Anatomy Act 1979* (Qld) s 47(1)(a), (b); *Human Tissue and Transplantation Act 1982* (WA) s 32(1)(a), (b); *Transplantation and Anatomy Act 1978* (ACT) s 46(1)(a), (b) and *Human Tissue Transplant Act 1979* (NT) s 26(1)(a), (b).

preparation of a body for burial or cremation.³⁴⁷

This exclusion presents a number of general problems. First, it excludes the major source of tissue used in research from the legal framework that otherwise deals with tissue used in this way. This leaves the vast majority of tissue samples used in research unregulated by law, as the Acts are the major legislation regulating how excised tissue may be used. Instead, this tissue is covered either by pathology guidelines and accreditation requirements, hospital policies or the National Health and Medical Research Council's ethical guidelines, which are considered in Chapter Five. As a consequence, there are no legal sanctions for misuse of these samples, beyond the more general prohibition on sale that will be discussed in section 4.

The distinction the Human Tissue Acts make between donated tissue and tissue removed during therapy also creates a division based on the source of tissue, and its use in research is only subject to regulation if it was obtained in accordance with the Acts. This requires researchers to remain aware of how the tissue was obtained, even if it is anonymised, to ensure that tissue is used in accordance with the Acts if it falls within their ambit. Given that many of the issues tissue use in research raises will be the same, regardless of how the sample was obtained, the distinction merely adds a layer of complexity in the legal regime to no useful end.

These areas of concern can be seen by applying the exclusion to some of the case studies. For example in Case Study 6: Tissue Research in Australia, researchers at the Walter and Eliza Hall Institute for Medical Research and the Murdoch Children's Research Institute obtained material for their research from hospital sources and from donors. In undertaking their research, the use of the hospital-sourced tissue would be excluded from the provisions of the Acts.³⁴⁸ By contrast, the samples obtained from donors would have to be used in accordance with the Acts. Hence, the researchers would need to keep samples from each source distinct if they were to use them in ways which might contravene the Acts. They would also be free to use the hospital-sourced samples largely as they chose without fear of legal repercussions.³⁴⁹

³⁴⁷ *Human Tissue Act 1985* (Tas) s 28(1)(c), (d); *Human Tissue Act 1982* (Vic) s 32(1)(c), (d); *Transplantation and Anatomy Act 1983* (SA) s 37(1)(c), (d); *Transplantation and Anatomy Act 1979* (Qld) s 47(1)(c), (d); *Human Tissue and Transplantation Act 1982* (WA) s 32(1)(c), (d); *Transplantation and Anatomy Act 1978* (ACT) s 46(1)(c), (d) and *Human Tissue Transplant Act 1979* (NT) s 26(1)(c), (d).

³⁴⁸ See sections 2 and 3 on the uses to which tissue may be put.

³⁴⁹ Although ethical constraints will apply. See Chapter Five, section 2.

Beyond the research context, pathology sample collections comprise a vast proportion of the overall quantity of stored tissue, as do collections held by genetic services and the newborn screening cards retained at hospitals. These materials are also excluded from the Acts as they were not explicitly donated for research or transplantation. As a result, the entire collection held by Hobart Pathology (Case Study 4: Hobart Pathology) and all newborn screening cards, such as those held by the South Australian Clinical Genetics Service (Case Study 5: Newborn Screening Card Collection) would not be covered by the major legal regime dealing with excised tissue in Australia. Research use, transplantation and therapeutic use of these tissues is not covered by law and consequently there is no legal guidance about how they may be dealt with in these contexts. As they remain unregulated, aside from ethical and accreditation requirements, they can be used in ways that might otherwise be illegal simply because they were obtained through avenues not covered by the Acts. This exclusion also means it is not unlawful for tissue to be collected and retained as occurred in the situations described by Case Study 1: Collecting Aboriginal Remains and in relation to the Bristol Royal Infirmary scandal in England (see also Case Study 2: Organ and Tissue Retention following Post-Mortem), despite the clear ethical and emotional concerns these examples have raised. Therefore, the Acts fail to take account of the Aboriginal cultural sensitivities to retaining tissue and the community desire to lay tissue to rest. The Acts also fail to account for the emotional distress that non-consensual retention of tissue from surgery may have on families, as evidenced at Bristol and more recently in Australia.³⁵⁰

The distinction simply continues the approach that has long been taken by the legal system to the use of medically obtained samples, which is to turn a blind eye to how they might be used. Research use was previously left to the discretion of the medical profession, and is now largely regulated by ethical and accreditation guidelines. This approach, as will be discussed further in Chapter Five, is increasingly unsatisfactory as the uses to which tissue may be put to widens, and the privacy issues raised by the development of genetic testing proliferate. By focusing on promoting the interests of researchers in allowing use, the Acts inadequately promote the autonomy of the person whose tissue has been removed if it was not explicitly donated, and no sanctions are provided for misuse of such tissue. Further, the distinction creates uncertainty for

³⁵⁰ See Chapter Two, section 3.2.

researchers about the legal status of the tissue they may use if they are unsure of how it was obtained originally. It therefore undermines the support for research use it intends to provide because researchers may err on the side of caution in using some samples to avoid using those samples illegally.

A preferable approach would be to include all tissue within the Acts and broaden the provisions to deal with the many interests people have in the wide variety of excised tissues that are removed, stored and used every day. A uniform, comprehensive legislative solution is more desirable than a piecemeal approach to a select set of tissue that does not form the major source of tissue as it is used today. The problems this exclusion creates demonstrate the desirability of a uniform approach, and ways for achieving such an approach will be considered further in subsequent chapters.

By contrast, the now amended NSW Human Tissue Act includes provisions dealing specifically with tissue removed during medical, dental or surgical treatment carried out in the interests of the health of that person. The Act authorises the use of such tissue removed from a living person for therapeutic, medical or scientific purposes where the person has given consent for this use in writing.³⁵¹ Where the tissue is removed during medical, dental or surgical treatment and the individual subsequently dies, the senior next of kin may authorise its use for the same purposes as long as it appears the deceased individual did not object to this use in during life.³⁵² The Act further makes it clear that these provisions do not authorise tissue to be taken during treatment *for these purposes*, but rather that tissue taken *for the purposes of the treatment* may subsequently be used for therapeutic, medical or scientific purposes.³⁵³

The New South Wales provisions are clearly preferable to those in the other Acts, both because they ensure such tissue is covered by the Acts, and because they provide clear mechanisms for respecting the autonomy of the person from whom the tissue was removed. In doing so, they also remove the legal uncertainty and complexity that surrounds research use of this tissue.

1.4 Previously Collected Tissue

No mention is made in the Human Tissue Acts of tissue that has already been collected

³⁵¹ *Human Tissue Act 1983* (NSW) s 21X.

³⁵² *Ibid* s 21ZA.

³⁵³ *Ibid* s 21ZB.

and stored. Hence, all tissue held in tissue banks that pre-date the enactment of the legislation is not covered and is not subject to regulation under the legislation. The Human Tissue Acts came into force only in the early 1980s, but tissue has been collected in Australia for at least a century. Given this, the collections held in identified in the censuses conducted over the past few years would not be covered.³⁵⁴ This exclusion also means that samples of unclear origin, such as de-identified samples in collections that do not pre-date the Acts, are not provided for. All samples will, however, be subject to the prohibition against sale.

This exclusion raises a range of concerns. First, it fails to provide any legal guidance for the use of these collections, leaving these samples in a legal vacuum. Regulation of this use will therefore be left to the parallel scheme of ethical guidelines, which may differ in scope. This ignores the interests of those who are affected by continued retention of samples, and misuse of stored materials. For example, where a teaching hospital uses tissue that was taken without consent before the Acts were created, that continuing use is unregulated. Imagine that a person discovers that his or her parent's brain is now preserved as part of a teaching collection in a hospital, as may well have occurred following the events described in Case Study 2: Organ and Tissue Retention following Post-Mortem. If the son or daughter objects to that use, he or she has no means of preventing the continued use and retention. In this kind of instance, the Human Tissue Acts fail to take account of the future interests of families in the tissue of their relatives and do not include provisions that would address these familial concerns if a situation like that at Bristol Royal Infirmary occurred in Australia.³⁵⁵

This situation is even more problematic where the retained tissue was removed from an Aboriginal person in the past, as described in Case Study 1: Collecting Aboriginal Remains. As noted previously, there is no legal recognition of an indigenous community's interest in tissue in the Human Tissue Acts, nor do they take account of indigenous sensitivities. In not covering previously collected tissue, the Acts do not provide any avenue for communities to seek the return of this tissue to lay it to rest. Effectively, the Human Tissue Acts provide no means of remedying the problems

³⁵⁴ See, eg, Crown Solicitor for Western Australia and Commissioner for Health for Western Australia, *Final Report: Removal and Retention of Organs and Tissue Following Post-mortem Examinations*, Department of Health Western Australia, Perth, 2001; South Australia Solicitor-General, *Report into the Retention of Body Parts after Post-Mortems*, Department of Health Services South Australia, Adelaide, 2001. See also Chapter One, section 3.2.

³⁵⁵ See further Chapter Two, section 3.2.

caused by past non-consensual retention of tissue.

Secondly, this exclusion leads to the same issue as noted in the previous section, that samples in collections that are excluded will be subject to different rules to those come within the Acts, despite the fact that they may be used in the same context and pose the same issues. Given the increasing value of large tissue sample collections for genetic research, as seen in Case Study 12: Iceland and deCODE, older collections will continue to be useful. Having these collections not subject to the general legal provisions on tissue use will result in continued confusion, while if a collection spans the period both before and after the Acts were created this may lead to even greater complexity in determining which rules will apply to which samples. It is possible to imagine a collection that contains pre-1980s samples, samples collected after the Acts were enacted but not in accordance with their consent procedures (for example, samples taken tissue removed in surgery) and samples acquired in accordance with the Acts. Ensuring that the samples are all used in accordance with the law may place a significant administrative burden on researchers if they are required to use different samples in different ways. It also results in increased complexity for no useful purpose, because as discussed previously, the issues tissue use raises are not necessarily related to how the tissue was collected, but instead the problems that its subsequent use present—for example, privacy concerns, potential discrimination, autonomy and even perhaps commercial uses.

Again, by leaving some tissue outside the scope of the Acts, and by framing the Acts around how tissue was obtained rather than how it will be used, the Human Tissue Acts provide a piecemeal approach to tissue use that leads to inconsistency, confusion and a lack of legal regulation in many areas. These concerns also apply to tissue taken for testing, as in Case Study 8: South Australian Clinical Genetics Service, which also fall outside the ambit of the Acts.

2. DONATIONS FROM LIVING ADULTS

Different provisions apply in the Acts to donations of regenerative and non-regenerative and blood. Each of these sections will now be considered in turn.

2.1 Regenerative Tissue

A living adult may donate specified regenerative tissue, other than blood, by voluntary consent in writing.³⁵⁶ For the consent to authorise removal, it must be certified by a medical practitioner who has explained to the person the nature and effect of the removal from the body of the person of the tissue specified in the consent.³⁵⁷ Tissue may be donated either for transplantation to the body of another living person, or for use for 'other therapeutic purposes or for medical or scientific purposes'. Consent authorises the removal of tissue and its use, but only for the removal of the tissue specified and it may only be used as specified in that consent.³⁵⁸

While these provisions are in some ways satisfactory because they require clear consent, they present a variety of problems for current tissue use, which are considered below. It should, however, be noted that it is not entirely clear whether donation for 'other therapeutic or medical or scientific purposes' means that the donation is specifically for one these purposes, and the tissue must be used for that purpose, or that it means the tissue is donated for any and all of these purposes. In either case, there is a lack of clarity about the extent and nature of the consent required, which relates to the first and second areas of concern identified in this section.

The first major problem with the Human Tissue Acts' consent provisions is that the apparent meaning of informed consent is too narrow. For a medical practitioner to certify the consent, the Acts provide that he or she needs only to have explained the nature and effect of the removal of the tissue. While it is implicit that the donor must know what the tissue is to be used for, as they must consent to either research, therapeutic or medical use, or transplantation use of the tissue, there is no requirement that the donor is more fully informed about exactly how the tissue will be used. The Acts do not require that the donor be informed about the nature of that research, therapeutic, medical or transplant use, nor about how the tissue will be stored, whether it will be transferred to other researchers, whether it will be identified and so on.

³⁵⁶ *Human Tissue Act 1985* (Tas) s 7. See also *Human Tissue Act 1982* (Vic) s 7; *Human Tissue Act 1983* (NSW) s 7; *Transplantation and Anatomy Act 1983* (SA) s 9; *Transplantation and Anatomy Act 1979* (Qld) s 9; *Human Tissue and Transplantation Act 1982* (WA) s 8; *Transplantation and Anatomy Act 1978* (ACT) s 8 and *Human Tissue Transplant Act 1979* (NT) s 8.

³⁵⁷ *Human Tissue Act 1985* (Tas) ss 9, 14. See also *Human Tissue Act 1983* (NSW) ss 9, 12; *Human Tissue Act 1982* (Vic) ss 9, 10; *Transplantation and Anatomy Act 1983* (SA) s 9; *Transplantation and Anatomy Act 1979* (Qld) s 9; *Human Tissue and Transplantation Act 1982* (WA) s 8; *Transplantation and Anatomy Act 1978* (ACT) ss 8, 10 and *Human Tissue Transplant Act 1979* (NT) ss 8, 10.

³⁵⁸ *Human Tissue Act 1985* (Tas) s 14; *Human Tissue Act 1982* (Vic) s 10; *Human Tissue Act 1983* (NSW) s 12; *Transplantation and Anatomy Act 1983* (SA) s 9; *Transplantation and Anatomy Act 1979* (Qld) s 9; *Human Tissue and Transplantation Act 1982* (WA) s 8; *Transplantation and Anatomy Act 1978* (ACT) s 10 and *Human Tissue Transplant Act 1979* (NT) s 10.

Therefore, if the donor understood the nature of the removal but later was concerned by how the tissue was used, the consent would remain valid and no sanctions would be applicable.

In the research and transplantation contexts, this form of consent is insufficient and inconsistent with ethical standards set in this country for the acquisition and use of tissue, as will be apparent following the discussion of ethical guidelines in Chapter Five. At a most basic level, for consent to be informed the donor should be aware with some degree of specificity of the use to which his or her tissue will be put, such as which of the three purposes it will be used for and some details of that use.

To demonstrate this problem, consider Case Study 15: Canavan Disease Research. The donors in that instance were informed that the tissue would be used for research and understood the nature of the removal, and consented to this. They did not, however, perceive that the results of that research, especially the genetic test for Tay-Sachs disease that was developed from them, would be patented and placed under a restrictive license agreement. Were they fully informed? Under the requirements of the Human Tissue Acts, if they understood the nature of the removal and that it would be used for research, then their consent would be valid. The legislation in this country does not specify that information disclosed must include commercial interests in the research to be conducted, nor whether any profits will be made from that research or that it will be used in a restrictive manner. Their valid concerns about the subsequent use of the results of research using their donated samples would have no impact on the validity of the consent and the Acts would provide them with no remedy for the harms they assert having suffered.

The issue is whether in fact this form of consent requirement is sufficient to ensure that the donor's autonomy is promoted in relation to the removal *and the use* of the tissue. From the statements of these participants, it appears that this was information that they would have regarded as relevant to their decision to donate tissue. What this demonstrates is that consent to donation is more than consent to removal, that the donor probably takes into account a variety of factors in deciding whether to give tissue. For that consent to be informed, he or she should be made aware of factors that would be relevant to the decision.

A further concern here is the commercial sphere. If a person chooses to donate material

which is supplied to a commercial venture, which is subject to ethical guidelines only on a voluntary basis, such donations would be controlled mainly by the Human Tissue Acts.³⁵⁹ The use might be for research, for which donation would clearly be allowed under the Acts provided the consent was certified by a medical practitioner. It might also lawfully be for therapeutic use. As therapeutic use of tissue is not defined in the Acts, it is not clear that it does not extend to the use of tissue in the development and manufacture of therapeutic goods such as drugs and test kits. It is possible, then, that tissue could be donated to commercial ventures for use in the creation of therapeutics. In both instances, the use of the tissue could generate financial returns or valuable intellectual property.

In such cases, if these ventures did not fully inform the participant of the exact scope of the research or therapeutic use, particularly that the tissue might be exploited commercially, but had explained the effect and nature of removal; they would have fulfilled the requirements of the legislation. As they are not subject to other guidelines, beyond their potential force in determining standard of care in negligence, this transaction would most likely be legitimate under the Human Tissue Acts.

However, there are clearly problems with the commercial use of tissue where the donor is not informed, most particularly the issue of benefit-sharing and whether the source should share in the profits of the research.³⁶⁰ In addition, as commercial use is not subject to ethical constraints, the sanctions provided by those guidelines, such as the withdrawal of funding for unethical use or peer sanctions for improper research and exploitation, will not apply. Therefore, there are far fewer restrictions to ensure tissue is used in a suitable manner within the commercial sphere. By regulating donations of this kind with only a simplistic information requirement for valid consent to be obtained, these potential abuses may in fact not be unlawful under the Acts. This leaves the legal system wholly unprepared to deal with the possible abuses of legitimately donated tissue within the commercial arena. It also fails to protect the individual's interests in controlling the use of his or her tissue.

Case Study 16: Ted Slavin and Diagnosing Hepatitis is an example of the kind of situation where such provisions might prove inadequate. It is possible that in this

³⁵⁹ As occurs in situations like the donated tissue used by Ardais, as described in Chapter Three, section 2.

³⁶⁰ See further Australian Law Reform Commission, *Gene Patenting and Human Health*, IP27, ALRC, Sydney, 2003, ch 4.

country someone in a similar situation to Slavin could make an arrangement with a company to donate his or her tissue to create new therapeutic products. The consent they might give to that donation would be fully informed if they knew how the tissue would be removed and that they were consenting to therapeutic use. But it is entirely possible that those therapeutics might be used or exploited in a way they find objectionable, such as pricing policies that exclude most people from accessing the drug. This might have affected their decision to donate. However, under the Acts, the company would be acting entirely legally in not informing them of how the treatment would be exploited. Clearly, the individuals involved might object, but the Human Tissue Acts would provide them with no remedy. While there is little purely commercial research using tissue in this country at present, commercial ventures are developing, and links between industry and research are being fostered. Therefore the current regulations may become, if they are not already, insufficient protection.

A second problem presented by the consent requirements in the Acts is that they extend only to removal and use; they do not cover subsequent use, storage, transfer or destruction. Thus, there is no explicit requirement that possessors of tissue obtain consent to any subsequent use of the tissue, although this often occurs in a research context. It is unclear whether this means that subsequent use is illegal, but this seems unlikely given the lack of any provision on this matter. Rather, subsequent use sits in the same vacuum as tissue that is excluded from the ambit of the Acts. It is simply not considered and there are no legal provisions to govern it. This is clearly unsatisfactory, as tissue is regularly used in other research projects. Similarly, tissue is often transferred between researchers and institutions. Spare sections of tissue, perhaps donated for transplant, might be stored and used in research or for other therapeutic purposes. These later uses are unregulated, save by ethical guidelines, and hence any objectionable uses will not be subject to legal sanction.

Thirdly, the consent model establishes a legal relationship between the donor and the person to whom the consent is given, but does not establish rights and duties beyond this. If tissue is misused, only the limited criminal sanctions in the Acts will apply. However, the donor will have no remedy—the Acts do not provide for the donor to be compensated or to have the tissue returned or interred.

Further, as the relationship set up by the Act is based on consent, the donor will have no legal relationship with any third party who may misuse tissue. As the Acts do not

prohibit the transfer of tissue, it is entirely possible that third parties may gain possession of donated samples. If the third party misuses the tissue, the Acts' sanctions may apply if the use falls outside those authorised by the consent. However, it is not clear that they will apply, as the consent provisions do not specify that the tissue may only be used by the medical practitioner authorised to remove it. Further, the Acts do not require the consent to specify the exact use of the tissue; hence their breadth may mean that any research, therapeutic or scientific use may be lawful. Arguably, use by a third party is not an offence, and even if it is, the donor is not legally entitled to compensation or the return of the tissue under the Acts. Effectively, then, the Acts again fail to adequately protect the privacy and autonomy interests of the individual donor.

A fourth problem raised by the consent provisions from living adults is that they allow only for the interests of the individual donor and the person receiving the tissue to be taken into account. They do not take into consideration possible objections on their community, which in this country is most important where samples are taken from Aboriginal people, as highlighted in Case Study 1: Collecting Aboriginal Remains. Research like that envisaged by the Human Genome Diversity Project is also a case in point, where individuals may be prepared to consent, but where their participation has broader impacts at a community level. In these instances, community views on donation and use of tissue might be relevant, yet there is no provision in the Acts for them to be considered. This is in contrast to ethical guidelines, such as those released by the National Health and Medical Research Council, which include matters to be taken into account in conducting research on collectivities.³⁶¹ Where research use is of a kind that may cause concern within a defined and interested community, such as the Aboriginal community, provision should be made both to inform the participant of this and to ensure that the consent of that community has been obtained for the research.

Finally, the Human Tissue Acts consent provisions limit donations of tissue from living adults to medical and scientific uses. They exclude donations for other, arguably legitimate purposes. Case Study 17: StarGene and Case Study 18: Orlan and Manipulation of the Flesh outlined some more diverse uses of tissue. Both of these uses would not covered be by the Human Tissue Acts but are arguably justifiable uses. Many of the artistic uses of tissue discussed in Chapter Three have been regarded as

³⁶¹ See further Chapter Five, section 2.1.

acceptable and important artistic expressions. Our culture is enriched by the work of painters and sculptors. If their means of expression is tissue, and the person from whom it is taken understands that use and the consequences of it, there should be provision for such donations to occur within the bounds of the law. However, these uses remain in the legal vacuum mentioned many times already.

The consequences of donations of this kind may have many repercussions for the person from whom they were taken. For example, their tissue might be tested and the information generated used in a discriminatory manner or it might be sold or destroyed in a way which they find objectionable. Any person who donates tissue for these purposes should have done so after giving fully informed consent, and it is unsatisfactory that accepted uses of this kind remain shrouded in legal uncertainty and not subject to adequate legal protections.

The provisions for donating regenerative tissue from living adults in the Human Tissue Acts suffer from a number of flaws and create a variety of problems, largely because they no longer stand the test of time. The uses of tissue have extended well beyond the limited situations with which they were designed to deal. They no longer provide an effective regulatory framework for dealing human tissue taken from living people. The Act should therefore be revised, or a better, alternative approach should be adopted.

2.2 Non-regenerative Tissue

Living adults may donate non-regenerative tissue, but only for the purpose of transplantation to the body of another living person. Consent procedures are similar to those required for the donation of regenerative tissue, and must be in writing, voluntary, and witnessed. The tissue may not be removed until twenty-four hours after the consent has been given. This is to allow the person time to revoke consent if they wish.³⁶² The donor must be informed of the nature and effect of the removal of tissue specified in the consent as for regenerative tissue.³⁶³

³⁶² *Human Tissue Act 1985* (Tas) s 8. See also *Human Tissue Act 1983* (NSW) s 8(1); *Human Tissue Act 1982* (Vic) s 8(1); *Transplantation and Anatomy Act 1983* (SA) s 10; *Transplantation and Anatomy Act 1979* (Qld) s 10; *Human Tissue and Transplantation Act 1982* (WA) s 9; *Transplantation and Anatomy Act 1978* (ACT) s 9 and *Human Tissue Transplant Act 1979* (NT) s 9.

³⁶³ *Human Tissue Act 1985* (Tas) s 9(b). See also *Human Tissue Act 1983* (NSW) s 9, 13; *Human Tissue Act 1982* (Vic) s 9, 11; *Transplantation and Anatomy Act 1983* (SA) s 10; *Transplantation and Anatomy Act 1979* (Qld) s 10; *Human Tissue and Transplantation Act 1982* (WA) s 9; *Transplantation and Anatomy Act 1978* (ACT) s 10, 16 and *Human Tissue Transplant Act 1979* (NT) s 10, 12.

It is clearly vital that the donor comprehend the nature and effect of the removal, and the legislation does provide for this. It provides also for a cooling-off period to allow the donor to revoke consent if they change their mind. This is important as the decision to donate may be a very serious one. Kidney donations between living persons are increasing, and the risks to donors are obvious. The donor is left with only one functioning kidney, and if that fails then they may find themselves in need of a kidney donation or face reliance on dialysis. Partial lung transplants have also been performed, where lobes of the donor's lung are used to replace the lungs of the recipient. In this kind of operation, the donor suffers a great deal of discomfort and reduced lung capacity in the future. The consequences of live donation of non-regenerative tissue can be onerous, and the legislation ensures that donors should be made aware of these risks.

As this tissue can be donated only for transplantation purposes, many of the issues identified in relation to donations of regenerative tissue will not apply. Research concerns and commercial issues are not relevant, as tissue cannot be donated for this purpose. The clear provisions for donation by consent are applicable in the context of transplantation donations and work well for the most part, because the purpose of the donation to which consent is given is clear. It is not, however, surprising, that there are few problems in relation to tissue use with this aspect of the Acts—this was the major purpose of their enactment. Rather, the problems identified in the preceding section are mainly the result of the Acts taking the same approach to donations of regenerative tissue for other purposes as they take to transplantation donations. These problems result because what is applicable to transplantation donation is not necessarily applicable to donation for research or therapeutic purposes, where the differing uses of tissue raise different issues such as those noted above.

However, one particular problem is raised by the provisions covering donation of non-regenerative tissue—the consent provisions do not cover subsequent use of any donated tissue that is not transplanted. While this may not occur often, there is potential for portions of non-regenerative tissue not to be usable. For example, the tissue may be found to be a poor match and will not be used; it may be damaged in some way after removal but before transplantation at which point it might only be useful for research; or sections of the tissue may not be needed and again might only be useful for research. In each case, these uses will not be legislatively regulated as the Acts' consent provisions do not cover subsequent use and will be subject to the same problems of uncertainty, lack of sanctions and lack of adequate consent as donations and uses of regenerative

tissue that are not covered by the Acts as discussed above.

2.3 Blood

Blood may be donated by living adults either for transfusion or for 'therapeutic uses or for medical or scientific purposes' and consent to donation authorises removal.³⁶⁴ Regenerative tissue and blood are covered separately by the Acts for the reasons outlined above, and the only difference between the provisions is the lack of a requirement that consent to blood donation be in writing. As blood can be donated for research and therapeutic uses, the same issues identified in relation to regenerative tissue in these contexts will also apply to blood donations.

3. DONATIONS FROM DECEASED ADULTS

3.1 Donations after Death

Donations after death are dealt with slightly differently to living donations. Legislation in each state and territory distinguishes between corpses held at hospitals and those that are held elsewhere.³⁶⁵ This distinction acts only to specify which persons are authorised to deal with the removal of tissue. As this distinction is not relevant to this discussion, the provisions will be discussed together. The only material difference is that where a body is held at a place other than a hospital, the Acts do not provide for tissue to be removed where no next of kin can be contacted and the wishes of the deceased are unknown.

Where the body of the deceased is held at a hospital or elsewhere, tissue may be removed for the purpose of transplantation into a living person, or for purposes of therapeutic, scientific or medical use. This may occur in one of three situations. In the first, tissue may be removed for these purposes where it can be ascertained that the deceased had, during life, expressed a wish for, or consented to, the removal of tissue following his or her death.³⁶⁶ This consent must be for the purposes permitted by the

³⁶⁴ *Human Tissue Act 1985* (Tas) ss 18, 20; *Human Tissue Act 1982* (Vic) ss 21, 23; *Human Tissue Act 1983* (NSW) ss 19, 21; *Transplantation and Anatomy Act 1983* (SA) ss 18, 20; *Transplantation and Anatomy Act 1979* (Qld) ss 18, 20; *Human Tissue and Transplantation Act 1982* (WA) ss 18, 20; *Transplantation and Anatomy Act 1978* (ACT) ss 20, 22 and *Human Tissue Transplant Act 1979* (NT) ss 14, 15. The New South Wales Act includes special provisions dealing with businesses supplying blood and blood products which cover certification of donor fitness and infection of blood samples. See *Human Tissue Act 1983* (NSW) Pt 3A.

³⁶⁵ Western Australia has no provisions for removal where the deceased is not held at a hospital.

³⁶⁶ *Human Tissue Act 1985* (Tas) ss 23(1), 24(1), 26(1); *Human Tissue Act 1982* (Vic) ss 25, 26(1)(a), (b), (c), (2)(a), (b), (c); *Human Tissue Act 1983* (NSW) ss 23(1), 24(1); *Transplantation and Anatomy Act 1983* (SA) ss 21(1), 22(3); *Transplantation and Anatomy Act 1979* (Qld) ss 21(1), (2), 22(3), 24; *Human Tissue and Transplantation Act 1982* (WA) ss 22(1), 2(a), 24; *Transplantation and Anatomy Act 1978* (ACT) ss 27(1), 28(3),

Act. The Acts outline two purposes—transplantation and other therapeutic, scientific or medical purposes. The tissue must be used in accordance with the uses specified in the consent. It appears that this means the deceased consents either to transplantation of tissue or to general use of the tissue for scientific, therapeutic or medical purposes generally, rather than for a more specific purpose. Although it is clear in the legislation of other states and territories, only the Western Australian Act explicitly requires that removed tissue may only be used for the purposes to which the consent refers.³⁶⁷

In the second situation, tissue may be removed if the senior available next of kin consents to removal of tissue in writing (or fails to object), where there is no evidence of consent or objection from the deceased during life and there is also no objection from other next of kin.³⁶⁸

Where no consent has been given during life and the next of kin of the deceased cannot be found, the third situation, the designated officer may authorise removal. This may only be done when, after making reasonable inquiries in the circumstances, the next of kin cannot be found, and if the officer has no reason to believe that the deceased objected to removal of tissue during their lifetime.³⁶⁹ In Queensland, Tasmania, the Northern Territory and South Australia, this provision only applies to bodies held in a hospital. The New South Wales Act does not allow for removal of tissue in either instance in the absence of consent from the deceased or the next of kin.

These provisions raise many of the same issues as discussed above in relation to how tissue so removed may be used. They are similarly vague on the specifics of future use, do not cover storage, transfer or subsequent use, take no account of other interests (such as community and indigenous interests), and do not address the access needs of families. However, they also raise a further concern. In most states and territories, the Acts allow for non-consensual taking of tissue in the absence of objections from the

31 and *Human Tissue Transplant Act 1979* (NT) ss 18(1), (2), 19(3), 22.

³⁶⁷ *Human Tissue and Transplantation Act 1982* (WA) s 22(3).

³⁶⁸ *Human Tissue Act 1985* (Tas) s 23(2); *Human Tissue Act 1982* (Vic) ss 25, 26(1)(a), (b), (d), (2)(a), (b), (d); *Human Tissue Act 1983* (NSW) ss 23(3), 24(3), 27; *Transplantation and Anatomy Act 1983* (SA) ss 21(3)(c), 22(1); *Transplantation and Anatomy Act 1979* (Qld) ss 21(3), 22(1), (2), 24; *Human Tissue and Transplantation Act 1982* (WA) s 22; *Transplantation and Anatomy Act 1978* (ACT) s 27(2), 28(1), (2), 31 and *Human Tissue Transplant Act 1979* (NT) ss 18(1), (3), 19(1), 22. The definitions section of each act outlines a hierarchy of seniority for next of kin to determine who may object.

³⁶⁹ *Human Tissue Act 1982* (Vic) ss 25, 26(1)(a), (b), (e), (2)(a), (b), (e); *Transplantation and Anatomy Act 1983* (SA) ss 21(3) (c), (d), 22(1); *Transplantation and Anatomy Act 1979* (Qld) ss 21(3), 24, 27; *Human Tissue and Transplantation Act 1982* (WA) s 22(1), (2)(b), 3(b), (4); *Transplantation and Anatomy Act 1978* (ACT) s 27(3), 31 and *Human Tissue Transplant Act 1979* (NT) s 18(3), 22.

deceased where the next of kin cannot be located. While there is not scope to examine the arguments surrounding an 'opt out' approach to tissue donation after death (which this effectively is), it can be said that this approach may violate the deceased individual's autonomy, and may fail to take account of familial interests if they later learn that the tissue has been taken. However, it does promote researcher interests in having access to tissue (and the interests of hospitals needing tissue for therapy), which in general serve the community. The problem is that the Acts favour these latter interests and do not include measures to deal with subsequent objections of relatives (for example, they do not provide for tissue to be returned to families for interring, which is particularly problematic if the deceased is Aboriginal).

3.2 Post-Mortems

The Human Tissue Acts diverge over the regulation of tissue removed at post-mortem and the anatomical use of bodies, and in some states and territories these removals are covered by other legislation. The provisions covering post-mortem procedures and donation for anatomy are relevant as they also provide authority for the removal and retention of tissue in some circumstances, and these do differ between jurisdictions. Additionally, post-mortems may be carried out for coronial purposes, to enable a hospital to determine cause of death, for teaching purposes and at the previously expressed wish of the deceased. Provisions in some of these situations may also differ. This section examines these provisions as they relate to the removal, use and retention of tissue.

3.2.1 Non-Coronial Post-Mortems

In most states and territories, non-coronial post-mortems are regulated by the Human Tissue Acts.³⁷⁰ In Tasmania, the Human Tissue Act does not provide for general post-mortems by hospitals to investigate the cause of death.

In other states and territories, a hospital may be authorised to conduct a post-mortem to examine the cause of death.³⁷¹ The consent provisions are similar to those for the donation of tissue from a deceased person, and in most cases may be performed either at the request of the deceased or to ascertain the extent or cause of the disease.

³⁷⁰ *Human Tissue Act 1982* (Vic) Pt V; *Human Tissue Act 1983* (NSW) Pt 4; *Transplantation and Anatomy Act 1983* (SA) Pt IV; *Transplantation and Anatomy Act 1979* (Qld) Pt IV; *Human Tissue and Transplant Act 1982* (WA) Pt IV; *Transplantation and Anatomy Act 1978* (ACT) Pt 4.

³⁷¹ *Human Tissue Act 1982* (Vic) ss 28–30; *Human Tissue Act 1983* (NSW) ss 28, 29, 31; *Transplantation and Anatomy Act 1983* (SA) ss 25, 26, 28; *Transplantation and Anatomy Act 1979* (Qld) ss 26, 27, 29; *Human Tissue and Transplant Act 1982* (WA) ss 25, 26, 28; *Transplantation and Anatomy Act 1978* (ACT) ss 32, 33, 35.

In these states and territories, the Acts also provide for tissue to be removed, and in some cases retained and used, during post-mortem. The states and territories have taken two different approaches. In some, the authority is only authority to remove tissue 'such tissue as is necessary for the purpose of the post-mortem examination'. However, this tissue may be subsequently used for therapeutic, medical and teaching purposes.³⁷²

In South Australia and Queensland, however, the authority to conduct a post-mortem is also a general authority to remove tissue, regardless of whether this is required for the purposes of the post-mortem. For example, section 28(1)(b) of the South Australian Act provides that the authority extends to the removal of

tissue from the body of the deceased person for the purpose of the post-mortem examination or for use for therapeutic, medical or scientific purposes.³⁷³

Only the New South Wales Act prevents this subsequent use of tissue. Section 31(2) of the New South Wales Act explicitly provides that

An authority under this Division does not authorise any person to use any tissue removed from a person's body for any therapeutic, medical or scientific purposes other than the purposes of the post-mortem examination.³⁷⁴

Such use is only authorised where the deceased had not objected and the next of kin consents.³⁷⁵

In each of the states that have passed legislation on this issue (aside from New South Wales), the authority to remove and use tissue is not subject to any objection expressed during life by the deceased or by the next of kin. Effectively, then, the tissue can be taken and used regardless of their wishes. Although in practice this may not always occur, and medical practitioners may take the objections of next of kin into account, they are not required to do so. Also, in some cases the next of kin will be unaware and unable to object. Similarly, while it has become the practice in some states to inform next of kin of any tissue that has been removed and retained, this does not provide them with a remedy to prevent this, to have it returned or to prevent its future research or therapeutic use.

³⁷² *Human Tissue and Transplantation Act 1982* (WA), s 28(1), (2); *Transplantation and Anatomy Act 1978* (ACT) s 35. The Victorian also seems to include a similar provision, although the drafting is somewhat unclear: *Human Tissue Act 1982* (Vic) s 30(1), (2).

³⁷³ *Transplantation and Anatomy Act 1983* (SA) s 28(1)(b). See also *Transplantation and Anatomy Act 1979* (Qld) s 28(1).

³⁷⁴ *Human Tissue Act 1983* (NSW) s 31(2).

³⁷⁵ *Ibid* s 31A.

These provisions, like those allowing for removal following death in the absence of objections, authorise doctors to take, use and retain tissue from individuals regardless of their wishes. It is an exception to the general consent model and reduces the control individuals and their families have over their tissue. These provisions raise many of the same issues noted above in relation to subsequent use of tissue in research, and the lack of control families may have over this use. The provisions also again fail to take account of indigenous interests, and favour those of doctors and researchers.

It should be noted, however, that despite this lack of legal regulation, guidelines released by the National Pathology Accreditation Advisory Council do require organs and tissue to be disposed in accordance with the wishes of the next of kin, where they are to be disposed of.³⁷⁶ Laboratories and hospitals must comply with these guidelines to maintain their accreditation.³⁷⁷ These guidelines do go some way to ensuring remains are dealt with sensitively, but it does not appear that they require hospitals to dispose of all remains, only that they respect the wishes of next of kin when they do.

However, the Human Tissue Act provisions are an even greater erosion of individual and familial control where they authorise tissue to be taken for research and therapeutic use even where the removal of this tissue is not necessary for the purposes of the post-mortem. These provisions would apply in relation to Case Study 2: Organ and Tissue Retention following Post-Mortem. In that instance, these provisions would legitimate the taking of tissue without the consent of the families, would give them no means of objecting or having the tissue returned. Only the New South Wales provisions prevent subsequent use, and limit the taking of tissue to the legitimate, authorised purpose of conducting the post-mortem in the absence of consent. In this, the majority of the provisions are problematic in their failure to take account of individual interests in control, familial interests and those of indigenous communities.

³⁷⁶ National Pathology Accreditation Advisory Council, *Guidelines for the Facilities and Operation of Hospital and Forensic Mortuaries*, NPAAC, Melbourne, 2004, [11.2.1].

³⁷⁷ See Chapter Five, section 3.

3.2.2 Coronial Post-Mortems

Coronial post-mortems are regulated by the Coroners Acts in each state and territory.³⁷⁸

Coronial post-mortems may be carried out if a reportable death has occurred and the coroner investigating that death believes that a post-mortem is necessary to determine its cause.³⁷⁹ Post-mortems are then conducted by either the State Forensic Pathologist, or a medical practitioner or pathologist directed to do so by the coroner.

In some states and territories, the next of kin may object to the post-mortem, however the coroner is authorised to conduct a post-mortem despite such objections. If the coroner decides to conduct the post-mortem despite objections, he or she must provide the next of kin with written notice of this decision and must not conduct the post-mortem for 48 hours. During this time, the next of kin may apply to the Supreme Court to prevent the post-mortem.³⁸⁰

Some states and territories also make provision for how tissue removed during the post-mortem is to be dealt with. These provisions vary widely between states and territories. In South Australia and the ACT, the legislation is entirely silent on the removal, retention and disposal of tissue removed during the post-mortem. In Tasmania, Victoria and the Northern Territory, in accordance with instructions from the coroner, the person performing the post-mortem may retain and preserve 'any material' that appears to them 'to relate to the cause of the death or the circumstances surrounding the death'³⁸¹ and 'such parts of the body as he or she considers necessary in order to determine the cause of death or the circumstances surrounding the death.'³⁸² However, in these states the legislation is silent on what is to be done with this material once the cause of death has been established, though some state that the tissue is to be retained for the period directed by the coroner.³⁸³ This, however, is not a prohibition on retention or secondary use.

³⁷⁸ *Coroners Act 1995* (Tas); *Coroners Act 1985* (Vic); *Coroners Act 1980* (NSW); *Coroners Act 2003* (Qld); *Coroners Act 2003* (SA); *Coroners Act 1996* (WA); *Coroners Act 1997* (ACT); *Coroners Act 1993* (NT).

³⁷⁹ *Ibid* ss 21, 36(1). See also *Coroners Act 1985* (Vic) ss 15, 22; *Coroners Act 1980* (NSW) ss 13, 48; *Coroners Act 2003* (Qld) ss 11, 19; *Coroners Act 2003* (SA) ss 21, 22; *Coroners Act 1996* (WA) ss 18, 34; *Coroners Act 1997* (ACT) ss 13, 21; *Coroners Act 1993* (NT) ss 14, 20.

³⁸⁰ *Ibid* s 38. See also *Coroners Act 1985* (Vic) s 29; *Coroners Act 1980* (NSW) s 48A, B; *Coroners Act 1996* (WA) s 37; *Coroners Act 1993* (NT) s 23. There is no provision for objection in Queensland and ACT, however coroners are required to consider the distress to the next of kin when determining whether a post-mortem is absolutely necessary. See *Coroners Act 2003* (Qld) s 19; *Coroners Act 1997* (ACT) s 28.

³⁸¹ *Ibid* s 36(3).

³⁸² *Ibid* s 36(4). See also *Coroners Act 1985* (Vic) s 27(2) and *Coroners Act 1993* (NT) s 20(2) which contain similar wording to these subsections.

³⁸³ See, eg, *Coroners Act 1985* (Vic) s 27(2).

It appears, then, that in these states and territories tissue removed during post-mortem may be used for other purposes, including research as there is no prohibition on doing so. This approach to the removal and use of tissue is subject to the same concerns about lack of consent, lack of respect for individual autonomy and familial concerns as noted above in relation to non-coronial post-mortems.

In Western Australia, tissue may be removed to investigate the cause of death or with the written permission of the deceased.³⁸⁴ The legislation is silent on whether this tissue may be retained and used for other purposes, stating only that it may be dealt with in accordance with the coroner's directions and any relevant guidelines.³⁸⁵ It is possible, then, in the absence of prohibition that secondary use may be permitted, and hence is subject (where the removal is not with the deceased's consent) to the same concerns noted above in relation to the other states.

The Western Australian legislation also provides specifically for tissue to be removed during post-mortem for the purpose of therapeutic, medical, teaching or scientific use with the consent of the next of kin where there is no evidence that this would be contrary to the wishes of the deceased.³⁸⁶ This provision is therefore similar to those in the Human Tissue Acts relating to donation of tissue from the deceased. While in terms of consent, they do reasonably protect the interests of the deceased and the next of kin, they are subject to the same concerns about storage, subsequent use, transfer and destruction raised in relation to donations for research under the Human Tissue Acts discussed above.

In New South Wales, tissue may be removed during the post-mortem and retained for the purposes of investigating the person's death, investigating an offence or for the purposes of proceedings relating to any offence.³⁸⁷ This provision authorises the retention of such tissue, and its secondary use where an authority (such as consent by next of kin) is given under the New South Wales Human Tissue Act. Again, this provision is subject to the same potential concerns about subsequent use noted above in this section.

³⁸⁴ *Coroners Act 1996* (WA) s 34(3).

³⁸⁵ *Ibid* s 34(6).

³⁸⁶ *Ibid* s 34(3)(c), 34(4).

³⁸⁷ *Coroners Act 1980* (NSW) s 48AA(1).

However, the New South Wales legislation goes one step further than the legislation in other states and territories and expressly permits the use of tissue slides and blocked created for the purposes of the post-mortem to be used for medical, scientific or therapeutic purposes without the consent of the deceased or the next of kin.³⁸⁸ In doing so, the legislation takes a pragmatic approach to the subsequent use of such tissue and does at least clarify that such use is lawful. However, as noted a number times in the course of this chapter, this may be considered problematic as it involves non-consensual use of a person's tissue and because it may raise privacy issues for the next of kin if the tissue is tested in some way.

In each of these states and territories, no provision is made for the return of any tissue to the next of kin for burial. Only the Queensland legislation does so. The legislation does not explicitly provide for the removal of tissue, but appears to assume that this will be part of the post-mortem process. However, it does provide that where tissue is removed, if that tissue is a whole organ or foetus, the coroner must be informed before the body's release. The coroner is then required to inform the next of kin that this has occurred before releasing the body.³⁸⁹ At six monthly intervals, the coroner must review whether it is necessary to continue retention of the organ or foetus, and if not, dispose of it.³⁹⁰ If any tissue, including an organ or foetus, is to be disposed of, it must be buried (except for tissue blocks and slides which must be retained indefinitely³⁹¹) or, where the next of kin has informed the coroner of their wish to bury it, be returned to the family for burial.³⁹² These provisions, unlike those in all other states and territories, are a significant protection of the interests of families and are also some protection from the subsequent problematic use of removed tissue.

The coronial post-mortem provisions in each state and territory are open to many of the objections made above to the retention of tissue where there is no clear statement on how and when it may be subsequently used, if at all. They also do not take much account of the possible privacy implications of continued retention, and in most cases fail to address familial concerns about the fate of removed tissue. Further, as only the Tasmanian legislation includes provisions to allow Aboriginal communities to determine if the remains are Aboriginal (if so, the post-mortem will be subject to special

³⁸⁸ Ibid s 48AA(2)(b)(v).

³⁸⁹ *Coroners Act 2003* (Qld) s 24(2), (4).

³⁹⁰ Ibid s 24(5).

³⁹¹ Ibid s 24(6).

³⁹² Ibid s 24(8).

provisions)³⁹³, the coronial legislation fails to take account of indigenous community concerns about the retention of remains.

3.3 Anatomical Use of Bodies

Donation of bodies for the teaching of anatomy is covered by the Human Tissue Acts in most states and territories, and by the Anatomy Acts in others. The provisions in each state and territory are largely the same. Donation must be consensual and must be made for the purpose of anatomical dissection of the body for the purposes of study and teaching. For example, under the *Anatomy Act 1964* (Tas) donation is authorised where the deceased has consented either in writing, or orally in the presence of two witnesses, to the donation or the deceased has nominated a legally-qualified medical practitioner to make an anatomical examination of his or her body.³⁹⁴ As with post-mortem examinations allowed under the Act, an examination may also be authorised by a person in lawful possession of a body, but this provision is subject to the absence of objections from both the deceased and near relatives such as spouses.³⁹⁵ Any body on which an anatomical examination is performed must be buried or cremated within thirty months of the exam, as must 'all human remains resulting from, or remaining after, that examination'.³⁹⁶ This addresses the concerns about retention noted in previous sections.

The provisions in the other states differ in some respects. In some states, the next of kin may also consent to the donation of a relative's body for anatomical study.³⁹⁷ In Western Australia, the donation of bodies will be prohibited where the next of kin object, even if the deceased has consented.³⁹⁸

These provisions, which largely follow the consent model used throughout the Act are

³⁹³ *Coroners Act 1995* (Tas) s 23.

³⁹⁴ *Anatomy Act 1964* (Tas) s 9(1). See also *Human Tissue Act 1982* (Vic) ss 32(1), (2), 34; *Anatomy Act 1977* (NSW) ss 8(1), 8A(1); *Transplantation and Anatomy Act 1983* (SA) ss 29(1), (2), 32; *Transplantation and Anatomy Act 1979* (Qld) s 33; *Human Tissue and Transplantation Act 1982* (WA) s 10 and *Transplantation and Anatomy Act 1978* (ACT) s 39. The Northern Territory has not passed legislation regulating the donation of bodies for anatomical study purposes.

³⁹⁵ *Anatomy Act 1964* (Tas) ss 9(2), 12(1). See also *Human Tissue Act 1982* (Vic) ss 32(5), 34; *Transplantation and Anatomy Act 1983* (SA) ss 29(3), 32; *Human Tissue and Transplantation Act 1982* (WA) s 9; *Transplantation and Anatomy Act 1978* (ACT) s 37(1); *Transplantation and Anatomy Act 1979* (Qld) s 29(3).

³⁹⁶ *Anatomy Act 1964* (Tas) s 13(3). See also *Anatomy Act 1977* (NSW) ss 8, 12 (which provide that bodies are to be disposed of in accordance with the wishes of the deceased's family, though the Act is silent as to whether removed tissue is to be included). In Victoria, no provision is made, however, for the disposal of the body or its remains, though the Act does allow for regulations to be created to do so. See *Human Tissue Act 1982* (Vic) s 37(1)(g). The other Acts are also silent.

³⁹⁷ *Human Tissue Act 1982* (Vic) ss 32(3), 34; *Transplantation and Anatomy Act 1979* (Qld) ss 31(3), 32(1); *Anatomy Act 1977* (NSW) ss 8(3), 8A(3), (4); *Anatomy Act 1930* (WA) s 9.

³⁹⁸ *Human Tissue Act 1983* (NSW) s *Human Tissue and Transplantation Act 1982* (WA) s 11.

not subject to concerns about consent, as the purpose for which the body is donated is clear. The major concern is that in some states there is no provision for the return of body parts. This will leave relatives in those states without any remedy or means to gain control of retained parts, unless the anatomy school agrees to return them. This may occur, but the problem is that if the anatomy school does not agree, the relatives have no legal grounds on which to require the parts to be returned. Therefore, the Acts would again fail families in the instances outlined in Case Study 1: Collecting Aboriginal Remains and Case Study 2: Organ and Tissue Retention following Post-Mortem (by analogy).

4. PROHIBITION AGAINST TRADE IN TISSUE

Each State and Territory has legislated against trade in human tissue, both before and after death, either by direct prohibition, and/or by rendering any contract for such sale void.³⁹⁹ These provisions apply to all tissue, not only tissue donated under the Acts. The Tasmanian legislation offers a typical example, with section 27(1) providing that:

Subject to this section, a person shall not enter into a contract or arrangement under which a person agrees, for valuable consideration, whether given or to be given to himself or to another person, to the sale or supply of tissue from his body or from the body of another person, whether before or after his death or the death of the other person, as the case may be.⁴⁰⁰

In some states it is a further offence to advertise the sale or purchase of tissue.⁴⁰¹ It is clear then, that sale of tissue is illegal, even by the person from whom it was removed. There are, however, certain exceptions to the general prohibition.

4.1 Ministerial Approval Exception

In all states and territories save Western Australia, trade in tissue is permissible with authorisation from the relevant government Minister.⁴⁰² This authorisation must be in writing and be based on the Minister's belief that there are special circumstances that justify the approval of trade. This exception allows tissue sale as provided already in the section, namely where approved by a medical practitioner for therapeutic, scientific or

³⁹⁹ *Human Tissue Act 1985* (Tas) s 27; *Human Tissue Act 1982* (Vic) ss 38, 39; *Human Tissue Act 1983* (NSW) s 32; *Transplantation and Anatomy Act 1983* (SA) s 35(1)–(6); *Transplantation and Anatomy Act 1979* (Qld) s 35(1)–(6); *Human Tissue and Transplantation Act 1982* (WA) s 29; *Transplantation and Anatomy Act 1978* (ACT) s 44 and *Human Tissue Transplant Act 1979* (NT) s 24.

⁴⁰⁰ *Human Tissue Act 1985* (Tas) s 27(1).

⁴⁰¹ *Transplantation and Anatomy Act 1979* (Qld) s 35(7); *Transplantation and Anatomy Act 1983* (SA) s 35(7); *Human Tissue Act 1982* (Vic) s 40; *Human Tissue and Transplantation Act 1982* (WA) s 30.

⁴⁰² *Human Tissue Act 1985* (Tas) s 27(4); *Human Tissue Act 1983* (NSW) s 32(4); *Transplantation and Anatomy Act 1979* (Qld) s 35(6); *Transplantation and Anatomy Act 1983* (SA) s 35(6); *Human Tissue Act 1982* (Vic) s 39(2); *Transplantation and Anatomy Act 1978* (ACT) s 44(4); *Human Tissue Transplant Act 1979* (NT) s 24(3).

medical use.

4.2 Processing Exception

Similarly, most States allow for sale and purchase of tissue where the tissue itself has undergone some form of what is generally referred to as 'treatment or processing'.⁴⁰³

For example, section 27(2) of the Tasmanian Human Tissue Act provides that:

Subsection (1) does not apply to or in relation to the sale or supply of tissue other than blood or any of its constituents if the tissue has been subjected to processing or treatment and the sale or supply is made for use, in accordance with the directions of a medical practitioner, for therapeutic or scientific purposes.⁴⁰⁴

Hence, the processed tissue must only be traded for therapeutic, medical or scientific purposes in accordance with the directions of a medical practitioner. The terms 'treatment', 'processing', 'therapeutic', 'medical' and 'scientific' are not defined in the legislation.

Two fundamental criticisms may be levelled at these provisions and their exclusions. First, the exclusion based on processing effectively renders the prohibition useless. In not defining what will constitute 'processing' or 'treatment', the legislation leaves much scope for argument as to what will fall within this exclusion. Almost all tissue that is removed will be processed in some way to preserve it, for example, by embedding it in paraffin, through vitrification or by preserving it in formalin. For example, if tissue taken from the brain of a deceased person is to be of value to many forms of research, it must first be embedded in wax to enable the material to be sliced thinly enough for observation under a microscope. How far such preservation techniques, and treatments to facilitate research equate to processing is as yet unclear. No case has been decided on this issue in Australia, and the only relevant common law is the exception to the rule against property rights in human tissue. The exception holds that tissue may become the subject of property rights following the application of human skill or work, but thus far this exception has only been accepted where some process of embalming or preservation in formalin solution has occurred. These cases are of little aid in determining what is meant by 'processing' or 'treatment' as their focus is specifically on preservation, rather than the broader concept of processing. They are also themselves in

⁴⁰³ *Human Tissue Act 1985* (Tas) s 27(2); *Human Tissue Act 1983* (NSW) s 32(2); *Transplantation and Anatomy Act 1979* (Qld) s 35(3); *Transplantation and Anatomy Act 1983* (SA) s 35(3); *Human Tissue and Transplantation Act 1982* (WA) s 29(4); *Transplantation and Anatomy Act 1978* (ACT) s 44(2); *Human Tissue Transplant Act 1979* (NT) s 24(4). In Victoria, the same provisions apply but Ministerial approval is also required. See *Human Tissue Act 1982* (Vic) ss 38(2), 39(2).

⁴⁰⁴ *Human Tissue Act 1985* (Tas) s 27(2).

disagreement over what will constitute preservation.⁴⁰⁵

Given the very broad possible meaning of processing or treatment, the provision may allow the sale of tissue in many instances. It effectively allows hospitals and medical practitioners to allow on-selling of tissue for any general scientific or therapeutic purpose. This would include selling tissue to other hospitals, to pharmaceutical companies for use in developing and testing treatments, and to researchers. Depending on how it is interpreted, the exception can arguably render the general prohibition on sale of tissue fairly meaningless.

Applying the exception to the case studies brings the potential problems this may cause into sharp focus. Samples retained from post-mortem (Case Study 2: Organ and Tissue Retention following Post-Mortem), leftover from organ or tissue transplantation (Case Study 3: Organ Transplantation), retained following testing (Case Study 4: Hobart Pathology, Case Study 8: SA Clinical Genetics Service), newborn screening cards (Case Study 5: Newborn Screening Card Collection), tissue taken for research (Case Study 6: Tissue in Australian Research, Case Study 9: Menzies Centre for Population Research) and tissue donated for transplant or therapeutic use (Case Study 7: Donor Tissue Bank of Victoria) could all be legitimately sold under this exception if certified by a medical practitioner.⁴⁰⁶ This potentially allows a wide range of tissue to be sold without the consent, or even the knowledge of the individual from whom it was taken. It would give rights to persons other than the person who took it to use it as they chose. Particularly problematic is the fact that the Acts do not cover how the buyer of tissue may use the tissue, only that it must be sold for therapeutic, scientific purposes. As discussed above, this lack of specificity means that the new possessor of the tissue could use it in a very broad range of ways, and do so without any need to consult the original donor.

These provisions, by sidestepping any implied limits on the use of tissue based on the nature of the consent (for example, where the donor specifies in their consent that it may be used only for some research purposes), further undermine any respect for individual autonomy in relation to one's tissue. Also, as the confidentiality provisions

⁴⁰⁵ See further Chapter Seven, sections 1, 3 and 4 which examine the related concept of 'preservation' used in the common law cases.

⁴⁰⁶ It is likely that samples retained in the other case studies could also be sold, however these are less likely to be held in a medical institution and therefore their certification by a medical practitioner might not be available, although a broad reading of the section would mean that any practitioner could authorise the sale and the exception would apply.

allow for information about the individual to be released with the tissue if it is to be used for a research purpose, these provisions may give the new possessor considerable scope to use the tissue and information in a way that invades that individual's privacy.⁴⁰⁷ Finally, in allowing the transfer of tissue outside the hospital from where it was taken, an individual's or a relative's capacity to later exert any control over the tissue is lessened, and they are denied the possibility of negotiating control of the tissue with the institution that originally removed it.

A second criticism of these exceptions is that they wholly exclude the individual from the sale of the tissue. They only afford this right to a person in possession of tissue who is able to have the sale certified by a medical practitioner. Hence, unless a patient is able to organise a sale through his or her doctor (which is unlikely to occur), he or she is largely prohibited from enjoying any profits from the use of his or her tissue. It is clearly unjust to allow one party, which is not even the party from whom the tissue came and who has intrinsic links to it, to profit from while denying the individual from whom it came. The arguments around allowing individuals to sell their own body parts are canvassed in Chapter Twelve, however it is sufficient to point out that these exceptions unjustly prevent individuals from making the same profits from themselves that others may make from them—and may make from them without needing their consent.

5. CONFIDENTIALITY PROVISIONS

Under the Human Tissue Acts, designated officers who authorise the removal of tissue, certifying medical practitioners, practitioners who remove tissue or perform transplants and others listed in the Acts may not disclose any information or release any documents that could make known the identity of a person, living or dead, from whom tissue has been removed or into whose body tissue has been transplanted. In Tasmania, South Australia, Queensland, and Western Australia donations of blood are excluded. All the Acts include a number of exceptions allowing release of identifying information by order of the court; for medical administration or bona fide medical research; with consent from the donor; or when the disclosure is made in privileged circumstances.⁴⁰⁸

This aspect of the legislation has implications for medical research, as in accordance

⁴⁰⁷ On the confidentiality provisions in the Human Tissue Acts, see below section 5.

⁴⁰⁸ *Human Tissue Act 1985* (Tas) s 31; *Human Tissue Act 1982* (Vic) s 45; *Human Tissue Act 1983* (NSW) s 37; *Transplantation and Anatomy Act 1983* (SA) s 39; *Transplantation and Anatomy Act 1979* (Qld) s 39; *Human Tissue and Transplantation Act 1982* (WA) s 34; *Transplantation and Anatomy Act 1978* (ACT) s 49 and *Human Tissue Transplant Act 1979* (NT) s 28.

with the exceptions identifying information can be released without consent where medical research is bona fide. Each of the exceptions operates separately, therefore either consent or research need provides an exception to the provision against the release of information.

While the provisions do address many of the privacy concerns that would arise in donation of tissue, they probably do not go far enough. As with the other provisions in the Acts, they do not protect previously acquired tissue, or (except in New South Wales) tissue removed during surgery or therapy. They would therefore not cover a range of samples discussed in the case studies, including newborn screening cards, which include the source individual's name as well as those of their mother and father, and their place of birth (see Case Study 5: Newborn Screening Card Collection); pathology samples, although these are protected through guidelines, they do not have legal force and hence do not carry sanctions nor provide remedies to those whose privacy is breached (see Case Study 4: Hobart Pathology); or tissue taken for genetic testing (see Case Study 8: SA Clinical Genetics Service). In these situations, beyond hospital policies, there are no legal requirements to protect the privacy of the information attached to these samples. However, privacy legislation will also cover the release of this information, which is discussed in the following section.

Despite the enactment of privacy legislation, concerns about the confidentiality of *samples* remain as the privacy legislation passed by the Commonwealth and in some states largely does not cover samples, but only information. Only newborn screening cards are likely to be covered, as the sample is an integral part of a health record, which is covered by the legislation.⁴⁰⁹ In most cases, however, the lack of individual control provided by the Acts fails to adequately protect individual interests.

5.1 Privacy Protection in Australia

It is beyond the scope of this thesis to comprehensively examine the Australian privacy regime. However, it should be noted that the ALRC and the Australian Health Ethics Committee (ALRC/AHEC) have together examined the application of privacy legislation to tissue samples in their recent report, *Essentially Yours: The Protection of Human Genetic Information*, and concluded genetic samples are not covered by the legislation, although newborn screening cards were found to be covered and

⁴⁰⁹ Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96, ALRC, Sydney, 2003, [8.20].

protected.⁴¹⁰ Some ethical guidelines on privacy protection have also been released by the National Health and Medical Research Council under s 95A of the Act. These are examined in Chapter Five.

The *Privacy Act 1988* (Cth) (*Privacy Act*) covers information held in Commonwealth and ACT public sector organisation,⁴¹¹ which are subject to the legally binding Information Privacy Principles (IPPs).⁴¹² The IPPs cover collection, storage, use and access to 'personal information' stored in 'records' held by these agencies. Following amendment, the *Privacy Act* also covers organisations, which include partnerships, unincorporated associations and bodies corporate.⁴¹³ Organisations holding personal or health information must comply with the National Privacy Principles (NPPs).⁴¹⁴ The IPPs and NPPs create a general scheme to protect the privacy of information by requiring, among other things, that

- the collection of information is limited to lawful, necessary and fair purposes;
- record-keepers inform the individual to whom information relates that it has been collected;
- information is stored securely and unauthorised release of information is prevented as far as possible;
- record-keepers enable individuals to whom information relates the ability, as far as possible, to ascertain whether information is held, the nature of the information and the purposes for which it is held;
- record-keepers inform individuals of steps that can be taken to access information;
- record-keepers allow access by the individual to the information where authorised;
- record-keepers limit the use and disclosure of information to purposes to which the individual has consented, or only as required by law or where the record-keeper believes on reasonable grounds that use of the information for that other purpose is necessary to prevent or lessen a serious and imminent threat to the

⁴¹⁰ Ibid, Ch 8, especially [8.20]. See also the arguments in L Skene, 'Access to and Ownership of Blood Samples for Genetic Tests: Guthrie Spots' (1997) 5 *Journal of Law and Medicine* 137.

⁴¹¹ Some states and territories have also enacted privacy legislation. See *Privacy and Personal Information Protection Act 1998* (NSW); *Health Records Act 2001* (Vic); *Information Privacy Act 2000* (Vic); *Health Records (Privacy and Access) Act 1997* (ACT).

⁴¹² *Privacy Act 1988* (Cth) s 15. The IPPs are laid down in s 14 of the Act.

⁴¹³ *Privacy Amendment (Private Sector) Act 2000* (Cth). See *Privacy Act 1988* (Cth) s 6C for a definition of 'organisation' under the *Privacy Act*.

⁴¹⁴ *Privacy Act 1988* (Cth) s 16C. The NPPs are laid down in Sch 3 of the Act.

life or health of the individual concerned or another person.⁴¹⁵

Applying these principles strictly to human tissue samples would require some adaptation. However, if adapted and applied to samples, they would prevent considerable misuse of tissue. They would potentially prevent unauthorised transfer of samples to persons other than the individual from whom they were taken (the disclosure and access restrictions). This could prevent unauthorised access and use by employers or insurance companies using samples to generate information about an individual's health. In this way, they could be used to prevent some discriminatory uses of tissue samples by preventing the initial testing.

They would also provide a mechanism for generally preventing access by family members to tissue samples, save where the relative justifiably needed access for the sake of their own health. This could be a successful mechanism to balance familial interests in tissue with individual desires to maintain privacy. Further, they would ensure that individuals are aware that their samples are held and of how they are being used. As samples could only be used for purposes that have been consented to, this could be a means to restrain non-consensual use.

Finally, unlike the Human Tissue Acts, the *Privacy Act* provides injunctive remedies against those who contravene the IPPs or NPPs.⁴¹⁶ Such remedies would provide individuals with a means to restrain unauthorised use, storage and disclosure of their samples which would be a significant improvement on the current framework's approach.⁴¹⁷

However, applying adapted privacy principles to human tissue would not address all the concerns about human tissue use. It would not regulate the sale of tissue. As currently framed, the *Privacy Act* provides injunctive remedies—it does not provide a mechanism that could be used to regain possession of tissue samples. Therefore, the scheme would not assist Aboriginal communities seeking the return of remains nor families trying to gain possession of retained organs. The scheme also does not appear to have the

⁴¹⁵ *Privacy Act 1988* (Cth) s 14. This list is based on the IPPs laid down in this section. The NPPs lay down similar requirements, although they do differ in some respects however it is not necessary to enter into a discussion of these differences here, as the general effect is similar.

⁴¹⁶ *Privacy Act 1988* (Cth) s 98.

⁴¹⁷ For a fuller discussion of the benefits of extending privacy legislation protection to genetic samples, see Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours*, ch 8.

capacity to deal with rights to abandoned tissue, and might create significant administrative burdens for researchers using and transferring tissue in research. Finally, the scheme does not apply to information (or samples) collected prior to the commencement of the *Privacy Act* and therefore would not provide protection for samples removed and stored before 1988.

For these reasons, the scheme would require significant, although not insurmountable amendment to achieve address these problems. It might be that some uses of tissue strain the limits of what could properly be called privacy law—to the point where it comes to resemble a property approach, because it will be focused on outlining rights of use, possession, transfer and the like in relation to an object.

It should be noted, also, that arguably the New South Wales *Privacy and Personal Information Protection Act 1998* (NSW) does cover samples. Section 4(2) of the Act defines personal information to include ‘such things as an individual’s fingerprints, retina prints, body samples or genetic characteristics’. The Information Protection Principles in the Act, which are similar to the IPPs, may therefore lend some protection to samples held in New South Wales. However, this is no solution to the concerns in relation to tissue in other states, and the application of these principles does not appear to be well adapted to samples. Therefore, this Act’s scheme is open to the same concerns noted above in relation to the potential application of the *Privacy Act*.

Following their inquiry, the ALRC and AHEC subsequently recommended that the Commonwealth, states and territories enact legislation to provide legally enforceable privacy standards for handling genetic samples, including in relation to the collection, storage, use and transfer of samples; and that the privacy legislation should be amended to cover samples.⁴¹⁸ However, as these recommendations have yet to be implemented, the issues outlined above remain live.

6. OVERALL EFFECTIVENESS OF THE HUMAN TISSUE ACTS

The foregoing discussion has identified a range of problems raised by the Human Tissue Acts, some of which apply to a number of different provisions in the Acts. To sum up, these concerns include issues of scope (including the exclusion of many types of tissue); perpetuating outmoded distinctions between tissues that are no longer useful; failure to

⁴¹⁸ Ibid, ch 8, Recommendations 8–1 – 8–4.

fully promote individual autonomy in relation to samples, particularly with regard to the future use of samples; failure to provide individual remedies for misuse of tissue; failure to protect individual privacy adequately; unjust and unreasonably wide provisions for the sale of tissue; and failure to accommodate familial and indigenous community interests in the use of tissue.

In addition, the Acts do not address some uses of, and interests in, tissue. They do not provide for access to samples for legitimate purposes, for example by a family member who may need access to test a sample for their own health care purposes. They do not include any directions on when and how tissue may be stored, transferred or destroyed, hence failing to cover the future use of tissue sufficiently.⁴¹⁹ They also do not deal with other interests in tissue, such as police interest in samples for forensic purposes. While the Acts were not intended to cover all uses of tissue, as they are the major legislation covering tissue these gaps are not so much failings of the Acts themselves, as general failings by the legal system to deal with the numerous current uses of tissue.

In a general sense, the Acts favour researcher interests over those of individuals and community groups. The Acts take an open approach to research use of tissue, by excluding much tissue from their ambit, by including broad consent provisions and by not covering subsequent re-use of tissue. To some degree this is a good, as it allows researchers to use tissue without fear of sanction, thus promoting medical research and the development of new tests and treatments, which in turn benefit the community. However, the Acts do so at the expense of individual interests in autonomy and privacy, by inadequately promoting individual control of excised tissue and by failing to provide remedies for those whose tissue is misused and retained.

These gaps and this failure to adequately protect individual interests in tissue highlight the need for the Acts to be reviewed. They also demonstrate that the scheme developed to address tissue use in the late 1970s can no longer effectively manage all the use of, and interests in tissue in the present day. While Chapter Five will show that ethics guidelines have gone some way to remedying these gaps, many areas of tissue use remain unregulated. Further, the defined but limited scope of the Acts and the guidelines mean that they are largely incapable of responding to newer uses of tissue

⁴¹⁹ It should be noted, however, the New South Wales Human Tissue Act does not provide for the retention and use in research of small samples of tissue in blocks or on slides. See *Human Tissue Act 1983* (NSW) s 34(1)(b1).

previously not considered. By failing to adopt a broad-based, principled approach that can apply in a range of situations, the Acts, even if amended, will not be sufficient to respond to the growing use of tissue. Further, in light of these new uses, there is a need to reconsider the original thinking behind the Acts (such as in relation to tissue sale), and to reconsider whether in fact there is a need to give tissue some legal status. This question, and other legal approaches to tissue use, will be considered in Part III following the discussion in Chapter Five of the various guidelines that also regulate tissue use in Australia.

Chapter Five

GUIDELINES

In Australia, much research and testing involving human tissue is regulated not by legal instruments, but by a collection of ethical and practice guidelines and policies. While these do not have binding legal force, they are highly influential in shaping tissue use practice. They work in tandem with the legal regulatory mechanisms, however unlike the Human Tissue Acts they have been developed and reshaped over the past two decades to respond to changes in practice and approach in the professions using tissue, and to changes in ethical thinking about the appropriate treatment of tissue. This chapter examines some of these non-legislative ethical and practice guidelines that affect how tissue may be treated, and also draws some conclusions on how these operate in conjunction with the Human Tissue Acts.

There is a very broad range of guidelines that may fall into this general category, ranging from guidelines released by national oversight bodies such as the National Health and Medical Research Council (NHMRC), the National Association of Testing Authorities (NATA) and the National Pathology Accreditation Advisory Council (NPAAC) to policies released by professional societies like the Human Genetics Society of Australasia (HGSA) and the Royal Society of Pathologists of Australasia (RCPA) to clinical practice and transplantation guidelines to internal guidelines developed by hospitals, universities and research organisations.

It is beyond the scope of this thesis to examine each of these in detail. For this reason, only a number are considered here. These are the ethical guidelines for research produced by the NHMRC, the pathology laboratory guidelines and policies produced by NATA, NPAAC and the RCPA and the policies for newborn screening card retention produced by the HGSA. These sources are chosen because they cover the major uses of human tissue, namely research use and pathology testing, they have national effect and they are influential on practice due to the organisation that has released them.

This chapter will first examine the general legal effect of guidelines, followed by an analysis of each set of guidelines and policies in turn. The approach to analysing these

guidelines is similar to that taken in the previous chapter, as it will involve outlining each guideline followed by a general analysis and then the application of the guideline to the case studies to consider whether the guideline is problematic or whether gaps exist in the framework. To avoid repetition, however, this chapter will not reiterate the general concerns in relation to a consent-based approach to tissue regulation, as these were covered in the previous chapter. It will also not go through each section of the guidelines to give an exhaustive overview, but instead structure the analysis around general approaches taken in the guidelines. Where necessary, specific sections or issues will be examined separately.

1. LEGAL EFFECT OF GUIDELINES

Guidelines released by non-regulatory bodies do not have the force of law and therefore are not legally binding.¹ This statement is largely self-evident; however it is worth noting a number of judicial decisions that have considered the meaning of ‘guidelines’ in various contexts. In the High Court decision in *Norbis v Norbis*,² (*Norbis*) which considered the legal validity of guidelines employed by the court system to constrain judicial discretion and how far the power of the Court should be bound by them, Mason and Deane JJ held guidelines to denote ‘rules or standards which are not binding’.³ Similarly, in the later case of *Smoker v Pharmacy Restructuring Authority and Others*,⁴ (*Smoker*) the Federal Court considered whether certain guidelines made under the *National Health Act 1958* (Cth) should be regarded as binding rules. The guidelines at issue were found to be binding, due to the wording of the legislation which required them to be binding. However, what is relevant in this context is the disclaimer the Court made in relation to this finding. The Court commented that the guidelines at issue were not what would normally be considered ‘guidelines’. In that decision, citing *Norbis* with approval, Justice Hill noted a distinction between ‘giving guidance in the form of guidelines and binding principles of law’⁵ and held that what Parliament had called ‘guidelines’ in the instant case should be more properly referred to as ‘rules’ only because of the wording of the legislation.⁶

¹ By contrast, guidelines released by Commonwealth, state and territory regulatory bodies may have legal force, however this will be determined by the powers and functions of the body and the force it ascribes to them. See further Australian Law Reform Commission, *Principled Regulation: Civil and Administrative Penalties in Australian Federal Regulation*, ALRC 95, ALRC, Sydney, 2002, [6.134]–[6.135].

² (1985–86) 161 CLR 513.

³ (1985–86) 161 CLR 513 at 519–20 per Mason and Deane JJ.

⁴ (1994) 53 FCR 287.

⁵ *Ibid*, [33] per Hill J.

⁶ *Ibid*, [44] per Hill J.

This said, ethical and practice guidelines may have legal effect in other ways. In particular, they might be admissible as evidence of a standard of conduct that is relevant in determining whether a person or organisation has failed to meet the required duty of care and acted negligently. Indeed, the development of legislation allowing clinical practice guidelines to be admissible evidence of the standard of care in providing information to patients has been suggested.⁷

As they do not have legal force, and cannot provide for legal sanctions, no offence is committed by a failure to comply with guidelines, and non-compliance is therefore not subject to legal penalty. However, this lack of legal force is not a reason to discount the effect of guidelines in shaping behaviour in relation to human tissue. Their possible role as evidence of a standard of care, coupled with the influence of the body that produces them and any sanctions open to it (these are discussed below), mean that guidelines can and do significantly affect how human tissue is treated in Australia.

2. NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL GUIDELINES

The NHMRC was originally established by executive order in 1936 to replace the Federal Health Council. It was created to promote the health of the Australian people and to co-ordinate and direct research into the causes of disease. It was reconstituted as a statutory corporation in 1992 by the *National Health and Medical Research Council Act 1992* (Cth) (NHMRC Act). The legislation was passed to protect the independence of the NHMRC and to ensure that its actions were open and accountable.⁸

The functions of the NHMRC, as prescribed in s 7 of the NHMRC Act are to inquire into, issue guidelines on, and advise the community on, matters relating to the improvement of health, the prevention, diagnosis and treatment of disease, the provision of health care, public health and medical research and ethical issues relating to health. It may also advise and make recommendations to the Commonwealth, the states

⁷ New South Wales Law Reform Commission, Victorian Law Reform Commission and Australian Law Reform Commission, *Informed Decisions about Medical Procedures*, ALRC 50, ALRC, Sydney, 1989, Recommendation 3. To date, this recommendation has not been implemented. See Australian Law Reform Commission, *Annual Report 2002–03*, ALRC 97, ALRC, Sydney, 2004, Appendix F: Implementation Status of ALRC Reports. However, at least in relation to medical practitioners, the decision in *Rogers v Whitaker* (1992) 175 CLR 479 means that the standard of care is not determined by professional standards, but is a question of what is considered reasonable at law. Despite this, guidelines likely remain an input to determining what is relevant. The courts may take a similar approach to guidelines in relation to research or testing.

⁸ Commonwealth of Australia, *Parliamentary Debates*, House of Representatives, National Health and Medical Research Council Bill 1992 Second Reading Speech, 25 June 1992, 3988–9 (Bob Howe, MP).

and territories.⁹

As part of the NHMRC, the Australian Health Ethics Committee (AHEC) develops ethical guidelines in relation to medical research involving humans, which must be released by the NHMRC without amendment.¹⁰ Those specifically relevant to tissue use are the *National Statement on Ethical Conduct in Research Involving Humans* (National Statement),¹¹ *Guidelines for Genetic Registers and Associated Genetic Material*¹² (Guidelines for Genetic Registers) and *Values and Ethics—Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*¹³ (*Values and Ethics*).¹⁴ These guidelines are also supplemented by the general guidelines on research practice in the *Joint NHMRC/AVCC Statement and Guidelines on Research Practice* released by the NHMRC and the Australian Vice Chancellors' Committee (AVCC) in 1997 and reviewed in 2004.¹⁵ These general guidelines are discussed below in the section considering the National Statement, but do apply generally. The NHMRC has also released guidelines on privacy, which are discussed in section 2.3, although as they do not cover samples they are considered only briefly.

As discussed above, such guidelines would not have legal force. In particular relation to the NHMRC, it is clear that the guidelines it produces through AHEC are not binding and do not fall into the categories of binding rules considered in *Norbis* and *Smoker*. For example, the NHMRC Act does not set up any administrative structures for dealing with non-compliance.¹⁶ Anita Stuhmcke, though, has argued that the requirement under s 35(4) of the NHMRC Act that any guidelines 'are to be laid before each House of the Parliament within 15 sitting days of that House of the issuing of the guidelines' renders

⁹ *National Health and Medical Research Council Act 1992* (Cth) s 7.

¹⁰ *Ibid* s 8.

¹¹ National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans*, Canberra, 1999.

¹² National Health and Medical Research Council, *Guidelines for Genetic Registers and Associated Genetic Material*, Canberra, 1999.

¹³ National Health and Medical Research Council, *Values and Ethics—Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*, Canberra, 2003.

¹⁴ The NHMRC has also released a range of issues papers covering some of the ethical issues raised by the use of tissue, including the use of tissue removed at autopsy and the issues raised by Project Sunshine (see Chapter One, section 3.2). However, as these papers are only discussions of issues, rather than guidelines, they are not considered here.

¹⁵ National Health and Medical Research Council, Australian Vice Chancellors' Committee and Australian Research Council, *Joint NHMRC/AVCC Statement and Guidelines on Research Practice*, NHMRC, Canberra, 1997 (revised 2004).

¹⁶ R S Magnusson, 'The Use of Human Tissue Samples in Medical Research: Legal Issues for Human Research Ethics Committees' (2000) 7 *Journal of Law and Medicine* 390, 392.

those guidelines 'into something more than being purely ethical guidelines'.¹⁷ She reasons that as Parliament is required to examine guidelines before they are released, some form of legislative sanction in favour of the guidelines is created, although she notes that this can only be implied. This view is rejected, however, as s 35 does no more than require Parliament be made aware of guidelines before their release, and says nothing in relation to any power of veto or power to order changes. The implication is at best tenuous, especially given that the Act specifically precludes the Minister from directing the NHMRC in the performance of its functions—a clear provision to prevent executive interference with NHMRC recommendations. For these reasons, the better view is that NHMRC guidelines do not have the force of law.

However, the NHMRC employs two main mechanisms to promote compliance which are generally very effective in ensuring adherence to the guidelines. First, as major funder of medical research on humans in Australia, the NHMRC may withdraw funding from an organisation where a research project is conducted by its member that fails to comply with the NHMRC guidelines. Second, the NHMRC monitors compliance through its requirement that each organisation receiving funding establish a Human Research Ethics Committee (HREC).¹⁸ Where researchers are not affiliated with an institution, approval must still be sought from an established HREC.¹⁹ HRECs must establish prescribed procedures to consider research proposals and monitor the conduct of this research.²⁰ If research projects are not being conducted in accordance with the approved ethics protocols, that HREC may withdraw approval and recommend to the institution or organisation involved that the project be discontinued, suspended or other necessary steps taken. A researcher is then precluded from continuing the project.²¹ In addition, AHEC is required to report annually to the NHMRC on the activities of HRECs, and the NHMRC subsequently reports to the Commonwealth Parliament. The report may note any non-compliant HRECs and institutions, which further reinforces the power of this mechanism for promoting compliance.

These procedures raise the first two possible concerns about the regulation of tissue use through ethical guidelines. First, it is arguable that the lack of legal penalties for non-

¹⁷ A Stuhmcke, 'The Legal Regulation of Fetal Tissue Transplantation' (1996) 4 *Journal of Law and Medicine* 131, 135.

¹⁸ National Health and Medical Research Council, *National Statement*, Ch 2.

¹⁹ *Ibid*, [2.4].

²⁰ *Ibid*, [2.1 3]–[2.24], [2.33]–[2.38].

²¹ *Ibid*, [2.33]–[2.38], [2.44]–[2.45].

compliance may mean that researchers will not work in accordance with the guidelines—that is, the penalty for non-compliance is insufficient to ensure the guidelines are followed. However, given the fact that the NHMRC is the largest funder of medical, peer-reviewed research in Australia, this is perhaps not a significant concern.²² This is particularly so as it is the institution at which the research is conducted that may lose some or all NHMRC funding. Therefore, the institution may use its own internal mechanisms to also punish non-compliance, such as refusing to renew the employment contract of a researcher, which may add to the incentive for a researcher to comply.

It should also be noted that in their inquiry into practice and compliance in genetic research, the Australian Law Reform Commission (ALRC) and the Australian Health Ethics Committee (AHEC) reported that there has been a high level of voluntary compliance with the National Statement, noted comments that research institutions in this country appear to have supported compliance with the National Statement.²³ The ALRC/AHEC also suggested that were the NHMRC to withdraw its funding, other bodies also funding the research would likely follow suit.²⁴ This is likely given the number of other bodies involved in research in Australia that have endorsed the National Statement, including the Australian Research Council, the AVCC and many of the science and research Academies.²⁵

This concern is more reasonable in relation to research undertaken with funding from other sources that is not conducted at an institution receiving NHMRC funding, such as a private company. Although companies may choose to be bound by the guidelines, they are not required to do so and hence may conduct research as they choose. However, there are three responses to this concern. First, some journals now require researchers to demonstrate that they have ethical approval for research for their work to be published, which may encourage companies to comply (although, again this may not be a significant incentive). Secondly, as the guidelines are highly regarded, non-compliant organisations may face peer disapproval, which may be some incentive for them to comply. Thirdly, many companies conducting research are linked with public

²² See, eg, Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96, ALRC, Sydney, 2003, [14.6], [14.9]–[14.20].

²³ *Ibid*, [14.5].

²⁴ *Ibid*, [14.13].

²⁵ National Health and Medical Research Council, *National Statement*, v.

research institutions, particularly through the Cooperative Research Centres programme.²⁶ If the company does not comply with the NHMRC guidelines, this may jeopardise the public institution's funding.

The second, more important concern is that this approach to regulation of tissue does not supply an individual or group whose tissue has been misused with any remedy. The NHMRC has means to punish those who do not comply, but has not established procedures for any form of compensation to those harmed, nor made arrangements for tissue to be returned or destroyed where the source individual wishes it. The guidelines also do not provide any means to prevent future misuse of tissue if it is transferred, or of the results of the research in which the tissue played a part. Therefore, while the general interest in promoting ethically sound research is met, individual, familial and indigenous group interests in compensation or the return of tissue are not. As the Human Tissue Acts also do not provide remedies for harmed individuals, this is a serious gap in the current regulatory framework.

Applying this approach to the case studies demonstrates how this kind of gap may leave some significantly harmed and without a remedy through either law or by appeal to the guidelines are meant to ensure research is conducted appropriately. For example, the families involved in research in Case Study 15: Canavan Disease Research would have no means under either the Human Tissue Acts or the NHMRC guidelines to legally effect the return of their samples to prevent further research to which they objected, nor would they be able to prevent the later use of the results of research (that is, the restrictions on access to the resulting test). John Moore (Case Study 14: John Moore's Spleen) would find a similar lack of support.

A third concern, that the guidelines do not provide harmed individuals with any remedy against third parties who gain access to tissue is considered below in relation to the general approach taken in the National Statement.²⁷

2.1 National Statement on Ethical Conduct in Research Involving

²⁶ See Department of Education, Science and Training, Australian Government, 'Welcome to the Cooperative Research Centres Programme', *Cooperative Research Centres Australia*, <www.crc.gov.au/Information/default.aspx> at 23 October 2004.

²⁷ The ALRC/AHEC has made a number of recommendations for strengthening the HREC review process, however these have yet to be implemented. See Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours*, Ch 17. On the lack of implementation to date, see Australian Law Reform Commission, *Annual Report 2003–04*, ALRC 100, ALRC, Sydney, 2004, Appendix E.

Humans

The NHMRC National Statement was released in June of 1999 and sets ethical standards for research involving humans. Its stated purpose is ‘to provide a national reference point for ethical consideration’.²⁸ It does not purport to have any binding effect, but states that it seeks only to offer ‘guidance for rather than prescription of ethically sound research design and practice’.²⁹ However, despite these statements, compliance with the National Statement (and all other relevant NHMRC guidelines) is a condition of NHMRC funding.³⁰ The guidance in the Statement also operates in conjunction with a range of supplementary notes³¹ and the *Joint NHMRC/AVCC Statement and Guidelines on Research Practice*.³²

The Statement is based around a number of general principles, with a particular focus on the need to obtain consent from research participants. It also includes guidance on specific aspects and types of research, including genetic research and research involving collectivities. The following sections examine these general principles as they apply to tissue use, the consent approach and some of the specific guidance that is relevant to tissue use.

2.1.1 General Principles

The National Statement requires researchers to be guided by certain overarching principles of ethical conduct. These include integrity, respect for persons, beneficence and justice. They must minimise the risk of harm to participants and ensure a balance of burdens and benefits is placed upon them.³³ Beneficence requires researchers to minimise the risk of harm to participants.³⁴ Respect for persons requires researchers to have regard for ‘the welfare, rights, beliefs, perceptions, customs and cultural heritage,

²⁸ National Health and Medical Research Council, *National Statement*, 1.

²⁹ *Ibid*, 1.

³⁰ For example, recipients of Project Grants, Program Grants, Partnership Grants, Development Grants, Strategic Research Development Committee (SRDC) Grants, Transitional Institute Grants and Transitional Block Grants are required to comply with these guidelines under the Deed of Agreement for funding. See National Health and Medical Research Council, ‘Deed of Agreement—NHMRC Research Funding Schemes’, *Deeds of Agreements and Conditions of Award for 2004*, <www.nhmrc.gov.au/research/deedfund.pdf> at 23 October 2004 (at 24).

³¹ See, eg, National Health and Medical Research Council, *NHMRC Statement on Human Experimentation and Supplementary Notes: Supplementary Note 5—The Human Fetus and the Use of Human Fetal Tissue*, NHMRC, Canberra, 1983.

³² National Health and Medical Research Council, Australian Vice Chancellors’ Committee and Australian Research Council, *Joint NHMRC/AVCC Statement and Guidelines on Research Practice*, NHMRC, Canberra, 1997 (revised 2004).

³³ National Health and Medical Research Council, *National Statement*, ch 1.

³⁴ *Ibid*, [1.3].

both individual and collective, of persons involved in research'.³⁵ These principles are also laid down in the *Joint NHMRC/AVCC Statement and Guidelines on Research Practice*.³⁶

In relation to tissue, then, researchers are required to treat the people from whom it is obtained with respect and to act justly, with integrity and with the goal of beneficence in their research that uses this tissue. They must take into account any harm the use of tissue may cause the participant, with particular reference to that person's cultural background and beliefs. This demonstrates that the National Statement is premised on a requirement to ensure that individual interests are protected.

The National Statement also distinguishes between three levels of identifiability of information and material. These are:

- 1. Identified:** The information or material has data attached that allows the identification of a specific individual. Examples of identifiers include the individual's name, date of birth or address.
- 2. Potentially identifiable (coded, re-identifiable):** The information or material has had identifiers removed and replaced by a code. The code may be used to reverse the de-identification process and so re-identify the data.
- 3. De-identified (not re-identifiable, anonymous):** Information or material that has been permanently de-identified or never identified. For example, identifiers have been removed and discarded, so any code assigned the material cannot be linked back to them.³⁷

The National Statement distinguishes between the responsibilities of researchers in relation to privacy concerns on the basis of these classes.

2.1.2 Consent Approach

Under the National Statement, consent must be obtained from individuals before participation in research, except in specific circumstances outlined in the Statement. Consent must be informed and voluntary, with the potential participant to be made aware of the purpose, methods, demands, risks, inconveniences, discomforts and possible outcomes of the research. This consent must be clearly established, and where the individual is a member of a collectivity which may have concerns relating to the research, that collectivity must also provide consent.³⁸

³⁵ Ibid, [1.2].

³⁶ National Health and Medical Research Council, Australian Vice Chancellors' Committee and Australian Research Council, *Joint NHMRC/AVCC Statement and Guidelines on Research Practice*, [1.5].

³⁷ National Health and Medical Research Council, *National Statement*, 9.

³⁸ Ibid, [1.7], [1.9].

A consent-based approach is an effective means of ensuring that tissue is used in accordance with the wishes of the participant, particularly given the specific requirements laid down in the Statement in relation to consent and the uses for which it must be obtained. However, as a general regulatory approach, it still suffers from the same concerns noted in relation to the Human Tissue Acts' consent approach noted in the previous chapter, namely that it does not define any status for tissue in a general sense that can be used to determine how tissue may be treated in other circumstances. Similarly, this approach does not establish any rights for the participant in their tissue that might be asserted against those who misuse tissue. This, and the lack of legal force of the National Statement (and other ethical guidelines) mean that it does not address some of the major concerns about the legislative framework—that it does not establish rights that can be held out against all others by the source of the tissue, nor any status that might be used to determine whether others have dealt with tissue improperly.

Some of these concerns are, however, met by the specific provisions in the National Statement that do lay down in more detail than the Human Tissue Acts how tissue is to be stored, transferred and used, and how the privacy of tissue used in research is to be protected. These provisions are considered below.

2.1.3 Specific Guidance on Tissue Use

The use of human tissue samples is covered by Chapter 15 of the Statement. It excludes foetal tissue, reproductive tissue and tissue from post-mortem, stating that additional legislation or guidelines may apply to these tissues.³⁹ The chapter lists a number of types of tissue that might be used in research. These include samples collected tissue collected in hospitals and health care institutions, samples collected for diagnostic purposes and archival pathology samples. Samples that might be used would also obviously include those specifically donated for research, namely under the provisions of the Human Tissue Acts.

Consent is generally required for the use of tissue.⁴⁰ The National Statement adds more specific requirements for appropriate consent than those given in the Human Tissue Acts. It holds that the principle of respect for persons must apply in the use of tissue, and requires this to be achieved by

- providing the donor with full information about the purposes of samples

³⁹ For example, the Human Tissue Acts.

⁴⁰ National Health and Medical Research Council, *National Statement*, [15.4].

and/or the plan of the research proposal;

- consent by the donor to the use of the sample;
- the professional removal of the sample to be used;
- the provision and maintenance of appropriate and secure systems to ensure confidentiality and privacy in the recording, storage and release of data; and
- accountability in the care and usage of samples.⁴¹

In this, the National Statement essentially picks up where the Human Tissue Acts leave off by addressing some of the issues that arise when tissue is taken for research, including issues around storage, security and privacy. It also improves on the consent requirements in the Human Tissue Acts by requiring greater stringency in what will constitute sufficient consent to the donation of samples for research. The Statement requires that for consent to donation to be valid, that consent should be voluntary, specific to the purpose for which the tissue is to be used, and follow the provision of full information about the project, including advice as to whether, after completion of the research, the samples will be stored.⁴²

These requirements improve on the approach taken in the Human Tissue Acts first by requiring that the individual is fully informed not only that the sample will be used in research, but also of the nature of that research. This requirement ensures that samples will not be used in research to which the individual might object, and that they are made fully aware of the goals of the research. It may also provide individuals with the opportunity to request that their samples are not stored once the research is completed. This approach therefore provides some capacity to ensure an individual's interest in the security of their samples is protected and that they have some control over the future use of their tissue.

Applying this to the case studies demonstrates how such provisions do not address some possible concerns about tissue use. For example, in the case of John Moore (Case Study 14: John Moore's Spleen), the National Statement would have required Moore to know not only that his sample was being used in research, but also the purpose of the research. He would have been made aware that the results might be patented, and hence had some opportunity to discuss his feelings about whether he wished a cell line based

⁴¹ Ibid, [15.1].

⁴² Ibid, [15.5].

on his tissue to be patented. It would also have opened the door for discussions about benefit sharing which, even if these had not been agreed to, would have allowed Moore to withdraw consent to the research on this basis if he chose—perhaps avoiding the subsequent problems faced by both Moore and the researchers.

Chapter 15 of the National Statement also deals with the use of samples collected previously, either for research or other purposes. To use samples previously collected for research (where consent to that research was obtained) in new research, consent for the new use must generally be obtained. The requirement to gain new consent may be waived by an HREC.⁴³ This also applies to the use of samples held in archives, removed during clinical procedures or held following clinical investigations, however consent in these cases must be obtained where they are to be used in ‘research that may be lead to harm, benefit or injustice to a donor of such tissue’.⁴⁴ Again, an HREC may waive the consent requirement.

These provisions go a long way to addressing some concerns raised by the use of tissue in research, as they give the individual some control over how their tissue, once taken, may be later used. In this again they address one of the problems with the Human Tissue Acts by promoting an approach to tissue use that covers not only present use, but also possible future uses. The National Statement again protects an individual’s interest in the security of their tissue, and promotes their autonomy in being able to choose how their body parts may be used. For example, this provision would require consent to be obtained to use samples and organs retained following clinical procedures, like some of those discussed in Case Study 2: Retention of Organs following Post-Mortem. In doing so, it would prevent situations where tissue samples and body parts taken during hospital procedures are used without consent for future research, and hence promote both individual autonomy and community confidence in the doctor/patient relationship by building trust that tissue will not be used without consent.

However, to some degree these protections are undermined to balance the need to protect individual interests with the need to promote research, as an HREC may waive the need to obtain consent. In deciding whether to do so, the National Statement requires the HREC to have regard to

⁴³ Ibid, [15.6].

⁴⁴ Ibid, [15.7].

- the nature of any existing consent relating to the collection and storage of the sample;
- the justification presented for seeking waiver or consent including the extent to which it is impossible or difficult or intrusive to obtain specific consent;
- the proposed arrangements to protect privacy including the extent to which it is possible to de-identify the sample;
- the extent to which the proposed research poses a risk to the privacy or well being of the individual;
- whether the research proposal is an extension of, or closely related to, a previously approved research project;
- the possibility of commercial exploitation of derivatives of the sample; and
- relevant statutory provisions.⁴⁵

Two aspects of this approach are unsatisfactory. First, the original and more stringent consent requirements are watered down where waiver is available. Secondly, there is no guidance as to how these matters must be taken into account. For instance, the commercial potential of samples must be considered, but there is no guidance on whether this should support a waiver of consent or not. For example, in circumstances similar to the Moore case (Case Study 14: John Moore's Spleen), it could be argued that the commercial potential of the research is a reason to ensure consent is obtained, as the source individual may have qualms about exploitation, or wish to discuss benefit sharing arrangements. However, it might also be argued that individuals should not be able to share in profits, and not be allowed to use the withholding of consent to research as a bargaining chip that may prevent research from being undertaken. Therefore, depending on the view it took, an HREC might either require consent or waive it to avoid the potential restriction on research if the possible harm to the individual is not considered sufficient to require consent, thereby denying individuals control over the fate of their tissue, possibly for reasons not related to their own personal welfare. Certainly, the HREC should be guided by the need to show respect for persons, but could waive consent where there is no perceived harm to the individual other than the lack of a chance to profit.

That said, as noted in Part I, medical research benefits the community as well as individuals, and there is a clear need to ensure that such research is not stymied by

⁴⁵ Ibid, [15.8].

unreasonably burdening researchers with the need to obtain consent in circumstances where it will be difficult and where there is little risk of harm to the individuals. This provision aids in promoting research by allowing HRECs to make a judgment of whether research can proceed without significantly harming individuals who are not contacted for consent, and hence attempts to balance research interests with those of individuals in a pragmatic, yet still sensitive manner. This is particularly so given that researchers are also required when using tissue to identify it with the minimum of information necessary for the research, which may minimise some harms to the individual.

In its approach to tissue use, the National Statement successfully supplements the broad, legislative consent provisions and balances researcher and individual interests. However, it still suffers from some of the concerns that have been previously levelled at a consent-based approach, and of course does not establish any rights that the individual may enforce against those who misuse their tissue. Despite this, the general force of the Statement does mean that well-informed consent to the use, future use and storage of tissue is obtained and helps to protect individual autonomy. This success is also due to other guidance in the Statement that covers research generally, but provides additional protections for individuals whose tissue is used in research.

2.1.4 Other Guidance on Research

In Part I, and above in Chapter Four, concern has been noted about the possibility that human tissue may be transferred and used without the individual's consent; that there is a need to protect the privacy of individuals whose tissue is used; and that the special interests of collectivities, such as indigenous groups, should be taken account of. It has also been noted that there are particular privacy issues raised by genetic analysis of human tissue. The Human Tissue Acts largely fail to address these concerns; however the National Statement contains some guidance that does manage to meet some of them.

First, samples of tissue are often transferred between research institutions, and it is possible that the individual may lose the capacity to control what is done with these samples. Where this is done between institutions officially part of a joint research project, such transfer will be covered by the HREC protocol of the particular institution or the protocol of the primary HREC if the researchers so decide.⁴⁶ In theory, this

⁴⁶ Ibid, [3.3]–[3.7].

system should be effective, particularly within Australia. Problems may arise, however, where research is conducted jointly with international organisations which will not be open to NHMRC sanctions for misuse of tissue. HREC monitoring procedures will obviously be less effective also, despite the Statement requirement that institutions consult and agree upon how research shall be monitored. However, at least to some extent, particularly in light of the regard paid to the Statement by local institutions, this is some protection for samples used by other institutions. As such, it affords individuals some protection by ensuring that other institutions should take account of the scope of consent they have given for the use of their tissue. It also, therefore, affords greater protection than the Human Tissue Acts when samples are transferred. Taken with the general provisions covering tissue use, the National Statement does then manage to ensure that tissue should not be used in any research without consent.

Secondly, the National Statement includes specific guidance on the treatment of collectivities in research, where are 'distinct human groups with their own social structures that link members with a common identity, with common customs and with designated leaders or other persons who represent collective interests in dealing with researchers.'⁴⁷ Researchers are to seek HREC before involving a collectivity in a project. In the case of tissue samples, this should involve consulting the collectivity on the use of samples taken from its members. HRECs should be satisfied that the research proposal adequately addresses

- whether, in addition to individual consent, collectivity leaders should be consulted for approval;
- whether arrangements to issues have followed a process of negotiation;
- issues of consent, privacy, confidentiality and harms within the collectivity, to either individuals or the collectivity;
- the ownership of data and the manner of dissemination of research findings; and
- the manner in which disagreements between the researcher and the collectivity will be resolved.⁴⁸

Coupled with the requirement that institutions where tissue research is conducted should develop research protocols that consider the 'cultural or religious sensitivity of

⁴⁷ Ibid, [8.1].

⁴⁸ Ibid, [8.2].

the sample'⁴⁹ this does go some way to ensuring the indigenous interests are taken into account in the use of tissue. Therefore, in situations like Case Study 1: Collecting Aboriginal Remains, the community's interest in the tissue is to be considered in determining how the tissue will be used, which fills one gap in the legislative framework to some degree.

These general guidelines are augmented by specific guidelines covering research involving Aboriginal and Torres Strait Islanders, *Values and Ethics*. These are designed to work in conjunction with the National Statement,⁵⁰ and detail a number of principles to inform research practice in this area. They do not deal with tissue use specifically, but require researchers to take account of six guiding principles in working with Aboriginal and Torres Strait Islanders. These are reciprocity, respect, equality, responsibility, survival and protection, and spirit and integrity.⁵¹ These affect how tissue should be treated by directing researchers to consider the spirit and integrity of communities in conducting research, which reinforces the National Statement's requirement that collectivities be consulted when consent for tissue use is obtained. The principle of respect for persons highlights the need to be aware of and respect the values of indigenous groups, reinforcing requirements in the National Statement that tissue samples should be dealt with in accordance with the views of the person from whom they are taken. These guidelines further ensure that indigenous interests are considered when tissue is used in research, and elucidate many of the particular aspects of these groups' beliefs that researchers should have regard to. In doing so, they address another gap in the legislative framework, as the Human Tissue Acts do not take account of cultural differences in the consent procedures they lay down, and hence fail to account for the need to consider community, as well as individual consent to tissue use.

Thirdly, the National Statement includes specific provisions to address the particular challenges presented by human genetic research, recognising that 'special care must be taken to protect the privacy and confidentiality of this information'.⁵² This recognition is based on the potential for stigmatisation and discrimination from the use of genetic information, and the familial nature of this information. This is relevant to the use of tissue where that tissue may be used to generate information about an individual in the

⁴⁹ Ibid, [15.3].

⁵⁰ National Health and Medical Research Council, *Values and Ethics*, [2.1].

⁵¹ Ibid, [2.2].

⁵² National Health and Medical Research Council, *National Statement*, 46.

course of genetic research, which raises privacy concerns as noted in Part I.⁵³

To address these potential issues, Chapter 16 of the National Statement lays down extra, detailed privacy and confidentiality requirements to apply to genetic research. These require researchers to protect the confidentiality and privacy of stored genetic information, including restrictions on the release of such information to family members.⁵⁴ Researchers must also specify in the research protocol whether information will be stored in identified form (which will therefore alert participants to this fact).⁵⁵ Further, researchers are precluded from transferring genetic material or related information to another research group unless that the researcher is working collaboratively with that group, HREC approval for the research and the material is provided in a form by which the source individual can be identified (unless approved by an HREC).⁵⁶

Each of the requirements noted in this section is a step towards protecting individuals whose tissue is used in research from the possibility that this use will result in a breach of their privacy, and as a result stigmatisation or discrimination. They again, therefore, fill another hole left by the legislative scheme, which currently does not protect the privacy of genetic samples, although as noted in Chapter Four, privacy legislation does protect information. In protecting samples also, the National Statement adds another layer of privacy protection by controlling who may access samples and how they may use them, thus preventing the generation of information in a manner that may subsequently breach privacy.

Chapter 16 adds to these protections also by laying down more stringent consent procedures than apply generally to research. It requires that genetic material is stored only following careful consideration of any consequences which may flow from doing so, even where it is de-identified.⁵⁷ Further, for consent to the use in research of genetic material, an individual must be informed of a broad range of matters. These include that they are free to refuse consent without giving reasons, and may withdraw from the research at any time. In doing so, they are able to request the destruction or de-identification of their genetic material. They must also be informed of the arrangement

⁵³ See Chapter Two, section 5.

⁵⁴ National Health and Medical Research Council, *National Statement*, [16.3].

⁵⁵ *Ibid*, [16.4].

⁵⁶ *Ibid*, [16.8].

⁵⁷ *Ibid*, [16.6].

to protect their confidentiality, whether any results will be generated by the research that are relevant to their health or that of their offspring and whether they will be informed of this. They may opt not to be given this information.

They must also be told whether their genetic material will be stored in identified, potentially identifiable or de-identified forms, and that their material will not be released for other research without their consent. They must be informed about any intention to store their genetic material for unspecified future research, and if they refuse to consent to this storage, that the material will be destroyed. They must be informed that if they have particular sensitivities about how their tissue may be disposed of, that these will be recorded and the destruction will be done in accordance with them.⁵⁸ Finally, where researchers propose to collect genetic material from a person because he or she is a member of a collectivity, consent should also be sought from an appropriate representative of that collectivity, as well as the individual.⁵⁹

Together, these requirements address many of the concerns noted both in relation to the Human Tissue Acts and in Part I generally, at least in relation to genetic research. They take account particularly of individual interests, while providing researchers with a means to conduct research and avoid potential future problems by fully informing individuals about what they plan to do with the tissue that is donated. They also take indigenous interests into account, which is especially important in genetic research to ensure that indigenous groups are not inadvertently made the subjects of potentially discriminatory research.

Applying these provisions to the case studies demonstrates how they may address some of the concerns raised in Part I. For example, in a situation like that described in Case Study 12: Iceland and deCODE, these provisions would ensure that participants in the database were made aware of how their samples would be used, stored and identified and also that they would be protected from being accessed by family members. This addresses many of the privacy concerns that such large scale storage of individual genetic material and information could raise.

One criticism, however, is that the same sensitivity is not recognised in relation to all tissue. For example, while the Statement requires sensitive destruction of genetic

⁵⁸ Ibid, [16.10].

⁵⁹ Ibid, [16.11].

material in accordance with the wishes of the donor where it is used in genetic research, there is no similar requirement in relation to tissue generally, despite the fact that this sensitivity will probably apply to tissue regardless of the research for which it is used. This kind of requirement should therefore apply generally, as should requirements allowing individuals to determine whether tissue may be stored for future research.

It should be noted that the ALRC/AHEC recommended that consent forms contain more detailed advice and requirements. In particular, it recommended that the NHMRC prepare advice on writing consent forms that covers graduate consent options, disclosure of actual or anticipated commercial arrangements, ownership or property interests in samples, methods of protecting privacy of participants, and withdrawal of consent.⁶⁰ If implemented, this recommendation would help to partially address the concerns noted in this chapter, however to date it has not been acted upon.

2.1.5 Conclusion

Overall, the National Statement provides a well-developed scheme for ensuring that the use of human tissue in research is both voluntary and informed. It also ensures that attention is paid to ensuring future research using stored material is consensual (addressing concerns about future use of tissue raised previously) and to ensuring that tissue is destroyed or de-identified to protect the interests of the source individual. At the same time, the National Statement also provides mechanism for enabling researchers to use tissue in valuable research where there is not likely to be significant harm to individuals.

However, while this approach does meet some of the concerns raised by tissue use, there remain a number of problems with the regulatory framework that National Statement combined with the Human Tissue Acts provides. First, the National Statement does not provide any individual penalties for third parties that may access and misuse tissue where they are not subject to the sanctions provided by the NHMRC. As the Human Tissue Acts also do not do so, this remains a gap in the regulation of tissue. Secondly, the National Statement provides no rights to individuals against such people who misuse tissue, and cannot assist them in having it returned or in seeking compensation. While it may provide an incentive for researchers to comply, and sanction them when they do not, the National Statement provides nothing that will

⁶⁰ Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours*, Recommendation 16–2.

improve the situation of individuals once their tissue has been misused. Again, the National Statement fails in the same way as the Human Tissue Acts in this situation. Privacy legislation at this stage will alleviate some of these concerns in relation to information, and if applied to tissue samples would go a long way to addressing these issues. However, at this stage the legislation does not apply.⁶¹

Thirdly, the National Statement is limited in application, as it will not necessarily cover commercial research using tissue. Finally, the Statement does not address issues around benefit sharing, and like the Human Tissue Acts leaves the possibility of an individual sharing in the profits of the research that their tissue aids in an unregulated vacuum. Clearly, then, while the National Statement does a great deal to supplement the consent requirements within the Human Tissue Acts, and promote ethical use of tissue, a number of gaps in the regulatory framework covering the research use of tissue remain.

2.2 Guidelines for Genetic Registers and Associated Genetic Material

Genetic registers maintain records of sufferers of genetic conditions in an attempt to identify family members who may be at risk of developing a condition or passing it on to their children. A register will generally focus on one disorder or a group of related disorders. A register usually aims to provide family members with the opportunity to be made aware of their risk, to have testing and to obtain information about the disorder and any preventative measures they may take or reproductive options they should consider. Registers may also sometimes participate in research on the disorder.⁶²

In 1999, the NHMRC released its Guidelines for Genetic Registers to provide ethical guidance on the maintenance of genetic registers. The scope of the Guidelines extends only to genetic registers, and does not include medical records held by health professionals or hospitals, records of research studies, databases maintained solely for research purposes, public health surveillance databases, registers dealing with non-genetic disorders, results of genetic tests or collections of tissue held by laboratories or blood banks and databases created to monitor the utilisation and impact of health services directed at inherited disorders.⁶³ The guidelines cover the establishment of a register, the recruitment of participants, consent, confidentiality, contacting family members and security of the register. Like the National Statement, the Guidelines take a

⁶¹ See section 2.3.

⁶² National Health and Medical Research Council, *Guidelines for Genetic Registers and Associated Genetic Material*, [1.2].

⁶³ *Ibid*, [1.2](c).

consent-based approach.

2.2.1 Consent requirements

Consent for taking material to be included in the register can be divided into two parts. First, consent to inclusion must be obtained after the provision of full information. Of relevance to tissue collection, the potential registrant must be informed that participation is voluntary and material collected must be de-identified or disposed of upon request; the nature of the material to be stored and the duration for which it will be kept; the register's policy on disclosure and release of material including policies against releasing material without informed consent unless required to do so by law; and the uses to which tissue may be put including research uses.⁶⁴

Once a volunteer has agreed to participate, further consents must be obtained to collect blood samples (no other form of tissue is specified in the guidelines) for DNA extraction or to gain access to previously collected material.⁶⁵ If material is to be disposed of after death, the participant's wishes should be recorded, and similarly consent should be gained before use in research even where material will be coded or de-identified.⁶⁶ Where the registrant is deceased, consent is to be gained from next of kin.⁶⁷

2.2.2 Storage and Access

Registers must provide or have access to facilities in which collected genetic material can be stored. This may be a laboratory which is an administrative part of the register or an independent laboratory. In either case the laboratory must be accredited by NATA.⁶⁸ Consent for storage must be obtained if genetic material is to be retained in addition to information or data derived from it. In accordance with NPAAC guidelines, this material should be stored indefinitely, and its status should be reassessed if disposal is proposed, and participants are to be informed of the nature of material collected, how it will be stored and the duration of that storage.⁶⁹ Facilities should be sufficiently secure to prevent unauthorised persons from accessing genetic material.⁷⁰

The participant must consent to collection before it occurs, or consent to the inclusion

⁶⁴ Ibid, [4.1] (a), (h), (i), (k), (n), (o).

⁶⁵ Ibid, [4.2.1] (b), (c).

⁶⁶ Ibid, [4.2.1] (e), (g).

⁶⁷ Ibid, [4.3].

⁶⁸ Ibid, [2.1] (j).

⁶⁹ Ibid, [4.2] (b), (c), (h), (i).

⁷⁰ Ibid, [7.1], [7.2].

of previously collected material in the register.⁷¹ If material is stored and the original patient from whom it was taken is deceased, consent must be sought from next of kin.⁷² The Guidelines do not lay down what is to happen where such consent cannot be obtained in relation to material, though stringent guidelines are made for dealing with information previously stored about persons now deceased. Such information can be used only if de-identified.⁷³ It should be noted that in other sections of the guidelines mention is made only of confidentiality of information, not material.⁷⁴

Due to the nature of genetic registers, material will be stored in identified form. To ensure security, the guidelines require that measures be taken to ensure security and to protect confidentiality. Those responsible for security are directed to relevant privacy protection standards such as Australian Standard AS 4400-1995 *Personal Privacy in Health Care Information Systems*.⁷⁵ Information must be coded, and the code should be used where it is not necessary to identify the material personally. The minimum amount of identifying information should also be used at all times.⁷⁶ Staff working with genetic material and tissue samples must ensure that access is restricted to authorised persons, that is, those who have the registrar's consent to access material.⁷⁷

Register participants must be informed of who may be given access to material as part of the initial consent requirements. Material is not to be released to insurers, employers, and family members who do not have the prior consent of the registrant without their written consent.⁷⁸ Participants must be made aware, however, that material may be released where required by law such as by court order and that material may be made available to researchers in potentially identifiable or de-identified form.⁷⁹

Participants must also be informed of the uses to which stored tissue may be put and that they will likely not receive any financial benefit if those used produce a commercially profitable result.⁸⁰ Where material may be used for research or disposed

⁷¹ Ibid, [4.2.1] (b), (c).

⁷² Ibid, [4.3].

⁷³ Ibid, [4.4].

⁷⁴ See, eg, Ibid, [5.1](b)(i), (ii), (iii).

⁷⁵ Ibid, [7.1].

⁷⁶ Ibid, [5.1](b)(vi), [7.3].

⁷⁷ Ibid, [5.1](b)(v).

⁷⁸ Ibid, [4.1](k), [5.1](b)(vii).

⁷⁹ Ibid, [4.1](k).

⁸⁰ Ibid, [4.1](n), (o).

of, participant consent must be sought before access can be granted.⁸¹ Researchers are directed to the National Statement for guidance on confidentiality when dealing with material supplied by the register, and must obtain consent for research. All information is to be kept confidential, including a requirement that no research results be published in a form which would enable identification of registrants. Genetic material must not be used for any purpose other than the research for which it was obtained, and material must be returned to the register at the completion of that research.⁸²

These guidelines apply mainly to the situation outlined in Case Study 8: South Australian Clinical Genetics Service. Like the National Statement, these guidelines work on a consent-based approach, and hence are subject to the same concerns noted in the previous section. To take a hypothetical example, laboratory workers are approached by an insurance company which seeks access to genetic material held by the register in laboratory storage facilities. They are prepared to pay for portions of each sample and the name of the participant from whom it was taken, as they intend to use them to test for genetic conditions which may affect persons applying for insurance. These samples are supplied to the company for a fee. On discovery, the laboratory workers are fired by the registrar in a bid to prevent the withdrawal of funding. Firing may also be taken as a step to avoid the revocation of laboratory accreditation by NATA or NPAAC. However, the question is then can the samples be reclaimed by the register or the participant? The guidelines do not make any statement on who owns them nor who has the best right of possession. Further, they do not outline the rights of the participant to their samples beyond the consent relationship defined between the register and registrant, to which the insurance company is a third party and not bound legally.

To promote valuable research that will aid families affected by a genetic disorder, however, the Guidelines need to balance research interests with protecting individual autonomy and privacy. Much genetic research of the kind undertaken by genetic registers requires the development of family trees and genealogical histories to study the inheritance of a disorder. Therefore, it is not always possible to remove all identifiers from samples and still conduct research effectively. The Guidelines address this by laying down detailed consent provisions that ensure participants are aware of this, to enable them to make their own fully informed choice about participation. However, if samples are misused this leaves them open to greater abuse, as they remain identified.

⁸¹ Ibid, [4.2.1](e), (g).

⁸² Ibid, [5.1](b)(vi).

This, though, is perhaps may only be solved to some extent through codification of samples, which is provided for in the National Statement and is also addressed in the Guidelines' requirement that researchers use the minimum amount of identifying information or by coding samples when conducting research using genetic material.⁸³

2.3 Privacy Guidelines

Finally, the collection of information for research purposes is also covered by privacy guidelines and the National Privacy Principles (NPPs). Under NPP 10.3, which applies to many research organisations, an organisation may collect identified health information for use in research where the research purpose could not be served without using identified information. It can also be collected without consent where it would be impractical to do so. However, the organisation will be bound by rules of professional confidentiality that bind health or medical bodies or in accordance with guidelines made under section 95A of the *Privacy Act 1988* (Cth) (*Privacy Act*). It must further take reasonable steps to permanently de-identify information before disclosing it.⁸⁴

In addition, section 95A *Privacy Act* allows the Federal Privacy Commissioner to approve guidelines released by the NHMRC that collection the collection, use and disclosure of information 'for the purposes of research, or the compilation or analysis of statistics, relevant to public health or public safety'.⁸⁵ The Privacy Commissioner may approve such guidelines, even when they do not provide the same level of privacy protection as the NPPs, 'only if satisfied that the public interest in the collection of health information for the purposes mentioned in that subsection in accordance with the guidelines substantially outweighs the public interest in maintaining the level of privacy protection afforded by the NPPs'.⁸⁶

In 2001, the NHMRC released the *Guidelines Approved under Section 95A of the Privacy Act 1988* (Cth) (Privacy Guidelines).⁸⁷ Their goal is to provide a mechanism for weighing the public interest in research relevant to public health or public safety against the public interest in the protection of privacy'.⁸⁸ The public interest in the research activity must substantially outweigh the public interest in maintaining the level of privacy protection

⁸³ Ibid, [5.1](b)(vi).

⁸⁴ *Privacy Act 1988* (Cth) NPP 10.3.

⁸⁵ *Privacy Act 1988* (Cth) s 95A(2), (4).

⁸⁶ *Privacy Act 1988* (Cth) s 95A(3), (5).

⁸⁷ National Health and Medical Research Council, *Guidelines Approved under Section 95A of the Privacy Act 1988* (Cth), NHMRC, Canberra, 2001.

⁸⁸ Ibid, A.1.1.

afforded by the NPPs for the guidelines to apply. This will be the case where it is necessary to collect, use and disclose the information for research purposes that will be have an impact on public health and it is impossible to conduct this research using de-identified data. It must also be impractical to contact the person to whom the information relates for consent and the research must have HREC approval.⁸⁹ As a general principle, they require all who collect, use and disclose health information to respect the dignity and privacy of the individual.⁹⁰

The Privacy Guidelines then lay down strict requirements for seeking and obtaining such approval, and that the collection, use and disclosure of the information must comply with the NPPs.⁹¹ In giving approval, the HREC must weight the public interest in the research against the public interest in maintaining individual privacy, taking a range of listed factors into account.⁹² These criteria include the degree to which the collection, use and disclosure is necessary to the functioning of the organisation, the benefits for public health and safety, the benefits to the individual or classes of individuals, the public importance of the research, the study design, the risks to the individual and the security measures in place to protect information.⁹³ The Privacy Guidelines also lay down protections for information privacy in relation to the running of a health service.⁹⁴

These guidelines augment the protections provided by the privacy legislation, and non-compliance is subject to the same sanctions as non-compliance with other NHMRC guidelines. They also provide for a complaints mechanism, unlike other guidelines, that allows individuals or institutions to complain to the individual(s), institution(s) or organisation(s) conducting the research, to the relevant HREC, or to the Federal Privacy Commissioner.⁹⁵ Injunctive relief might therefore be available under the Privacy Act, or the Privacy Commissioner may investigate the privacy breach. This is a significant step towards protecting the privacy of individuals whose information is used in research. However, like the Privacy Act, these guidelines do not explicitly cover samples, only 'health information' and hence do not provide these protections to excised tissue. As

⁸⁹ Ibid, A.1.2–A.1.4.

⁹⁰ Ibid, A.2.2, A.3.2.

⁹¹ Ibid, A.2, A.3. The criteria are set out in section D.5 of the Privacy Guidelines.

⁹² Ibid, A.2.10, A.3.11. The HREC must also ensure that the collection, use and disclosure complies with the relevant NPPs. See National Health and Medical Research Council, *Section 95A Guidelines*, D.2.

⁹³ National Health and Medical Research Council, *Section 95A Guidelines*, D.5.

⁹⁴ Ibid, C.1, C.2.

⁹⁵ Ibid, G.

noted in relation to the Privacy Act in Chapter Four, if extended to samples they would provide some strong protections for the collection, use and disclosure of samples. However, pending implementation of the ALRC/AHEC recommendation to this effect, the privacy of samples remains unprotected by the requirements in these guidelines.⁹⁶

3. LABORATORY PRACTICE GUIDELINES

Another major use of human tissue aside from research and genetic testing is general pathology testing. As noted in Part I, pathology testing is used to diagnose medical conditions and requires access to samples of many kinds of tissue. In Australia, the practice of pathology testing is regulated by a number of guidelines and accreditation standards.

The first of these is NATA, the National Association of Testing Authorities, Australia. It is a private, not-for-profit company owned by its member laboratories and representatives from industry, government and professional bodies and is endorsed by the Australian Government to provide accreditation for laboratories and testing facilities.⁹⁷ It is also Australia's Good Laboratory Practice compliance monitoring authority.⁹⁸ NATA operates the accreditation scheme in cooperation with the Royal College of Pathologists Australasia (RCPA) and on the basis of policy advice from the National Pathology Accreditation Advisory Council (NPAAC).⁹⁹ This scheme operates to assess the competence of a laboratory to conduct pathology testing.

To obtain accreditation, NATA requires laboratories to meet standards of practice that cover many aspects of testing, some of which relate to tissue handling and which cover security procedures. It also requires laboratories to comply with standards issued by NPAAC, which are described below. Accreditation is required for a laboratory to offer testing that will attract benefits under the Australian Government Medicare Benefits

⁹⁶ However, see the ALRC/AHEC's discussion of what constitutes 'information', where it is argued that it could be extended to genetic samples. The ALRC/AHEC argued that '[m]odern genetic sequencing technology may make genetic samples as immediate a source of information as, for example, a computer disk or database, which are already covered by the *Privacy Act*'. To date this view has not led to a different approach to interpreting the Privacy Act, and hence information under the legislation and guidelines made under that legislation does not include samples. See Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours*, [8.29].

⁹⁷ National Association of Testing Authorities, Australia, 'Memorandum of Understanding between NATA and the Australian Government 2003', *NATA Publications*, <www.nata.asn.au/publications/downloads/NATA_MoU_2003_final.pdf> at 24 October 2004.

⁹⁸ National Association of Testing Authorities Australia, 'What is NATA', <www.nata.asn.au/fs_whats_nata.htm> at 23 October 2004.

⁹⁹ Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours*, [11.7].

Scheme.¹⁰⁰ This effect of accreditation creates a strong incentive for laboratories to comply as without it, they will be unable to provide a testing service that enables consumers to access Medicare benefits, and hence without accreditation the laboratory will not be an attractive service provider for customers.

NPAAC is managed by the Australian Government Department of Health and Ageing. It is made up of representatives from all states and territories and nominees from peak professional bodies and the Department of Health and Ageing and develops and maintains standards for good pathology practice.¹⁰¹ These guidelines cover, among other things, transportation of specimens,¹⁰² laboratory supervision,¹⁰³ and pathology collection centres.¹⁰⁴ It is beyond the scope of this thesis to examine each of these in detail. Instead, the general approach in the two most relevant guidelines will be briefly considered. These are the *Standards for Pathology Laboratories*¹⁰⁵ (Standards) and the *Guidelines for Retention of Laboratory Records and Diagnostic Materials*¹⁰⁶ (Guidelines for Retention).

The Standards require staff at laboratories to treat samples with respect and operate the laboratory in an ethical manner. They must maintain treat the confidentiality of information and the wellbeing of patients as the primary considerations, and must release information only to medical practitioners or healthcare providers or in accordance with relevant privacy legislation.¹⁰⁷ Pathology laboratories will also be covered by the NPPs. These standards therefore lay down procedures to ensure that individual privacy is protected by prohibiting the release of information to unauthorised persons. They also work to ensure that samples are treated with appropriate respect. However, their lack of specificity about what this requires is a concern, as they do not

¹⁰⁰ *Health Insurance Act 1973* (Cth) s 16A(2). To attract benefits, laboratories must also be deemed an Approved Pathology Laboratory by the Health Insurance Commission. See Health Insurance Commission, *Health Insurance (Accredited Pathology Laboratories — Approval) Principles*, Commonwealth of Australia, Canberra, 1999, [6]. The Principles are made under *Health Insurance Act 1973* (Cth) s 23DNA(1).

¹⁰¹ National Pathology Accreditation Advisory Council, 'About Us', *Homepage for the National Pathology Accreditation Advisory Council*, <www.health.gov.au/internet/wcms/Publishing.nsf/Content/health-npaac-index.htm> at 23 October 2004.

¹⁰² National Pathology Accreditation Advisory Council, *Information on the Transport of Pathology Specimens*, NPAAC, Melbourne, 1998.

¹⁰³ National Pathology Accreditation Advisory Council, *Requirements for Supervision of Pathology Laboratories*, NPAAC, Melbourne, 1999.

¹⁰⁴ National Pathology Accreditation Advisory Council, *Guidelines for Approved Pathology Collection Centres*, NPAAC, Melbourne, 2001.

¹⁰⁵ National Pathology Accreditation Advisory Council, *Standards for Pathology Laboratories*, NPAAC, Melbourne, 2002.

¹⁰⁶ National Pathology Accreditation Advisory Council, *Guidelines for Retention of Laboratory Records and Diagnostic Materials*, NPAAC, Melbourne, 2002.

¹⁰⁷ National Pathology Accreditation Advisory Council, *Standards for Pathology Laboratories*, Standard 1.

provide guidance on appropriate disposal or how indigenous concerns may be met.

The Guidelines for Retention lay down time periods for appropriate retention of samples and records based on the tissue type and the form of testing it is to undergo. In general, specimens should be retained for seven days following receipt, or for two days after a report on testing has been issued.¹⁰⁸ However, extended retention periods are required for many sample types. For example, blocked samples used in anatomical pathology analysis must be retained for 20 years.¹⁰⁹ The Guidelines state that retention is required 'to allow for review and confirmation of sample identity, diagnoses and reports, and appropriate further testing, once the report is received by the requesting practitioner'.¹¹⁰ It also addresses the possibility that samples may be accessed for research by stating that this use is to be covered by the National Statement.¹¹¹ It addresses confidentiality issues by requiring that inappropriate access is prevented by 'inbuilt security checks and restrictions on accessibility of confidential information'. It further notes that 'care should be taken in regard to limiting access to test results to those entitled to have access for professional purposes'.¹¹²

The Guidelines and Standards do not consider consent issues, however this is largely because it is probably assumed that this is covered by laws relating to the doctor/patient relationship. They are, however, a significant safeguard on the confidentiality of samples taken for testing, as they restrict access to samples and the information generated from testing them to those who are authorised to access it. The threat of losing accreditation is also a strong incentive for compliance due to the consequences this may have for the laboratory's practice.

One concern about the guidelines is that they do promote continued retention of samples and do not appear to allow for individuals to request the disposal of their tissue if they are concerned about privacy or for cultural reasons. In this, pathology practice may fail some individuals in protecting their autonomy and respecting their beliefs about how tissue should be treated. However, retention is aimed at providing the best provision of pathology services, and hence occurs in the interests of the health of these

¹⁰⁸ National Pathology Accreditation Advisory Council, *Guidelines for Retention of Laboratory Records and Diagnostic Materials*, [1.6].

¹⁰⁹ Ibid, [2.3].

¹¹⁰ Ibid, 3.

¹¹¹ Ibid, 3.

¹¹² Ibid, 4.

individuals, which may offset the seriousness of this concern to some degree.

The most obvious example in which the Guidelines and Standards may apply is Case Study 11: Roche v Douglas, where a woman sought access to tissue blocks retained after the death of a man whom she alleged was her father. In such a situation, the Guidelines and Retention Standards would prevent a laboratory releasing these blocks except in accordance with legal requirements, as was the case in that situation. While this may not promote the interests of the family member who seeks access, it does ensure that the privacy of the source individual is maintained and protects their ability, to some degree, to ensure that when they give samples for pathology testing, they will not be used purposes of this kind without their consent. The Guidelines and Standards therefore promote individual control of samples. However, these Guidelines and Standards, like the NHMRC guidelines, do not provide for any mechanisms to address harms done to individuals where tissue is released to unauthorised individuals, nor provide any means by which that individual might prevent further misuse or seek to have the tissue returned. Again, if the NPPs applied to samples as well as information, then issues about consent, access and disclosure would be more effectively addressed and some remedies available. However, they do not and hence the concerns remain.

In addition to these standards for pathology laboratories, the RCPA requires its members to adhere to the Australian Medical Association *Code of Ethics*¹¹³ and any policies the RCPA releases. More relevant in this context is the specific policy released by the RCPA in relation to tissue retained at autopsy, *Policy Statement on Autopsies and Use of Tissue Removed during Autopsies*.¹¹⁴ The effect of this has already been discussed above in relation to non-coronial autopsies.¹¹⁵

4. HUMAN GENETICS SOCIETY OF AUSTRALASIA POLICIES

The HGSA is the Human Genetics Society of Australasia, an association of professionals working in the area of human genetic medicine and research. Among its objectives, two aims are to promote high ethical standards among those working in

¹¹³ Royal College of Pathologists of Australasia, *Code of Ethics*, Sydney, 1999 (reviewed 2002). The Australian Association of Pathology Practices has also released its *Code of Ethics and Practice Guidelines* however this relevantly states only that pathology practices should operate in accordance with the requirements laid down by the RCPA and the Australian Medical Association. See 'Code of Ethics and Practice Guidelines', *AAPP Annual Report 2001*, Australian Association of Pathology Practices, <www.aapp.asn.au/code.pdf> at 21 October 2004.

¹¹⁴ Royal College of Pathologists of Australasia, *Policy Statement on Autopsies and Use of Tissue Removed during Autopsies*, Sydney, 1993 (reviewed 2002).

¹¹⁵ See Chapter Four, section 3.2.1.

human genetics and to promote and support human genetic research.¹¹⁶ The HGSA releases policies to guide its members in the practices of genetic medicine and research. While these are not binding, they affect practice as failure to comply will probably result in censure from their professional peers and the Society.

The HGSA has released three policies that are relevant to the use of human tissue, *Guidelines for Human DNA Banking*¹¹⁷ (Banking Guidelines), the *Policy Statement on Newborn Blood Spot Screening*¹¹⁸ (Screening Statement) and the *Policy Statement on the Retention, Storage and Use of Sample Cards from Newborn Screening Programs*¹¹⁹ (Retention Statement).

4.1 Guidelines for Human DNA Banking

The Banking Guidelines were released in 1990 and cover the storage of genetic material by clinical service providers and researchers. Their purpose is to ensure the future service needs of families affected by a genetic disorder are met, and to provide information on the technical aspects of DNA storage to promote the integrity of stored genetic material.¹²⁰

The Guidelines take a pragmatic approach to both storage and consent. They note a range of matters that should be discussed with the individual when DNA is taken and stored, including the duration of storage, the uses to which DNA will be put while banked (including research), the potential of DNA testing to demonstrate non-paternity, the impact of results on the genetic status of family members, conditions under which DNA may be transferred to another laboratory for testing, and the potential future diagnostic use of the DNA and their implications for the individual.¹²¹

These consent requirements do give the individual a good account of how a DNA bank may work and the implications of giving a sample to it. In particular, the Guidelines require that individuals are informed of the possible research use of their stored DNA.

¹¹⁶ Human Genetics Society of Australasia, 'Constitution of the Human Genetics Society of Australasia', <www.hgsa.com.au> at 24 October 2004.

¹¹⁷ Human Genetics Society of Australasia, *Guidelines for Human DNA Banking*, HGSA, Melbourne, 1990

¹¹⁸ Human Genetics Society of Australasia, *Policy Statement on Newborn Blood Spot Screening*, HGSA, Melbourne, 2004.

¹¹⁹ Human Genetics Society of Australasia, *Policy Statement on the Retention, Storage and Use of Sample Cards from Newborn Screening Programs*, HGSA, Melbourne, as at October 2004.

¹²⁰ Human Genetics Society of Australasia, *Guidelines for Human DNA Banking*, HGSA, Melbourne, 1990, [1.1].

¹²¹ *Ibid*, [2.6].

This provision is important, as the work done by DNA banks in investigating a genetic disorder often blurs the line between research and service provision because service providers continue to learn about the disorder by examining the familial pattern of inheritance. The Guidelines also note that all research will be subject to NHMRC guidelines, ensuring that research practice is in line with the nationally accepted ethical standards. Therefore, in a situation like that outlined in Case Study 8: South Australian Clinical Genetics Service, participants would be made aware that the service will also be undertaking research, clarifying to them the nature of the tissue use and hence promoting their autonomy by allowing them to decide on donation whether they wish their samples to be used in this way. They will also be contacted for further consent, in compliance with the National Statement, if their tissue is used in other research, giving them control over future uses of their tissue.

In addition, the Guidelines recognise that samples of tissue will often be taken as part of the diagnostic process without specifying that they will be tested genetically, but rather that they will be used for diagnostic purposes generally. The Guidelines take a pragmatic approach to this by noting that while consent to genetic testing has not been specifically given in written form, such consent is implicit as families involved in this form of diagnosis will thoroughly appreciate the general purpose for which the sample is taken.¹²²

Finally, the Guidelines suggest that DNA banks should set up adequate confidentiality procedures. These should be based on the general principle that the 'results of an individual's DNA tests will not be provided to third parties without the written permission of the individual whose DNA has been banked and tested'.¹²³ Again, these provisions operate to ensure that the individual has control over the information about them that is released to others, protecting both their privacy and their autonomy. However, this may prevent family members from accessing results that are relevant to their healthcare, hence placing individual interests over familial interests.

In general, the Guidelines set up a basic, recommended scheme for ensuring the DNA samples are stored consensually and that the individual is aware of the purposes of storage. While not binding, the Guidelines direct service providers to establish reasonable protections of privacy that supplement legislative privacy protection. The

¹²² Ibid, [2.6].

¹²³ Ibid, [2.7].

Guidelines do not lay down specific protections for access to samples, only to information. However these might implicitly apply to samples as part of the general approach to confidentiality taken in the Guidelines, and hence prevent third parties accessing samples as well as information and thereby preventing them from testing those samples themselves. The Guidelines do not aim to be comprehensive, and need not be as other guidelines, such as those released by NPAAC as well as health privacy legislation also lend protection to the privacy of stored samples in the scenario covered by the Guidelines.

4.2 Newborn Screening Policy Statements

These two statements are considered together as they both regulate the process of newborn screening and card storage. The process of newborn screening was described in Case Study 5: Newborn Screening Card Collection.

The Screening Statement outlines policies for, among other things, obtaining consent, informing parents about the implications of screening and the use of screening cards in research. It directs that individuals responsible for testing should provide information about the test when obtaining consent, and that this should include informing parents of the storage and potential future uses of the cards.¹²⁴ Parents should be informed that testing is not mandatory, but should be requested to sign a statement that they have refused after being provided with full information about the screening test. This information is to be stored with demographic information about the newborn.¹²⁵ Screening laboratories are to have appropriate confidentiality and privacy protection procedures in place to protect individuals and families, although it does not outline the form these should take.¹²⁶

Cards are to be stored for a period determined by the laboratory determined with regard to relevant pathology accreditation requirements.¹²⁷ Future use of the cards in should not occur without the written permission of parents, guardian or the individual from whom the sample was taken, or may be undertaken in accordance with a legally binding directive (such as a Memorandum of Understanding with police services to use cards in forensic investigations) or with appropriate HREC approval for research.¹²⁸ The

¹²⁴ Human Genetics Society of Australasia, *Policy Statement on Newborn Blood Spot Screening*, [2.7], [4.4](iii).

¹²⁵ Ibid, [2.8], [4.1].

¹²⁶ Ibid, [4.2].

¹²⁷ Ibid, [4.4](i).

¹²⁸ Ibid, [4.4](ii).

Screening Statement also suggests that screening programs should support research related to newborn screening and be conducted in line with relevant ethical and HREC recommendations.¹²⁹

The Retention Statement, released prior to the revised Screening Statement, provides that screening programs should have a policy on storage that is publicly available but does not suggest what that policy should be (though it notes the retention periods recommended by a number of other bodies).¹³⁰ It does, however, direct that parents be informed of the intended duration of storage and potential future uses of the cards (in line with the Screening Statement).¹³¹ It directs that access to cards be restricted to authorised individual.¹³² It also notes the range of reasonable future uses of cards. These are:

- Investigation of cases missed by the screening program, which is the primary purpose of retaining cards;¹³³
- Screening program development—this use does not require consent but cards should be anonymised and HREC approval is required;¹³⁴
- Individual requests for the return of cards by families—screening programs should develop policies to deal with such requests which should discourage the return of cards and should not allow released to persons other than the individual whose blood is stored or if he or she is a minor, a parent;¹³⁵
- Requests from health professionals to determine the cause of death of a deceased person, which should only be acceded to where the custodial parent or next of kin has consented to the release;¹³⁶
- Research studies, where appropriate HREC approval has been obtained and which conforms to NHMRC guidelines;¹³⁷
- Coronial and forensic purposes, where permission has been obtained from parents or the next of kin except where appropriate legal authority may override this requirement. However, such requests without specific legal authority should not be acceded to where there is the alternative of obtaining a sample from

¹²⁹ Ibid, [5.1].

¹³⁰ Human Genetics Society of Australasia, *Policy Statement on the Retention, Storage and Use of Sample Cards from Newborn Screening Programs*, [2.1]–[2.4].

¹³¹ Ibid, [3.2].

¹³² Ibid, [4.1].

¹³³ Ibid, [4.3.1].

¹³⁴ Ibid, [4.3.2].

¹³⁵ Ibid, [4.3.3].

¹³⁶ Ibid, [4.3.4].

¹³⁷ Ibid, [4.3.5].

another source.¹³⁸

These Statements are also supplemented by state and territory health authority policies on card retention and use, including Memoranda of Understanding between health authorities and police services in Victoria and New South Wales. These lay down recommendations for the duration of storage and policies for future use that reflect the policies in these Statements.¹³⁹

Together, these Statements lay down clear guidance to restrict access to sample cards containing blood without the consent of a parent, or where the individual is competent to consent, the person from whom blood was taken. In doing so, they provide important protections for stored tissue from these individuals, including supplementing legislative privacy protections by limiting access to cards, which prevents information being generated by testing stored genetic material. They also promote the autonomy of individuals by allowing them to have their cards returned to them, although in practice as this is discouraged, it may be difficult for individuals to ensure that this occurs. However, by allowing for research use with appropriate HREC approval and in accordance with NHMRC guidelines, they balance individual protections with the need to promote research that benefits both individuals and the community.

In addition, though not explicitly stated, by ensuring that parents are aware that testing is not mandatory, the Statements have scope to take account of indigenous interests by allowing refusal to testing. However, it would be preferable to allow for testing to occur without continued storage of tissue to address indigenous concerns about retention of tissue while still allowing for testing. This would also address general individual concerns about storage and subsequent use better than simply allowing for testing to be refused. As testing is highly important for the health of the newborn, care should be taken to prevent parents from refusing testing because they are concerned about storage of the blood sample.

While the concerns about the validity of consent given at the time of testing noted in Part I remain,¹⁴⁰ it should be recognised that these Statements attempt to remedy this

¹³⁸ Ibid, [4.3.6].

¹³⁹ These policies and memoranda are outlined and discussed in Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours*, ch 19. It should be noted that Western Australia has established more restrictive policies that limit the research use of stored cards and limit the duration of storage to two years. See WA Newborn Screening Program, *Policy for the Retention, Storage and Use of Dried Blood Spot Samples Collected by the Western Australian Newborn Screening Program*, 2002.

¹⁴⁰ See Chapter Two, section 2.

through the provision of detailed written information and through requiring an individual at the program to be responsible for providing that information. Further, while these Statements and the Banking Guidelines above are subject to the same concerns about lack of legal force, they are effective because they are released by a well-regarded professional body and developed in consultation with representatives from health authorities responsible for screening. They are therefore likely to be followed because of the risk of peer-sanction and because they are developed by and for the bodies who conduct screening.

That said, they do suffer again from the lack of any means to provide remedies to individuals whose stored tissue is misused and their failure to establish mechanisms for sanctioning third parties who access and misuse tissue.

5. CONCLUSION

This chapter has identified a number of core concerns about the regulation of tissue use through ethical and practice guidelines. One major concern identified in this chapter is that the sanction available to the NHMRC may not be sufficient to ensure compliance. A related concern is that the NHMRC guidelines do not generally apply to private sector organisations, and the sanctions they provide may be ineffective in ensuring compliance even where such organisations choose to be bound. This concern has also been noted by the ALRC/AHEC, which has recommended that the NHMRC review its mechanisms for achieving compliance, with particular regard to research conducted wholly within the private sector.¹⁴¹

Another concern is that none of the guidelines considered in this chapter provide remedies for the harms that may be suffered by individuals whose tissue is misused, and even if they did they would not be legally enforceable. This raises the third major concern, that although the guidelines have considerable strength to encourage compliance, they may have limited effect in some instances as they do not have the force of law to compel compliance.¹⁴²

¹⁴¹ Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours*, Recommendation 14-1.

¹⁴² The ALRC/AHEC made a range of recommendations on improving this situation, however they have yet to be implemented. See Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours*, chs 14-17, especially Recommendations 14-1, 15-1, 15-2, 16-1, 16-2, 17-1, 17-2.

Fourth, the guidelines do not define any clear status for tissue or cover situations where tissue once removed and used comes into the possession of an individual or organisation not subject to the guidelines. Similarly, they do not consider issues of who owns tissue and therefore who has rights to access, possess or use it in other situations. Therefore, they do not remedy the concern noted in relation to the Human Tissue Acts that the specificity of the legislation (and now the guidelines) mean that tissue used in contexts beyond these instruments is not covered by any regulatory framework, and hence any misuse is not addressed. Further, they do not provide any means of determining who will have the right to regain control of tissue in other circumstances beyond those covered by the framework.

Despite these concerns, however, it should be recognised that the ethical and accreditation framework for regulating tissue use appears to have been relatively successful in this country and there appear to have been few reports of abuses.¹⁴³

¹⁴³ See, eg, Ibid, [11.10], [14.36].

CONCLUSION

In many ways, the combined framework of legislative regulation and ethical guidance provides strong protection for individual interests in sampled human tissue, while still promoting the valuable research to leads to improved healthcare provision. However, a range of concerns have been identified throughout this Part, many of which appear repeatedly in relation to different schemes for regulating tissue use. Briefly summarised these are:

- a lack of remedies for harmed individuals;
- a lack of mechanisms for individuals to seek discontinuation of tissue misuse once tissue has passed into the hands of individuals or organisations covered by the framework;
- a lack of any defined status from which rights to tissue where use is not covered by the framework might be derived (one of the failings of the consent approach);
- the absence of sufficient legal protections for individuals and families in relation to tissue retained during post-mortem;
- insufficient attention to indigenous concerns in the legislative framework;
- the lack of legal enforceability of ethical and practice guidelines;
- the absence of legislative or ethical provisions covering benefit sharing and the commercial use and sale of tissue, particularly by individuals if this is regarded as appropriate; and
- a lack of legal or ethical guidance on the use of tissue in areas not covered by the framework.

This final point has not been covered previously in this Part as it concerns a wider gap in the framework that is not specific to any particular instrument. Part I detailed a very broad range of uses for tissue, some which are either not contemplated or not allowed (despite the fact that they may be reasonable uses) by the current regulatory approach. These include the use of tissue in commercial products (such as in Case Study 17: StarGene), the commercial sale of tissue, such as commercial firms like Ardais, and the use of tissue in artistic works (such as in Case Study 18: Orlan and Manipulation of the Flesh). At present, the limitations of the framework mean that such uses, and others that may emerge, are not regulated and hence may occur in objectionable ways yet not be open to legal sanctions or restrictions established through ethical guidelines.

Further, the framework focuses on providing guidance on particular uses of tissue, rather than providing a comprehensive scheme that can be applied generally to use. It also does not establish any rights for individuals or for lawful possessors of tissue that apply generally, instead only providing rights or capacities to use tissue as outlined in the legislation or guidelines. This is probably the most problematic aspect of the current framework as there will always be uses that are not covered and hence not regulated (as no scheme can hope to specifically regulate every conceivable use for tissue), yet the varied approaches to tissue regulation mean it will be difficult to extrapolate legally how misuse of such tissue is to be treated. Part III evidences the difficulties this has already raised for the courts.

Finally, it means that there is no guidance on how tissue that is abandoned can be treated. Therefore, skin cells left behind on a coffee cup, or toenail clippings, cut hair or blood from a cut and all the other tissue that everyone regularly loses during a normal day is not covered by any regulation and individuals have no clear rights over it beyond the highly specific research guidelines and legislation. As genetic testing improves, clearly it will become even easier for anyone to have such tissue tested to yield vast amounts of personal information about the person from whom it was obtained. In the absence of privacy legislation protecting tissue samples, this is already a significant concern and will only become more significant as genetic testing improves and becomes cheaper and more accessible. The possibilities for using this information to stigmatise, to discriminate, to blackmail or to simply pry into the lives of others are many. It is highly possible that the lack of regulation in this area will become a significant concern in the future.

Having examined the legislative and ethical framework, Part III now analyses how the courts have approached situations where human tissue has arguably been misused. This Part will trace the history of regulation of tissue use by the courts, and introduce the issue of whether human tissue is property. Following a discussion of the concept of property and its applicability to tissue in Part IV, Part V will pick up the concerns raised in this Part (and Part III) and examine whether property law may be a good solution to address them.

Part III

The Common Law and the Body

Contents

INTRODUCTION	191
 <i>Chapter Six</i>	
CORPSES AND THE COMMON LAW	194
1. Buried Corpses: Fending off the Body-snatchers	194
2. Unburied Corpses	202
3. Temporary Right to Possession for the Purpose of Burial	207
 <i>Chapter Seven</i>	
MODERN USES: STRAINING AT THE CONFINES OF THE COFFIN	210
1. A New Era of Case Law: <i>Doodeward v Spence</i>	211
2. Tissue Taken for Testing: Police and Forensic Use	218
3. Access to Stored Tissue Samples	222
4. Appropriation of Retained Body Parts: <i>R v Kelly</i>	233
5. Tissue as Commercial Object, Commodity and Product	242
5.1 <i>Moore v The Regents of the University of California and others</i>	247
 CONCLUSION	 260

INTRODUCTION

Mastering the lawless science of our law,—
That codeless myriad of precedent,
That wilderness of single instances.

Alfred, Lord Tennyson, Aylmer's Field

Although there is relatively comprehensive legislation regulating the consensual donation of human tissue in some areas, there is no specific statement on the legal status of human materials. A wide variety of tissue uses remain legislatively unregulated. When there is no legislation to deal with a legal problem such as this, the common law is left to fill the void. This Part will examine the Australian and English authorities that have dealt with human tissue use, and consider whether they have evolved a clear legal position. This Part will also outline gaps in the common law and identify failures in the current approach to dealing with the increasing use of human tissue.

There are relatively few cases that have dealt with human tissue use. Of these, some have dealt with entire corpses, and hence are not entirely relevant here. However, as this chapter will demonstrate, the body of case law concerning human tissue in Australia and England has largely grown out of the early proposition that there can be no property rights held in a corpse.

The earliest cases dealing with human bodies and tissues arose in the era of the body-snatchers, when theft of corpses from graveyards became rife in the 18th century. The scientific study of anatomy and the growing practice of dissection created a demand, and the resurrectionists emerged to meet it. The need for cadavers for scientific study led eventually to the passing in England of the *Anatomy Act 1832* (UK) to provide a supply of bodies for dissection. Before this time, however, cases of body theft and the invasion of graves had already come before the courts. Just as people had begun to booby trap graves and bury their dead in metal coffins to ward off the body-snatchers, so the legal system began to respond to the new profession of grave-robbing. These cases dealt with interference with entire corpses after burial, and developed a line of precedent distinct to that issue.

Later cases attempted to apply or extend the rule against property in a corpse to more modern uses of tissue, such as testing of samples for paternity purposes. However, in

some instances, the courts found the rule wanting and were prepared to accept that tissue might be property in some circumstances. As a result, there is arguably a developing, if tentative, trend in the case law towards according limited property rights in some circumstances.

Because the courts have examined the regulation of human tissue in the context of property law, academic debate about the status of human tissue has also centred on this area of law. Much of this debate has been concerned with defining the common law position—namely, whether the law regarded human tissue as property or not. A secondary debate has developed around whether it is appropriate for human body parts to be deemed property. This debate has considered the issue from various perspectives, including ethics and public policy. This Part is concerned with the first area of debate, while Part V will consider whether human tissue should in fact be property.

Within the case law and commentary on this area of law, a clear theme has emerged. The cases consider whether there is a rule against property in corpses, and perhaps also body parts, and how and where that rule should be applied. This Part will analyse these cases to determine whether they do take a property approach and in what circumstances. More generally, it will consider whether a coherent and principled approach to the issues raised by human tissue has developed at common law and the strength of any precedent that emerges. As there is little Australian case law outside of the English cases that form part of the precedential history in Australia, the English cases on point will also be considered.

This Part will examine cases under three main headings: cases dealing with buried corpses; those dealing with unburied corpses and the temporary right to possession (in Chapter Six); and the diverse range of decisions that deal with more recent and novel uses of tissue (in Chapter Seven). Within Chapter Seven, the cases will be further divided into cases dealing with: forensic use of tissue; access to pathology samples; theft of preserved body parts; and tissue as a commodity. These categories follow the historic development of legal rules in this area and reflect the different legal approaches taken in different contexts.

Finally, this Part will consider the feasibility of the court decisions when applied to the problems raised by modern tissue use. In doing so, the effectiveness of the current legal position will be evaluated, and areas of inadequacy in the common law will be detected.

This will be achieved by applying the holdings in each case, or the general position determined by the analysis, to the case studies developed in Part I. As this thesis is not concerned with buried corpses or bodies awaiting burial as such, this analysis will be limited to the more modern cases in considered in Chapter Seven.

Chapter Six

CORPSES AND THE COMMON LAW

1. BURIED CORPSES: FENDING OFF THE BODY-SNATCHERS

Haynes' case of 1614 is the first reported case dealing with interference with buried corpses.¹ It is in this case, or at least in its misinterpretation, that the foundations of the rule against property rights in dead bodies can be found. William Haynes, having disinterred the bodies of three men and one woman, removed the winding sheets in which they were wrapped and subsequently reburied the bodies. The issue was to whom the sheets belonged before they were taken. The court decided that the property vested in whoever had owned the sheets before the bodies were wrapped in them, and the justices of Serjeant's Inn found Haynes guilty of petty larceny.²

As the bodies were replaced, clearly *Haynes* did not concern the taking of a body, or who might own that body. Despite this, the case has been regularly cited by both modern writers and classical legal commentators as an authority for the rule against property in a buried corpse.³ As Paul Matthews has correctly stated, to cite *Haynes* thus is 'a complete perversion' of the case.⁴ He argues that the perverse interpretation of the case comes from an inaccurate reading of the phrase 'that the property of the sheets remain in the owners, that is, in him who had the property therein, when the dead body was wrapped therewith; for the dead body is not capable of it...'⁵ In other words, a dead body is not capable of owning the sheets. It appears that the expression 'for the dead body is not capable of it' has been misread to mean the dead body is not capable of *being* property. However, in the context of the statement and the case as a whole, it is obvious that the justices of Serjeants' Inn were asserting that a dead body could not *hold* property. The issue the court was dealing with was who owned the sheets, not who, if anyone, owned the body, and the court was stating that the deceased could not be the owner of the sheets.

¹ (1614) 77 ER 1389.

² *Haynes'* case (1614) 77 ER 1389, 1389.

³ See, eg. L Griggs, 'The Ownership of Excised Body Parts: Does an Individual Have the Right to Sell?' (1994) 1 *Journal of Law and Medicine* 223.

⁴ P Matthews, 'Whose Body: People as Property' (1983) 36 *Current Legal Problems* 193, 197.

⁵ *Haynes'* case, 1389.

There is, however, some basis for the perversion, though a perversion it remains. The notion that the case founds a rule against property in a dead body more likely comes from the assertion in the case that 'a dead body, being but a lump of earth, hath no capacity: Also, it is no gift to the person but bestowed on the body for the reverence towards it, to express the hope of resurrection'.⁶ This comment on the nature of the body, suggesting that it is bestowed on the person by God, is *obiter dicta* as it was not material to the matter at issue. Further, the Court did not discuss the exact legal status of the body—obviously because it was not at issue—it merely noted that the body was given to the person to 'express the hope of resurrection'.⁷ Reliance on *Haynes* as a source of the rule of no property in the corpse is both incorrect and simply accords an aside by the Court more force and meaning than it merits.⁸

Regardless, early commentators such as Sir James Stephen cited *Haynes* as authority for the proposition that '[the] dead body of a human being is not capable of being stolen'.⁹ In 1803, Sir Edward East agreed, also citing *Haynes* as a precedent for the rule against property in the body.¹⁰ Others, such as Sir Edward Coke writing at the time of *Haynes*, stated that there could be no property rights in a corpse, but did not cite *Haynes* as authority. Coke asserted in his commentaries that a cadaver was *nullius in bonis*, which may be translated as 'among the property of no-one'.¹¹ Instead of citing a case as authority, he cited a work from the 13th century text *Britton*.¹² There is nothing in *Britton*, however, to support Coke's assertion. The passage to which the reader is referred is entitled 'Of Purchase' and discusses what may and may not be legally bought, sold and

⁶ Ibid, 1389.

⁷ Ibid, 1389.

⁸ S Huynen, 'Biotechnology—A Challenge for Hippocrates' (1990) 6 *Auckland Law Review* 534, 537; R Magnusson, 'The Recognition of Proprietary Rights in Human Tissue in Common Law Jurisdictions' (1992) 18 *Melbourne University Law Review* 601, 197–198.

⁹ Stephen did, however, predict the future debate on the status of the body, having posed the question 'Can skeletons and anatomical preparations of parts of dead bodies, or which formerly formed parts of bodies when living, be stolen?—teeth, for instance, intended to be used for false teeth?' J Stephen, *A Digest of the Criminal Law (Crimes and Punishments)*, Macmillan, London, 1977, 252, Art 318.

¹⁰ E East, *Pleas of the Crown, 1803*, vol 2, Professional Books, London, 1972, 652. Sir Edward Coke, who has on occasion been cited by modern writers as one source of the 'no property' rule (see, eg, Griggs, 'The Ownership of Excised Body Parts', 225) merely reported the case accurately as holding that 'the dead body is not capable of any property'. See E Coke, *The Third Part of the Institutes of the Laws of England: Concerning High Treason, and other Pleas of the Crown, and Criminal Causes*, Thomas Bassett, London, 1680, 110. What should be noted at this point is that only Coke was writing at the time *Haynes*' case was heard. Indeed, he gave advice on the case to the judges of Serjeant's Inn. Both East and Stephen made their commentary on *Haynes* after the later case of *R v Lynn* (1788) 100 ER 395 was decided.

¹¹ Trans. 'among the property of no-one'.

¹² See P Skegg, 'Human Corpses, Medical Specimens and the Law of Property' (1975) *Anglo-American Law Review* 412, 412; F Nichols, *Britton: The French Text Carefully Revised with an English Translation, Introduction and Notes*, vol I, W W Gaunt, Florida, 1983, fo 84b.

consequently owned. Though it does state that '[t]here are things which are no one's property' (including churches, consecrated places and burial-places), there is no mention of corpses in the passage.¹³

In the 19th century, Sir William Blackstone also asserted the existence of a rule against property in a buried corpse. He stated that 'stealing the corpse itself, which has no owner, though a matter of great indecency, is no felony...' but cited no judicial authority in support.¹⁴ Instead, the reader is directed to a paragraph relating to the property rights of an heir, wherein *Haynes* case was noted but not examined. Whether he regarded *Haynes* as authority for the rule is unclear, but it does appear that Blackstone believed there was a prohibition on property rights being held in a buried corpse.¹⁵ These early legal commentaries have in large part come to be regarded as misinterpretations and do not form an acceptable basis for a rule against property in corpses.¹⁶

What this demonstrates is that there was legal opinion that a rule against property rights in a corpse existed at the time *Haynes* was decided, and that even those who did not view *Haynes* as support for this proposition, did believe that the rule against property in corpses was established.¹⁷ The legal commentaries are, however, of historical interest only, as this view of the case does not alter the fact that it forms no real basis for a rule against property in buried corpses. The decision in *Haynes* holds that the practice of disinterring bodies is indecent and should be an offence but beyond that it does not define any clear rule on how bodies should be treated legally.

The case of *R v Lynn*¹⁸ followed *Haynes* in 1788, and involved the taking of a corpse from a graveyard for dissection. This was the first real case dealing with actual theft of a

¹³ Nichols, *Britton*, 214.

¹⁴ W Blackstone, *Commentaries on the Law of England*, 19th edn, vol 4, Sweet, Maxwell and Stevens, London, 1836, 236.

¹⁵ By contrast, William Hawkins and Sir Matthew Hale, both writing in the 17th century, made no allusions to whether the corpse may itself be property. Both wrote of *Haynes* only as a reference for the rule that a corpse may not itself hold property: W Hawkins, *Pleas of the Crown, 1716–1721*, vol 1, Professional Books, London, 1973, 94; M Hale, *Pleas of the Crown: A Methodical Summary, 1678*, Professional Books, London, 1972, 515.

¹⁶ See, eg, L Griggs, 'A Property Analysis to Genetic Material: Historical Underpinnings and Future Possibilities' (2001) 3 *Centre for Law and Genetics Occasional Papers Series* 4, 6; A Grubb, "'I, Me, Mine': Bodies, Parts and Property' (1998) 3 *Medical Law International* 299, 307.

¹⁷ Coke, Blackstone, Hale and Hawkins made their commentary on *Haynes* before *Sharpe* and *Lynn* were heard, Hale's *Pleas* being published in 1678, and Hawkins' between 1716 and 1721. Thus their opinion on the rule of no property rests solely on their reading of *Haynes*' case itself, and whether they previously believed such a rule existed. Stephen and East, however, made their commentary on *Haynes* after the decision in *Lynn* was handed down. Stephen's *Digest of the Criminal Law* was first published in 1877, East's *Pleas of the Crown* in 1803.

¹⁸ (1788) 100 ER 395.

body. An appeal was brought on the ground that the offence of removing the body came only within ecclesiastical cognisance, and was therefore not a matter for the Court of Criminal Jurisdiction. Coke was cited as authority for this appeal, with the appellant quoting Coke's assertion that 'the burial of the cadaver is *nullius in bonis*, and belongs to the ecclesiastical cognizance'.¹⁹ The Court held that the taking of bodies for dissection was, however, cognisable in the Criminal Court due to the gross indecency of the act, being a practice that 'should be put a stop to' and one which was '*contra bonos mores*'. The Court pointed out also that it was 'the practice of the Old Bailey in modern times to try charges of this nature' though it cited no examples.²⁰ Noting that previous (unspecified) writers had held that the taking of bodies was not criminal except for the purposes of witchcraft, the Court decided regardless that the taking of bodies for dissection was an indictable offence. Lynn was found guilty.

As an authority for the rule against property in a corpse, *R v Lynn* is far from satisfactory for at least three reasons. First, and most clear, is the fact that the case was not on point. The appeal was brought to determine whether the removal of a body from a graveyard was solely within ecclesiastical cognisance, that is, not a matter for the Criminal Court. Any discussion of property issues could not be anything but *obiter dicta* as the court was not required to rule on such matters. Secondly, and in accordance with the purpose of the appeal, the Court itself made no comment upon property issues. The perhaps misleading reference to the writing of Sir Edward Coke was, as Roger Magnusson and Peter Skegg have pointed out, made by the counsel for the appellant.²¹ The Court did not comment upon it, as it apparently did not believe that this section of the statement required address. Lastly, on examination of the context in which Coke's statement was used, it is clear that it was quoted not as an authority for a rule against property in the corpse, but to support counsel's submission that the case ought not have been brought before the Criminal Court. Having repeated Coke's words, counsel immediately went on to state 'that it was also the opinion of Lord Coke that the present charge was not the subject of an indictment in a Criminal Court'.²² No mention was made, nor any argument put, in relation to the property status of the body itself. Rather, the case was decided on the grounds that the practice of disinterring bodies was one which went against common decency. The Court ruled upon its jurisdiction to hear the case, and did

¹⁹ Coke, *The Institutes of the Laws of England*, 395.

²⁰ *R v Lynn*, 395.

²¹ Magnusson, 'The Recognition of Proprietary Rights in Human Tissue', 604; Skegg, 'Human Corpses', 413.

²² *R v Lynn*, 395.

not refer to property issues in its judgment. Also, the act of removing bodies was regarded as criminal not due to the existence of any property rights in that body, but by reason of the indecency inherent in the practice.

Despite the lack of explicit ruling on the subject of property rights in buried corpses, *Lynn* was cited as precedent in the subsequent 1857 case of *R v Sharpe*.²³ It is at this point that the rule seems to have gained judicial support. The defendant, George Sharpe, deceitfully obtained access to burial grounds and disinterred the body of Louisa Sharpe, his mother. He subsequently transported the body to another churchyard where he intended to re-bury it. Sharpe was charged with the 'misdemeanour at common law [of] remov[ing] without authority a corpse from a grave in a burying ground belonging to a congregation of Protestant dissenters'.²⁴ He was found guilty of opening the grave, that is, trespass, and the removal of the corpse. On appeal, the Court of Criminal Appeal affirmed the lower court's decision.

Sharpe is the first case in which a legal prohibition against property rights in a buried corpse is actually stated in the judgment. Sharpe argued in his defence that he, as the child of Louisa Sharpe, has a right to her body, a right which Justice Erle of the Appeal Court rejected, stating:

Neither does our law recognise the right of any one child to the corpse of its parent ... Our law recognises no property in a corpse, and the protection of the grave at common law, as contradistinguished from the ecclesiastical protection to consecrated ground, depends upon this form of indictment; and there is no authority for saying that relationship will justify the taking a corpse away from the grave where it has been buried.²⁵

Erle J's statement makes clear that a familial relationship between a person charged with removing a body and the person of the deceased is not sufficient defence to the charge of removing a body from a grave. The defendant's assertion that he had a right to the body of his mother as though it were property was found unacceptable to the court, as it might 'lay down a rule which might lessen the only protection the law affords in respect of burials of dissenters', that is, people buried in unconsecrated ground.²⁶

As an authority for a rule against property in a corpse, however, *R v Sharpe* is somewhat

²³ (1857) 169 ER 969. Though the case was not cited to the Court by counsel, it was footnoted by the Court in confirmation of the appeal. See *R v Sharpe* (1857) 169 ER 969, 961, note (a).

²⁴ *Ibid*, 959 per Erle J.

²⁵ *Ibid*, 960 per Erle J.

²⁶ *Ibid*.

problematic. While the court did uphold the offence of removing bodies, the decision on the issue of property is best regarded as *obiter dicta*. The Court was not required to determine if the body was property, nor whether Sharpe had a right to it, only whether he was guilty of the recognised misdemeanour of removing a body from its grave. The discussion of property in that body was merely a response to an alleged defence to the misdemeanour by the appellant.²⁷

A second interpretation of Erle J's remarks in *Sharpe* is that he was in fact rejecting a defence raised by the appellant that he had a proprietary right to possession of his mother's body. Roger Magnusson has rightly rejected this view of the case, asserting that 'it is highly unlikely that the right the defendant was asserting to his mother's body was asserted as a *proprietary right* to the whole body *as a chattel*'.²⁸ That is, in reply to the charge of trespass, the appellant argued that he had a right to enter the burial ground to recover an object lawfully his. Debra Mortimer, however, has argued the contrary view—the appellant *must* have raised some form of defence based on property rights for Erle J's comments to make any sense.²⁹ As she points out, Erle J's discussion of property is given in response to the appellant's defence: his Honour was stating there was no property in a corpse in order to reject that defence.

While Mortimer's argument has its merits, it should be recalled that the defendant was not represented. For this reason, it is unlikely that he was aware of any rule against property in a corpse, and might have believed that indeed he did have some right of possession to the body of his parent. The law does grant such a right of possession to corpses awaiting burial to those who are responsible for its disposition to enable them to handle and inter the body.³⁰ It may have been that the defendant, having observed this right, saw no reason why it did not extend to a buried body which he believed ought to be disinterred and re-buried elsewhere. Rather than claiming her body as his property to do with as he wished, it is more likely that he was asserting some lay view that he had a right to ensure her body was properly buried. Alternately, he may have been using the language of property as a means of expressing how strong he thought his right to take charge of the body was, rather than in the legal sense. The basis of his defence seems

²⁷ By contrast, Debra Mortimer has argued that this rejection of the defence's alleged exception was part of the decision, and that the discussion of the rule against property was therefore also part of the judgment: D Mortimer, 'Proprietary Rights in Body Parts: The Relevance of Moore's Case in Australia' (1993) 19 *Monash University Law Review* 217, 236.

²⁸ Magnusson, 'The Recognition of Proprietary Rights in Human Tissue', 605.

²⁹ Mortimer, 'Proprietary Rights in Body Parts', 236.

³⁰ See section 2 of this chapter, particularly the case of *Williams v Williams* (1882) 20 ChD 659.

more to be an assertion of filial duty to inter his parent respectfully, and the right to pursue that duty, rather than a right to obtain the body and treat it as property. Though Erle J responded with the language of property, he was not actually disputing an alleged property right but rejecting the assertion that as a relative, the defendant had a right to take the corpse. His comments on the property status were therefore *obiter*.

Roger Magnusson and Peter Skegg, however, have a more convincing explanation of Erle J's comments. They argue that the discussion of this exception and the property rule was directed at the form of the indictment. Skegg's argument, and subsequently that of Magnusson, is based on a reading of this passage which places emphasis on Erle J's reference to the form of the indictment, namely that the protection of graves at common law, outside the ecclesiastical laws, is achieved through charging the accused with the misdemeanour of *removing* the body rather than *theft* of the body. As Skegg has asserted, the Court's judgment stated that there could be no property in the corpse 'simply to explain the form of the indictment'.³¹ The question of property or otherwise was not at issue and could only be *obiter*. Erle J's comments as to property in the corpse 'could only have been *obiter dicta*, since the defendant had been charged with trespass to land'.³² Significantly, there is no mention in the case of theft. The case is no authority for the rule because the Court's comment on that rule was included only to explain why the prosecution had not brought its case on the ground of larceny—because it would have failed due to the absence of property in the corpse.

This is the essential 'Catch-22' of the debate surrounding the origins of the no property rule. Due to a prior assumption that there could be no property in a corpse, those who removed bodies from graves were not charged with larceny but with trespass. Subsequently, any comments regarding property in *R v Lynn* and *R v Sharpe* could only be *obiter*. Such cases therefore could not form a basis for the rule of no property—but only because there was a prior belief in the rule. This may explain the dearth of early relevant cases referring to the rule as part of the case *ratio*.

Matthews has argued that to make such an inference is difficult to say the least.³³ Yet, given the writings of Coke and others, the law against property in a corpse appears to have been accepted in spite of the lack of case law on the subject. That few early

³¹ Skegg, 'Human Corpses', 414.

³² Magnusson, 'The Recognition of Proprietary Rights in Human Tissue', 605.

³³ Matthews, 'Whose Body: People as Property', 199.

commentators chose to cite authority for the proposition suggests that it was so widely recognized as a rule as to require no authoritative statement. Whatever the case, it does make sense that the Crown would not bother to charge grave robbers with theft of something that presumably could not be owned. This also explains the development of another form of indictment—trespass—as a means of prosecuting an act that was nonetheless objectionable.³⁴

The few modern cases that have dealt with removal of bodies have not directly considered issues of property. In the 1975 case of *R v Harmsworth* (only very briefly reported as an appeal of sentence), the appellant was convicted of ‘unlawfully opening coffins and removing parts of deceased persons therefrom’.³⁵ The case of *R v Farrant* was decided on the same day, and was also an appeal of sentence.³⁶ In that case, the appellant had been convicted of ‘breaking open and entering a catacomb in Highgate Cemetery and interfering with and offering indignities to the remains of a body in part of the catacomb’. Paul Matthews has suggested that under the *Burial Act 1857* (UK) protection of corpses in vaults is included in references to interment.³⁷ Hence, these cases fall into the same general category as other buried corpses, and in these cases no reference is made to property rights. Instead, they display an acceptance of a misdemeanour of removal, or in the case of *Farrant*, interference with interred bodies.

The origins of the rule against property in a corpse are hazy and largely the result of misinterpretation. Classical writers believed that a rule against property rights in a corpse existed, but on examination, the writings of Coke and others appear unsatisfactory as support for such a rule. There is nothing in these sources which shows the genesis of the rule, nor can any sound precedent be found within their pages. It appears, rather, that these legal commentators created the rule using each other as sources, and their words were accepted by the Courts. These cases may have founded a misdemeanour of disinterring a corpse, but they did not truly establish any principle whereby a corpse is

³⁴ See further on this in the discussion of *R v Price* (1884) 12 QB 247 in section 2 of this chapter. *Sharpe* was followed in 1867 by *Foster v Dodd* (1867) 3 QB 67. The case concerned whether churchwardens were authorised to enter onto land on which corpses were buried in accordance with *Burial Act 1852* (UK) and subsequent legislation (see *Burial Acts 20 & 21 Vict c 81, s 23; 22 Vict c 1, 2 1* as cited in *Foster v Dodd*, 67 and n 2 per Byles J). The case did not consider the removal or theft of bodies. However, Byles J stated in *obiter* that ‘[a] dead body by law belongs to no one, and is, therefore, under the protection of the public’ to explain his judgment on whether the Act permitted the wardens to enter (*Foster v Dodd*, 77 per Byles J). Despite this, the case is not on point and does not form any precedent relevant to the rule against property in a corpse.

³⁵ *R v Harmsworth* [1975] Crim LR 525, 525.

³⁶ [1975] Crim LR 524.

³⁷ Matthews, ‘Whose Body: People as Property’, 205.

an object of property that can be stolen.

In light of the later cases of *Farrant* and *Harmsworth*, the older cases can only be said to have established that interference with interred bodies is an offence. They do not include any discussion of the principles or reasoning on which a rule against property in corpses might be based, nor do they provide any sound reason for such a prohibition. They are very much cases of their time, and the judgments were directed at halting body-snatching, which was also a practice of that particular era. In this context, these cases made some reasonable sense. But just as this historical context explains these cases, it also demonstrates why their holdings are not pertinent to the law as it currently stands. They lack coherence and sound legal basis, and their facts are largely irrelevant to the present issues surrounding the modern use of human bodies.

2. UNBURIED CORPSES

The common law has treated unburied corpses differently to those already interred. These cases are distinguished from those dealing with unburied corpses because historically corpses buried in consecrated ground came within the jurisdiction of ecclesiastical law. Those corpses which had not been buried or were placed in unconsecrated ground did not, and a separate line of precedent developed to deal with those corpses. It is in the history of corpses awaiting burial that prohibitions against property rights have been more coherently considered and applied. These cases, particularly the earliest decisions, were directed at concerns over the fate of corpses in a time of body-snatching, but as will be seen, the rule they developed was later applied to wider and perhaps less suitable situations.

Exelby v Handyside is generally cited as the earliest authority for the rule against property in unburied corpses.³⁸ Paul Matthews has described it as a case ‘remarkable for its influence being quite disproportionate to the information available about it’.³⁹ The case concerned possessory rights over a pair of stillborn Siamese twins. Dr Handyside, a male midwife, delivered the twins and took them with him after the birth. The twins’ father brought an action in trover for their return. As reported in East’s *Pleas of the Crown* in 1803, the court found that Dr Handyside should return the children to their father for burial ‘as no person had any property in corpses’.⁴⁰ There is some question, however,

³⁸ East, *Pleas of the Crown*, vol 2, 652; Hawkins, *Pleas of the Crown*, 148.

³⁹ Matthews, ‘Whose Body: People as Property’, 208.

⁴⁰ East, *Pleas of the Crown*, vol 2, 652.

about whether this was the actual reason for the children being returned, as no official report of the 1749 *Handyside* case has yet been traced. It is not reported in any series of law reports, possibly because no actual verdict was delivered. In addition to East, the main source of information about the case is Hawkins' *Pleas of the Crown*.⁴¹ This lack of reliable commentary undermines its place as good precedent for a rule in law. In the main, the facts and holding of the case have been obtained from the work of East, reporting more than fifty years after it was decided, and no source for his information has been located.⁴² East had not even been born before the justice in *Handyside*, Sir John Willes CJ died. Therefore, he could have had no personal knowledge of the case, and it is doubtful that his report is entirely reliable. Hawkin's later account of the case is likewise unreliable, for as Matthews has pointed out, the source was most likely East himself.⁴³

Of the scant facts of the case, it is reported that the case was decided while the jury was in deliberation.⁴⁴ During their absence, Willes CJ dismissed the case on the grounds that the action would not lie as no person had property in a corpse.⁴⁵ Because no verdict was delivered, *Handyside* cannot be said to have actually been decided, and thus no *ratio decidendi* exists. Having no *ratio*, the case cannot be regarded as a statement of the law to bind future courts.

The inadequacy of *Handyside* as an authority is further confirmed by the fact that the plaintiff succeeded in having the twins returned to him, it being agreed in the absence of the jury that *Handyside* should give up possession of them to their father. The reason for this is unclear, and one must wonder why, if Willes CJ was adamant that no property would lie, the defendant would yield up possession. If the bodies were not the subject of property, the father could not have had any right to have them returned. Despite the fact that *Handyside* is more directly on point with regard to ownership of a body than the cases concerning buried corpses, its age, the lack of *ratio*, as well as the lack of reliable information altogether, detracts from the case's efficacy as an authority. However, like the commentaries of Blackstone and others, it does demonstrate that there was, at this time, at least one Lord Chief Justice in England who believed that no property could be

⁴¹ Published in 1803 and 1824 respectively. Paul Matthews provides a valuable account of his own search for information about this case in Matthews, 'Whose Body: People as Property', 208ff.

⁴² See East, *Pleas of the Crown*, vol 2, 652; Matthews, 'Whose Body: People as Property', 208.

⁴³ Matthews, 'Whose Body: People as Property', 208.

⁴⁴ *Ibid*, 209.

⁴⁵ East, *Pleas of the Crown*, vol 2, 652.

held in a corpse, whatever his other reasoning in the case may have been.

In the 1840s, the judgments of *R v Fox* and *R v Scott* established that there was a right to possession of a body for the purpose of disposing of it.⁴⁶ In 1882, the next major case regarding the property status of bodies, *Williams v Williams*,⁴⁷ relied upon this established right. In *Williams*, the defendant, Eliza Williams, fraudulently gained access to Henry Crookenden's grave.⁴⁸ She did so to comply with the fourth codicil to Crookenden's will which requested that she be given his body to have it cremated. She had the corpse disinterred and removed to Italy where it was cremated. She then sued the executors for her expenses. The action failed on three grounds. First, the Court held that the removal of the body for cremation and the act of cremating it were both illegal acts and therefore she could not recover her costs in doing so. Second, a remedy in equity was denied due to the plaintiff's original fraud on the Home Secretary to gain access to the body. Third, and most important to this discussion, the Court declared that there was no property in a dead body. The Court held instead that the executors of the will held limited possessory rights in the body to enable them to fulfil their duty to bury it.⁴⁹ The crux of the case was the issue of a right to dispose of a body posthumously, and though the corpse in question had been buried previously, the dispute centred on whether the codicil directing the defendant to cremate it was binding and legal.⁵⁰ That is, the issue was rights to the body before burial.

Kay J, in giving judgment, declared himself to be in no doubt of the law, stating that '[i]t is quite clearly the law of this country that there can be no property in the dead body of a human being'.⁵¹ In support of this assertion, his Honour cited *R v Sharpe*.⁵² *Sharpe*, however, deals with *buried* corpses, whereas *Williams* concerns rights to a body before burial. Further, as previously argued, *Sharpe* is not a satisfactory authority for prohibitions on property rights in bodies. Nonetheless, Kay J's statement that a body cannot be property meant that it could not be disposed of via the will.

⁴⁶ *R v Fox* [1841] 2 QB 346; *R v Scott* [1842] 2 QB 248 (cited in *Williams v Williams*). In both cases, a gaoler refused to deliver up a body and it was held that though the body was not property, the executors had a right to possession of it.

⁴⁷ (1882) 20 ChD 659.

⁴⁸ It should also be noted that while *Williams* concerned a body that had been previously buried and then disinterred, is more suitably discussed here in the context of unburied corpses because much of the discussion in that case was concerned with the right to burial rather than the offence of disinterring a corpse.

⁴⁹ *Williams v Williams*, 663–665 per Kay J.

⁵⁰ See further on transfer of bodies by will L Griggs and K Mackie, 'Burial Rights: The Contemporary Australian Position' (2000) 7 *Journal of Law and Medicine* 404, 406.

⁵¹ *Williams v Williams*, 662–663 per Kay J.

⁵² *Ibid*, 663 per Kay J.

Kay J's remarks on the no property rule are better regarded as *obiter* because the issue was how the right to possession for burial could be effected. Crookenden was not seeking to dispose of his remains as property in the same manner he would dispose of his house, like an object of property. Instead, the issue was whether he could bequeath the *right to possession* of the body for burial, or alternately cremation, to Eliza Williams rather than have it vest in the executors of his will. The court accepted that such a right to possession existed until the body was put to rest, and deemed it a non-proprietary right, following *R v Fox*. This right vests automatically in the executors of a will, and the deceased attempted to circumvent this through the codicil to his will, which gave this right to Ms Williams. The discussion of property rights in the body itself was immaterial to determining the outcome of this question, as it was not property but a right to possession that was being bequeathed. As such, *Williams* does not support the proposition that there can be no property rights in the body, as any comments to this effect were merely *obiter*. Instead, this case is only precedent for a right to possession of a body before burial. The nature of this right will be considered in more detail shortly.

Two years later in *R v Price*, the defendant was indicted for attempting to burn the body of his child to avoid an inquest into that child's death.⁵³ The court held that it was not a misdemeanour to burn the body unless the act caused a public nuisance, but ruled that it was an offence to prevent the holding of an inquest. This case requires examination as in the course of his judgment Stephen J made a direct reference to the absence of property rights in a corpse.

The misdemeanour in *Price* was twofold. The defendant was indicted first for attempting to burn the body of his child instead of burying it, and second for attempting to prevent an inquest—the second charge is not relevant to this discussion. Though the case does relate to how a corpse is dealt with and by whom, it is not, in actuality, a case that deals with property issues. Indeed, his Honour summed the matter up concisely in stating that the question was 'whether it [was] a misdemeanour at common law to burn a dead body instead of burying it'.⁵⁴ In other words, the question was not whether a dead body might be the subject of property. The defendant was convicted of causing nuisance to the public by burning the body—and hence the issue of property existing in the body was immaterial. Despite this, Justice Stephen made reference to *R v Lynn*, *R v Sharpe* and the

⁵³ (1884) 12 QB 247.

⁵⁴ *R v Price*, 249 per Stephen J.

purported rule against property rights in corpses awaiting burial by stating that 'the act done would have been a peculiarly indecent theft if it had not been for the technical reason that a dead body is not the subject of property'.⁵⁵ It is on this basis that the case has later been cited as authority for the rule against property rights in bodies awaiting burial.

The case does not form a precedent for the rule, however, for two reasons. The first, already evident from the foregoing discussion, is that any mention of property rights must be *obiter* only, as the case was one of nuisance to which property rights were not relevant. Second, Stephen J's reference to *Sharpe* and *Lynn* was not to allow him to decide the case in terms of property rights in the child's corpse held by the father or any other person. The judgment is not framed in terms of property nor based on the argument that the absence of property rights in a corpse prevents a person from disposing of their remains as they choose. As he himself explained, following a discussion of those cases:

The law to be collected from these authorities seems to me to be this:—The practice of anatomy is lawful and useful though it may involve an unusual means of disposing of dead bodies, and though it certainly shocks the feelings of many persons, but to open a grave and disinter a dead body without authority is a misdemeanour, even if it is done for a laudable purpose.

These cases [*R v Lynn* and *R v Sharpe*], for the reasons I have given, have some analogy to the case of burying a dead body, but they are remote from it. They certainly do not warrant the proposition that to burn a dead body is in itself a misdemeanour.⁵⁶

Clearly, *Lynn* and *Sharpe* were mentioned as a means of drawing a comparison with the issue of how a body was to be disposed. That the comment was made in the context of a lengthy discourse on the historical methods of dealing with a corpse supports this conclusion. Stephen J did not cite these cases to support a rule that would have a bearing on the case before him, but to add to a discussion on the ways in which corpses were regarded and treated. Thus the reference these cases can again be viewed as *obiter* and not as support for a rule against property rights in corpses.

On balance, the early cases dealing with unburied corpses, including most notably *Handyside*, *Williams* and *Price*, have supported the existence of a right to possession of a body for the purposes of burial, which will be considered further in the following section. However, these cases have not produced a coherent rule against property in

⁵⁵ *Ibid*, 252 per Stephen J.

⁵⁶ *Ibid*.

corpses and instead only demonstrate the weak foundations of the rule. Analysis of these cases concurs with Skegg's apt comment, that '[i]t is remarkable how slight is the authority in favour of the no property rule'.⁵⁷

3. TEMPORARY RIGHT TO POSSESSION FOR THE PURPOSE OF BURIAL

On the right to possession for burial specifically, the leading Australian case is *Calma v Sesar*, decided in 1992.⁵⁸ In that case, both parents claimed a possessory right to the body of their son to undertake arrangements for his burial. It was held both were entitled to such a right as next of kin for, as Martin J stated, though '[i]t is clear that there is no property in a human corpse held for the purposes of burial' there could be a 'right to the possession of the body until it is disposed of'.⁵⁹ A similar right rests in coroners and those lawfully entitled to use corpses for medical education purposes.⁶⁰ Such a right is tacitly supported by the Human Tissue Acts and other legislation allowing possession for anatomical purposes in Australia.⁶¹

The only coherent principle that can be drawn from this case (and the earlier English cases) is that the executors of an estate have a right to the possession of a body for burial. As uses of bodies have expanded, so the later case of *Calma v Sesar* has shown that this right has been extended to include other, similar worthwhile purposes where required. These cases do not, however, present any consistent or established precedent that there cannot be property rights in bodies awaiting burial. The only relevance they have to present uses of tissue is to affirm that those who are charged with interring or cremating a body will have the right to take possession for that purpose only.

Though the right is established, whether it is in fact proprietary in nature is still at issue. In *Williams*, Justice Kay asserted that the right was not proprietary, in accordance with *R v Fox*.⁶² However, in *Doodeward v Spence*,⁶³ which will be considered in more detail in the following section, Chief Justice Griffith also spoke of the right of possession as part of the definition of property rights, in the course of asserting that a human body or its parts could be property. In doing so, he touched upon the essential fiction of regarding the possessory right for burial purposes as non-proprietary. Indeed, Justice Higgins in

⁵⁷ Skegg, 'Human Corpses', 417.

⁵⁸ *Calma v Sesar* (1992) 2 NTLR 37.

⁵⁹ *Ibid*, 57 per Martin J.

⁶⁰ See Chapter Four, section 3.

⁶¹ See Chapter Four, section 3.3.

⁶² [1841] 2 QB 346.

⁶³ *Doodeward v Spence* (1908) 6 CLR 406.

his dissent inadvertently referred to the nature of this possessory right as a property right when he stated that he could 'find no instance of any Court asserting any property in a corpse except in favour of persons who wanted it for purposes of burial'.⁶⁴

A right to possess a body does by its very nature appear to be proprietary, for the right to possession is one of the accepted incidents of property.⁶⁵ The difficulty has come from the Courts' refusal to recognise any property in the corpse itself, and hence they have been left with the dilemma of allowing a right of property in something that has been deemed not property. As Ian Kennedy has remarked, '[q]uite how to reconcile these propositions has remained something of a mystery' and rather than attempt to clarify the inconsistency, the English law 'appears to give up and hope for the best'.⁶⁶

The relevance of this right lies in its effect on the retention of bodies for medical, scientific and other uses. Given that the right to possess exists, and is supported by provisions in the Human Tissue Acts and Anatomy Acts to retain bodies, arguably these acts allow for that right to include continued possession. As the Human Tissue Acts allow for parts of bodies to be removed and used in research, clearly this is conferring a right to continue in possession beyond the time at which the body would be buried.⁶⁷ Similarly, bodies held for anatomy purposes may be retained well after the normal period that would elapse before burial, and in some cases parts of the body may be retained for collection and study, as they may also be retained after autopsy.⁶⁸

In effect, then, this supposedly non-proprietary right has been extended by legislation to enable possession not only for longer periods, but also for purposes other than disposal of bodies. This extension and the fact that possession is an element of property point to a need to reassess the nature of this right.

The right to possess a body has its origins in a time when the rule against property in corpses was regarded as established, hence subsequent refusals to accept the inherently proprietary aspects of this right. However, following from this, someone whose possessory right is interfered with would have access to neither conversion nor detinue, as such remedies would fail to lie if the right were not proprietary. Interference would

⁶⁴ Ibid, 421–422 per Higgins J.

⁶⁵ See further Chapter Nine.

⁶⁶ I Kennedy, 'Negligence: Interference with the Right to Possession of a Body' (1995) *Medical Law Review* 222, 223.

⁶⁷ See further Chapter Four, sections 2, 3.

⁶⁸ See further Chapter Four, section 3.

now most likely involve either the taking of tissue or the unlawful retention of the body by others, for which conversion in the former, and detinue in the latter would be the more appropriate remedies. Damages, obtained through a tort of negligence (the only current remedy), would be wholly unsatisfactory to the person who sought the return of a body in order to bury it. Regarding the right as proprietary would address these issues.

Alternately, it may be better to view this possessory right as a form of bailment, rather than as ownership.⁶⁹ As this is an argument that has been made in relation to later cases and a variety of situations of tissue use, discussion of this approach will be given at the end of this chapter. Further consideration to the current view of the right to possession for burial will also be given at that time, so that the two issues may be examined together more effectively and in the light of all the decisions on point to date.

⁶⁹ P Skegg, 'Medical Uses of Corpses and the "No Property" Rule' (1992) 32 *Medicine, Science and the Law* 311, 315.

Chapter Seven

MODERN USES: STRAINING AT THE CONFINES OF THE COFFIN

The no property rule can be regarded as the relic of an age when corpses were of very limited use for medical and other purposes. Its rejection can be regarded as in keeping with the gradual evolution of the common law concerning corpses, and also with the greatly increased importance of corpses for medical purposes.

Peter Skegg¹

In response to suggestions that the rule against property rights in corpses be repudiated, Professor Glanville Williams has asserted that the rule:

is now too embedded in the law for this course to be possible. Overturning the rule would deprive the common law and statutory exceptions of their *raison d'être* and so make nonsense of them.²

Yet in the cases of the 20th century and later, the rule against property rights in corpses has become increasingly difficult to apply. As discussed in Part I, the uses of tissue have expanded considerably since the emergence of the rule. In a time when organs are transplanted³ and tissue samples stored for forensic purposes,⁴ genetic and other testing⁵ and research use⁶ the continued rejection of property rights in human tissues seems like wilful clinging to outdated tradition.

Modern cases have considered, among other things, the theft of body parts from a museum, access to tissue samples for paternity testing and the use of biological materials in developing a cell line. Clearly, the classifications made by earlier decisions based on whether a corpse had been buried or was awaiting burial are now much too narrow. The following discussion of these cases will therefore be structured around four broad

¹ Ibid, 314.

² G Williams, *Textbook of Criminal Law*, 1st edn, Stevens and Sons, London, 1978, 679–680 as cited in *ibid*, 315.

³ See Case Study 3: Organ Transplantation.

⁴ See Case Study 10: Forensic DNA Testing.

⁵ See Case Study 4: Hobart Pathology; Case Study 5: Newborn Screening Card Collection; Case Study 8: South Australian Clinical Genetics Service; Case Study 11: Roche v Douglas.

⁶ See Case Study 6: Tissue in Australian Research; Case Study 12: Iceland and deCODE; Case Study 14: John Moore's Spleen; Case Study 15: Canavan Disease Research.

categories: forensic use of tissue; access to pathology samples; theft of preserved body parts; tissue as a commodity. In addition, the case of *R v Herbert*⁷ and the American case of *Moore v Regents of the University of California*⁸ will be examined.

These cases, in which the courts have attempted to apply the rule against property in corpses, will demonstrate how far the limits of the supposed rule have been stretched. Most tissues now excised in the course of surgery, supplied for testing or donated for research are not fated for burial or cremation, but are treated either as waste or stored as the raw materials for later research. Now the corpse is often out of the coffin, and the rule so hampered by the confines of its walls may no longer be appropriate, or even able to be applied. This section will consider how successful the application of that rule has been in these cases and whether any workable principle can be derived from those cases that have attempted to apply it to the new uses of tissue.

These new uses, as outlined in detail in Part I, now raise their own set of complex issues: Who has rights to tissue once excised? What form are those rights to take? Are actions available in detinue for their return, or in conversion to make claims against those who use tissue to create valuable products and therapies? What is the position where tissues are misused or stolen? The cases in this section will also be analysed to determine how far they will stand up as authorities to deal with such questions and the many more that are raised by tissue use in the modern context. To do so, the precedents they lay down, and any distinct principles they uphold will be applied to the case studies.

1. A NEW ERA OF CASE LAW: *DOODEWARD V SPENCE*

The Australian High Court case of *Doodeward v Spence* marks the beginning of the new phase of case law regarding the status and use of bodies and their parts.⁹ Decided in 1908, the case has been cited with approval by almost all subsequent judgments in this area of law, in both Australia and the United Kingdom.¹⁰ As a High Court decision, the case is entitled to considerable respect.¹¹ Its influence has been profound because it was the first case to deal with a more modern problem of tissue and body use, that is, a use that did not fit into the old categories of buried and unburied corpses. As such, it

⁷ *R v Herbert* (1961) 25 J CR L 163.

⁸ *Moore v The Regents of the University of California and others* (1990) 51 Cal 3d 120.

⁹ (1908) 6 CLR 406.

¹⁰ See, eg, *Dobson and Another v North Tyneside Health Authority and Another* [1996] 4 All ER 474; *R v Kelly* [1998] 3 All ER 741; *Roche v Douglas as Administrator of the Estate of Edward Rowan (dec'd)* (2000) WASC 146.

¹¹ See Matthews, 'Whose Body: People as Property', 212.

ushered in a new era of cases that began to take new approaches to the emerging uses of bodies and tissue in displays, pathology and scientific research.

The facts of the case in fact bear some similarity to those of *Dr Handyside's* case. The plaintiff, a showman, had for some time been exhibiting a jar of spirits containing the corpse of an infant with two heads. After charging the plaintiff with indecent exhibition of a corpse, the defendant, a policeman, took the body, still in its jar, and retained it. When the plaintiff requested the return of the jar and the body, the police returned only the jar and the spirits that had preserved the corpse. The plaintiff then brought an action in the District Court against the policeman in detinue for the return of the body. The court gave a judgment of nonsuit, and the matter was appealed to the Supreme Court of New South Wales. The Court dismissed the appeal, and the plaintiff appealed to the High Court. The High Court reversed the decision to find in favour of the original plaintiff, holding that in some circumstances a dead body could become the subject of property rights and hence an action in detinue could lie. Their judgments, however, were hardly a model of unified thought.

The case turned on whether the foetus could be deemed a subject of property rights. Griffith CJ took the view that a rule against property rights in corpses did exist, but he drew a particular distinction. All the cases cited as authority for the rule, he noted, were decided in relation to bodies awaiting burial. He held however that 'it [did] not follow from the mere fact that a human body at death is not the subject of ownership that it [was] for ever incapable of having an owner'.¹² His Honour made clear that he did not accept the writings of the classical legal commentators who may be seen as the original source of the rule. He argued that they were outdated, stating that none of the old authorities afforded 'any assistance in the present case'. Nor did he 'accept the dogma of the verbal inerrancy of ancient text writers'.¹³ On this reasoning, Griffith CJ considered that the matter before him could therefore be decided as one of first instance 'in accordance with general principles of law, which are usually in accord with reason and common sense'.¹⁴ It is in this fact that the case is also a landmark and a turning point. Here for the first time the rule against property is examined on the basis of principle, and an exception to it made also on principle, rather than mere rote repetition of its existence.

¹² *Doodeward v Spence*, 412 per Griffith CJ.

¹³ *Ibid*, 412 per Griffith CJ. Griffith CJ justified his view on the grounds that 'equally respectable authority, and of equal antiquity, may be cited for establishing as a matter of law the reality of witchcraft'.

¹⁴ *Ibid*, 412 per Griffith CJ.

Thus, the Chief Justice's conclusion was that although the rule against property existed, it did not hold in all circumstances. There was no law, in his opinion, 'forbidding the mere possession of a human body ... for purposes other than immediate burial,' and such possession was lawful where 'the body possesses attributes of such a nature that its preservation may afford valuable or interesting information or instruction'.¹⁵ Where there were no public health or public decency reasons for prohibiting continued possession, Griffith CJ held that possession could be lawful, having already pointed to the fact that it was 'idle to contend in these days that the possession of a mummy, or of a prepared skeleton, or of a skull, or other parts of a human body is necessarily unlawful'.¹⁶

Griffith CJ's principles here are a departure from previous judicial approaches. He found that public decency and health were not endangered by mere preservation of specimens of human bodies and parts, though their exhibition might be offensive. By basing his decision on this reasoning, Griffith CJ accepted the existence of the rule against property in corpses but held that it had never been intended to be of general application. He was also recognising that a certain pragmatism ought to be employed when considering the issue of property in the body. Given that the law had accepted the need to possess a body for burial, and later sanctioned possession of bodies for anatomical study, there is no common law barrier to similar arguments being made for a possessory right in other, related circumstances.

In Griffith CJ's opinion, this continued right to possession was a form of property right, as he did not know 'of any definition of property which is not wide enough to include such a right of permanent possession. By whatever name the right is called,' he stated, 'it exists, and that 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'.¹⁷ Having held that a proprietary right to possession could exist and be protected by property remedies, Griffith CJ then considered in more detail the circumstances in which a body or its parts could become subject to this right.

He held that bodies and parts could become the subject of property rights 'when a

¹⁵ Ibid, 414 per Griffith CJ.

¹⁶ Ibid, 413 per Griffith CJ.

¹⁷ Ibid, 414 per Griffith CJ.

person has by 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 against any person not entitled to have it delivered to him for the purpose of burial'.¹⁸ Griffith CJ did not, however, limit the possible situations in which a body might become property to those merely where work or skill had been employed. He held that it was 'not necessary to give an exhaustive enumeration of the circumstances under which such a right [to permanent possession] may be acquired'.¹⁹ The phrasing of this statement suggests that he regarded the application of work or skill as only one instance in which property rights may be created, as he noted there were many categories, but that he would name just one about which there was no doubt.

Of the remaining two justices, Justice Barton, also in the majority, made clear that he accepted that there was no property in corpses awaiting burial and agreed with Chief Justice Griffith's opinion as to the rule's existence. However, Barton J did not discuss the exception to the rule based on work or skill. Instead, he upheld the appeal on the basis that the foetus in question did not come within any definition of a body to be buried. He reasoned that a stillborn child could not be seen as such because it had

never existed independently of the physical attachment to the mother. It was never alive in the ordinary sense of human life ... it ha[d] been preserved in a jar or bottle with spirits since the day of its birth, now forty years ago. Add[ed] to these facts that it [was] an aberration of nature, having two heads. Can such a thing be, without shock to the mind, associated with the notion of the process that we know as a Christian burial?

20

Though he inadvertently admitted it had been born, Barton J held the foetus had never lived, had not died and therefore was not a fit subject for burial. Not having ever been a person, it did not come within the ambit of the rule against property rights in bodies.

Given that such an opinion is likely an anathema to modern thinking, Barton J's argument probably should not be accorded much weight. To classify a stillborn child, whatever its appearance, as non-human is unlikely to be accepted in the current moral and ethical climate.²¹ Despite outlining his own peculiar distinction to the rule, it does seem that Barton J also accepted the exception of work or skill made by Griffith CJ, having stated 'I have read the judgment of the Chief Justice, and I entirely agreed with

¹⁸ Ibid.

¹⁹ Ibid.

²⁰ Ibid, 416–7 per Barton J.

²¹ Griffith CJ and Higgins J both rejected this distinction between live and stillborn babies.

the reasons it embodies, which I hold it unnecessary to amplify'.²²

In contrast, Higgins J's dissenting opinion stated that 'there can be no right to recover in trover or in detinue in respect of a thing which is incapable of being property',²³ and that '[n]o one can have, under British law, property in another human being—alive or dead'.²⁴ He then proceeded to outline the law in relation to the no property rule, citing Stephen's *Digest of Criminal Law*, Coke's *Institutes*, Blackstone's *Commentaries*, East's *Pleas of the Crown*, Hawkins' *Pleas of the Crown* and the cases of *Haynes*, *Handyside* and *Sharpe*.²⁵ For the reasons given previously in this chapter, his Honour's reference to these sources does not produce a convincing authority for this position.

Higgins J also outlined certain circumstances where it was 'urged' that property rights be found in human remains, listing mummies, skeletons and other exhibits to be housed in museums and anatomical schools.²⁶ Egyptian mummies, he suggested, had become something other than corpses due to the work of the embalmer, however he did not explain how this differed from a body deceased in England which has also been worked upon before burial to preserve it for funereal purposes. There is little if no distinction on this basis save the amount of work done and the time at which it was performed. Higgins J also suggested that mummies were a distinct case because they were originally buried overseas where English law did not prevail. These two arguments appear to be based more in the interests of expediency rather than strict logical distinctions between situations. This is the more apparent in the light of Higgins J's subsequent comment that discussion of the law in this area was all somewhat beside the point as 'there is no one insisting that the mummy shall not be disturbed'.²⁷

Similarly, Higgins J argued that those specimens held for anatomical and medical display purposes were treated as property by those who dealt with them—'no doubt, these things are bought and sold—money is paid for them as property'—but that this had not been tested in any British court.²⁸ It was also, he noted, not the question before the court to determine if they were in fact property, particularly as some such uses were covered by legislation. However, as he explained, he 'rather [thought] that sundry

²² *Doodeward v Spence*, 417 per Barton J.

²³ *Ibid*, 417 per Higgins J.

²⁴ *Ibid*, 419 per Higgins J.

²⁵ *Ibid*, 418–419 per Higgins J.

²⁶ *Ibid*, 422–3 per Higgins J.

²⁷ *Ibid*, 423 per Higgins J.

²⁸ *Ibid*.

contraventions of the strict law as to dead bodies [were] winked at in the interests of medical science, and also for the practical reasons that no one [could] identify the bones or parts, and that no one [was] interested in putting the law into motion'.²⁹ Higgins J did not accept the exception to the rule made by Griffith CJ, but in his comments was in fact pointing to the precise reason why the Chief Justice had rightly believed that re-evaluation of this area of the law was necessary.

What, then, is the position in relation to unburied corpses that arises from this case? All of the judges agreed there was no property to be had in a corpse awaiting burial, though as has been argued previously the basis on which they did so is unsatisfactory. Nonetheless, of them two were willing to allow property rights in corpses not awaiting burial. Only Griffith CJ's exception, which has been accepted in later cases, can be regarded as justified, and it appears that Barton J may also have agreed that the exception existed. Hence both justices of the majority were prepared to uphold an exception to the general rule that where a body or its parts had taken on attributes distinguishing it from a corpse awaiting burial; whether through the application of work and skill or some other means, then there could be property rights in that body or its parts.

However, Paul Matthews has argued that Barton J's support for the exception in relation to parts taken from live bodies can only be *obiter* as his Honour was only prepared to apply the rule to a stillborn foetus. Based on this, he asserts that only one *ratio* in the case supports the exception, while the *obiter* of another majority justice, Barton J, and the *ratio* of Higgins J in dissent were in favour of the rule against property rights in bodies in general.³⁰ Hence, he argues, the weight to be given this case is difficult to assess.³¹

This is perhaps a slight overstatement, as Barton J explicitly noted his agreement with the reasons embodied in the Chief Justice's judgment.³² Although he chose only to address the issue of a stillborn child, it is not clear from his judgment that this equated to a rejection of the exception to the rule in other instances. In fact, Barton J made his

²⁹ Ibid.

³⁰ Mark Pawlowski and Matthew Lynch have made similar assessments of Barton J's judgment. See M Pawlowski, 'Dead Bodies as Property' (1996) 146 *New Law Journal* 1828, 1829; M Lynch, 'Property in Human Gametic Material and the New Reproductive Technologies' (1999) 6 *Journal of Law and Medicine* 348, 351.

³¹ Matthews, 'Whose Body: People as Property', 214.

³² This view is supported in Skegg, 'Medical Uses of Corpses', 317.

decision on another ground, namely that it was not work or skill that excluded the foetus from the rule, but the fact that it had never been a fit subject for Christian burial and could not thus be said to be a corpse awaiting burial.³³

Debra Mortimer also argues that a consistent approach to corpses awaiting burial can be detected in this case following *Williams* and *Sharpe* to the extent that they support a right to possession. In this she is correct, and consequently a better view of the decision in *Doodeward* is perhaps that it at least clearly recognises the proprietary nature of a right to possession of bodies and their parts where that possession is lawful. That is, where the possession is accepted as lawful, it should be protected through property remedies. This is a perspective which will be developed in the course of this chapter.

Beyond recognising such limited proprietary rights when possession is lawful, *Doodeward* remains questionable. In accepting the rule against property rights, albeit with an exception, the decision in *Doodeward* is open to the same criticisms as the aging buried and unburied corpse cases.³⁴ Its value and weight lie in the new perspective it brought to the issue, the introduction of at least limited principled consideration of the rule and its ambit, and its support for the proprietary nature of a continued right to possession. As such it introduced a possible solution to the problem through the extension of the accepted right to possess. By demonstrating that the old categories of buried and unburied corpses were no longer workable, or in some cases even relevant, it paved the way for a new approach to the emerging problems of tissue use. It also introduced a clearly stated exception to the rule against property rights in corpses accepted by at least one, and probably two, justices of the High Court.

In terms of its application, as the case concerns an entire corpse it has no direct application to tissue samples and body parts. However, its possible application to such tissue has been considered in the later cases, and particularly the possibility that the exception it founds could be applied to preserved tissue. For this reason, it will not be applied to the case studies. Instead, the exception as reiterated in later cases will be applied to the case studies in later sections.

³³ In support of this view see D Brahams, 'Body Parts as Property' (1998) 66 *Medico-Legal Journal* 45, 45; Mortimer, 'Proprietary Rights in Body Parts', 240. Debra Mortimer has asserted that the case does indeed support a proprietary interest in tissue—on her view, Higgins J was in fact prepared to admit the exception and merely disagreed on the types of possession that public policy deemed lawful

³⁴ See, eg, Magnusson, 'The Recognition of Proprietary Rights in Human Tissue', 606–607.

2. TISSUE TAKEN FOR TESTING: POLICE AND FORENSIC USE

Generally, in Australia, the use of tissue samples and body parts in forensic investigations is covered by legislation, but this legislation may not cover all possible circumstances.³⁵ Two English cases have considered the particular issue of samples being taken for testing by the police.³⁶ The approaches taken in these cases have been regarded by some commentators as part of the precedent on the rule against property in corpses.

The first of these decisions is the English criminal case of *R v Welsh* in which the defendant had provided police with a urine sample to be tested for blood alcohol levels in accordance with s 9 of the *Road Traffic Act 1972* (UK) (Road Traffic Act).³⁷ The defendant gave the sample and then tipped it down the sink. Welsh was subsequently found guilty of theft of the urine. An appeal was made on sentence only, in which the Court of Appeal referred to the conviction for theft as a technical offence. The Court did not query the correctness of the conviction.

In the second case, *R v Rothery*, the facts were similar.³⁸ The defendant gave a blood sample to police and later removed both the blood and the capsule in which it was contained from the police station. He was convicted of theft under s 5(1) of the *Theft Act 1968* (UK) (Theft Act) and of failing to supply a specimen under s 9(2) of the Road Traffic Act. Rothery appealed the conviction, and the Court of Appeal upheld the conviction on the theft count, but quashed the conviction for failure to supply a specimen. Rothery had argued that he did supply the specimen, but admitted he had later taken it back. On appeal Scarman LJ addressed the question of theft and the failure to provide a specimen together, holding that it was illogical for the defendant to be guilty of both. The defendant had to have provided a sample 'in the sense of putting [the police officer] in possession or control of it, otherwise he could not have stolen it

³⁵ See Case Study 10: Forensic DNA Testing and accompanying text.

³⁶ See also the United States case of *People v Young* 42 Misc 2d 540, 248 NYS 2d 287 (NY Ct Cl, 1964). At the direction of a state trooper, a doctor took a blood sample from. The defendant made a claim for suppression of the evidence (ie the sample) based on the fourth amendment, asserting that the taking of the blood equated to an unreasonable search and seizure of the defendant's property. The court held that taking the blood was both an unauthorised search and an unauthorised seizing of property, namely the defendant's blood. See also *State v Kroening* 274 Wis 266, 272-73, 79 NW 2d 810 (1957) cited in J A Potts, 'Moore v Regents of the University of California: Expanded Disclosure, Limited Property Rights' (1992) 86 *Northwestern University Law Review* 453, 488, n 220. It was stated in that case, as cited by Potts, that 'It is thoroughly recognized that property on the person is not to be seized ... We do not understand that the constitutional provision in question forbids officers to go through one's pockets but permits them to go through his veins' (at 814-5).

³⁷ *R v Welsh* [1974] RTR 478.

³⁸ *R v Rothery* [1976] Crim LR 691; [1975] RTR 550.

from him under section 5(1) of the *Theft Act 1968*.³⁹ Hence, Scarman LJ held that the sample was stolen and therefore obviously capable of being so.

It appears, then, that once police obtain possession of blood or urine to be used as a sample, they are accorded sufficient property in it to uphold a charge of theft against another—even the person from whom that sample was taken.⁴⁰ Logically, unless property rights have been created only once the sample has been transferred to the police, which is highly unlikely and not legally sound, then the provider of the sample has transferred their proprietary interest in it to police.⁴¹ This is the case it seems for at least the limited purposes of the Road Traffic Act in the United Kingdom, and there is little reason to see why the Australian courts would not view the matter similarly. In effect, these cases support property rights in tissue at least for this limited purpose.⁴²

Mortimer has asserted, however, that in both *R v Welsh* and *R v Rothery*, conviction did not require a direct ruling on whether the tissue was property. The former case, she argues, is merely a judgment on appeal against sentence and thus not sufficient to be deemed an authority.⁴³ As to the latter, she has argued that Scarman LJ was referring only to the capsule in which the blood was contained as the thing capable of being stolen. The charge in that case was the theft of ‘a capsule containing a specimen of [the defendant’s] blood’ and Mortimer regards the wording of this charge as highly important. The wording, she asserts, removed the prosecution’s need to argue whether the blood itself was property, for the ‘property’ in question was clearly the capsule full of blood.⁴⁴ Mortimer alleges that Scarman LJ’s comments were not directed at showing that blood could be stolen, but at whether the entire sample could be stolen.⁴⁵

In relation to *Rothery*, Mortimer’s interpretation is weak. While Scarman LJ was referring to both the blood and the capsule in his judgment, it is clear from his words is that he regarded the sample, that is the blood itself, as property capable of being stolen. His Honour stated as much himself in accepting that the defendant had put the police

³⁹ *R v Rothery* [1976] RTR 550, 552–553.

⁴⁰ Matthews, ‘Whose Body: People as Property’, 223.

⁴¹ Magnusson, ‘The Recognition of Proprietary Rights in Human Tissue’, 617.

⁴² G Dworkin and I Kennedy, ‘Human Tissue: Rights in the Body and its Parts’ (1993) 1 *Medical Law Review* 291, 223; Magnusson, ‘The Recognition of Proprietary Rights in Human Tissue’, 617.

⁴³ Mortimer, ‘Proprietary Rights in Body Parts’, 244.

⁴⁴ *Ibid.*, 245.

⁴⁵ *Ibid.* See also Matthews, ‘Whose Body: People as Property’, 224.

officer in possession and control of the blood.⁴⁶ Although he referred to 'specimen' generally, meaning both blood and capsule, it is clear that the only item whose property status was an issue was the blood; the capsule was without question police property. His words are clearly meant to suggest that there is property in the blood. Mortimer's view is also particularly untenable in light of the prior holding in *Welsh* where urine was capable of being stolen and there was no container involved.

In addition, the commentary on *Rothery* when it was reported in the Criminal Law Reports noted the rule against property in corpses, and stated that 'only the operation of [this] technical rule could preclude the blood from 'belonging to' [the police] within section 5(1) of the *Theft Act 1968* ... It would be unfortunate if the prosecution were driven to such expedients as charging theft of the container ...'⁴⁷ The better view is that the Court made a tacit acceptance of property in the blood and urine for the limited purpose of those instances. It should also be noted that the statement on theft in *Rothery* was *obiter* as only the conviction for failure to supply a sample was at issue.

These two cases demonstrate that the Courts are prepared to allow samples to be property for statutory testing purposes, at least in the limited context of theft from governmental organisations. Their scope, however, is limited because both are directed at a very specific fact situation.⁴⁸ Further, the inference that they allow property rights is only based on the assumption that they must have done so tacitly for the purposes of the case as there is no explicit statement on the rule against property rights in either case. As precedents, *Welsh* and *Rothery* are not strong cases, as they do not state any clear principle nor do they discuss any legal basis for their conclusions beyond some assumed expediency. However, the judgments do at least point to an owner of the samples—the police—who appears to have acquired ownership through their statutory power to take the samples. On this basis some clear approach can be seen: where samples have been taken through such duty, the person doing so has a claim to possession greater than that of the person from whom it was taken. It is unlikely that the cases are sufficient to deem

⁴⁶ *R v Rothery*, 552–3

⁴⁷ *R v Rothery* [1976] Crim LR 691, 692.

⁴⁸ Theft of tissue has, however, also been considered in the rather unique case of *R v Herbert* (1961) 25 J CR L 163 in which a man was convicted of larceny (taking and carrying away) some of a woman's hair. He cut the hair while she was a passenger in his car and kept it. Though it was argued in that case that the hair was not property, the larceny charge was upheld. However, the case turned more on whether the severed hair had become a chattel for the purposes of the *Larceny Act 1916* (UK), than on its property status. It is not precisely a case on point, but does demonstrate that the courts might take a wider view of the circumstances in which tissue could be stolen. See further Matthews, 'Whose Body: People as Property', 224–5.

this a property right that can be extended to other situations, but they do at least support a possessory right that will be protected from interference in similar fact situations.

These cases are mainly relevant where forensic samples have been taken by the police for investigative purposes, as noted in Case Study 10: Forensic DNA Testing. Under Australian law, where samples are taken for these purposes the *Crimes Act 1914* (Cth) and State legislation will allow police to obtain and retain samples from suspects, volunteers, unidentified corpses, serious offenders and crime scenes. It is conceivable that a scenario similar to that in the cases considered above could arise, and there is nothing to suggest that these cases would not be followed. The right of police to take and keep tissue under these Acts is hence likely to be enforced if others attempt to remove the samples.

These cases clearly do not provide much assistance in other situations as they so specifically relate to police possession of samples. It may be that they found a general view that samples are capable of being stolen, which if extended beyond police possession might cover samples taken without consent—for example, a father taking hair from a child's brush to have it tested for paternity. On this reasoning, they might also be applied to the theft of preserved pathology samples (like those discussed in Case Study 4: Hobart Pathology) or retained organs (as in Case Study 2: Organs and Tissue Retained following Post-Mortem). However, later cases made clearer statements on these issues, and are more likely to be relevant than the police theft cases.

Similarly, the cases have little bearing on samples taken in other contexts, such as those examined in Case Study 8: South Australian Clinical Genetics Service. There, the samples have been voluntarily donated and have not been acquired by any police or government authority. Nor have they been obtained for the purpose of crime detection or other public purpose, but instead have been collected to be tested for the private health reasons of the donor. They are distinguishable from samples collected for the purposes in *Rothery* and *Welsh* on both these bases, and it is unlikely that those cases could be extended to include samples taken for voluntary genetic testing. *Rothery* and *Welsh* would not provide a remedy, for example, if a donor of tissue wished to regain possession of the sample in order to prevent misuse of it by the testing authority. Neither would the cases provide a remedy if samples are misappropriated from the testing authority and subsequently misused by a third party. For the same reasons, it is

unlikely that *Rothery* and *Welsb* could be extended to protect samples and body parts in any of the other contexts outlined in Part I, as the samples and organs are not acquired pursuant to a statutory duty.

3. ACCESS TO STORED TISSUE SAMPLES

Access to stored samples of tissue has been considered in two major cases and one unreported judgment. The first is the 1996 English decision *Dobson and another v North Tyneside Health Authority and another (Dobson)*.⁴⁹ Deborah Dobson died of a brain tumour at a hospital run by the Newcastle Health Authority and her body was autopsied. Her brain was removed and set in paraffin wax to preserve it, and subsequently stored at the hospital. When, two years after her death, the deceased's family requested histology information relating to the brain tumour, they learned that the hospital had disposed of the preserved brain. At this time, the family instituted proceedings against the North Tyneside Health Authority claiming they were negligent in not diagnosing Mrs Dobson's condition early enough for it to be treated. As the destruction of the brain had destroyed a source of evidence to prove their claim, the family also brought proceedings against the Newcastle Health Authority as second defendant, seeking damages for their failure to preserve it through an action in bailment.

On first hearing, the district Court held that there was no property in a corpse, and that the hospital was not under a duty to retain the preserved brain. On this basis the Court upheld that defendant's application to strike out the plaintiffs' claim as there no cause of action. The plaintiffs appealed the decision to the County Court, where Harkins J upheld the original court's rejection of the plaintiff's claim against the second defendant. The plaintiffs appealed once more and their claim against the second defendant was struck out once more on the basis that the brain was not property and could not be subject to a bailment.

The plaintiffs alleged on appeal that the Newcastle Health Authority, in holding the brain, were gratuitous bailees and were therefore not permitted to destroy, lose or convert or otherwise wrongfully interfere with it.⁵⁰ To support this claim, they had to prove that the brain was property—that is, an object that could be subject to a bailment agreement. As claims of action can be struck out where they are either incontestably bad

⁴⁹ [1996] 4 All ER 474.

⁵⁰ *Dobson v North Tyneside Health Authority*, 477 per Peter Gibson LJ.

or unarguable, for the claim to avoid being struck out, the Court had to accept that it was at least arguable that human tissue could be property. The Court in *Dobson* did hold that the claim was neither incontestable nor unarguable, acknowledging that it was at least questionable whether the rule against property rights in corpses still held.

The plaintiffs cited *Doodeward v Spence* as a decision in support of the proposition that a corpse or a part thereof could be the subject of property rights if it had undergone some process or application of human skill. They alleged that the preservation of the brain in wax satisfied this requirement. Lord Justice Peter Gibson rejected *Doodeward* as an authority for this proposition, reasoning that while the majority in that decision did allow the action in *detinue* to lie, this was due only to the distinction Barton J in *Doodeward* was prepared to make between a still-born foetus and a corpse awaiting burial. It is respectfully submitted that for the reasons previously given, Peter Gibson LJ's view of the case was based on an incorrect reading of Barton J's judgment. However, the Lord Justice was prepared to accept that there was academic opinion to support the proposition, citing *Clerk and Lindsell on Torts*. That text stated that there is an exception to the general prohibition on property rights in corpses when a body has undergone 'a process or other application of human skill, such as stuffing or embalming'.⁵¹ This exception included cadavers used for research and parts and substances taken from living persons.

Peter Gibson LJ proceeded to consider whether the fixing of the brain in paraffin was sufficient processing to make the brain an object of property, and found that it was not for two reasons. First, his Honour stated that fixing in paraffin was not a process of the kind meant by the qualification to the rule against property in corpses. He asserted that generally this qualification has been expressed using examples such as embalming or stuffing as sufficient work, or the preservation of pathological specimens for scientific collections, and his Honour did not regard the processing of this brain as equivalent.

It is unclear how his Honour made the distinction between the fixing of a brain in paraffin after post-mortem and the preservation of tissue for scientific collections. In many cases, the technique would be the same, and so one can only assume that it was the purpose for which it was fixed that provided the distinction in this case. If this is so, then it is not a good ground for rejecting the exception that is not based on the future

⁵¹ See, eg, the text cited in the case itself, J F Clerk, *Clerk and Lindsell on Torts*, 17th edn, Sweet & Maxwell, London, 1995, 653, [13]–[50].

use of the tissue once processed, but only on the means of processing itself. On a more general view, the means of preservation is the same in purpose and similar in effect—to alter tissue through applying chemicals to prevent it deteriorating—to processes used to preserve museum specimens, which were noted in *Doodeward* as falling within the exception. The preservation of the brain therefore seems sufficient to meet the qualification and should satisfy the requirements of the qualification. Also, if *Doodeward* does form an authority for the exception, there is no restriction in that case on the type of work or skill that must be performed, as Griffith CJ left the matter open. Instead, Griffith CJ focused on lawful preservation and the altered nature of the tissue, and in that respect, preservation in wax for testing and retention is no different from preservation for museum collections.

Peter Gibson LJ's second reason for rejecting the argument that the brain could be property, if worked upon, was the fact that it was not a body or part of a body awaiting burial. The qualification of the rule against property in a corpse is stated twice in Peter Gibson LJ's judgment, once derived from the text noted above, the other quoting from Griffith CJ's judgment in *Doodeward*, and neither statement includes any requirement that the body or body part in question be awaiting burial. Griffith CJ did speak of work differentiating a body from merely a corpse awaiting burial, but as this is the most common and likely fate of most bodies, his Honour was not stating this as a requirement. Instead he was referring to the difference between a body which has no other use and must be disposed of, and something that has obviously been processed to ensure it can be retained and used. Having rejected the proposition that the brain could be property, Peter Gibson LJ therefore held that the claims in conversion and wrongful interference failed as the plaintiffs could not show a right to possession or a property interest in the brain.

He did not, however, reject the likelihood that a body part could become property. Peter Gibson LJ took a very narrow view of the qualification of the rule, particularly by placing on it the added requirement that the tissue be awaiting burial. While this case does not form a strong precedent for property rights being accorded in tissue, nor does it bar such a possibility. Gibson LJ's discussion of the rule was directly relevant to the determination of whether there was a cause of action, and is therefore *ratio decidendi*. As such, his statement of the situation in which tissue could become property—where work has been applied or the tissue has undergone processing—could stand as precedent. The requirement that the tissue be awaiting burial is not stated elsewhere,

and as it appears to have been a misreading of the rule's exception, it should not be regarded as part of that exception. It is possible, and perhaps likely, that on a wider reading of the exception the brain could have been property.

Dobson is somewhat unsatisfactory as an authority for or against property rights in tissue. It does include a relatively high level acceptance of the general rule, and it also accepts the exception to this rule asserted in *Doodeward*. However, the decision takes a step backwards from the advances made through *Doodeward* both by attempting to limit the scope of the exception by excluding pathology samples. Arguably, as Peter Gibson LJ's limitation of the exception has no precedent, and as *Doodeward* is a case of the High Court of Australia, at least in this country Griffith CJ's view of that exception is likely to hold sway.⁵² The effect of this decision for current use will be considered after analysis of the somewhat similar Australian case of *Roche v Douglas as Administrator of the Estate of Edward Rowan (dec'd)*⁵³ (*Roche*) and the unreported judgment in *Pecar v National Australia Trustees Ltd & Another (the Estate of Ivan Urlich dec'd)* (*Pecar*).⁵⁴

Pecar has been given little mention in discussions of property rights in tissue, despite the fact that judgment contains a statement on the property status of pathology samples. The case concerned the administration of the estate of Ivan Urlich, who died intestate in 1995. The plaintiff, the deceased's only son, brought proceedings in 1996 to seek entitlement to a share in the distribution of the estate pursuant to s 61B of the *Wills, Probate and Administration Act 1988* (NSW) and consequential declarations and orders regulating his share of the estate. The second defendant, Urlich's widow Vesna, had authorised the first defendant, National Australia Trustees, to apply for administration of the estate, and it had been conducted on the basis that only she was entitled to the estate.

Urlich's widow disputed the plaintiff's allegation that he was the son of the deceased, and hence the plaintiff Pecar sought an order for tissue taken from the deceased to be DNA tested to prove his allegation. The order required Hanly Moir Pathology, which held the paraffin-embedded tissue, to release it to the plaintiff's expert for testing.⁵⁵ The

⁵² Diana Brahams has suggested that 'the Court's reluctance to 'impose a duty on hospitals to retain tissue removed in a post-mortem against the possibility that it might be used in future litigation' was probably responsible for its flawed reasoning'. See Brahams, 'Body Parts as Property', 46. This, however, is not sufficient basis for rejecting the case as an authority.

⁵³ (2000) WASC 146.

⁵⁴ Unreported, Supreme Court of NSW, Bryson J, 2518 of 1996, BC9605678, 27 November 1996.

⁵⁵ Pecar's background requires some elucidation. His mother, Anne Pecar, had immigrated to Australia

order was sought under Pt 25 r 8 of the *Supreme Court Rules 1970* (NSW) which allows for the inspection of property. Hence, the issue revolved around whether the samples could be deemed property. The Court held that the sample was property for the purpose of the rules, and made a preliminary order that the plaintiff could access the tissue if the matter proceeded to trial.

In making his decision, Justice Bryson referred to *Doodeward v Spence* as an authority that work or skill could transform a part of a human body into an object of property. He stated that the view in that case 'would justify a right to retain possession of autopsy specimens, especially in this case where the human tissue is fixed in and an accretion to a paraffin block which itself is susceptible of ownership'.⁵⁶ In his Honour's opinion the pathology samples was property 'within the general meaning of that term which connotes that property has an owner'. He continued, however, to conclude the word 'property' in context of the Supreme Court rule was not used so as to require that there be any right of ownership, as the rule dealt only with the adduction of evidence.⁵⁷

The decision only relates to preliminary orders, which may limit its weight as an authority. It is however, still a decision of a Supreme Court judge, and this does give it authority at least in the limited case of property rights where samples are sought as evidence. Even if it is not considered a strong precedent (though this is not necessarily the case), it is a demonstration that the courts have accepted the view put in *Doodeward* that an exception to the no property rule exists. However, in not defining who the owner of the tissue would be, it is authority only for samples to be property in the specific context of a rule of Court rather than in a broad sense where an individual could hold ownership rights in it. As these remarks apply similarly to the decision in *Roche*, this decision's effect will be further considered after analysis of that case.

In *Roche*, a decision of Western Australian Supreme Court in 2000, the original action was a claim brought under s 6(1) of the *Inheritance (Family and Dependents Provision) Act 1972* (WA).⁵⁸ The plaintiff, Susan Roche, alleged that the deceased (Edward Rowan) was

and during her relationship with Ivan Ulrich had fallen pregnant with the plaintiff. She subsequently married Chris Pecar and the plaintiff was raised as their son. He was informed of his true parentage when he was fifteen, with the deceased telling him that all his possessions would pass to the plaintiff on his death 'providing you look after your grandmother in Croatia'. On Anne Pecar's death in 1979 the deceased made similar comments.

⁵⁶ *Pecar v National Australia Trustees*, 4 per Bryson J.

⁵⁷ *Ibid.*

⁵⁸ (2000) WASC 146.

her natural father and that she was entitled to make a claim under s 6(1) of the Act for a portion of his estate.⁵⁹ Roche alleged that she was a person entitled under s 7(1)(c) of the Act to maintenance from the deceased's estate. The defendant Ronald Douglas was the administrator of Rowan's estate and asserted in reply that Roche had no right to make a claim as she was not among the class of people included in s 7(1). That section lists those people who may make claims for support, and includes in subs (1)(c) 'a child of the deceased living at the date of the death of the deceased, or then *en ventre sa mère*'. The issue was whether Roche was in fact the child of Rowan.

To explain the defendant's position some account of the plaintiff's heritage must be given. Susan Roche was born on 11 June 1936 and her original birth certificate listed her parents as Gwendoline Tetlow and Harold Gibson. She was legally adopted by Florence Rowan, Edward Rowan's mother, in 1952. The plaintiff asserted that Edward Rowan was in fact her father. The defence claimed in reply that as Florence Rowan was the mother of the deceased, Roche had become his legal sister upon her adoption. Thus she was not entitled to make an application for support as she did not fall within the class of persons set down in s 7(1).

To prove her relationship to the deceased, Roche sought an order that DNA testing be carried out on a sample of tissue taken from Edward Rowan during surgery he had undergone in 1998. The samples in question were preserved in paraffin wax and held by Western Diagnostic Pathology. The order was sought on two grounds. First, that the court had power to request such testing under O 52 r 3(1) of the *Rules of the Supreme Court 1971* (WA) which states:

The Court may for the purpose of enabling proper determination of any cause or matter or any question arising therein, make orders on terms for—

- (a) the taking of samples of any property;
- (b) the making of any observation of any property;
- (c) the trying of any experiment on or with any property; or
- (d) the observation of any process.

Second, the plaintiff argued that the court had the power to order the executor of the estate to arrange for DNA testing of the samples.

⁵⁹ Section 6(1) provides: 'If any person (in this Act called 'the deceased') dies, then, if the Court is of the opinion that the disposition of the deceased's estate effected by his will, or the law relating to intestacy, or the combination of his will and that law, is not such as to make adequate provision from his estate for the proper maintenance, support, education or advancement in life of any of the persons mentioned in section 7 of this Act as being persons by whom or on whose behalf application may be made under this Act, the Court may, at its discretion, on application made by or on behalf of any such person, order that such provision as the Court thinks fit is made out of the estate of the deceased for that purpose'.

The defendant replied to the first ground that the tissue in question was not property and therefore an order could not be made under O 52 r 3. In relation to the second ground, the defendant submitted that the court could not order the executor to have testing performed. Further to that submission it was asserted that as the tissue was not property the defendant was not in a position to deal with the tissue except to arrange for its disposal in the same manner as a body is to be disposed of by the executor of any will. Master Sanderson found that the samples could be considered property for the purposes of the order, which was granted, and the samples were acquired by the Court for testing.

In this matter, the case turned on the question of whether the samples could be regarded as property. Master Sanderson considered the long line of common law cases in this area, including *Haynes*, *Williams v Williams*, *R v Fox*, *R v Scott* and *Doodeward v Spence*, and also the opinions of the classical writers Sir Edward Coke and Sir William Blackstone,⁶⁰ all of which he found to support the fact that ‘the common law has long held there is no property in a corpse’.⁶¹ He gave particular attention to *Doodeward* and concluded that Griffith CJ had allowed property in a corpse where work or skill had been applied to it, and that Barton J agreed with him on this.

From this analysis of the preceding cases the Master drew two conclusions: *Doodeward* was not directly relevant to the case at issue, and in any case, it was decided well before the advent of genetics. Sanderson M did not expressly state why the case was not relevant, but he had previously noted that Higgins J’s judgment mentioned but did not decide upon the status of tissue removed during surgery.⁶² Given this comment, he may have rejected *Doodeward* because it dealt with an entire corpse while the instance case was concerned with a sample of tissue.

Having come to this conclusion, the Master turned to the more recent decision in *Dobson*. After giving an exhaustive account of that case, he also cited ‘Proprietary Rights in Human Tissue’ by Roger Magnusson.⁶³ Based on the writer’s opinion, the Master noted the significant problems that arose from the resistance to recognising property

⁶⁰ *Roche v Douglas*, [9]–[19] per Sanderson M.

⁶¹ *Ibid*, [9] per Sanderson M.

⁶² *Ibid*, [13] per Sanderson M citing *Doodeward v Spence*, 423 per Higgins J.

⁶³ R S Magnusson, ‘Proprietary Rights in Tissue’ in N Palmer and E McKendrick, (eds) *Interests in Goods*, 2nd edn, LLP Reference Publishing, Hong Kong and London, 1998.

rights in tissue. He noted also the author's assertion that tissue donated to a hospital should be regarded as gifted, and that this can only be achieved if that tissue is property. Citing the Australian Law Reform Commission's 1977 report on *Human Tissue Transplants*, the Master responded to the report's assertion that there was no need to accord property rights to human tissue by asserting that 'the world has moved on' since it was written.⁶⁴

On the basis of *Dobson* and these two texts, the Master felt it expedient to reassess the rule against property in body parts, concluding that in the absence of any binding authority to the contrary, it was proper to hold human tissue to be property.⁶⁵ Holding that the principles of law should be applied 'in line with reason and good sense' he found that it defied reason not to regard tissue as property as it has a real physical presence.⁶⁶ Also, such an approach avoided the difficulties of denying what he regarded as the reality of the situation, that tissue is dealt with as property.⁶⁷ He pointed out that those cases that deny its property status were of some age and decided before the discovery of DNA. To recognise property in tissue also avoids the needs to resort to legal fictions, such as that it is the paraffin in which a sample is embedded or the jar in which it is kept that is the property stolen. Although Sanderson M agreed Griffith CJ's judgment in *Doodeward*, he nonetheless did not state that the tissue sample in the case before him was property because of the exception to the common law rule, only that it was good sense to do so.

The *Roche* decision has its merits, and may help to lay foundations for a new approach to tissue. It contains a clear affirmation of property rights in excised tissue in general, and specifically in pathology samples held by hospitals. There is, however, little other relevant case law on tissue removed from a living person during surgery (as the main case law refers to parts taken from corpses). It was on this issue that the Master sought guidance in precedent and found none, instead distinguishing the line of cases denying property rights from *Roche*. Hence, the binding *ratio* in *Roche* is really limited to property rights in pathology samples removed during surgery and arguably only where they are sought for the purposes of the Court. These arguments apply equally to the decision in *Pecar* discussed above, and *Roche* has similar precedential weight to that case.

⁶⁴ *Roche v Douglas*, [22] per Sanderson M.

⁶⁵ *Ibid*, [23] per Sanderson M.

⁶⁶ *Ibid*.

⁶⁷ *Ibid*, [14], [20], [22] and [23] per Sanderson M.

Roche is also only the decision of the Master of a State Supreme Court and therefore not a strong precedent. Additionally the decision on the property status of the tissue sample was only a preliminary ruling to enable the plaintiff to make out one aspect of her case. This lessens its weight, and also demonstrates that the decision was in part made on the basis of reason and common sense rather than legal principle.⁶⁸ However, it does lend general support, if not binding force to the trend towards recognising property rights in some tissue.

The other major criticism of the decision in *Roche*, made by Loane Skene, is that it makes a decision on *property* but not on *ownership* of the sample.⁶⁹ This criticism can also be levelled at the decision in *Pecar*. While holding that the tissue had sufficient attributes of property to allow an order to be made for testing, these decisions, following Skene's argument, avoided the difficult question of who in fact owned this piece of property. The decisions did not, on Skene's view, determine who would thus have powers to sell or bequeath the tissue, nor whether it could be bought or stolen. The decisions are certainly limited by this fact.

Despite these limitations, *Pecar*, *Dobson* and *Roche* remain turning points and provide room for tissue samples to be property were another court to make a decision on the wider aspects of their ownership—but can a coherent principle be derived from these cases? In *Dobson* a sample was declared not to be property, though the possibility of property in other tissue was allowed. In *Roche* and *Pecar* such a sample was found to be property, but no owner was defined nor were the decisions good authorities. The three cases are thus at odds, and the reasoning applied in each is incompatible. Peter Gibson LJ in *Dobson* considered the matter by accepting the rule against property in corpses but found an exception to it, while in *Roche* that rule was distinguished and in the absence of authority, property was declared on the basis of common sense and good reason. *Pecar* however stands somewhere between the two, having accepted the position in *Dobson* though it did not cite that case, but taking a different view of its application. In *Pecar* the exception was held to include fixing in paraffin, and used this approach to reach the same conclusion given in *Roche*.

Although these cases when taken together cannot provide a coherent precedent, they do

⁶⁸ L Skene, 'Ownership of and Access to Genetic Material' (2000) 3 *Centre for Law and Genetics Occasional Paper Series* 18, 22.

⁶⁹ *Ibid*, 22–23.

pave the way for later decisions to find property in tissue. Following *Dobson* and *Doodeward*, it appears that at least an exception to the rule against property in a corpse is accepted at law, even though its scope and application is less settled. A wide view of the exception may also develop, if it is recognised that the crucial aspect of the exception is not so much the manner of the preservation, but the purpose for undertaking the work or skill, its effect, and the lawfulness of the work done. This work or skill must be undertaken with the aim of creating a novel item with a use of its own.⁷⁰ The judgments in *Doodeward* and *Pecar* support such an interpretation of the exception. This perspective would also clarify who owned the tissue, as the exception propounded in *Doodeward* holds that the person who undertakes the work and skill acquires ownership rights over it.⁷¹

To apply *Dobson*, *Roche* and *Pecar* to the case studies demonstrates the unsatisfactory position they have developed regarding preserved tissue samples. For example, in relation to Case Study 4: Hobart Pathology, Case Study 5: Newborn Screening Cards and Case Study 8: SA Clinical Genetics Service—all case studies involving stored, preserved samples—the decision in *Pecar* and *Roche* leave their status unclear. The samples held by these organisations are property but not clearly *their* property. They would have possessory rights, but it would not be clear how these could be exercised, nor whether they had rights to manage, use or transfer the samples. By contrast, applying *Dobson*, the samples in each case would not be property at all and no clear rights of the hospital over those samples would be defined. The organisation would have no clear possessory rights over them. In each case, the lack of clear case law and the absence of legislation means the regulation of these samples is left to the laboratory guidelines discussed in Part II, where they were found to be unsatisfactory in providing remedies. Particularly problematic is that fact that these decisions would mean that were an individual to seek access to his or her sample, it would be unclear who had rights to determine whether access should be given and whether it could be returned.

The absence of well-defined status also means that it is unclear what the pathology laboratory may do with the samples, beyond the consent relationship with the person who supplied the tissue. If a sample is transferred or used in research without consent, does the donor have a remedy? Certainly, *Dobson* provides no solution and denies the individual the right to sue, say, in conversion, if their tissue is used in a manner they find

⁷⁰ Grubb, “I, Me, Mine”, 311.

⁷¹ *Doodeward v Spence*, 414 per Griffith CJ.

objectionable. Only if the samples were stolen might these cases lend a solution, with *Roche* and *Pecar* likely to be accepted as authority that the samples are property in the sense that they can be subject to theft, even if no owner can be defined. However, the Court in *Dobson* was not prepared to view small pathology samples as property, even of the hospitals that possessed them. As a result, it would be difficult for the hospitals to have such theft prosecuted, and they would have to rely more on the fact of their possession and control of the samples than any declaration of property rights. Based on *Rothery* and *Welsh* this might be sufficient, but *Dobson* would lend little support to such an argument.

Because *Dobson*, *Pecar* and *Roche* are limited to pathology samples, and in the case of *Dobson*, take a narrow view of the *Doodeward* exception, it is unlikely that they would provide any guidance in other instances. It is possible that they could be extended to preserved samples held by a researcher as in Case Study 6: Tissue in Australian Research, or by a biotechnology company as in Case Study 12: Iceland and deCODE. However, they would again fail to clarify the status of that tissue, and not provide any clear rights for either the researcher or the individual from whom the tissue was taken. Were a preserved sample used in a manner objectionable to the source individual, *Dobson*, *Pecar*, and *Roche* would all prevent the individual from using conversion or detinue to bring a claim for its misuse, or to have it returned. The individual would be left to rely on the Human Tissue Acts which, as noted in Chapter Four, are silent on such matters. In effect, the cases add little to the current legislative position and hence do not remedy any of the gaps that have been identified.

Where pathology samples have been used in commercial contexts (eg, a company such as Arda's selling processed samples) or in research that leads to profits (eg, the Moore cell-line patent in Case Study 14: John Moore's Spleen) the cases are also unsatisfactory. Although the holdings of *Roche* and *Pecar* appear to support the notion of property of in tissue, they do not consider the rights that individuals might exercise in relation to that tissue, and as such, the cases do little to clarify whether tissue is property that might be sold or used to generate income. *Dobson* on the other hand, does not even admit tissue as property, which means that in commercial and profit-earning situations, the lack of property status in tissue is at odds with the ability for it to be sold. Moreover, by not according an owner to the tissue, none of these cases is useful in dealing with questions of benefit sharing.

These cases demonstrate the problems created both by the outdated rule against property in corpses, and by its extension to tissues and body parts that were never intended to be buried. By applying the rule in these circumstances, exceptions to it have been necessary in order to account for the realities of tissue use—but the exception is still grounded in the old rule. The rule refers to changing a body to something other than a corpse awaiting burial, which is not truly appropriate for tissues that were removed during life and would never have been equated with something fated for burial. In effect, the Court in *Dobson* attempted to fit the square peg of pathology samples into the round hole of the exception and in doing so arrived at an inadequate result. *Roche* moved away from this approach but did not go far enough, while *Pecar* applied the exception in too limited a fashion to be of much use either.

As a decision which takes account of the present realities of tissue and body part use in current time, *Roche* is to be preferred, and through application of the *Doodeward* exception allowed in *Dobson*, this common sense approach could be used to identify an owner of a tissue sample. Better still would be for subsequent decisions to take the *Roche* view that there is no binding authority in relation to such samples and make decisions on whether they are property and who would be the owners by developing the *Doodeward* principles, tempered with a consideration for the issues surrounding current tissue use.

4. APPROPRIATION OF RETAINED BODY PARTS: *R v KELLY*

The good old rule
Sufficeth them, the simple plan,
That they should take, who have the power,
And they should keep who can...

William Wordsworth, Rob Roy's Grave

The cases discussed in the previous section dealt with pathology samples from living people, and are distinct from the next English court case, which concerns entire body parts taken from corpses. *R v Kelly*⁷² took a different approach to the status of body parts, and has developed the *Doodeward* exception differently than the decisions of *Dobson*, *Pecar*, and *Roche*. A small sample of tissue fixed in paraffin was judged not to be property in *Dobson*, yet in *Kelly*, retained sections of corpses were deemed capable of being property, demonstrating once more that the case law in this area has not dealt

⁷² [1998] 3 All ER 741.

with human tissue consistently.

Some two years after *Dobson* was decided, the slightly gruesome case of *Kelly* came before the English Court of Appeal. Anthony Noel Kelly was an artist, and between 1992 and 1994 the Royal College of Surgeons granted him access to their premises to draw some of the collection of anatomical specimens held there. Kelly befriended a technician who worked at the College, Neil Lindsay, and during 1993 and 1994 convinced Lindsay to remove specimens. Lindsay did so, and brought them to Kelly who then took casts of the specimens. These were later displayed at a London gallery. Lindsay supplied Kelly with more than thirty-five separate body parts during this period, including part of a brain, six arms or parts of arms, parts from three human torsos and ten legs or feet. All the specimens had been preserved, and some had also been expertly dissected. Kelly kept some of the body parts at his own apartment, others he and Lindsay buried. They were charged with theft under s 4 of the *Theft Act 1968* (UK) (*Theft Act*) when their actions were discovered.

The defendants argued that the rule against property in a corpse precluded a charge of theft as it was impossible to steal something that was not property. They also submitted in the original trial that the College itself did not have lawful possession of the specimens as they had been retained beyond the two-year period stipulated by the *Anatomy Act 1832* (UK), after which they should have been interred.⁷³ The trial judge, Rivlin J, rejected both arguments on the same grounds—that there was an exception to the rule against property in a corpse, under which the specimens had become property by the application of skill in preserving them. As such they could be stolen. Furthermore, the College had a right to continued retention because possession of tissue which is property was not dependent on the period of possession.

Kelly and Lindsay appealed both conviction and sentence on the basis that the trial judge had erred in finding an exception to the prohibition against property rights in a corpse or its parts (that is, the exception accepted in *Doodeward*, *Dobson* and *Pecar*). They also appealed against the finding that the College was in lawful possession of the body parts and claimed that the trial judge had made a prejudicial misdirection to the jury on the issue of possession by the College. Though the defendants' appeal on sentence was successful, the appeal on conviction was not. It is the Appeal Court's response to the

⁷³ The body parts had been acquired, it appears from the case, before the enactment of the new *Anatomy Act* in 1984.

first appeal claim—i.e. that the body parts in question could not be property—that is salient to this chapter’s analysis of property rights in human remains.

Under s 4(1) of the *Theft Act*, property ‘includes money and all other property, real or personal, including things in action and other intangible property’. Hence the Court had to decide whether the body parts were property for the purposes of s 4(1) to determine whether they had been stolen according to the provisions of the Act. The defendants made eight propositions in support of their submissions, of which the following five are relevant to the issue of whether the body parts were property under the Act:

1. the common law rule applied only to corpses to be buried but not yet buried;
2. there had been no convictions for theft of bodies or body parts until this case;
3. the common law rule extended to parts of bodies;
4. the body parts in this instance were intended by their donors to be buried (as the *Anatomy Act 1832* (UK), which provided for the donation of parts for study, providing that they were interred after two years)
5. there was no exception to the common law rule.⁷⁴

In support of these propositions, the defendants cited *Doodeward v Spence*, relying on Justice Higgins’ dissenting judgment, that there could not be property in human corpses or their parts. The defendants also cited Higgins J’s comment that ‘sundry contraventions of the strict law as to dead bodies are winked at in the interests of medical science’.⁷⁵

Lord Justice Rose responded to these arguments first by stating that the prohibition on property rights in corpses and their parts was an accepted common law rule, ‘however questionable the historical origins of the principle’. His Honour cited *R v Sharpe* in support of this proposition, and held that the rule could now only be altered by Parliament.⁷⁶ He went on to consider whether the application of skill or work could make body parts a fit subject for property rights and found that the exception had been accepted in *Doodeward* and in *Dobson*. Rose LJ considered work and skill to include both dissection and preservation techniques for the purposes of exhibition and teaching.⁷⁷

Though his comments were *obiter*, the Lord Justice also made mention of other possible

⁷⁴ *R v Kelly*, 745 per Rose LJ.

⁷⁵ *Ibid*, 746 per Rose LJ citing *Doodeward v Spence*, 423 per Higgins J. Justice Higgins had gone on to say that these contraventions were winked at also ‘for the practical reasons than no one can identify the bones or parts, and that no one is interested in putting the law in motion’.

⁷⁶ *R v Kelly*, 749 per Rose LJ.

⁷⁷ *Ibid*, 741 per Rose LJ.

situations in which the rule might have exceptions. Noting that the common law does not stand still, he suggested that body parts might become property, at least within the meaning of s 4 of the *Theft Act*, even where they had not acquired different attributes, but had a use beyond their mere existence. For example, he cited both organs destined to be transplanted and extracted DNA to be used as an exhibit in a trial.⁷⁸

Rose LJ's decision is a clear statement of principle, with an unambiguous acceptance of the exception to the rule against property rights. In accepting that the exception included body parts preserved for medical purposes, it is a better view of the exception than that given in *Dobson* and takes the judgment in *Doodeward* to its logical conclusion. Considered in the light of *Roche* and *Pecar* it is also further evidence of a trend towards accepting the property status of human tissues as a solution to the expanding situations in which tissue is stored and used.

However, as with *Roche* and *Pecar*, the decision is still less than satisfactory in three ways. First, it is only a decision in relation to preserved body parts and its applicability in other fact situations is likely to be limited. Secondly, there is no indication in the judgment as to whether ownership rights could be accorded in anyone in relation to the specimens, only that as in *Rothery* and *Welsh* also, it could be regarded as property for the purposes of a theft prosecution. It is thus less useful for the same reasons elucidated in the analysis of *Roche* and *Pecar*, particularly because the court held that the specimens were property but did not extend this conclusion to mean that the Royal College had a right to possession. Instead, it accepted that the Royal College was factually in possession only, and did not consider the matter further. However, by accepting these two propositions, and that the possession was lawful, Andrew Grubb has argued that the decision went further than merely deeming the body parts property, and deemed them 'property over which the Royal College had rights—to possess—which entitled them to exclude others from the parts'.⁷⁹ This view does make sense, as for the parts to be stolen the right to exclude others must have vested in someone, in contrast to the decisions in *Roche* and *Pecar* where an owner did not have to be identified.

On this view, then, the decision does describe some relationship between individuals with regard to an object—between the Royal College and the rest of the world—thereby admitting a property relationship, rather than merely according property status to the

⁷⁸ Ibid.

⁷⁹ Grubb, "I, Me, Mine", 311.

object itself. As the Royal College had a right to possess the parts for a specific purpose, that is as specimens for study and display, it is logical to assume that they also possessed a right to use, and perhaps also to manage. Here, then, the decision would seem to support the existence of at least three of the incidents that make up a property relationship⁸⁰ and more than a mere possessory interest. This is supported further because the decision upheld the rights of the Royal College to possess the parts under the *Anatomy Act*, which allowed retention for the purposes of study. On such a reading, which is tenable, the decision does support at least a limited property right far more so than any of the previous decisions and would be an authority for such.

Following *Kelly* two views can be taken of the state of the law. On one hand, Matthew Lynch for example, states that the law will continue to uphold the ‘no property in a body’ proposition and then make modifications to it as circumstances demand.⁸¹ By Grubb’s reckoning, however, the reverse will be true, that if Rose LJ’s view is followed, and more exceptions are made, there will be an effective re-writing of the rule. As there are few removals of tissue and parts that would not have use, instead the widening of the exception ‘would now prove a new, and more limited, rule’ that while there is no property in entire corpses, but excised parts do not fall within the ambit of this rule.⁸² The decision in *Kelly* does at the very least support property status for excised parts and probably ownership rights for those who lawfully possess them. However, as it deals only with parts held for medical use, a limited but prevalent use, it is unclear whether other decisions will extend its ambit to other uses. Further, it is at odds with the strong authority of *Dobson* and it is unclear which approach might be subsequently followed. Finally, it is potentially distinguishable because it deals with parts from corpses (and the facts are therefore more similar to *Doodeward*), therefore, the exception might be limited to cases of this kind, and the *Dobson* approach taken to samples from living people. Hence, at present it is still only one of the myriad of single instances, but an instance that may have resonance for later decisions considered wider use and possession.

Applying *Kelly* to the case studies, the most obvious example where the case would be directly relevant is Case Study 2: Organ and Tissue Retention following Post-Mortem. Indeed, the facts are almost identical, as many of the organs retained in by Australian institutions would have been in medical museums and used for teaching. Once the

⁸⁰ See further Chapter Nine.

⁸¹ Lynch, ‘Property in Human Gametic Material’, 352.

⁸² Grubb, “I, Me, Mine”, 312.

hospital holding the body parts had preserved them, it would have acquired property rights through the exercise of work and skill. On the limited view of *Kelly* the specimens would have been property for the purposes of theft, and the hospitals would have had some form of possession. On the wider view, the hospitals would have obtained at least a right to possession, and perhaps also rights to use and manage. This accords with the general view held by hospitals and pathology laboratories have of their specimens, that they have the right to possess and manage the specimens they hold, though not to use them without consent or unless they are de-identified. This wider view is preferable because it enables the hospital to lawfully possess the parts and to keep them secure when they use them for accepted, useful purposes such as testing and research. In this way it protects the valid interests of hospitals and researchers in holding tissue for some purposes.

However, a number of problems arise. As the case does not fully elucidate the property rights that someone preserving body parts acquires through the application of work, the scope of the hospital's property right is not clear. *Kelly*, like the pathology sample cases, referred to the specimens as property, only in the context of possession and perhaps retention. The case does not give any indication of what other property rights the person who preserves a sample acquires. Do they acquire the right to sell it? To destroy it? To use it to generate income? To transfer it to others or to use it for any purpose they choose?⁸³ It would probably be regarded as ethically unacceptable for the hospital to sell the tissue, given the generally accepted ethical position on tissue use in Australia. To exercise rights of this kind would also probably have an adverse affect on the privacy and autonomy interests of the individual from whom the tissue was taken—for example, the individual's privacy might be breached if the hospital decided to supply the sample to an insurer, who tested it and used the results to discriminate against the individual. It appears that a direct application of the common law position, taken to its logical conclusions, would be highly problematic in this context because the current position does not identify the scope of the rights it confers. Further, if the samples were misused or stolen, the hospital would have a claim for their return, but the individual from whom they were taken would not. In effect, the current position would entirely ignore the individual's relationship to and interest in his or her tissue. It would allow others to exercise greater rights over it than the person from whom it was taken. Finally, such a position would actually most often exclude individuals from obtaining property

⁸³ Each of these rights falls within the ambit of property rights. See further Chapter Nine.

in their own bodies, as it would be rare for an individual to be able to preserve his or her own tissue as required by the exception outlined in *Doodeward* and *Kelly*. Effectively, other people could own my body, but I could not. Or put another way, a hospital could own my baby's heart, but I could not.

By taking the Lockean view that something may become one's property after one has applied to work and skill to it,⁸⁴ the exception to the rule upheld in *Kelly*, and also *Doodeward* and *Dobson*, deprives the source of that tissue of any property rights to it of their own. The act of applying skill give an individual greater rights, protected by remedies through conversion, detinue and prosecution for theft, than are given to the person from whom it was taken.

The *Kelly* approach also assumes that before the work or skill was applied, no rights protected by such remedies would have been available, as the part or tissue was not property and would not support such claims. Thus it seems to assume that the source had no protectable interest, and leaves that source only with a claim if the tissue or part was used without consent or in violation of the consent given. Hence, security of samples would be compromised, as if the samples was transferred to a third party, even unlawfully, the source would have no claim against that third part as they would be unable to show a property interest. As any consent relationship would be between the source and the person to whom it was originally given, the source would also not have a fiduciary relationship with the third party on which to base an alternate claim. If samples were supplied to an employer, for example, and used to obtain information through DNA testing, the individual would have no ability to regain the samples or sue in conversion.

The problems inherent in this are most clearly shown by application of the decision to the facts of Case Study 15: Canavan Disease Research. Greenberg and others had given their tissue freely in that case and it had then been worked on for use in research. According to *Kelly*, the man who undertook that research, Reuben Matalon, would thus have gained property rights sufficient to support a prosecution for theft if they attempted to take the tissue back. As it was his property, a claim for conversion or detinue would have to fail, as they had no property rights to protect before he had

⁸⁴ See further on Lockean Labour Theory, Chapter Ten, section 1.

gained possession of the tissue.⁸⁵ In effect, they would have been left with no remedy once the tissue had been used to develop a test for Canavan disease beyond claims based on breach of consent.

This is the essential problem with decisions which uphold the exception to the rule, as that exception prevents the source of tissue having any rights. Only in Case Study 18: Orlan and Manipulation of the Flesh would it possibly provide the source with any remedy in property, as Orlan herself carries out the work on her own tissue and places it in her own form of museum, perhaps. Where tissue and parts are removed in surgery, for research and retained for study, the source has no part in this process of removal and preservation. Instead, there will always be another person who performs that work before they have access to it and therefore will gain rights ahead of them. The decision, like those before it upholding the exception, makes the problematic Lockean assumption that before the work was done on the part or tissue, no one had any possessory or ownership interest in it, and thereby ignores the prime interest of the person from whom it was taken. It also accepts the view that work and skill do create rights, to the exclusion of other rights and interests that might already exist and of which account should also be taken.

As the exception extends to remains preserved for display in museums, it also has direct application to Case Study 1: Aboriginal Remains. In this instance, clearly the remains have been kept for the purpose of study, and have been preserved by the museum which holds them. According to *Kelly*, however, it would be the museum that holds them which would gain ownership rights. While this preserves the security of museum collections, which is in the interests of the general community as well as the museum and the scientific community, it also excludes the indigenous community from any legal recognition that it has similarly strong rights to possess and manage remains. It is not that the indigenous interest should necessarily prevail over that of the museum, or vice versa, rather that in applying *Kelly* one of these parties in conflict is given stronger rights than the other based on the act of preservation instead of on the merits of their interests. In giving those who preserve the strength of property rights, the law must also recognise that one party in a conflict over body parts has legal rights—property rights—that must be taken account of regardless of public policy considerations, such as the

⁸⁵ In the *Greenberg* case, plaintiffs asserted conversion as a cause of action, but this was dismissed. See *Greenberg v Miami Children's Hospital Research Institute* (Unreported, District Court for the Southern District of Florida, Moreno J, 29 May 2003).

interest of indigenous communities in ensuring their members are decently laid to rest.

Were the exception to be read widely, it might apply to tissues taken post-mortem and preserved for research, for example like the samples obtained from the Victorian Institute of Forensic Medicine in Case Study 6: Tissue in Australian Research. Again, the researcher's collection would be secure, the community interest in medical advances would be promoted by a secure supply of tissue for research, but the individual would lack remedies for misuse and theft, and also would have no property basis on which to sell or reclaim tissue. This is particularly problematic in this situation given the lack of personal remedies for misuse in both the legislation and ethics guidelines, as discussed in Chapters Four and Five.

It is, however, questionable how far the rule in *Kelly* could be extended, for example to cover to newborn screening cards (Case Study 5: Newborn Screening Card Collection) or DNA samples held by testing authorities (Case Study 8: SA Clinical Genetics Service). This will depend on how much weight is given to the distinction between removal of tissue from corpses and from living people. Perhaps property rights were most acceptable to the court where the source of the tissue was dead as the interests of the person from whom it was taken would not be a large issue. Or it may be that the court in *Kelly* simply took a more open view of the *Doodeward* exception, rather than taking the limited view as in *Dobson*. Most recently, however, the distinction has been affirmed in part when the Supreme Court of New South Wales held in 2002 that the rule in *Roche* was limited to samples taken during life, not following death.⁸⁶ Despite this, the uses of tissue, the sources of tissue and the fate of tissue no longer fit within the clear divisions—some may be taken during life, but sought after someone has died as in *Dobson*, *Pecar* and *Roche*; tissue may be de-identified; tissue may have been retained and it is not known if the person from whom it came has died. It is unlikely that this distinction will continue to be workable in the face of the expanding uses of tissue.

In addition to these problems, *Kelly* also remains a single case on a particular fact situation, although it contains a clear principle to determine the status of tissue, this only applies in the limited instances described in the case. Hence, it does not clarify the status or legal rights over tissue for transplant beyond those in the Human Tissue Act relating to consent to donate (Case Study 3: Organ Transplantation), or more particularly the

⁸⁶ *AW v CW* [2002] NSWSC 301. This case is not considered in detail for reasons of scope and because it did not consider the property issue in any detail. It concerned an order for parentage testing.

status of store tissue for later use in therapy or research. For example, in the context of Case Study 7: Donor Tissue Bank of Victoria, the tissue has not been preserved for teaching or as a display, but for later transplantation. As it is intended to be returned to a human body, it could not have been said to have acquired new attributes, and hence would probably fall outside the *Doodenard* exception but within the broader *Kelly* view. Even if it were property, the same problems would arise about which rights could be exercised, and in this instance, what happens to those rights when the tissue is transplanted, or transferred for research.

The principle in *Kelly* also does not apply in many areas where the legislation and ethical guidelines are also silent or inadequate—on individual rights in relation to tissue; or on commercial interests and benefit sharing—and because of the limits on it, does not found a more general view of tissue. Finally, the decision and all those before it upholding the exception do nothing to address the illogic of enabling people to donate tissue and transfer it for transplant when it is not, legally, property. This issue, however, will be considered in greater detail in Chapter Nine.

5. TISSUE AS COMMERCIAL OBJECT, COMMODITY AND PRODUCT

One of the potential implications of body parts and tissue being deemed property is that they must then be treated as a good, subject perhaps to tax if sold or supplied. As yet, no decisions have recognised any rights to sell body parts, but there has been discussion of whether blood donations equate to the supply of a good. This issue has been considered in two Australian cases, *E v Australian Red Cross Society*⁸⁷ (*E*) and *PQ v Australian Red Cross Society*⁸⁸ (*PQ*). As these cases are only relevant to one aspect of the property debate—whether tissue is legally regarded as a good, and hence an object suitable for trade which can be possessed and alienated—these cases will be considered only briefly.

Discussion of these cases leads into the use of tissue for manufacture or to create profit, as in the case of *Moore v The Regents of the University of California and Others*.⁸⁹ In that case tissue was used to create a cell-line, which was subsequently patented. Though not an Australian case, as no decisions have been made on similar issues in Australia, it is examined here both for its influence and to examine how such a situation might be dealt

⁸⁷ (1991) 105 ALR 53.

⁸⁸ [1992] 1 VR 19.

⁸⁹ (1990) 51 Cal 3d 120.

with in this country.

Both *E* and *PQ* concerned problems with blood donated in the early 1980s that was contaminated with HIV. In both cases, the plaintiff had contracted the AIDS virus after receiving a transfusion of contaminated blood. Among the actions brought in each case (particularly negligence), in both cases the plaintiffs brought actions under the *Trade Practices Act 1974* (Cth) (TPA). The specifics of these actions do not need to be considered here. What is relevant is that to make a determination on these actions, in each case the court had to consider whether the blood was a 'good' within the meaning of the TPA.⁹⁰

In *E*, the issue was whether the supply of blood plasma to the plaintiffs was a contract for supply of goods. Wilcox J found at first instance that it was not, and this decision was upheld when appealed to the Federal Court of Australia. On further appeal, Lockhart J found that the contract was a supply of services as part of medical treatment, but did not make a determination on whether the blood was a good.⁹¹ In *PQ*,⁹² McGarvie J found that the blood supplied was capable of being a good for the purposes of s 74J(2)(a)(iii) of the TPA.⁹³

The two decisions are somewhat at odds. In both cases whether blood was a good for the purposes of the Act was a side issue and as support for the recognition of property rights in human tissues they have little weight. In *E* the question was left open, and hence this case has virtually no relevance. In *PQ*, however, there is a tacit assumption in McGarvie J's judgment that blood at least has qualities that allow it to be regarded as a good and an object to be traded and supplied. However, Roger Magnusson has argued that the decision 'lends support to the general recognition of proprietary rights in human tissue'.⁹⁴ In one sense it does, as by allowing blood to be a good, the decision does recognise it as an object that can be traded. If it can be traded, it must therefore be capable of being both possessed and alienated, two rights that form part of a property interest. The decision therefore can be seen as supporting at least a proprietary interest

⁹⁰ In *E*, the plaintiffs relied on ss 71 and 74 of the *Trade Practices Act 1974* (Cth) (TPA), importing implied terms as to fitness for purchase and merchantability into some contracts for supply of goods. The plaintiffs also relied on similar provisions in ss 74 and 19 of the *Sale of Goods Act 1923* (NSW) (*Sale of Goods Act*) (*E v Australian Red Cross Society*, 57 per Lockhart J).

⁹¹ *E v Australian Red Cross Society*, 59 per Lockhart J.

⁹² The plaintiff brought a further action under ss 74B and 74D of the TPA, which provide for compensation where goods supplied are not fit for purpose.

⁹³ *PQ v Australian Red Cross Society* [1992] 1 VR 19, 41–42 per McGarvie J.

⁹⁴ Magnusson, 'The Recognition of Proprietary Rights in Human Tissue', 619.

sufficient to alienate tissue.

The decision in *E*, however, may be important in demonstrating the courts' view of introducing commercial concepts into the transfer and use of blood. For example, Debra Mortimer has asserted that instead the decision in *E* demonstrates the Federal Court's reluctance to view supply of blood as a transaction akin to a general trading agreement. That by declining to decide whether blood was a good and not recognising a contract for supply, the Court was in fact refusing 'to introduce commercial consumer protection notions into cases dealing with the donation and transfusion of blood'.⁹⁵ In support of this argument, she has cited Wilcox J's statement that 'it is not possible to put a price on blood plasma. Blood products are not sold in Australia'.⁹⁶ But the issue was not whether blood supply is commercialised, for donation is voluntary and blood is not sold in Australia, but whether that blood is transferred in a manner similar to other goods and should therefore be protected in the same way. In *PQ* this was clearly the Court's view, while in *E* the Court did not have to deal with the issue. Wilcox' J's statement is not to the point, for as will be seen in Parts IV and V, recognising property rights in tissue does not equate to commercialising that tissue.

In effect, only in *PQ* can any relevant determination be found, and on that decision blood products can be goods to be regulated like other objects that are traded. Though not a precedent in support of property rights, it does have a role in furthering the Court's trend towards recognising that blood and other tissues are transferred and used and should be dealt under the same laws that regulate the supply of many other objects. These other objects, cars, food and the like, are deemed property. Recognition that blood products are dealt with in the same way demonstrates that at least in some respects blood and other tissues have qualities in common with objects already regarded as property. This is one step towards accepting that tissues and blood should therefore be regarded as property also.

In terms of their influence as decisions, *PQ* is only a decision on whether there was a case to answer, and therefore has less precedential force. That it is a decision of the Federal Court of Australia lends it greater weight, however, than *E* which is a State Supreme Court decision. As the Court in *E* did not address the question of whether blood was a good, the statement in *PQ* must therefore be determinative, as it contains

⁹⁵ Mortimer, 'Proprietary Rights in Body Parts', 246–7.

⁹⁶ *Ibid.*

the only clear statement on the issue. Based on this, likely the current position is that blood is a good for the purposes of consumer protection law. Whether this could extend to other forms of tissue is perhaps doubtful, as the decisions do recognise the prevalence and acceptance of blood donation and supply in this country. Tissue donation of other kinds does not have such a long history nor is there such an entrenched system of collection and use.

For this reason, the decisions would have little relevance in relation to any of the case studies outlined in Part I. As the cases relate specifically to supply of goods and consumer protection laws, it is conceivable that they could have influence where tissue is supplied to researchers (Case Study 6: Human Tissue in Australian Research, Case Study 12: Iceland and DeCODE, Case Study 14: John Moore's Spleen, Case Study 15: Canavan Disease Research). In cases of tissue supplied for research, the process is somewhat similar to blood donation, as tissue is given voluntarily. The decisions could only be relevant however if the researcher could be characterised as a consumer and the tissue as not fit for purpose. If the product were not fit for purpose, a researcher might suffer setbacks to research or damage to experiments and hence wish to claim as a consumer.

While researchers may resemble consumers to an extent, it is unlikely that the courts would extent the decisions in *PQ* and *E* to cover the supply of tissue for research and treat them as consumers. Supply of tissue for research is not an entrenched practice like that of supplying blood. Often, as these case studies demonstrate, it is received following medical treatment or through voluntary participation in research where there is a direct relationship between the researcher and the subject. Blood donation is distinguishable from tissue donation on both these bases, as it has been well-established practice for some time, and also is performed through an intermediary—the Australian Red Cross Society. This second factor sets blood donation apart as an organised supply process rather than *ad hoc* acquisition on a case by case basis. Finally, just as the legislation distinguishes between blood and other tissues, so it is likely that the courts will follow the legislative approach and set blood apart from other tissues.

This distinction, however, makes little sense. Whatever the means of supplying tissue, the fact would remain that one party had supplied tissue to another for certain purposes and those purposes could not be met by that product. Whether it is blood for transfusion or tissue for research, the practical difference is little. The distinction

becomes even less meaningful where tissue is supplied by a tissue bank such as Ardaïs.⁹⁷ In such a case it is more likely that the decisions could be applied, as there is both an intermediary and an organised system of collection and supply for purpose. In such cases, it may be that researchers could bring an action based on *PQ* against tissue banks which have supplied the wrong form of tissue or tissue not in a condition for use in research.

There is no commercial use of tissue in Australia such as that considered in Case Study 17: StarGene. There, tissue is used to create a commercial product that should be fit for sale. Tissue is used much more in the capacity of materials for producing an object of commerce, and therefore its lack of fitness has commercial implications. In such a case, as tissue is being used as a product in a clearly commercial dealing, it is quite likely that the decision in *PQ* would be applied.

Finally, the only other situation in which the decision might have implications in Australia is where organs and tissues have been transplanted (Case Study 3: Organ Transplantation). The case is similar to the supply of blood, and one can imagine a situation where an organ infected with some undetected disease is transplanted and the recipient contracts that condition. In such a case the recipient might have an action against the transplant unit which supplied the organ or tissue. Were *PQ* to be followed, the recipient might be able to argue that the organ, being infected or defective, was not fit to be transplanted and therefore not be a good fit for the purpose supplied.

Given the courts' reluctance to view body parts as objects of commerce and the legislative prohibition on sale, it is unlikely, however, that the courts would view an organ as a product. Even though no consideration is given for organs received, these factors might mean that the courts are more reluctant to place entire body parts or tissues in the same class as blood which is often supplied in a product-like relationship. While it is only rational to accept that blood is supplied like other products, this does not mean that the courts will wish to place the stamp of such a supply-demand paradigm on other types of tissues, particularly organs. There is clear support for altruistic donation of organs in this country, and in this there is an implicit rejection of any market-like supply arrangements for organs and body parts. This rejection reflects that of the legislation, though there is little logical difference between blood supply that

⁹⁷ See Chapter Three, section 1.

infects a recipient and organ supply that infects a recipient. Probably, courts would be less amenable to allowing the language and mores of the market to impinge on tissue and organ supply any more than they have done so already.

It is clearly possible that these decisions might be applicable in wider situations. The issue, however, is whether they support a view of body parts as property. As noted above, it is possible to see *PQ* as a decision recognising some form of proprietary interest and were it to be applied in other situations, such as organ transplantation, then it is again possible that organ in those cases could be the subject of such an interest. However, as has been argued, the courts' reluctance to accord such property interests in other situations might lead them to balk at the idea of extending the principle in *PQ* to other parts of the body. As such, these decisions do little to answer the question of whether the common law allows for body parts to be dealt with as property. The best that can be said is that the decision in *PQ* does recognise some form of proprietary interest and the need to accept that the realities of tissue use now demand that at least some concepts of property and commercial dealings be applied to that use to regulate it effectively.

5.1 Moore v The Regents of the University of California and others

The case of *Moore v The Regents of the University of California*⁹⁸ has drawn considerable attention over the past decade as the first common law case to clearly consider whether an individual can exercise property rights over his or her excised body parts. While not binding precedent in Australia, the case is of interest here for two reasons—it considers the relatively novel situation of an individual attempting to assert rights over his or her excised tissue, and it deals directly with the issue of conversion and property interests. A detailed account of each of the judgments in the Supreme Court decision will also be given, as the arguments they raise will be revisited in Part V on the issue of whether tissue should be deemed property. Only a limited critique of these views will therefore be given here.

The facts of the John Moore case have already been outlined in Case Study 14: John Moore's Spleen, but they bear repeating briefly here. In 1976, Moore underwent treatment for hairy-cell leukaemia at the Medical Centre of the University of California (UCLA Medical Centre), where he was treated by Dr David Golde. During the course

⁹⁸ (1990) 51 Cal 3d 120.

of the treatment, which involved removing blood, bone marrow and other tissues, Golde discovered that some of Moore's blood products had significant scientific and commercial potential. As part of the treatment, Moore's spleen was removed in 1976. Golde retained some of the spleen for research use without informing Moore. For the next six years, as Moore continued to seek treatment, Golde removed more blood, skin, bone marrow and other tissues without informing Moore that he was using them for research. In 1979, Golde established a cell line of Moore's tissue, and applied to patent what became known as the 'Mo cell line' in 1981. The cell-line was valued at \$US3 billion in 1990. Golde and his assistant Shirley Quan, with the assistance of the Regents of the University of California, subsequently began work on commercially exploiting the cell-line.⁹⁹

When Moore learned of Golde and Quan's actions, he brought a complaint in which he stated thirteen causes of action.¹⁰⁰ The original court rejected Moore's claim, but on appeal, the judgment was overturned. The Court of Appeal found that Moore had stated a cause of action in relation to conversion. On subsequent appeal to the Supreme Court of California, the Court considered three of Moore's asserted causes of action: breach of fiduciary duty, lack of informed consent and conversion. The Supreme Court rejected the conversion claim, but did remand the claims of breach of fiduciary duty and lack of informed consent to the superior court to be considered. In the context of this thesis, it is the conversion claim that is relevant, and therefore analysis of the case will focus on this aspect of the courts' decisions.

In his claim, Moore asserted the cells taken from his body by Golde and Quan were his property, which he continued to own once they were removed. He argued that in removing his cells and using them to create a cell line, Golde and Quan had interfered with his right to possess and own those cells. Moore further argued that due to the alleged conversion of his property, he had a proprietary interest in all the products made from his cells or the cell line developed from them by Golde and Quan.¹⁰¹ To determine whether Moore had such a claim for conversion, the Court first had to decide whether cells and human tissue were a proper subject for a conversion claim, that is,

⁹⁹ *Moore v The Regents of the University of California*, 124–128 per Panelli J.

¹⁰⁰ *Ibid*, 128–9 per Panelli J. These were: (1) 'Conversion', (2) 'lack of informed consent', (3) 'breach of fiduciary duty', (4) 'fraud and deceit', (5) 'unjust enrichment', (6) 'quasi-contract', (7) 'bad faith breach of the implied covenant of good faith and fair dealing', (8) 'intentional infliction of emotional distress', (9) 'negligent misrepresentation', (10) 'intentional interference with prospective advantageous economic relationships', (11) 'slander of title', (12) 'accounting', and (13) 'declaratory relief'.

¹⁰¹ *Ibid*, 134 per Panelli J.

whether they were property.

Of the Supreme Court judges, Panelli J, with Lucas CJ, Eagleson and Kennard JJ concurring, held that Moore did have claims for breach of fiduciary duty and lack of informed consent, but that he did not have a claim for conversion. Justice Arabian gave a separate, concurring opinion. Justice Broussard, though concurring with the majority's acceptance of the claims for breach of fiduciary duty and lack of informed consent, dissented on the issue of conversion, finding that Moore did have such a claim. Justice Mosk also dissented, finding Moore had a claim for conversion.

Under Californian law, for a claim for conversion to succeed, the plaintiff must first demonstrate either a right to possession or an ownership interest in the object.¹⁰² Moore had not sought possession of the cells, nor the right to possess them, and hence in the majority's opinion he needed to demonstrate an ownership interest in them. Such an interest was rejected on three grounds: lack of judicial decisions in support of such an interest; Californian statute law that limited the continuing right of a patient in their excised tissue; and the assertion that Moore could not have property rights in the subject of a patent held by the Regents of the University.¹⁰³

The majority decision was based on a number of grounds. First, that there was no reported case of a conversion claim being successfully brought for the use of human materials in medical research. To accept Moore's claim they would effectively have had to impose a tort duty on researchers to trace the source of every tissue sample used and request permission to utilise it in their research. As Moore's claim was novel, this would involve an extension of the current theory of conversion and such extension required consideration of any policy concerns that could be raised. Extending conversion to encompass the use of human tissue, asserted the majority, raised policy concerns as the imposition of a tortious duty to investigate the origin of all research samples would affect the performance of socially desirable medical research.¹⁰⁴ The majority also noted that human biological materials were treated as objects *sui generis* in the specific legislation created to regulate them, citing the *Uniform Anatomical Gift Act* and the *Health and Safety Code* as support for this assertion.

¹⁰² *Del E Webb Corp v Structural Materials Co* (1981) 123 Cal App 3d 593 at 610–611 as cited in *Ibid*, 136 per Panelli J.

¹⁰³ *Ibid*, 137 per Panelli J.

¹⁰⁴ *Ibid*, 135–136 per Panelli J.

The majority's decision was therefore based on both a lack of previous cases and legislation that apparently denied property interests in human materials. However, the passages from these pieces of legislation cited by the majority do not explicitly reject property interests in tissue. First, the majority cited the *Uniform Anatomical Gift Act's* provisions allowing a competent adult to 'give all or part of [his] body' for certain purposes outlined in the Act, namely 'transplantation, therapy, medical or dental education, research, or the advancement of medical or dental science'.¹⁰⁵ The majority then cited the prohibition against receiving valuable consideration for such transfers.¹⁰⁶ It appears that the majority argued that this lack of ability to receive consideration meant that there was no ownership interest in transferred tissue. Yet, bearing in mind the 'bundle of rights' view of property, clearly the legislation provided for a right to alienate tissue by allowing an individual to transfer it.¹⁰⁷ The Act also allows for possession and use of tissue for medical research, demonstrating an implicit acceptance that rights to use and possess—also rights exercised as part of property ownership—could subsist in tissue.

Similarly, the other legislative provisions cited by the majority do not expressly reject an ownership interest. For one, the majority cited the Government Code allowing a coroner to retain (right to possess) and transfer (right to alienate) pituitary glands from autopsy to a university for use in research (right to use) or to manufacture hormones (which will likely be sold, thus demonstrating a right to the income).¹⁰⁸ It also cited legislation providing for a right to possession of a corpse for burial, which could infer some level of ownership interest.

However, the majority did address this issue. California statute law does limit the control a patient may have over their excised tissue, which must be interred or incinerated in accordance with the *Health and Safety Code* once it is no longer used for research.¹⁰⁹ 'By restricting how excised cells may be used and requiring their eventual destruction', asserted the majority, 'the statute eliminates so many of the rights ordinarily attached to property that one cannot simply assume that what is left amounts to 'property' or 'ownership' for the purposes of conversion law'.¹¹⁰ All that remained,

¹⁰⁵ *Uniform Anatomical Gift Act, Health and Safety Code (UAGA)* §§7151, 7153.

¹⁰⁶ *UAGA* §7155.

¹⁰⁷ On the 'bundle of rights' view of property, and the rights comprising a property relationship, see Chapter Nine.

¹⁰⁸ *Moore v The Regents of the University of California*, 137 per Panelli J.

¹⁰⁹ *UAGA* §7054.4.

¹¹⁰ *Moore v The Regents of the University of California*, 140–1 per Panelli J.

according to the majority's opinion, was a limited right to control the use of tissue.

While this is true to an extent, true that the patient from whom tissue was removed does not have all the rights of property, or indeed most of them, these rights have not been extinguished. Rather, they have been transferred to the researcher who then uses, possesses, controls and possibly obtains financial benefit from the tissue. Hence, though the patient cannot assert a right of ownership once the tissue has been transferred to the researcher, if these rights can be exercised over that tissue after transferral, clearly it is still property when held by the researcher. Accepting this, one is left with only two possible situations: either the rights *were* held by the patient and then transferred upon donation, or they came into existence only after the researcher gained possession of the tissue. As the court held, these rights as held by the individual may be extinguished by the restrictions, but it still implicitly accepted that they had once existed (otherwise, they could not subsequently have been extinguished). Hence, at least at some point, it is arguable that on this decision, individuals (such as Moore) possess sufficient property interest in his tissue for a conversion action.

Given also that the legislation does not prevent other uses, merely the sale of tissue for consideration, it would appear that it does not preclude such rights being held by the patient before transfer. This being so, it could then be argued that indeed the patient did have an ownership interest before most of the rights of which it was comprised were later transferred when the tissue was donated. And indeed the patient must have had at least the right to possess, use and transfer or alienate before the donation for him or her to have effected the donation at all. Hence, on this view the legislation does not preclude the existence of property rights at all.

In the latter situation, where rights must have come into existence after transfer, a basis for their creation would need to be found. Presumably, this basis is policy considerations and simple practicality, for the researcher must be able to possess and use tissue if they are to undertake research on it. If policy is the basis, then again the argument must turn, as it will at a later stage in this section, to which concerns are most important and whether they do indeed preclude the according of property rights to the source of the tissue as well as the researcher who later uses it.

It is, however, accepted that the legislation does not specifically state that property rights can be held in tissue, and was probably not meant to be so interpreted. However,

it also does not explicitly reject ownership interests and mimics their form. Therefore, it may not form a strong basis for the majority's first argument.

On this issue Moore also cited *Venner v State*.¹¹¹ That case, police officer's had seized faeces taken from the defendant's bedpan while he was in hospital to search for narcotics previously swallowed by the defendant. It was held that the defendant had abandoned the faeces, but in the course of the case the Court stated in *obiter* that '[I]t is not unknown for a person to assert a continuing right of ownership, dominion, or control, for good reason or for no reason, over such things as excrement, fluid waste, secretions, hair, fingernails, toenails, blood, and organs or other parts of the body...'¹¹² Though the California Court of Appeal had accepted this case in support of Moore's argument, the majority in the Supreme Court rejected it as a precedent for according property rights in tissue. They asserted that the case had no relevance as it was a case concerned with criminal procedures, rather than a civil dispute over monetary gain made from tissue use. The policy concerns in *Venner* on which the decision was based were entirely different to those faced in the present case, asserted the majority, and hence it had little relevance to their own determination.¹¹³

Certainly the policy concerns in *Venner* were different to those relevant to *Moore*, but a similar feature can be detected in both. In each case, the Court was concerned to achieve an outcome based on needs that were regarded as worthy of fulfilling—the need to ensure police are able to obtain access to material required for investigations, and in *Moore* an avowed need to protect the medical and scientific research communities from an excessively onerous duty to discover the origins of every tissue sample used. In each case, then, the decision to accord property status was based partially on expediency rather than theoretical concerns. Given this, there appear to be grounds for making arguments for property rights in other context on the basis of policy concerns where the laws of property provide the desired outcome.

Moore also argued that a property interest could be found through analogy with cases establishing the right of a patient to refuse medical treatment, effectively as the Court in *Bouvia v Superior Court* stated, the right of '[e]very human being of adult years and sound

¹¹¹ *Venner v State* (1976) 354 A 2d 483.

¹¹² *Ibid*, 498.

¹¹³ *Moore v The Regents of the University of California*, 138 per Panelli J.

mind ... to determine what shall be done with his own body'.¹¹⁴ Moore's argument was that this right was a right to control, and therefore extended to a right to control the use of any part of that body even once it had been excised (including the cells used to produce the cell line). Although the Appeal Court accepted this argument, the majority in the Supreme Court did not, holding that the interest in controlling what happens to one's body in treatment could be protected better through fiduciary duties and informed consent requirements.¹¹⁵

Having held that Moore's cells were not his property, and therefore did not come within the bounds of a normal claim for conversion, the majority came then to consider whether the tort should be extended to include such claims. It held that it should not on three grounds, the first based on a balancing of policy considerations; the second, that an issue of this kind was better dealt with through legislative means; and third, because the tort of conversion was not necessary to protect the interests of patients.¹¹⁶ It did, however, leave open the possibility of conferring property rights in other situations.¹¹⁷

Two policy considerations were balanced by the majority—the need to protect patients' rights to make decisions about their bodies and their medical treatment; and the desire not to inhibit socially useful activities like medical research where the researchers have no reason to believe that their activities are contrary to the donor's wishes.¹¹⁸ Conversion is a tort of strict liability, and therefore any person holding cells is subject to it, regardless of whether that person knew they were violating the wishes of the owner or not. The majority held that to extend conversion to include tissue used in research would protect individual source rights but also that 'it would utterly sacrifice the other goal of protecting innocent parties' because anyone who gained possession of the cells, in whatever manner, would be liable in conversion. It would also disrupt the free transfer of tissue for research and prevent access to raw materials. In doing so, it would have an unacceptably adverse impact on important medical research. Finally, the majority considered that the problems of misuse of tissue could be dealt with through claims in relation to a physician's fiduciary duty to a patient, and hence did not necessitate expanding another area of law.¹¹⁹

¹¹⁴ (1986) 179 Cal App 3d 1127, 1139 as cited in *Ibid*, 139 per Panelli J.

¹¹⁵ *Ibid*, 139–140 per Panelli J.

¹¹⁶ *Ibid*, 142–3 per Panelli J.

¹¹⁷ *Ibid*, 142 per Panelli J.

¹¹⁸ *Ibid*, 143 per Panelli J.

¹¹⁹ *Ibid*, 144–147 per Panelli J.

In concurring, Arabian J considered the issue of conversion first in relation to questions of morality, asking '[d]oes it uplift or degrade the 'unique human persona' to treat tissue as a fungible article of commerce?'.¹²⁰ He also noted the potential consequences of recognising property in tissue, including competitive bidding for tissue for research, the exposure of researchers to tort liability for the use of tissue and the detrimental social effects of placing body parts in the market place. These considerations were, in his view, determinative and the 'troubling questions' these issues raised should not be treated simply as matters of tort law.¹²¹ Based on these reservations, Arabian J agreed with the majority that a property interest for the purposes of conversion should not be found.¹²²

These justifications for rejecting property rights are highly persuasive, and it is likely that a court in Australia facing a similar fact situation would find them attractive. As a basis for rejecting property rights in human tissue, they will be considered in more detail in Part V. At this point, it is sufficient to say that the majority decision in *Moore* was founded in part on policy concerns, which led to the rejection of individual property rights in tissue.

In dissent on the issue of conversion, Justice Broussard pointed out that as the law would very likely uphold a charge of theft if the tissue had been stolen from the hospital, it was unlikely that the cells could not have been property for some purposes under the law. Therefore, he thought the issue was in fact whether Moore had a sufficient ownership interest in the cells, that is, a right to determine how they should be used once excised. By analogy to the approach taken in the *Uniform Anatomical Gift Act*, Broussard J found that a patient did have such a right.¹²³

In conclusion, Broussard J also rejected the policy basis of the majority decision, and considered the immunity it sought to create for researchers and doctors was unreasonable. He argued that claims for breach of fiduciary duty would not suffice to solve all problems; that as most tissue samples were not a potential source of liability the application of conversion would not cause undue problems on a large scale; that bulk of profits to made from tissue will still be attributable to the skill and labour of scientists and patients would not be entitled to such a large share as to remove the profit motive

¹²⁰ Ibid, 149 per Arabian J.

¹²¹ Ibid.

¹²² Ibid, 149–150, per Arabian J.

¹²³ *UAGA* § 7150 as cited in Ibid, 155–156 per Broussard J.

for research; and finally, that the fact that the source of tissue might have a right to decide how tissue used in research and hence acquire some financial return was not a good reason for excluding such a claim or for creating a novel exception to conversion liability.¹²⁴

Mosk J concurred with Broussard J that by analogy Moore's statutory right to direct how the tissue was used equated to a property interest. He found that on the 'bundle of rights' view of property, this right to direct use fell within the broad concept of property at common law.¹²⁵ Mosk J also rejected the three policy grounds for rejecting the conversion claim, but on a slightly different basis to that of Broussard J. First, Mosk J asserted that there was no longer a free and efficient transfer of tissue for research, and that instead access to research materials was not restricted in the case of valuable cell lines awaiting patents. He also argued that research tissue samples were now regularly collected with clear consent, of which records were maintained and hence allowing conversion for non-consensual use would not lead to an explosion of cases as for the most part it would be apparent that consent had been given. The majority view that allowing conversion claims would destroy the economic incentive for research was rejected by Mosk J as hyperbole.¹²⁶

In response to the majority's policy arguments, Mosk J raised two contrary considerations. First, that society 'acknowledges a profound ethical imperative to respect the human body as the physical and temporal expression of the unique human persona' and that

the dignity and sanctity with which we regard the human whole, body as well as mind, are absent when we allow researchers to further their interests without the patient's participation by using the patient's cells as the basis for a marketable product.¹²⁷

This respect would be upheld by recognising the individual's right to direct how the parts of his or her body were used, that is by recognising such a property interest in the body.

Second, Mosk J cited notions of equity as a policy consideration in favour of admitting conversion. The researchers and commercial developers had gained from research on

¹²⁴ Ibid, 157–160 per Broussard J.

¹²⁵ Ibid, 167 per Mosk J.

¹²⁶ Ibid, 170–173 per Mosk J.

¹²⁷ M Danforth, 'Cells, Sales and Royalties: The Patient's Right to a Portion of the Profits' (1988) 6 *Yale Law and Policy Review* 179 as cited in *Moore v The Regents of the University of California*, 173 per Mosk J.

Moore's cells, and Mosk J considered the contribution of the source of the raw materials was excluded from a share in these financial rewards. He regarded excluding Moore from sharing in the profits from the cell line as immoral and inequitable, and held that the source of the tissue should be fairly compensated. This, he argued, could be achieved by recognising that the patient who gave the cells had a property interest in his or her body and its products.¹²⁸

Finally, Mosk J rejected the majority conclusion that there was no need to allow conversion on the basis that the matter could be dealt with through a breach of fiduciary duty claim. He gave a number of reasons, of which in this context two are relevant. First, basing the matter on fiduciary duty would still exclude the source from actively consenting to the use of his or her tissue in research, and from sharing in commercialisation, as the duty only required the doctor to inform the patient of competing interests—in contrast with the rights given by a property right as discussed above. Second, he noted that only Golde stood in a fiduciary relationship with Moore, and hence an action based on breach of fiduciary duty could not be maintained against any others—such as Quan and the commercial partners—who took and misused his excised tissue. As Mosk J stated, a cause of action based on non-disclosure within a fiduciary relationship was not substitutable for a conversion cause of action because it

(1) was unlikely to be successful in most cases;

(2) fails to protect patients' rights to share in the proceeds of the commercial exploitation of their tissue; and

(3) may allow the true exploiters to escape liability.¹²⁹

The *Moore* decision presents a variety of perspectives on whether human tissue is property at law, and includes an elucidating discussion of the policy reasons for doing so. Aside from this, the decision in *Moore* does point to the kind of reasoning that Australian courts might use if a similar fact situation arises in this country. As the only decision directly on the issue of patient's rights to tissue, though not binding it would certainly be influential.

In application to the Case Studies, *Moore* is most relevant to Case Study 15: Canavan Disease Research; and perhaps, Case Study 17: StarGene. Were the same decision applied in the Canavan case, Greenberg and the other plaintiffs would similarly be

¹²⁸ *Moore v The Regents of the University of California*, 176–177 per Mosk J.

¹²⁹ *Ibid*, 180–181 per Mosk J.

denied any remedy against the other holders of the patent such as the Miami Children's Hospital Research Institute. The families supplied tissue to Dr Matalon, not the Hospital or its research institute, and hence an action based on fiduciary duty would provide no remedy against its having patented and enriched itself from the use of their samples. They may, however, have a fiduciary claim against Matalon, as they did stand in a consent relationship with him. The real problem with applying *Moore* here is that their claims and remedies are so limited, and would not stand against anyone save the person to whom they initially gave the tissue. They would therefore be unable to achieve the actual goal they had when donating tissue—making a test generally available—as they have no claim against at least one of the holders of the patent.

Case Study 17: StarGene assumes that the celebrities who gave their DNA to be immortalised did so consensually. However, it is easy to imagine a situation where a stray hair from a pop star is secretly taken and preserved by such a company. In such a case, the pop star would not have been in a fiduciary relationship with the person who took it or the company that preserved and sold it. Being a loose hair, there would be no question of assault. Were the pop star to seek its return, fearing invasion of privacy or even simply distaste that others have possession of parts of his body, the decision in *Moore* would not allow for a property right to possession or an action in conversion. Indeed, given the expediency considerations in the majority judgment and their fears of an explosion of liability, it is likely the same reasoning could be used to argue that then all people taking stray tissue—for example, cleaners cleaning hotel rooms or hairdressers sweeping up clippings—would be liable. But this view assumes that actions would be brought far more often than is probable because most tissue is treated as waste and thrown away. Where the tissue is misused, any claim brought would in fact more likely be reasonable as someone would have actively taken and misused tissue that had clearly been intended to be treated as waste.

Following Mosk J's view, fearing too many instances of liability is not a sound basis for denying relief where a real harm could be caused. The majority position in *Moore*, therefore, would unreasonably limit possible claims and leave many people who might have been harmed without a remedy. Not only those in an example such as StarGene, but one can imagine similar situations, such as a parent taking a child's hair to test it for paternity, or an employer using a sample left by an employee to test for future predispositions that might affect his or her capacity to work. Again, in these situations where it appears a legitimate claim of harm would exist, the *Moore* decision (in relying on

the existence of a breached consent relationship) would fail to provide a solution.

The majority position in *Moore* also rejected allowing individuals to share in the profits of research using their tissue. Were *Moore* applied, say, in an example like Case Study 16: Ted Slavin and Diagnosing Hepatitis, if Slavin had sought more return for his tissue, the Supreme Court would have rejected his claim. On the majority view, Slavin should not have been able to sell and profit from his tissue at all, despite the life-saving uses it had. Similarly, the *Moore* decision would deny any claims in conversion from individuals who discovered their tissue had been used in profitable research, like that in Case Study 13: Bionomics or Case Study 12: Iceland and deCODE; should they subsequently assert that their tissue was used without consent and seek a share of the profits.

Finally, by denying a property right in tissue generally, the majority decision in *Moore* has implications for the general view of tissue at law, and the rights the law accepts may be exercised over it. The decision undermines respect for individual autonomy in relation to one's body by excluding a legal means of protecting that autonomy. Taken to its logical conclusion, it also undermines the growing trend to recognising some possessory rights in tissue, such as might be accorded hospitals, pathology laboratories and researchers. In fact, by rejecting the property status of tissue, the decision actually excluded one means such groups have of securing the samples they use for the medical research the majority sought to protect.

The majority decision in *Moore* has been criticised for its focus on the economic interests of researchers over the interests of individuals from whom tissue is taken.¹³⁰ Others have criticised it for denying Moore control over his tissue once excised, particularly when free exchange of tissue for research is becoming less common.¹³¹ By contrast some, such as Thomas Dillon, have argued that at least to the extent of excluding the source from being able to claim compensation for donated tissue, such denial of control was correct.¹³² It has been suggested, however, that although the majority's economic focus may have influenced the treatment of the conversion claim, this fact should not

¹³⁰ Mortimer, 'Proprietary Rights in Body Parts', 227–8.

¹³¹ J Gilmour, "'Our' Bodies: Property Rights in Human Tissue' (1993) 8(2) *Canadian Journal of Law and Society* 113, 122–3, 127.

¹³² T Dillon, 'Source Compensation for Tissues and Cells Used in Biotechnological Research: Why a Source Shouldn't Share in the Profits' (1989) 64 *Notre Dame Law Review* 628, 630, 633 and generally. Dillon's argument was made in relation to the Appeal Court decision, however its reasoning is still relevant here as a comment on the rights of Moore in relation to his tissue and the profits generated from the cell-line. Dillon reasoned that sources should not be compensated because of the added strain this would place on health care research funding and research costs.

overshadow the Court's other concern—avoiding the extension of strict liability to any person who handles the tissue of another without consent¹³³—and this is a valid point.

These views will be considered further in Part V. The influence of the *Moore* decision on Australian law remains to be seen. As a decision on the property status of tissue, the decision clearly rejects deeming tissue property, and hence merely adds to the inconsistency in decisions about the status of tissue. What can be said, however, is that in any similar case the policy reasoning given by each justice in *Moore* will probably be as influential on the outcome as the legal reasoning on the status of tissue itself.

¹³³ B M Dickens, 'Living Tissue and Organ Donor and Property Law: More on Moore' (1992) 8 *Journal of Contemporary Health Law and Policy* 73, 76, 79.

CONCLUSION

On close examination of the cases on which it is based, the law in support of the no property in buried and unburied corpses rule emerges as less well-founded than its long acceptance would suggest. The rule has attained a somewhat rarefied status and it is likely this that has discouraged its re-evaluation. The lack of clarity as to the non-proprietary right to possession of corpses has further muddled the waters in this area.

The foregoing analysis has demonstrated that there are no truly strong precedents to be found at common law which preclude the classification of parts of human corpses as some form of property, or at least as objects to which property rights may attach. The age of the cases that have founded the rule against property in corpses has begun to show, and in examining the line of cases that has developed during the 20th century it is clear that the rule is being reconsidered in the light of the expanding uses of tissue and new technological developments.

It is apparent that the courts have to some limited degree begun to reject the blanket application of the rule against property rights in tissue, and have made exceptions to the rule, albeit in limited circumstances. It can thus be concluded that there is precedent for property rights over tissue to be created, though most likely only through the lawful application of work and skill. What is also apparent is that there are significant gaps the common law approach to tissue samples. This is in part because it does not address those areas in which the legislation and ethical guidelines have failed, but it also because the approach developed by the courts so far is too limited, piecemeal and unclear to form a well-defined and comprehensive approach to modern human tissue use. In allowing sale of some parts of the body and not others such as preventing sale of organs but allowing sale of hair; and in holding donation to be legal but supply for any form of consideration not to be shows an approach which is not based on a consistent view of the status of the body. The law currently concentrates on the details of each situation without dealing with the essential issue of the status of the body. While the trend towards recognising property rights is beginning to address this failing, the law still needs to develop principled solutions in line with a general view of the body to enable it to deal with new uses and challenging new issues around the use of tissue. Further reconsideration of the rule against property rights and its exception is also required to clarify the scope of the new approach to tissue and to develop a consistent view of its

status in a wide range of fact situations.

As Parts II and III have demonstrated, the current legal approach to excised body parts is greatly lacking some areas. In the absence of a consistent view on the status of those parts, the law is currently unable to develop new solutions effectively. However, the emerging property approach taken by the courts is beginning to address this problem, and the following Parts will evaluate whether such an approach can address the problems presented by modern uses of tissue. Part IV will analyse whether it is conceptually possible to include human tissue within the ambit of property law, and whether such an approach would be generally workable. Part V will examine other concerns, such as ethical and social values as well as legal considerations, to analyse whether human tissue should be property. These chapters will take up where the courts have left off and explore whether the logical conclusion of this new common law approach can be developed to solve the problems of tissue use in the 21st century.

Part IV

Human Tissue and the Concept of Property

Contents

INTRODUCTION	262
 <i>Chapter Eight</i>	
WHAT IS PROPERTY?	268
1. Hohfeldian Analysis and the Notion of Rights	271
2. The Nature of Property Rights	277
 <i>Chapter Nine</i>	
CAN HUMAN TISSUE FIT WITHIN THE CONCEPT OF PROPERTY?	280
1. Right to Possess	280
2. Right to Use	282
3. Right to Manage	284
4. Right to the Income	286
5. Right to the Capital	287
6. Right to Security	289
7. Incident of Transmissibility	291
8. Incident of Absence of Term	291
9. Prohibition against Harmful Use	293
10. Liability to Execution	295
11. Residuary Character	296
12. Conclusion	297
 <i>Chapter Ten</i>	
HUMAN TISSUE AND PHILOSOPHICAL JUSTIFICATIONS FOR PROPERTY	299
1. Natural Rights and Locke's Labour Theory	300
2. First Occupancy Theory	305
3. Utilitarianism	312
4. Conclusion	319
 CONCLUSION	 321

INTRODUCTION

...the legal treatment of bodies and body parts sounds suspiciously like property treatment.

*Lori Andrews*¹

...the granting of a proprietary interest by the law is significant for what it says about the empowerment of the individual. By granting the notion of proprietary interests, we provide the judicial basis on which an individual can seek a remedy.

*Ken Mackie and Lynden Griggs*²

One of the crucial themes running through this thesis is the fact that human tissue sits at the nexus of a variety of intersecting, and sometimes conflicting, interests. Often there are competing demands for a portion of human tissue—a researcher wishes to use a blood sample for study, while the donor wishes to be paid for that use; a hospital stores a newborn screening card for testing and research, while the police wish to obtain a DNA profile from it as part of their investigations. It is when these demands cannot all be met, or are mutually exclusive, that conflict arises. To date, the Australian legal system has failed to produce an adequate solution to regulate these conflicting interests.

Of the legislation that is in place to address some conflicts, the Human Tissue Acts are both very limited in scope and deal only with consent to the removal of tissue, not with its subsequent use.³ These Acts also cover only the removal of tissue for transplantation, medical and research purposes which, as the panoply of examples presented in Part I illustrated, are rapidly becoming only a few of many uses to which human tissue may now be put. Beyond these Acts, only the collection, use and storage of tissue samples for forensic purposes is legislatively controlled.⁴

Ethical guidelines, particularly those released by the National Health and Medical Research Council (NHMRC), play a significant role in deterring misuse of tissue within

¹ L. B. Andrews, 'My Body, My Property' (1986) 16 *Hastings Center Report* 28, 29.

² L. Griggs and K. Mackie, 'Burial Rights: The Contemporary Australian Position' (2000) 7 *Journal of Law and Medicine* 404, 413.

³ See Chapter Four, sections 1–3.

⁴ See Chapter Four, section 7.

a research context.⁵ While such guidelines have, however, been greatly influential in encouraging ethical research practice, their lack of legal force precludes them from providing enforceable resolutions to conflicts of interest. As ethical guidelines do not provide a legal cause of action, individuals may be left without a remedy against a person or institution who has misused their tissue.

Of the common law cases that have considered human tissue use and abuse, the precedent that has emerged—that human tissue is subject to property law once it has been altered through the application of work or skill⁶—provides a legal answer only within the very restricted class of situations that have as yet come before the courts.⁷ Thus far, only the theft of tissue⁸ and applications for access to test samples have been considered⁹ and even within this class, the courts have been divided on both the law and its application.¹⁰

As a result, human tissue exists largely in a legal vacuum. Increasingly, this situation is becoming untenable, for the uses of tissue, and the interests held in it are expanding, while the legal system fails to keep up. For one example, human tissue is now used to develop valuable therapeutic products, yet the only controls on who may buy and sell are the Human Tissue Acts' prohibitions on sale without processing.¹¹ Beyond this, there is little or no judicial opinion and no legislative mechanisms addressing commercial dealings with tissue, even though they occur in many contexts. In addition, ethical guidelines largely exclude individuals from sharing in the profit that research on their tissue may generate.¹²

As another example, where organs and bones are retained, an individual seeking their return for burial has no legal means of compelling return and in Australia must rely only on the goodwill of researchers and hospitals. Aboriginal communities that have sought the return of their ancestors' remains from museums are a particular example of the

⁵ See, eg, National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans*, NHMRC, Canberra, 1999. See discussion on ethical guidelines in Chapter Five, section 2.

⁶ See *Doodeward v Spence* (1908) 6 CLR 406; *R v Kelly* [1998] 3 All ER 741; *Roche v Douglas as Administrator of the Estate of Edward Rowan (dec'd)* (2000) WASC 146. See further Chapter Seven.

⁷ See Part III for a full consideration of the common law legal status of human tissue.

⁸ *R v Kelly* but compare *R v Herbert* (1961) 25 J CR L 163 and *R v Rothery* [1976] Crim LR 691, which contain no mention of either the rule or the exception.

⁹ *Roche v Douglas*.

¹⁰ See *Dobson and Another v North Tyneside Health Authority and Another* [1996] 4 All ER 474 and compare *R v Kelly*.

¹¹ See Chapter Four, section 4.

¹² See Chapter Five, section 2.

problems that can arise in this context, with many recent efforts to have remains returned refused. Without a legal remedy, they are unable to give those remains a proper burial, and to their minds the spirits of those who died cannot be laid to rest.¹³ Similarly, the law provides few answers to questions of who has rights to store and use banked cord blood; or how disputes over access to tissue samples for paternity or DNA testing are to be solved.

In more general terms, the law as it now stands does not provide guidance on most of the potential future uses for tissue, on its storage, on how and when it may be removed (save in the context of research, forensics and transplantation), on the rights of the person from whom it was taken and on those of the person who gains possession of it. The consent approach adopted in the Human Tissue Acts adds to this problem, as any sanctions and restrictions those Acts contain extend only to the parties within the consent relationship. The specificity of the Acts and the ethics guidelines in place also mean that they have neither the breadth nor the flexibility to deal with new uses and problems.

There is a need for reassessment of the status of human tissue and how it is regulated by the law, and a reassessment with broad and comprehensive vision rather than one directed at solving only a small subset of problems. In response to this need and the problems that the use of human tissue presents, both the courts and legal commentators begun to consider the concept of property as a potential legal tool for regulating human tissue.¹⁴ Why property law? At one level, the language and laws of property have an intuitive appeal as a means to control human tissue, as they accord with the way people speak about their bodies—‘I broke my finger’; ‘She pulled my hair’. People often describe their bodies from the perspective of possession, using what James Harris has referred to as ‘body-ownership rhetoric’, to add power to assertions of control.¹⁵ Such language is used to express the sense that one’s body is something over which one has exclusive rights, both to determine what it does and what is done to it and its parts.

¹³ See further Case Study 1: Collecting Aboriginal Remains.

¹⁴ See Part III generally on the courts’ shift towards regarding human body parts as property. See also Andrews, ‘My Body, My Property’; L Andrews, ‘The Body as Property: Some Philosophical Reflections—A Response to J F Childress’ (1992) 245 *Transplantation Proceedings* 2149; L Andrews and D Nelkin, ‘Whose Body is it Anyway? Disputes over Body Tissue in a Biotechnology Age’ (1998) 351 *Lancet* 53; R Atherton, ‘Claims on the Deceased: The Corpse as Property’ (2000) 7 *Journal of Law and Medicine* 361; R Magnusson, ‘The Recognition of Proprietary Rights in Human Tissue in Common Law Jurisdictions’ (1992) 18 *Melbourne University Law Review* 601; L Skene, ‘Arguments against People Legally ‘Owning’ Their Own Bodies, Body Parts and Tissue’ (2002) 2 *Macquarie Law Journal* 165.

¹⁵ J W Harris, ‘Who Owns My Body?’ (1996) 161 *Oxford Journal of Legal Studies* 55, 62.

The language of property is also used to describe what is done with excised human tissue—‘I gave blood yesterday’; ‘The police took a DNA sample and matched it to the samples found at the crime scene’; ‘She sold her hair to a wig company, they gave her two hundred dollars!’ Here, tissue is spoken of as something that is transferred, something that is used and something that is exchanged in return for money. Beyond mere rhetoric, this use of language reflects the way human tissue is often treated—as an item of property. Consider a car, indisputably the subject of property law. A man buys it from a car dealer and drives the car regularly, but the car is later stolen and used in a robbery. When eventually found, the police keep possession of the car to use it in evidence. Consider now a piece of human hair. It too can be bought and sold, as hair often is to wigmakers. When stolen, it has been taken into evidence,¹⁶ while a hair left at a crime scene can be retained and used by police for forensic matching as discussed in Case Study 9: Forensic DNA Testing. In the case of both the car and the hair, there is an object that can be bought, sold, used, possessed, retained and stolen. Demonstrably, the ways in which they are treated bear many similarities. Despite this, while there is no question that the car is property, it is far from clear whether human hair is under the current legal regime.

Not only is tissue treated similarly to property by society, the laws which regulate tissue mirror some aspects of property law. In the comparison above, the man’s right to possess and use his car is protected from interference by others and the car must not be taken without his consent. This is property law, and in many ways it works in the same way as the Human Tissue Act provisions that prohibit the taking of organs or tissue from a person without his or her consent. While the Human Tissue Acts are worded in terms of consent, they seek to achieve the same end by different (and more limited) means, namely that a person’s organ must not be taken against their wishes, just as the law of property protects the man’s car from being taken against his wishes.¹⁷

These comparisons demonstrate one of the most fundamental reasons some academics and courts have begun to regard property rights as an appropriate mechanism for regulating tissue. In many instances, the way human tissue is dealt with closely reflects

¹⁶ *R. v Herbert*.

¹⁷ There are, obviously, fundamental legal differences between property relationships and consent relationships, which have different legal consequences. However, this example is meant to demonstrate that often in relation to tissue use, the consent provisions seem directed at achieving similar control of tissue to a property relationship, at least in a limited sense.

the way items of property are treated, both by society and by the legal system. If they are dealt with in the same way, then it may be that the laws of property are a suitable means of regulating dealings with human tissue. These similarities have already led to a minor shift in judicial opinion towards the use of property law to regulate tissue. This is seen in the very limited trend in the cases to recognise restricted property rights, as in the cases of *R v Kelly*¹⁸ and *Doodeward v Spence*.¹⁹ As a result, the major debate in this area of has been concerned with whether excised human tissue should be accorded the status of legal property.²⁰

Generally, this debate has been cast in terms of a property/no property dichotomy, and has been argued from legal and ethical perspectives (often focusing on achieving desired outcomes, rather than the strict application of principle). The debate has not, however, been characterised by a focus on whether the law can admit human tissue as an object of property, but on the pros and cons of according tissue property status in a particular setting. Such an approach only really addresses part of the issue. The issue is better approached broken down into three, more focused questions. The first, and most basic, is what in fact is property? This question is not so easily answered as it might appear, and the complexity inherent in defining property will be briefly considered in the course of Chapter Eight.

The second question is whether human tissue can fit within the legal concept of property as described in the answer to question one. Having defined property, this question seeks to determine whether tissue bears enough of the hallmarks of an object of property to be legally treated in the same way.²¹ The final question is whether according human tissue property status is the best solution to the problems its use presents. It may be that human tissue fits well within the concept of property, but also that there are compelling extrinsic reasons for excluding it from the ambit of property law.

¹⁸ [1998] 3 All ER 741.

¹⁹ [1908] 6 CLR 406. See further the cases considered in Chapter Seven.

²⁰ Some authors have asserted that the debate as to whether human biological materials should be deemed property is a debate about the wrong issue altogether (see, eg, A George, 'Property in the Human Body and its Parts: Reflections on Self-Determination in Liberal Society' (2001) *European University Institute Working Paper No. 2001/8*). This may be true to an extent, but the reality of the present legal situation is that some courts and many legal commentators have moved towards considering a property system for dealing with human tissue. Given that this is the current focus of the debate, it is appropriate for this thesis to focus on this approach to regulating tissue use.

²¹ Rosalind Atherton has taken a similar approach to claims on deceased bodies, arguing that the question of whether a body is property is in fact two questions: '(1) Is it capable of "thing-ness", does it fit the idea of things that are capable of being owned?' and '(2) What is the range of rights in relation to that thing?': see Atherton, 'Claims on the Deceased', 362

This Part will consider the first two questions. Chapter Eight will provide background to rights relationships in property, while Chapter Nine will outline the concept of common law property followed by an analysis of whether human tissue fits within that concept. This analysis will examine the fundamental incidents of property institutions and their application to tissue, focusing on the seminal work of Professor A M Honoré.²² Philosophical perspectives on the nature of property will also be considered in Chapter Ten to examine whether some of the philosophical justifications for property systems can support the inclusion of human tissue within the sphere of property. In effect, this chapter will appraise whether tissue can be property, as a prelude to Part V which will deal with the third question, whether it should be property.

²² See, eg, A M Honoré, 'Ownership' in A Guest, (ed.) *Oxford Essays in Jurisprudence*, Clarendon Press, Oxford, 1961.

Chapter Eight

WHAT IS PROPERTY?

...legal relations cannot exist between people and Porsches, because Porsches cannot have rights or duties or be bound to recognise rules.

*Jeremy Waldron*¹

Common law property systems are essentially mechanisms by which access to, and control of, resources are regulated. They are both legal and social institutions, acting as an organising system where a resource is relatively scarce. As such, common law property is a system for resolving disputes between parties with different interests in an object or thing. It is not an immutable edifice, but rather a flexible means of recognising each of these interests and according parties the ability to uphold them. Where more than one party wishes to use or possess an object or thing, property rules work to determine who has the better claim to it and to protect that claim, or right, from others. These rights are protected by a rules-based designation of control and the protection of that designation until it is lawfully altered.

It becomes apparent, then, why the idea of regulating human tissue through such a system has been suggested, for that tissue is rapidly becoming a substance which different groups wish to access and control. Where a particular tissue sample is sought (either for forensic purposes or because it has unique uses in research) tissue also has one of the other characteristics of objects of property—relative scarcity. It is a substance in which different people have competing interests, and the most basic purpose of property systems is to determine whose interest, claim or right will prevail.

However, although the essential reasoning behind property systems can be easily identified, ‘property’ itself is not an easy term to define,² for as Wesley Hohfeld asserted ‘[b]oth with lawyers and with laymen this term has no definite or stable connotation’.³

¹ J Waldron, ‘What is Private Property?’ (1985) 5 *Oxford Journal of Legal Studies* 313, 314.

² Jeremy Waldron has asserted that for many writers the concept of private property defies definition. If this were true, argues Waldron, then property as a concept would no longer serve a useful purpose and one would be best speaking only of economic organisation or focussing one’s attention on the particular rights people have in relation to certain objects. See *Ibid*, 313.

³ W Hohfeld, ‘Some Fundamental Legal Conceptions as Applied in Judicial Reasoning’ (1913) 26 *Yale Law*

The lay conception is that property is generally a tangible thing, something that is possessed or controlled, an object of some kind. This is one of the initial difficulties in defining property—the general perception of what is meant by the word ‘property’ differs from its legal sense, which is in turn often complex and difficult to define. Indeed, the term ‘property’ is used in both lay and legal senses, often interchangeably either to refer to the subject of property rights (for example ‘this book is my property’) and to those rights themselves (for example ‘I own this book’). Often there is also, as Hohfeld has called it, ‘a fallacious and rapid shift from the one meaning to the other’.⁴

When dealing with corporeal objects, the common law does not really determine whether an object is in itself ‘property’. Rather, it is more accurate to view the law of property as a system delineating which things may have property rights exercised over them and what may be included within those rights.⁵ Objects themselves are not capable of having any legal capacity, for quite obviously an object is incapable of exercising a right or fulfilling a duty via its will, as it has none. Instead, an object forms the centre of a web of relationships between people, each of whom has rights with regard to that object.⁶ Together, these rights determine how each person may deal with the object.⁷

Under common law, all the possible rights in an object, also known as ‘absolute title’, rarely, if ever, vest in one person. Rather, title to an object is more often divided among a number of parties. Each has one or more rights which interact with those of others. The holder of certain of these rights may be regarded as the ‘owner’, but this is more a lay conception of ownership. Who takes this role will be of far less importance to the common law theorist than who has a particular right and how that right will interact

Journal 16, 21. ‘Sometimes’, Hohfeld continued, ‘it is employed to indicate the physical object to which various legal rights, privileges, etc, relate; then again—with far greater discrimination and accuracy—the word is used to denote the legal interest (or aggregate of legal relations) appertaining to such physical object. Frequently there is a rapid and fallacious shift from the one meaning to the other. At times, also, the term is used in such a ‘blended’ sense as to convey no definite meaning whatever’.

⁴ *Ibid*, 21–22.

⁵ See, eg, R Hardiman, ‘Toward the Right of Commerciality: Recognizing Property Rights in the Commercial Value of Human Tissue’ (1986) 34 *University of California Los Angeles Law Review* 207, 214.

⁶ See S Munzer, *A Theory of Property*, Cambridge University Press, Cambridge, 1990, 16–17 on the occasional need to use also the simple conception of ‘property as things’. It is, Munzer argues, ‘perfectly sound to think of property both as things (the popular conception) and as relations among persons or other entities with respect to things (the sophisticated conception)—provided that the context makes clear which conception is meant’: Munzer, *A Theory of Property*, 17.

⁷ It bears noting that simply listing the rights that make up the common law concept of property (as will be done later in this Part) does not wholly capture the concept of ‘ownership’. Jeremy Waldron suggests that defining an owner as someone who may only use an objects in accordance with their rights and the law is ‘vacuous’ because it defines ownership only be reference to external criteria to explain ownership itself (Waldron, ‘What is Private Property?’, 6). However, it is not necessary for the purposes of this thesis to delve into this complexity, as it seeks only to determine whether the rights of property as accepted as common law can be workably applied to human tissue. Hence, this issue will not be explored further.

with those of others.⁸ In this sense, each of the legal relations arising from these rights is distinct.

Take the example of a house and the person who owns it. To the lay person, the relationship involved exists between the house and the person who is perceived as its owner. However, as we have seen, houses cannot have rights and perform duties and thus cannot be a party in a legal relationship. Rather, the owner is in fact involved in a number of relationships with varying people. For instance, the owner (let's call him Richard) has the right to exclusive possession and use of the house, and to prevent others from entering. This is a relationship between Richard and all other people. He also has, as part of those rights, the right to alter the relations between himself and others with regard to it.

Richard may rent his house to someone else, and in effect he has exercised his power to alter these rights and relationships. To the lay person, Richard would still be regarded as the owner, yet in leasing his house he has passed the rights to exclusive use and to exclude others to another person. Depending on the form of the lease, Richard has retained other rights involving the house, such as a later right to regain possession when the lease is at an end. There are now two people who have some rights in the same object and who are part of relationships which centre on it. Richard may also have certain duties, such as a duty to keep the house in sufficient repair.

A difficulty which dogs any attempt to categorically define property can be identified at this point. Property rights are numerous and intertwined. They may be held by different people, giving each a certain amount of control over, or interest in, the object. These rights may be transferred, permanently through gift or sale, or temporarily and with restriction via agreements such as a lease. What becomes apparent at this point is that property is not a simple relationship between persons with regard to an object, but rather a collective term which encompasses a wide group of rights which may be held over an object and against different parties. This is generally what is referred to as a

⁸ This can be contrasted with the Roman Law concept of *dominium* where a single, absolute owner of an object is defined and all other interests are burdens on this title (see further B Nicholas, *An Introduction to Roman Law*, Clarendon Press, Oxford, 1962, ch III). The Roman law approach delineates distinct owners and objects, while the common law allows for perhaps more flexible and more complex interests to be held over an object by a range of parties. For this reason many continental systems have adapted the Roman law approach to property to allow for greater sophistication. See further on this contrast R Cotterell, 'The Law of Property and Legal Theory' in W Twining, *Legal Theory and the Common Law*, Basil Blackwell, Oxford, 1986, 95ff.

'bundle of rights' and these rights differ from one another in their nature and in their effect.

The final complexity in defining property is that the rights of which it is composed may differ in scope, in definition, in character and in effect. The bundle is not the same nor does it work in the same way in relation to every object. Rights may vary due to the character of the person who possesses them, when they are possessed and the nature of the subject of those rights. For example, the property rights which may be vested in a person over an intangible object such as some form of intellectual property will differ from those which may vest over a tangible object like a chair. An object may be owned in a number of distinct ways and these rights are all theoretically separable from one another. Yet, it is this complexity that lends the concept of property the very flexibility that suits it regulating the wide and varied range of relationships that individuals may have with regard to human tissue. With flexibility comes the ability to adapt to novel forms of property, of which human tissue may be one.⁹ This complexity also highlights the conceptual heart of property law, namely that it aims to recognise and regulate conflicting interests and relationships.

1. HOHFELDIAN ANALYSIS AND THE NOTION OF RIGHTS¹⁰

Using a conceptual language to consider the question of whether human tissue is property is a departure from the approaches taken in the legislation, case law and guidelines that currently regulate human tissue. For the most part, the legislation and guidelines in relation to tissue have not been based on a conceptual analysis of the nature of property rights, but rather make rules to achieve a specific purpose or deal with a particular use. Similarly, as discussed in Part II, the judicial decisions have been directed as consideration of very specific fact situations and the application of an outmoded rule. This method has produced the patchwork of laws that presently deal with tissue. There is now a need to address the problem *de novo*. By starting from the first principles of property laws, a precise analysis of whether property law is a workable legal tool for regulating the use of tissue can be undertaken.

Such a conceptual language is necessary to examine the content of the rights that make

⁹ Hardiman, 'Toward the Right of Commerciality', 215.

¹⁰ It is not the intention of this thesis to delve into the complex question of what is meant by a 'right'. An outline of the Hohfeldian approach to rights is provided to aid analysis of the incidents of property developed by A M Honoré. See further on the concept of a right in relation to property L Becker, *Property Rights: Philosophic Foundations*, Routledge and Keegan Paul, Boston, London and Henley, 1977, ch 2.

up property relationships. It has been established that property is a complex aggregate of diverse legal rights over an object, but this in itself is insufficient to explain the concept of property and whether human tissue could fit within that concept. The types of rights, the relationships they create and the content of those rights must also be elucidated. For legal rights to be workable, they must be definable, identifiable by third parties, have a degree of permanence and stability and generally be capable of assumption by third parties.¹¹ The content of these will be examined in later sections, but first the form these rights may take will be described by adopting an analytical framework.

In discussing property rights and the idea of ownership, often legal writers have drawn on the so-called 'analytical vocabulary'¹² developed in Wesley Hohfeld's *Fundamental Legal Conceptions*.¹³ This approach, which will be accepted for the purposes of this thesis, is one which Stephen Munzer has described as having 'no serious rival of its kind in intellectual clarity, rigour and power'.¹⁴

The value of adopting an approach to rights as proposed by Hohfeld is the precision it lends to the process of determining exactly what the individuals' relations with each other are and how those are to work. For example, by delineating between whether A has a claim-right or a privilege to drive her car, it becomes clear whether others then have a duty to allow her to do so, placing some positive requirement on them not to interfere, or merely giving them no right to interfere.

Hohfeldian analysis is particularly useful for considering whether human tissue is capable of fitting within the notion of property. The Hohfeldian approach to rights conceptualises them as aspects of a relationship between individuals over an object. It has been noted at many points in this and the preceding chapters that human tissue is often an object over which individuals have a relationship—the relationship between a hospital that takes tissue and the person from whom it was removed during surgery; the relationship between a medical researcher and a tissue donor; the relationship between the police force and the offender from whom a sample has been acquired. Utilising this

¹¹ P Matthews, 'The Man of Property' (1995) 3 *Medical Law Review* 251, 252.

¹² Munzer, *A Theory of Property*, 18

¹³ W N Hohfeld, *Fundamental Legal Conceptions as Applied in Judicial Reasoning*, Yale University Press, New Haven, 1964.

¹⁴ Munzer, *A Theory of Property*, 19. See also Cotterell, 'The Law of Property and Legal Theory', 87 on the usefulness of Hohfeld's analysis.

kind of analysis should therefore make it possible to discern how far the relationships individuals can have over human tissue are in fact akin to those individuals have over objects accepted as items of property.

In accordance with the Hohfeldian model, legal relations are organised into elements, opposites and correlatives. The four elements of legal relations are: rights, privileges, powers and immunities. A correlative means a duty, no-right, liability or disability that corresponds to a particular element.¹⁵ Where the one arises, the other arises with it, as a relationship will always involve more than one party (even if one party is 'all the world'). Each element and correlative describe the position in which those parties sit—the power they may hold, the immunity they may enjoy or the right they may claim. Opposites represent the situation that exists when the element is not held. For example, where a person does not have a power, he or she can be said to be 'disabled'. These elements, opposites and correlatives have been termed the 'lowest common denominators of the law',¹⁶ and are summarised in Table 1. Collectively, they will be referred to as 'rights' for the purposes of this thesis.

Table 1. The Hohfeldian Analytical Vocabulary

Jural Correlatives	Right	Privilege	Power	Immunity
	Duty	No-right	Liability	Disability
Jural Opposites	Right	Privilege	Power	Immunity
	No-right	Duty	Disability	Liability

The four relations can be regarded as in some sense a 'give-and-take' form of entailment, hence the organisation of each into opposites and correlatives.¹⁷ For instance, where one person holds a power to alter their legal relations, a correlative

¹⁵ It can be argued, however, that although Hohfeld takes pains to make clear that not all legal relationships are rights-based, in a broader sense each of the relationships he outlines are in some way of a rights-based nature. All the relationships outlined by Hohfeld have one common feature that can be regarded as a broad form of right. The unifying feature of each element of the relationships—claim-right, privilege, power and immunity—is that all involve the securing of some individual advantage. In the clear case of the claim-right, this interest is secured by a duty placed on another person—the correlative of the claim-right. In the other three instances, however, the correlative is not a duty and hence the advantage is secured a means other than that most precisely involved in a strict rights relationship. Yet, each relationship works to the same end, that of ensuring the advantage of an individual, which brings each of the three remaining elements under the broad umbrella of 'rights', for each is therefore protecting the right or claim of the individual to the advantage protected. See, eg, *Ibid*, 20.

¹⁶ Hohfeld, *Fundamental Legal Conceptions as Applied in Judicial Reasoning*, 64. This notion has been criticised by Stephen Munzer, who has argued that in fact the elements as expounded by Hohfeld are reducible to two elements only: 'power' and 'duty', where these two elements are conceived in a slightly different manner: see Munzer, *A Theory of Property*, 17–22.

¹⁷ See Munzer, *A Theory of Property*, 18.

liability will be placed on another individual, that is, the power of one entails a liability on another. Failure to behave in accordance with the correlative will be a violation of the element.

Rights and Duties: By Hohfeld's account, the clue to determining the precise ambit of the term 'right' lies in an acceptance of 'duty' as its correlative.¹⁸ Given that a duty is a legal obligation to do or not do something, a 'right' in this context is more akin to a claim that the something in question is done or not done.¹⁹ A duty forms the correlative of a right as a failure to fulfil that duty will equate to a violation of the right. In the interests of clarity these rights will be referred to as 'claim-rights'. The opposite of a claim-right is what Hohfeld termed a 'no-right',²⁰ or the lack of any claim.²¹

In an example of a claim-right held by X to exclusive occupation of a piece of land, all others, including Y, are under a correlative duty not to enter onto that land.²² If Y enters onto X's land, he has consequently violated X's claim-right. In a legal context, where a duty exists and is not performed, the right-holder may justifiably seek to have it fulfilled. This may be via specific performance where the individual who owes the duty will be required to fulfil the duty, or compensation might be claimed in place of such performance.²³

*Privileges and No-Rights:*²⁴ A privilege allows the holder to choose not to do something.²⁵ Privileges can therefore also be seen as liberties or freedoms.²⁶ Where one person has

¹⁸ Hohfeld, 'Some Fundamental Legal Conceptions', 31.

¹⁹ A 'positive' claim-right is a claim that something should be done, placing a 'positive' duty on another to perform that act. Conversely, a 'negative' claim-right is a claim that another should refrain from doing a particular act, placing a 'negative' duty on another not to perform the act.

²⁰ Hohfeld, 'Some Fundamental Legal Conceptions', 33.

²¹ Additionally, an individual may have a 'capacity-claim', which is the potential to hold rights. For example, if A has a capacity-claim right to leave the country, she may later assert the right to do so. In effect, she is not presently exercising that right, but she is not impeded from doing so in the future. See further on the potential complexities of capacity-claims: Becker, *Property Rights*, 12. This capacity rests on the existence of other rights, in the broader sense, such as the liberty to leave the country and the power to put that into effect. For further discussion, see Hohfeld, *Fundamental Legal Conceptions as Applied in Judicial Reasoning*, 65ff.

²² Hohfeld, 'Some Fundamental Legal Conceptions', 32.

²³ See Becker, *Property Rights*, 11.

²⁴ For the purposes of property law, it is legal privileges which are considered here. However, a distinction can be drawn between *natural* and *derived* privileges or liberties. Natural privileges are those which, arguably, exist without the enforcement of the law. They stem from the so-called state of natural freedom in which human beings are suggested to exist. Derived privileges are those created by the rule of law and exist only due to the existence of that law. Often, natural liberties may be enshrined by the law, such as perhaps freedom of speech. See further Ibid, 13.

²⁵ See further on the notion of a privilege in Hohfeld's analysis, Hohfeld, 'Some Fundamental Legal Conceptions', 32–44.

²⁶ See, eg, Munzer, *A Theory of Property*, 18. See also Hohfeld, 'Some Fundamental Legal Conceptions', 36–

the privilege to do something, other will correlatively have 'no right' to prevent them from doing so.²⁷ In the example used above, Y was under a duty not to enter the land of X. X's privilege was the option to enter that land at will, and Y would have no right to stop him. The opposite of a privilege or freedom is a duty or obligation that one must do something and has no choice to refuse.

Powers and Liabilities: A legal 'power' is the ability to do something, in effect to alter one's legal position (or that of another). For instance, the ability to donate an object equates to a legal power to transfer title to another, altering both one's own legal relationships and those of the donee. This donee's legal relations have been altered by the effect of the power, and the correlative therefore of a power is a liability or susceptibility to having one's legal relations changed.²⁸ It follows then that the opposite of a power will be a disability, that is, the inability to alter legal relations.

Such powers may be either perfect or imperfect. The holder of a perfect power may alter the relations of another purely by their own volition. However, where a power is imperfect, such desire to alter relations is insufficient. There may be limits on the action of that power, and Lawrence Becker uses the good example of a priest's power to marry others. In doing so, the priest has altered their legal relations, but this is not to say that he or she may marry people at will. Rather, some participation by the unmarried couple is also required—they must agree to have their relations changed.²⁹

Immunities and Disabilities: An immunity is the absence of susceptibility to having one's legal relations changed by another. This does not however place a duty on others to avoid altering those relations, rather others are under a correlative disability as they may not alter the legal relations of the person holding the immunity. For example, where A has an immunity that prevents others from forcing him to sell his car, then B has a correlative disability to compel him to sell his car, that is, she lacks any power to make A sell.³⁰ The opposite of an immunity is a liability, or a susceptibility to having one's legal

37. Lawrence Becker also refers to them as liberties. See Becker, *Property Rights*, 12.

27 'The existence of a liberty in one entails only the *absence* of claim rights in others. It does not entail the existence of duties'. and see further on the notion that such privileges are often protected through the law by the addition of certain right and duties Becker, *Property Rights*, 13.

28 See further Hohfeld, 'Some Fundamental Legal Conceptions', 44–54.

29 See Becker, *Property Rights*, 13–14.

30 Hohfeld makes the further point that the contrast between a power and an immunity is generally the same as that between a right and privilege. Where a right is a claim over the legal relations of someone else and a privilege is the freedom from such rights, a power is control over the legal relations of another while an immunity is freedom from any such control. See Hohfeld, 'Some Fundamental Legal

relations changed.

These four sets of elements, correlatives and opposites are the basic structures of property rights. However, alone they say nothing of the content of those rights, but describe only the form those rights may take. The content of these rights will be examined in the following Chapter, but it is possible at this point to observe that in many ways the relationships these sets of elements describe do resemble the relationships individuals have or would wish to have over human tissue. For example, one could cast my desire to have my body buried as I choose as a claim-right to determine the fate of my remains. Others may be seen as under a duty to respect that desire and refrain from interfering with my body once buried. Between me and the rest of the world is a relationship where I hold the right to make decisions about an object, my body, and all others must respect that right.

In another example, I may cut my hair and give it to someone else to make a wig. I would not wish others to cut my hair, and social rules seem to deter others from cutting my hair without my permission. In effect, I have a privilege and others behaviour towards me shows that they do not believe they have a right to cut my hair of their own accord. They act as though they have no-right and that I would be within my rights to actively prevent them from trying to cut my hair. These basic examples begin to demonstrate some of the reasons why it may be that human tissue can fit within the notion of property, as they show that human tissue can be the object of a relationship between individuals with competing demands and desires and property law is fundamentally about regulating relationships. The following section will outline the content of the various property rights, which will be considered in more detail in Chapter Nine.

2. THE NATURE OF PROPERTY RIGHTS³¹

There are eleven generally accepted property rights, though they are more often referred

Conceptions', 55. However, Stephen Munzer has criticised the parallel nature of the two contrasts. This, he argues, is one of the flaws in Hohfeld's analysis as it demonstrates that within the two groups of relationships (right/duty and privilege/no-right being the first, power/liability and immunity/disability the second), the conceptions within them are not wholly distinct. That is, because in both groupings the conceptions are interdefinable, those conceptions are not distinct from one another. The only main distinction, according to Munzer, lies between the two groupings themselves: see Munzer, *A Theory of Property*, 19.

³¹ The author would like to acknowledge the kind help of Professors Tony Honoré and James Harris with regard to this section.

to as the 'incidents' of property as they include powers, liabilities and the like.³² This is usually called the 'bundle of rights' approach, which as it is now conceived is essentially a combination of Hohfeldian rights analysis and the later work of A M Honoré.³³ Honoré outlined the eleven incidents and used Hohfeldian terms to describe them, including the notion of rights and correlatives. These incidents of property, according to Honoré, are each aggregates of various forms of 'rights', such as the right to use which consists of both a claim-right to use and the privilege to exercise that claim-right over a certain object.³⁴ These incidents are descriptive of the rights that common law property systems allow to be held in objects to regulate allocation, and Honoré describes them as the 'standard incidents of ownership'³⁵ common to 'mature' legal systems.

If all eleven incidents are vested in one individual then that individual possesses full ownership of the object to which those incidents relate. However, property law within the common law system does not require that one individual hold all eleven incidents to have a property interest in an object. Rather, the common law as described by Honoré's concept of ownership allows for a more fragmented approach to the ownership of object, wherein a number of individuals may hold certain rights in an object and each will possess a property interest though not full ownership itself.³⁶ Indeed, it is rare for any one individual to hold the entire set of rights in an object. An individual will more often possess a combination of them, while another will possess some of the remaining rights.

The aim of listing these incidents is not to define any necessary conditions of a property relationship, but to illustrate certain common features which link such relationships. The incidents aim to sum up the diverse range of property rights and relationships existing at common law by creating a wide catch-all list of possible interests, rather than by providing an exclusive list of compulsory aspects. Further, the inclusion of various other liabilities and prohibitions is an attempt to shift focus from a view of property centred on rights, to clarify that the property relationship is complicated by other interests

³² Some legal scholars reject the incident of prohibition of harmful use (for example, Jeremy Waldron). Their views will be discussed in the context of analysing that prohibition in Chapter Nine.

³³ See, eg, J E Penner, 'The "Bundle of Rights" Picture of Property', (1996) 43 *University of California Los Angeles Law Review* 711.

³⁴ E Seeney, 'Note: *Moore* 10 Years Later—Still Trying to Fill the Gap: Creating a Personal Property Right in Genetic Material', (1998) 32 *New England Law Review* 1131, n 177. See also Becker, *Property Rights*, 21.

³⁵ Honoré, 'Ownership', 113ff. For discussion of this list in other works see, eg, Becker, *Property Rights*, 18–20; Waldron, 'What is Private Property?'. See also S Hepburn, *Principles of Property Law*, Cavendish, Sydney, 1998, 2–3.

³⁶ F H Lawson and B Rudden, *The Law of Property*, 2nd edn, Oxford, Clarendon Press, 1982, 9.

beyond those which constitute the powers held by an individual over an object. While each of these incidents or rights have particular characteristics as privileges, powers and the like, the general descriptors ‘incident’ and ‘right’ will be used to refer to them collectively. Honoré and others use this method, and it is grammatically less confusing. Each incident’s specific character will however, be discussed and referred to in the course of this analysis.

Some legal commentators such as J. E. Penner have argued that the ‘bundle of rights’ theory is ‘no explanatory model at all, but represents the absence of one’.³⁷ Such criticisms stem from the absence of any defining criteria or feature in the model by which a property interest could be identified. But while the bundle of rights model does not define the concept of property itself, the incidents of property amount to what Jeremy Waldron has called ‘a particular concrete conception of these abstract concepts’.³⁸ Hence, the incidents outlined by Honoré can be accepted as conceptions of what is meant by property in the common law sense, as they form the basis of how property is organised in countries such as Australia and the United Kingdom. Lack of complete conceptual precision, though not preferable, does not preclude discussion of property and its incidents in the more practical sense of how they may work in relation to human tissues. As these incidents can be pointed to and have widespread acceptance, it is justifiable to use them to determine what is meant by property in the common law system. The eleven incidents are listed below in Table 2. Each of these incidents and their application to human tissue will now be described in detail in Chapter Nine.

Table 2. The Eleven Incidents of Property³⁹

Right to Possess	Incident of Transmissibility
Right to Use	Incident of Absence of Term
Right to Manage	Prohibition on Harmful Use
Right to the Income	Liability to Execution
Right to the Capital	Residuary Character
Right to Security	

³⁷ Penner, ‘The “Bundle of Rights” Picture of Property’, 712.

³⁸ Waldron, ‘What is Private Property?’, 317.

³⁹ As stated in Honoré, ‘Ownership’, 113–128.

Chapter Nine

CAN HUMAN TISSUE FIT WITHIN THE CONCEPT OF PROPERTY?

Corpses were bought and sold, they were touted, priced, haggled over, negotiated for, discussed in terms of supply and demand, delivered, imported, exported, and transported. Human bodies were compressed into boxes, packed in sawdust, packed in hay, trussed up in sacks, roped up like hams, sewn in canvas, packed in cases, barrels, crates and hampers; salted, pickled or injected with preservative. They were carried in carts and waggons, in barrows and steam-boats; manhandled, damaged in transit, and hidden under loads of vegetables. They were stored in cellars and on quays. Human bodies were dismembered and sold in pieces, or measured and sold by the inch.

*Ruth Richardson*¹

Ruth Richardson's somewhat gruesome account of the treatment of human bodies in the 19th century is a fitting prelude to this section. Having begun to unravel what property is, it now becomes possible to consider whether human tissue does bear its hallmarks. To determine whether human tissue can fit within the concept of property, three further questions will be posed in the context of each of the eleven property incidents. First, can the incident be applied to human tissue, meaning is it possible to do so effectively and without producing absurdity? Second, is this incident already reflected in the way human tissue is dealt with? Third, does the legal system uphold or recognise this incident in relation to human tissue? The answers to these questions will show not only how far tissue could be fitted into a property system, but perhaps how far it already has been.

1. RIGHT TO POSSESS

The right to possess is a claim-right to exclusive physical control of an object, and with this comes the complementary claim-right to exclude others from controlling the object.² If the object cannot be physically possessed, that is, where the object is intangible or immovable, this right may be regarded as a right to exclude others from

¹ R Richardson, *Death, Dissection and the Destitute*, Routledge and Kegan Paul, London, 1987, 72.

² In some instances it could also be regarded as a privilege. For example, a transplant surgeon may possess an organ to place into the body of her patient, but it is unlikely that the law would accord the same right to someone who was not qualified to do so.

use or from benefit derivable from the object. Others are under a correlative duty not to take exclusive control, which is reflected in laws prohibiting theft.³

This right to possess is, according to Honoré, ‘the foundation on which the whole superstructure of ownership rests’.⁴ Property systems often focus on protecting possessory rights to enable protection of other property rights. For instance, in many cases it would be nearly impossible for a legal system to protect the rights to use and manage if anyone was free to take possession of the object of those rights. For example, a person may have the right to drive their car as and when they wish. However, if they do not have a right to possession which is upheld against others, anyone may rightfully sit in the car, take control of it or exclude the individual from entering it.⁵ For this reason, the right to possess is a right *in rem*, that is one which can be held out against all other people, aside from those who fall within certain exceptions.⁶

Could a right of possession be exercised over human tissue? Tissue is a tangible, visible object, whether in the liquid form of blood or as a solid organ or piece of skin. As such, clearly it can be physically held, and thus it is possible for tissue to be held in an individual’s physical control. It is also possible to exclude others from it either by placing it inside a safe or securing it in some other form of container which is protected from removal, as even an entire body is small enough and sufficiently containable to be kept in a secure container. Tissue, in fact, is more amenable to being the object of a possessory right than many other objects which one may already legally possess, land being a prime example.

³ Yet if this right to possession was merely a right to have present possession protected, possession itself would not be well protected. Instead, it is necessary to add another dimension to the right to possess—a claim-right to be put in control. The need for this is illustrated simply by considering what would happen if only present possession were protected. If A has possession of an object, and that possession is taken over by B, A no longer has present possession. If the right to possession was protected only by prohibiting others from taking possession, once dispossessed A would have no right to regain possession of what was hers. Protection of that original right to possess is properly upheld against all persons only where it remains in effect after unlawful dispossession, giving A the ability to have her possession of the object restored. That is, A is no longer in exclusive control of the object, but she has not lost her right to be in control. She has the right to have that exclusive control still and hence may claim against B that the object be handed back. Honoré has expressed this as a distinction between ‘having’ an object and ‘having a right to’ an object, or the distinction between ‘rules allocating things to people as opposed to rules merely forbidding forcible taking’. See Honoré, ‘Ownership’, 115.

⁴ Ibid, 113.

⁵ It is in this sense, as discussed above, that while each property interest is separable in theory, in practice in many cases such a separation would be unworkable (although this will be dependent on the type of object in which rights are held and how those rights are divided).

⁶ For example, government officials and police often have the right to enter onto land owned by an individual in certain exceptional circumstances laid down by the law.

Is something akin to a right of possession already asserted over human tissue? Case Study 5: Newborn Screening Card Collection showed that newborn screening cards are securely stored in hospitals, and others are prevented from using them without permission. The same can be said of tissue held for pathology or testing purposes which, as in Case Study 4: Hobart Pathology, are retained by laboratories and are not released under any circumstances, even to the person from whom they were originally taken. As noted in Case Study 12: Iceland and deCODE, tissue is possessed when stored in the company databases. Case Study 1: Collecting Aboriginal Remains gave a grisly and distressing example of a right of possession being asserted over remains by museums for many decades, and pointed out that until recently, interference has long been resisted.

The law has upheld these and other possessions, and in some cases made it an offence to interfere with possession. Theft prosecutions in the cases of *R v Rothery*,⁷ *R v Welsh*⁸ and most recently *R v Kelly*⁹ are instances where the legal system has upheld a right to possession. In *Kelly*, the Royal College's right to possess was tacitly recognised by the finding that Kelly had stolen preserved body parts from its museum, while in *Rothery* and *Welsh*, the police having possession of blood and urine samples were able to defend that right against interference even from the source of the tissue. Both *Rothery* and *Welsh* were effectively regarded as under a duty not to interfere with the samples taken from them. Human tissue both lends itself to being possessed and is in fact often already possessed, both in a real and in a legal sense.

2. RIGHT TO USE

Taking a narrow view of 'use', the right to use does not include the rights to manage and to reap the income of an object. It is a claim-right to the personal enjoyment of an object, or in some cases a privilege to use it. The list of uses to which an object may be put is open-ended, but its scope may be limited by rule of law. Where a person has a right or privilege to use an object, others will either be under a duty not to use it, or have no right to do so.

Whether it is possible to uphold a right or privilege to use human tissue is perhaps best answered simply by pointing to the vast array of uses to which it is already is put. Part I

⁷ *R v Rothery*.

⁸ [1974] RTR 478.

⁹ [1998] 3 All ER 741.

demonstrated that human tissue has acquired a myriad of uses in recent times, but even before the advent of scientific and medical developments it has long had a place as a valuable resource. In Case Study 7: SA Clinical Genetics Service, tissue is used for testing to see if a patient has a genetic condition, and in Case Study 3: Organ Transplantation, body parts are used to treat patients with liver failure. Police use tissue to identify bodies and as evidence to trace criminals, as in Case Study 9: Forensic DNA Testing, while Orlan has taken her own tissue and used it in her artistic work in Case Study 18: Orlan and Manipulation of the Flesh. It is in fact almost trite to ask if tissue is used, as it has been for centuries.

Tissue use is also increasing. As Part I demonstrated, the uses to which human tissue can be put have been expanding with developments in medicine and science. Further, advances in genetic science have lent new uses to tissue, which to some extent has become as much information as a tangible object. The DNA found in almost every cell of the human body holds vast arrays of information about the person from whom it was taken, as well as information about their genetic relatives. This thesis does not directly consider the use of information derived from tissue. However, it does bear noting that often the uses of physical tissue that property law could perhaps regulate are those that extract the information held in the tissue itself. This fact adds still greater imperative to the need to regulate human tissue, not only to control its use, but as a means of protecting individual and familial privacy.¹⁰

Many of these uses are sanctioned by the legal system, though often as privileges rather than as rights to use. The Human Tissue Acts are explicitly designed to legalise certain uses, though as noted in Chapter Four, they do not entirely achieve this. Use of organs for transplantation is legal, and can be regarded as giving surgeons a privilege to use organs for treatment. Similarly, the NHMRC *National Statement on Ethical Conduct in Research Involving Humans* (National Statement) in conjunction with the Human Tissue Acts condone the use of tissue for research. The police have the claim-right to take blood samples for forensic purposes in accordance with the *Crimes Act 1914* (Cth) and state legislation,¹¹ and individuals are under a correlative duty to supply samples where

¹⁰ See further on the issue of privacy of genetic samples and the Australian Law Reform Commission's proposed criminal offence of non-consensual testing: Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96, ALRC, Sydney, 2003, ch 12.

¹¹ See, eg, *Crimes Act 1914* (Cth), Pt 1D; *Crimes (Forensic Procedures) Act 2000* (NSW), Pts 3–8.

the law requires.¹² Tissue use is both possible, and legally sanctioned.

3. RIGHT TO MANAGE

The right to manage is a combination of a power to determine who may use an object and how they may do so, and a claim-right that the object is dealt with as directed.¹³ Others are under a correlative liability to having had their relationship to the object altered, perhaps by having been given a right to possession and a duty to use it only as authorised. Management power allows a person to enable others to deal with the object in a manner which would otherwise be prohibited. For instance, the owner of a car may allow a person who has no right to use his car to do so—perhaps via a licensing agreement, as is the case in car rental operations.

Honoré uses the example of a deck chair to explain management power. An individual may own a deck chair and hence be allowed to sit in it and exclude others from sitting in it at will. By exercising his power of management, he may extend a licence to another allowing her to sit in it if she fulfils the conditions of the licence. These may include a requirement that she treat the object with care, clean it after use and not sub-licence it to others. The owner might also contract with a repair company to fix any damage which has occurred to the deck chair, enabling the company to lawfully take possession of it for these purposes and perform work on it, both of which actions might otherwise breach their right to exclusive control of the object.¹⁴

There is little difficulty with according a power of management over human tissue. The person holding that power could use it to allow others to perform research on a sample, to test it, to store it as part of a research database or to dispose of it after removing it during surgery. In fact, human tissue is well-suited to being subject to a management power. Such a power could be given to a person who has a very strong interest in tissue, most likely the person from whom it was taken. That person would then be able to empower a pathology laboratory to perform a genetic test on it, but would still be able to prohibit them from using the sample in research. Management power works well in

¹² On situations where supply of blood samples is required by the law, see generally Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours*, ch 39.

¹³ Some legal writers have held that the power to alienate comes within the aggregate of powers that make up the management power. See, eg, Lawson and Rudden, *The Law of Property*, 8–9. However, following the Honoré model, this power will be examined within the context of rights to the capital of an object.

¹⁴ Management powers are often exercised through the use of contracts, particularly when the object is a valuable resource. In relation to resources, management powers play a highly significant role in the division and exercise of political and economic power. See further Honoré, 'Ownership', 116.

the context of tissue as it allows for more than one person who has an interest in a portion of tissue to pursue that interest, while giving overarching control to a person who will be the most detrimentally affected if it is dealt with in a way that conflicts with their interests.

Examples of management powers and rights being asserted over tissue can be readily found. It could be said that when a person supplies tissue to a testing laboratory, as in Case Study 7: SA Clinical Genetics Service, they are authorising that laboratory to perform tests on it. The Genetics Services would not perform tests that were not authorised, and in effect they would be acting as if under a duty to deal with the sample provided only as requested. For example, a pathology laboratory is not permitted to later sell tissue or test it for other conditions.¹⁵ This kind of restriction could be constructed as a management power, although the legal and ethical regulations that cover pathology laboratory use of tissue do not legally construct it in this way.

In Case Study 14: Canavan Disease Research, David Greenberg and others clearly thought that when they supplied tissue to Reuben Matalon they were giving him only the authority to undertake research on the tissue to produce a test for disease carrier status. They did not wish for him to patent his research based on use of their tissue. Greenberg's intention was to give Matalon some rights to use the tissue, and place Matalon under a correlative duty to use it as authorised, which is an example of perceived management power being asserted. This example also demonstrates that people act as though they believe they have management power over their tissue, even if the law does not support this view.

Finally, where tissue samples are stored, the organisation that stores them exercises management powers by determining who may have access to them. For example, Case Study 5: Newborn Screening Card Collection showed how the SA Women's and Children's Hospital restricts access to cards, allowing some researchers access under certain provisos.

The laws and ethical guidelines regulating the use of tissue can be viewed as protections of management rights and powers, as they are in some ways mirrored in requirements of consent. Tissue cannot be removed without consent, according to the Human Tissue

¹⁵ See Chapter Four, section 4.

Acts, and those Acts aim to restrict use of removed tissue only to certain purposes, such as transplantation, as determined by the source. The National Health and Medical Research Council National Statement is a better example, however, as it explicitly requires that tissue samples be used only in accordance with the terms of consent given by the person from whom the sample was taken. Effectively, the *National Statement* is recognising a power or right of the source of the sample to direct what sort of research may be performed on it, by whom and whether it may be stored. The researcher is placed under a correlative duty by the *National Statement* only to use the sample in accordance with those terms, and is sanctioned if they fail to do so.

4. RIGHT TO THE INCOME

This claim-right partially overlaps with the right to use. The right to the income allows the owner to benefit from any profits that may be generated by the object, either through using it themselves or following its use by others. Income may be derived simply by using something, such as living in a house.¹⁶ Income might also be generated by using the object to produce a valuable product or service; through exploitation of the object via working on or with it, or by allowing others to use the object in return for something else, such as money.

One example of this occurring (and being sanctioned by the law and ethics guidelines) is that researchers using tissue are not precluded from profiting from the developments achieved through their research, particularly pharmaceutical companies developing drugs for sale. Tissue can be used to test pharmaceuticals which are sold for profit. It can also be used cell lines that can then be maintained for varying lengths of time and profitable uses made from them, such as in research or in producing therapeutic substances. Case Study 15: Canavan Disease Research and Case Study 14: John Moore's Spleen are examples of tissue being used to generate income by being used in lucrative research. Tissue could also be used, as in Case Study 14: John Moore's Spleen, to develop a valuable cell line which is subsequently patented and profits generated from exploiting the patent. In such an instance, the law would not prevent profit being made from the patent, and hence indirectly at least, legal sanction if given to using human tissue to generate income.

¹⁶ Honoré points out that under English tax law, rent-free use or occupation of a house is regarded as a form of income. See Honoré, 'Ownership', 117.

This is one of the most difficult issues in the debate about applying property rights to tissue. As will be discussed further in Part V, generating income from tissue has been harshly criticised. But showing that such a right already exists does not suggest either way that it is right or wrong for this to be so. Nor does it mean that allowing tissue to be property is inherently problematic—each of the incidents of property are separable, and the right to the income can be excluded as a right in tissue. What this section shows, though, is that that right is already being exercised in accordance with the law and hence that tissue has the capacity to be subject to a right to income.

5. RIGHT TO THE CAPITAL

The right to the capital of an object is an aggregate of a power to alienate it, and privileges to consume it or to waste it. It is a right to access the value held in the object itself, rather than value it may generate without being diminished. The power of alienation accorded by a right to the capital of an object allows the owner to alienate it during life or after death, and this may be done via sale, gift or other means.¹⁷ This power will pass to another when the owner has passed title to them. The privilege to destroy enables the holder of the right to use it as a resource that will be consumed by that use, while the privilege to waste allows the holder to let it degenerate.¹⁸ This right may, like others, have restrictions upon it, perhaps where it is in the public interest for an object not to be destroyed, though this approach is somewhat at odds with a liberal conception of ownership.

It is certainly possible that tissue may be wholly transferred by gift or by sale (where the capital value is obtained by the source). Tissue is exchanged for financial consideration in many instances, though generally not in Australia. Part I pointed to many examples of black market organ sales, and also demonstrated in Case Study 16: Ted Slavin and Diagnosing Hepatitis that in the United States tissue is sold. Chapter Three also noted that tissue can be commercially purchased from tissue suppliers, such as Arda in the United States, and in Case Study 13: Bionomics, it was noted that tissue is sometimes bought from tissue suppliers to be used in research. In Case Study 17: StarGene it is even more apparent that a transfer of tissue for money is occurring. Genetic material, imbedded in resin, is transferred for value to another (clearly an alienation) and one

¹⁷ Honoré said of this incident 'Most people do not wilfully destroy permanent assets; hence the power of alienation is the more important aspect of the owner's right to the capital of the thing owned'. See Ibid, 107.

¹⁸ See further on the privilege to waste. See E J McCaffrey, 'Must We Have the Right to Waste?' *University of Southern California Olin Research Paper* No. 00-16.

where the company intends to transfer all rights to the sample to the person who buys it.

It should be highlighted that the power to alienate under this incident does not have to equate to a power to alienate within the market. It can mean simply gifting tissue, and clearly many of the examples provided in Part I show this occurs often. Excised tissue is already transferred between research facilities with ease. With equal ease an individual can have a pint of blood removed and transfer it to a blood bank. Transplantation of an organ, as in Case Study 3: Organ Transplantation, is akin to a transfer of capital, for the entirety of the object is given to another for their exclusive use as part of his or her body.

The right to the capital value of tissue, and gifted transfers of tissue without compensation, are both legally possible in Australia. As outlined in Chapter Four, the sale of human tissue is generally prohibited in Australia, with the exception of 'processed' tissue for therapeutic, scientific and medical purposes. This would seem to allow commercial sale of preserved tissue, as sold by companies such as Ardaïs and bought by Bionomics. Generally, the legislation has been interpreted as prohibiting sale, particularly of entire organs for transplant. There is no legislative interpretation of the scope of the processing exception, but it is most likely to apply only to researchers and perhaps hospitals that have stored tissue rather than individuals who seek to sell their own body parts.¹⁹

Donation of tissue is a form of transference, and one which is not only possible under current laws regulating tissue, but one which is actively encouraged at many levels. For example, research participants involved in the psoriasis study outlined in Case Study 6: Tissue in Australian Research, give portions of their skin to researchers who may then possess and use them as part of their study. They gain full control over the samples, subject of course to ethical requirements. So too, in Case Study 3: Organ Transplantation and Case Study 7: Donor Tissue Bank of Victoria, tissue is freely given by one party to be used (and consumed) by another. The reality is that a relationship of transfer surrounds tissue in all facets of its use once excised. Indeed the very reason for excision, especially after death, is to transfer that tissue permanently to others, and this reason is

¹⁹ As the exception extends only to processing where 'the sale or supply is made for the purpose of enabling the tissue to be used for therapeutic purposes, medical purposes or scientific purpose'. See, eg, *Human Tissue Act 1983* (NSW) s 32(2). There are no examples of the exception being interpreted more broadly than this.

not only sanctioned, but promoted through organ donor programs and the Human Tissue Acts.

6. RIGHT TO SECURITY

Security in the context of property means an immunity from expropriation of the object. The owner may control and possess the object for as long as they choose, provided there is no rule of law that allows circumvention of this right. In general, this immunity will exist until the owner becomes bankrupt or the property is liable to execution for a debt. State authorities may also retain powers to expropriate property in some limited, legally permitted circumstances, in which case appropriate compensation must be paid. As Honoré notes, if a general power to expropriate made the taking of property legitimate as long as reasonable compensation was given, a system of property would again be incapable of functioning.²⁰ For example, if A cannot be sure that he will have possession of his land, he will have little incentive to plant crops on it or improve it if it could be arbitrarily taken away from him at any time. Therefore, it would be irrational for anyone to improve or use their property in any but a very short-term sense, which would prevent production and hence the functioning of the economy.

It would generally be possible to make tissue immune from expropriation in the same way other items of property are immune. This may, however, interfere with the accepted practice of taking organs from the deceased where no dissent has been expressed²¹ and also with the accepted ethical practice of using anonymised tissue samples for research.²² In these cases, however, it is of course possible to make exceptions to the immunity if these practices are to continue. Similarly, police could be given powers to appropriate tissue samples found at crime scenes and taken from suspects where the exception is in the public interest.

There does appear to be an expectation that excised human tissue will be immune to arbitrary expropriation. In many of the interviews conducted by the author, pathology laboratory technicians, hospital staff and medical researchers all spoke of tissue as something they were able to use without fear of its being claimed by others.²³

²⁰ Honoré, 'Ownership', 119.

²¹ See Chapter Four, section 3.

²² See Chapter Five, section 2.

²³ For example, the author was informed that companies collecting samples inform the donors that they will regard it as their property, and if the donor does not accept this that they should not donate. See Associate Professor Eric Haan, South Australian Clinical Genetics Service, Women's and Children's

Conversely, Case Study 2: Organ and Tissue Retention and the recent Alder Hey and Glebe Morgue incidences demonstrate that people are incensed when body parts are taken without consent.²⁴

A general immunity from expropriation also appears to be protected by the law in some situations. In *Roche v Douglas as Administrator of the Estate of Edward Rowan (dec'd)*²⁵ the Supreme Court of Western Australia did appropriate a tissue sample from the Western Diagnostic Pathology, but this can be regarded as a legal limitation on the immunity, and it is not unique in law for there to be such limitations where it is necessary for the courts or the government to acquire property which it requires.²⁶ These instances are again only limits, rather than evidence that there is no immunity from expropriation. The case of *R v Kelly*²⁷ is another example of the law preventing expropriation, with the court upholding the security of the preserved body parts held by the Royal College. Further, having once obtained possession for an authorised use, there are as yet few, if any, rules enabling others to reclaim tissue. The best that can be said is that tissue samples used in research that the individual later objects to may see researchers required to cease that use in accordance with ethical guidelines.²⁸ Similarly, while genetic profiles must in some cases later be destroyed by police after use in forensic investigations, the police have a right to continued possession of the actual sample which is secured by the legislative provisions and the common law.²⁹

7. INCIDENT OF TRANSMISSIBILITY

The power of transmissibility gives the owner the ability to devise or bequeath the object. Hence, upon death the object will be transmissible by will or otherwise in accordance with the rules of succession to the owner's successors.³⁰ The owner's

Hospital (Personal interview, Women's and Children's Hospital, Adelaide, 25 May 2000).

²⁴ See further Case Study 2: Organ and Tissue Retention. The distress people experienced following the revelations of organ retention appears to have been considerable and widespread: (Interview with Mary Dorcan, Retained Organs Office, Oxford Radcliffe Hospital, (Personal interview, Oxford Radcliffe Hospital, 25 September 2001)). This is also demonstrated in government inquiries on the organ retention. See, eg, 'Witness statement of Paul Bradley, WIT02290001' *Bristol Royal Infirmary Inquiry*, <www.bristol-inquiry.org.uk/evidence/wit/WitSMent/witPBradley.htm> at 25 October 2005 as discussed in Chapter One.

²⁵ (2000) WASC 146.

²⁶ For example, the Constitution of Australia gives the Federal Government power for '[t]he acquisition of property on just terms from any State or person for any purpose in respect of which the Parliament has power to make laws'. See *Commonwealth of Australia Constitution Act 1900* (UK) s 51(xxxi).

²⁷ [1998] 3 All ER 741.

²⁸ See Chapter Five, sections 1, 2.

²⁹ *Crimes Act 1914* (Cth) ss 3ZK, 23WA(5). Destruction of 'forensic material' under the Act merely requires destroying any identifiers. See also *R v Rothery* [1976] RTR 550; *R v Welsh* [1974] RTR 478.

³⁰ The incident of transmissibility differs from the right to alienate found in the right to the capital as it

interest is indefinitely transmissible—there being no limit on the number of transmissions which may be made.

Allowing people to devise excised portions of tissue and organs upon death would not produce absurdity per se. Organs and tissues are already taken from dead bodies and given to others, the only difference would be that the person from whom they are taken would previously have chosen the recipient. For example, a person could choose to bequeath their kidneys to a relative who needs a transplant. While this is not absurd, it would disrupt the present methods of organ allocation which, as discussed in Case Study 3: Organ Transplantation, is determined based on the need and health of the potential recipient. Allowing people to donate their organs to family members who may not be yet in grave need would exclude others who need the organs more, and hence may not be ethically defensible. But as donation of non-essential organs by living donors is already lawful, expanding this to donation after death may not too problematic. Tissue donations also occur every day, with many people transferring organs, corneas, bone and skin for transplantation and to benefit scientific research, as discussed throughout Part I.

The law does currently allow for bodies and their parts to be donated upon death in some contexts—a person may donate his body for scientific or anatomical use and of course, donate all his organs for transplantation—however a person cannot legally direct to whom these will be transferred (and not by will).³¹ The testator may make directions in his or her will as to the disposition of the body in general, but these will have no legal force.³² It appears, then, that the law does not presently allow transmissibility of tissue by will or after death to a great extent. This might, however, be partially attributed to the limited uses after death that are currently condoned by the law, rather than a principled objection to directing how they should be dealt with through succession laws. Also, for the policy reasons noted above, it has not been considered acceptable to directly donate organs, as they can be better distributed through central processes, which may also explain the lack of legal capacity to donate them to a particular person on death.

deals specifically with transmission upon death.

³¹ See Chapter Four, section 3 for legal provisions relating to the donation of tissues and organs after death.

³² General authority for this principle is the English case of *Williams v Williams* (1882) 20 ChD 659. See further Griggs and Mackie, 'Burial Rights'.

8. INCIDENT OF ABSENCE OF TERM

The incident of absence of term is somewhat related to transmissibility as both affect the duration of ownership. Absence of term refers to the indeterminate length of one's ownership rights. This differs from other legal situations, such as a lease which has a definite and determined time limit placed upon it (as does patent law). Ownership, thus, would continue indefinitely unless terminated by the owner, but for the fact that at some point the owner will die. It is for this reason that an indeterminate interest must be linked to a power of transmissibility to deal with the fate of the object upon the owner's death.³³ An interest for life differs slightly, as it is determinate, ceasing at death.

It would be possible to allow for absence of term in relation to human tissue. This would mean that an individual with rights over the tissue would hold those rights indefinitely. In itself, there is no absurdity in this as for the most part individuals using tissue would wish to be able to do so as long as they chose. However, there may be problems with determining who the owner who has an indefinite interest is. Consider a situation where a woman transfers her tissue sample to a hospital when she allows them to take a biopsy of a suspected tumour. The hospital now has a right to possess the sample to test it, but of the two of them who will have an indefinite interest? It may be that both have indefinite but specific interests, for instance the hospital may possess the sample indefinitely but the woman will always hold the power to manage the tissue. These complexities do not preclude the incident of absence of term existing in relation to tissue, but they do require consideration. This will be considered further in Part V.

At present, neither the Human Tissue Acts nor the few common law cases deal with absence of term in relation to tissue. As the legislation works on a consent model, and defines only the uses to which tissue may be put, it does not make any determination on what happens to that tissue once the specified use has been made. The legislation does not, however, contain any suggestion that once used that the right to do so ceases, or that possessory rights cease either. In the absence of such provision, it seems that most researchers, hospitals and tissue banks have simply continued to hold tissue indefinitely. For example, newborn screening cards are created initially for screening purposes, but are held indefinitely after that and there is no legal requirement that prevents this. As noted in Case Study 5: Newborn Screening Card Collection, the Adelaide Women's and

³³ Although there would still be some value in an indeterminate interest as no fixed date would be set for its end. See Honoré, 'Ownership', 122.

Children's Hospital operates on this assumption, now retaining cards indefinitely. Similarly, though the genetic profile created from a sample by forensic investigators must later be destroyed or de-identified, there is provision in the *Crimes Act 1914* (Cth) for samples to be retained indefinitely.³⁴ That legislation provides specifically then for absence of term in some situations, as discussed in Case Study 9: Forensic DNA Testing. Where specimens are held by museums or anatomical schools, they are usually retained indefinitely, as the recent attempts by Aboriginal leaders to have their ancestors' remains returned attest.³⁵

In some instances, however, there is a definite term of ownership. Pathology samples collected for the purpose of testing are to be held for up to fifty years for quality assurance and future testing purposes. Once that time has expired, they must be destroyed.³⁶ Despite this particular case, in most situations no limits have been put on how long tissue may be retained. For the most part ownership rights end when there is a specified legal direction that they must be destroyed, but in the majority of instances such as forensics, tissue banks and the like, there is no legal direction either way. Ethical guidelines also do not require use and possession to cease—often it is only required that a piece of tissue be de-identified. At that point, most uses are permitted indefinitely.³⁷

9. PROHIBITION AGAINST HARMFUL USE

This duty, imposed on the person who holds property rights in an object, is subject to debate. Some commentators, such as Jeremy Waldron³⁸ and Alan Carter,³⁹ have argued that it does not form one of the standard incidents of property at all. If it exists, this prohibition acts to place a duty on owners not to put their property to harmful uses. What constitutes harm and how far this prohibition extends is arguable also, but is best viewed as harm in a very broad sense including invasions of privacy and physical harm.

Honoré uses the example of a car—the owner is free to use it as and how she pleases, but she is prohibited from using it to run down other citizens. Waldron, however, argues that such a prohibition is best viewed as a separate rule of law which acts upon those who hold property, rather than as a possible incident of the property relationship.

³⁴ *Crimes Act 1914* (Cth) s 23WA(5). See Case Study 10: Forensic DNA Testing.

³⁵ See further Case Study 1: Collecting Aboriginal Remains.

³⁶ See Chapter Five, section 3.

³⁷ See Chapter Five, section 2.

³⁸ See, eg, Waldron, 'What is Private Property?', 320–321.

³⁹ A Carter, *Philosophical Foundations of Property Rights*, Harvester Wheatsheaf, New York, 1989, 5.

Waldron asserts that the concept of property and the legal rules that govern it determine 'which individuals are entitled to realise which of the constrained set of options socially available with respect to [an] object at [a certain] time'.⁴⁰ These options have been determined by other legal rules that regulate what may be done in society. It is within this wider set of rules that the rules of property sit. These wider rules control what any person may do with any object, regardless of whether or not it is that person's property, such as rules prohibiting reckless driving of cars, the use of clubs to assault others or of a gun to shoot someone. These rules do not change based on whose property is involved, the question of to whom the object involved belongs does not affect whether the prohibited action occurred. The property issue is separate and prohibitive rules exist above and beyond property interests, and it is submitted that such prohibitions do not form one of the standard incidents of ownership.⁴¹ For this reason, this 'incident' as applied to tissue will be considered only very briefly.

It would certainly be possible to limit the uses to which tissue is put because they may cause harm. There are many harmful ways tissue can be used, such as unwanted testing for a genetic condition which will invade the privacy of the person from whom it was taken; or planting a sample at a crime scene to falsely incriminate someone; or injecting someone with blood carrying a virus without their consent. Prohibitions on these actions would, in part, equate to this incident of property, if it were one.

Prohibitions on harmful use of tissue are already in place. If harm is conceived as doing something with tissue that would offend or distress the person from whom it was taken, then the NHMRC *National Statement* is a good example of such prohibitions, despite the fact that it does not have the same force as legislative measures.⁴² It provides that researchers should not use tissue except in accordance with the wishes of the person from whom it was taken. Generally, however, it is more likely that legal prohibitions are directed at the harm done, not who owns the tissue. Hence, injecting someone with

⁴⁰ Waldron, 'What is Private Property?', 321.

⁴¹ Honoré justifies the need to include prohibition against harmful use within the incidents of property by arguing that without it, "ownership" would be a destructive force: Honoré, 'Ownership', 123. Yet, it is not ownership itself which allows object to be used in a destructive manner, for as noted above such destruction can and does occur without the object involved being owned by its user. If the fact of property rights can be divorced from the act harmful use, then the two are separate concerns and neither relies on the other. The wrong of harmful use will exist whether ownership interests do or not, and therefore cannot be said to be an incident as such.

⁴² See further on the legal force or otherwise of the National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* and other ethical guidelines I Goold, 'Tissue Donation: When Does Ethical Guidance Become Legal Enforceability?' (2000) 3 *Centre for Law and Genetics Occasional Paper Series* 92 and see further Chapter Five.

infected blood would be treated as a battery by the law, and it would be the person who injected the blood, regardless of whether he or she 'owned' the blood, who would be prosecuted.

10. LIABILITY TO EXECUTION

Liability to execution is a liability on the owner, with a correlative right vesting in others against the owner, allowing the object to be taken from the owner in lieu of payment of debts. Honoré argues that such a liability an incident of property as without it both the growth of credit would be hampered and property rights would be a means for the owner to defraud creditors.⁴³

Once human tissue has been excised from the body, it is separate from the person. This thesis deals only with tissue already excised, so liability to execution in this context would not mean forcing a person to remove part of his or her body, such as a kidney. Instead, it would mean allowing creditors to take sections of tissue already removed in payment of a debt. It is easy to imagine this being possible in the case of a valuable cell line, made from a sample taken from someone. A company which has developed the cell line makes profits from its exclusive control of the cell line and its power to let others access sections of it. Rights to manage and derive income from this cell line are lucrative, and there is no reason why it would not be possible to transfer them to another company, with the value of the line being taken in lieu of a debt.⁴⁴

At present, however, tissue does not appear to be liable to such execution and there are no specific laws in relation to expropriation of tissues to pay debts. While this incident is not reflected in current practice and law, there is little save moral argument to prevent it being so, but that issue will be dealt with in Chapter Five.

11. RESIDUARY CHARACTER

This area of property rights covers rules governing the reversion of lapsed rights. In

⁴³ Honoré, 'Ownership', 123 and see 123–124 for discussion of Honoré's speculation on whether any other limitations on ownership (such as a liability to tax or expropriability by the State) could be regarded as standard incidents of property.

⁴⁴ Generally, however, tissue on its own has not been regarded as valuable (except when very rare and useful), rather it is seen as valuable once worked on (as in a cell line). Therefore, it is unlikely that the law has had to deal with this aspect of dealings with tissue, and that anyone would have sought access to tissue in lieu of a debt. This is particularly the case as tissue usually does not have a clear market value, as for the most part it has not been treated as a commodity like other products—that is, there is no defined market value for my finger if I cut it off to pay a debt, even though in some cases tissue is sold once processed.

accordance with the rules of a particular legal system, when an owner's property rights in an object lapse, corresponding rights will vest in another.⁴⁵ Honoré uses the example of an easement, where for instance the easement holder has a right to exclude the owner, but upon the lapse of this right the owner gains the right to exclude the previous easement holder. These rights are corresponding but not identical.

Rights that lapse may not always pass to another in a corresponding form. It is possible for rights to lapse and vest in no-one, the object becoming ownerless or *res derelicta*. Conversely, the right may lapse and vest in the state. Generally, however, rights lapse and it is the individual who has a residuary right in the object who will regain these rights. This is often the owner and this may occur, say, upon the cessation of an easement or bailment. In other situations, such as a sub-lease, it will be the lessee who regains the rights which correspond with those of the sub-lessee when the sub-lease terminates, rather than the owner. That is, the rights will return to the previous and still legitimate right holder, namely in this case the lessee who is still acting within some agreement with the owner allowing him or her to exercise these particular rights.

Whether it would be possible for human tissue to have residuary character is perhaps not too difficult a question to answer. If rights in that tissue lapse, and the material is still identified, it will always be possible to find at least one party who may have some claim to the rights as residuary—the person from whom it was first taken (or his or her family, if deceased). It will almost always contain his or her DNA, and hence have an intrinsic link to him or her on which to base residuary status. Where the sample is no longer identified, the research and forensic value of tissue may mean that the state has a good claim as residuary, as it can put the tissue to some use that is of general benefit to the community.

For the present, this incident does not seem to have arisen in the context of biological materials. However, in Case Study 1: Collecting Aboriginal Remains, the desire of those attempting to have remains returned could be cast in terms of residuary character. Their claim to the remains is based on their place as descendants of the people whose remains are held, and if the residuary nature of tissue is linked to its place as part of a person, then those people with the closest link as relations may be the proper residuaries.

⁴⁵ Meaning rights which are similar, but cannot be precisely the same rights as they are exercised by another person.

At present, there do not appear to be any legal provisions in relation to tissue that deem it to have residuary character. On the contrary, in some cases where there is no apparent residuary to determine what will be done with tissue, then without his or her consent, nothing can be done with the tissue. The Human Tissue Acts provide that the hospital holding a body may only use its organs for transplantation with the consent of the deceased or of a next of kin. To some extent, the next of kin could be regarded as a form of residuary, but beyond this, it appears none is identified by the legislation and hence nothing can be done with the body.

However, where tissue is de-identified, ethical guidelines take a different view, and tissue may then be used in research without consent. It appears that the ethical guidelines ignore the possibility of residuary rights, or regard them as extinguished if tissue is de-identified. For the most part, though, it does not appear that tissue has been treated by the law as though it any character, residuary or otherwise.

12. CONCLUSION

The question this section addressed was whether human tissue could fit within the concept of property, and three things have been demonstrated in answering it. First, it is possible to apply almost all of the incidents of property to excised human tissue. Second, in practice human tissue is regularly dealt with in the same way as an object of property. Third, in quite a number of instances, they are already applied by the legal system in some form. On this analysis, human tissue clearly fits very well within the legal concept of property.

More generally, this analysis shows that at the conceptual level, there are few legal difficulties with viewing human tissue as property. There may be other barriers to admitting human tissue as property (including legal barriers), and these will be considered in due course. There may also be a need to adapt the particular rights that may be exercised over human tissue to promote social goals and prevent unjust legal results. But by taking an analytical approach to the question of whether human tissue can be property, a definite answer in the affirmative has been reached which can now form the basis of further investigation of other aspects of applying property law to tissue.

These conclusions also begin to put paid to the idea that it is not workable to allow property rights to be held in human tissue. On the contrary, they demonstrate that the

concept of property has the flexibility to accommodate this novel object, just as it once expanded to include intangibles and the abstract in the form of intellectual property. Human tissue has been found to be capable of being property on a conceptual level; the next task is to determine whether there is also support for its being deemed property having regard to the philosophical justifications for property rights and systems. This will be considered in Chapter Ten.

Chapter Ten

HUMAN TISSUE AND PHILOSOPHICAL JUSTIFICATIONS FOR PROPERTY

The preceding two chapters examined the nature of property and property rights as they operate in Western, common law legal systems. They considered whether human tissue could fit within the concept of property as conceived in such systems, and largely concluded that it could.

However, property is not an absolute concept. Rather, property systems are social institutions that have emerged to meet social needs and 'property' is a legal and social construct. Such a social institution operates effectively in part because it rests on accepted social needs and understandings, which are largely enforced in the form of legal rights. As C B MacPherson suggests, there is a need for property rights to rest on society's morality, and hence they are both legal and moral rights.¹ This chapter steps behind the established, common law conception of property and examines this moral and social basis of property systems by considering some of the fundamental philosophical justifications for Western common law property systems that have been put forward. It considers some of the suggested explanations for what a property system is and does, and how things may be deemed property.

In doing so, it takes an alternative approach to the question of whether human tissue fits within the concept of property taken in the previous two chapters. First, through considering some philosophical justifications for property systems, a fuller conception of what is meant by 'property' may be developed. Whether human tissue fits within this conception, that is, whether in fact it accords with what society perceives as a proper subject for property rights, will then be considered.

Second, it will seek to determine whether the philosophical explanations for property systems can explain the needs a property system serves and the values on which they are based. If human tissue is a subject of similar needs and affected by similar values, it may

¹ C B MacPherson (ed.), *Property: Mainstream and Critical Positions*, University of Toronto Press, Toronto, 1983, 1, 11–12 as cited in M A Neave, C J Rossiter and M A Stone, *Sackville and Neave Property Law: Cases and Materials*, 6th edn, Butterworths, Sydney, 1999, 12.

be that one of these philosophical justifications will support the inclusion of tissue within the notion of 'property'.

To achieve this, this chapter will outline the three major philosophical perspectives that may give some indication of whether tissue can fit within the concept of property. These are Labour theory; First Occupancy theory and Utilitarianism. Though there are many other theories that could be examined, this thesis will focus on only these few for reasons of scope and because they provide perhaps the most intuitively appropriate justifications in the context of human tissue.²

The general justifications for property given in each theory will be outlined and critically appraised. Whether the conception of property derived from these justifications can include human tissue, and support deeming it property, will then be considered. In effect, each theory of property will be analysed to determine whether it supports the admission of human tissue into the sphere of things deemed property. Each theory will also be briefly applied to the case studies to determine whether the theory would admit tissue as property and whether this would be an effective approach to tissue regulation.

1. NATURAL RIGHTS AND LOCKE'S LABOUR THEORY

Natural rights theories maintain that the rules of society and law have developed from some original state of nature in which there were no rules or political relations. Labour theory has its roots in natural rights theory, with its major proponent John Locke arguing in *Two Treatises of Government* that the 'Fruits of Nature' were owned in common by all men, given as a gift from God.³ With this gift came a natural right to appropriate some of these fruits, such as the land and the animals that lived on it, for an individual's private use to enable subsistence. Further, a natural duty to improve the Earth was attached to this right, and holding private property was a means by which it was allowable to do this. Locke argued that these rights and duties derived from the will of God but were to be discovered by reason.⁴

² For example, socialist theories of property are not examined because this thesis focuses on the common law property systems of Australia and United Kingdom, which are not based on a socialist property system. Also, although a system of communal property interests in tissue has been mooted by at least one pair of legal commentators, the general debate has not focused on this view. See R Marusyk and M Swain, 'An Alternative to Property Rights in Human Tissue' (1990) 20(5) *Hastings Center Report* 12; R Marusyk and M Swain, 'A Question of Property Rights in the Human Body' (1989) 21(2) *Ottawa Law Review* 351.

³ J Locke, *Two Treatises of Government*, New American Library, New York, 1965, 328–9, Art 27.

⁴ Ibid, Art 26.

Locke regarded private property as necessary to improve the earth and sustain human beings. He argued first that all people⁵ had property in their own bodies, and on this view it followed that all people had property in the labour of their own bodies.⁶ Private property was acquired by mixing one's own labour with the natural common bounty of the earth.⁷ Once done, the object previously owned in common became the property of the person whose labour had become inextricably mixed with it, and that mixing altered its nature irreversibly so that it became something that could be owned by an individual, rather than in common. This held true only where whoever appropriated the common property left enough and good enough for others and did not take more than he or she needed.⁸ This was Locke's solution to the problem his theory had set him, for without some form of private property allowing individual exclusive use, no one would have been able to use the common property of all without impinging upon the rights of others to also use those fruits of nature.

Before examining whether this justification for property rights can include human tissue as an object of property, one of the problematic aspects of Locke's labour theory should be addressed. The problem is that Locke's theory relies on the mixing of material objects with labour, which is not itself a material object. The theory works best if instead it is the *products* of the activity of labour that must be mingled with an object for it to become property; that is that value is added to an object by working on it. On this view, labour is what is produced by working, via which a person creates something or makes some material alteration in an object. From this perspective, the products of labour are clearly capable of being mixed with material objects. If an individual owns a field and ploughs it, it becomes a tilled field which is materially different from its original state. It is the product of their activity—tilled soil—that is now part of the original field. However, if one accepts this argument, one must also accept that labour by this definition is not inalienable, as Locke suggested it was. Indeed, capitalist economies rely greatly on the very fact that the product of labour is alienable, for otherwise it would be impossible to exchange money for work done.

Setting this concern aside for the moment, it appears that to some extent, human tissue

⁵ While Locke's original arguments mentioned only men, these arguments will be discussed in gender neutral terms in this thesis.

⁶ Locke, *Two Treatises of Government*, Art 27.

⁷ Ibid, Arts 26, 27, 28 and 32. By an act of labour, Locke meant an act directed at adding something to the common property, not some accidental action that has improvement as a side-effect.

⁸ Ibid, Art 27.

can fit within this view of property. Human tissue is an object that is worked on and generally this work, like the extraction of DNA or its inclusion in artistic works will leave it in a state where the labour cannot be untangled from the original tissue. In this sense, tissue could come within the ambit of property as conceived by labour theory. However, to completely accept Locke's theory one would first have to accept that tissue is the common property of all at the moment of excision and can be appropriated by a person who works on it.

When tissue is removed from the body or limbs are amputated, its nature changes. Tissue shifts from being something that was part of an autonomous person, protected by criminal laws against assault, into being an object and something that is no longer a person with legal standing. In effect, it changes from being part of the object of law and to become the subject. Hence, not only must its actual character change, its legal character should be regarded as changed to reflect the fact that excised tissue can be treated differently to an autonomous person, and is regarded differently. For example, a sample of tissue can be stored, and this would not be regarded as slavery. Similarly, excised tissue can be destroyed but it is unlikely anyone would regard this as the same kind of act as killing a person. Clearly, then, tissue once removed from the body is not the same as a living person. It is now an object and potentially one that might become property once worked on under labour theory.

On Locke's view, if no other owner can be found to exist at the moment of excision, then whoever mixed their labour with that tissue first would gain ownership rights over it.⁹ However, this view is sustainable only if one can accept that there is no owner at the moment of excision, but instead that tissue is owned in common. For two reasons this is problematic. First, it can be argued that at the moment of excision there is at least one person—the person from whom it was taken—with a stronger claim to the tissue than anyone else. This claim rests on the intimate emotional, spiritual and psychological relationship a person has with their own body, as well as the fact that it has been physically part of them. Further, the tissue contains DNA unique to that person, creating an ongoing link between the person and the sample. To suggest that once it is removed all people have an equal interest in that tissue flies in the face of notions of bodily autonomy and also accepted practice that allows people to direct the fate of their

⁹ Doubt has also been cast on Locke's assertion that it is the mixing of labour with an object that creates a property right in the entire object, rather than merely giving the labourer rights in the value added by their work. See, eg, C B Macpherson, *The Political Theory of Possessive Individualism: Hobbes to Locke*, Oxford University Press, Oxford, 1964, 194–5 as cited in Carter, *Philosophical Foundations of Property Rights*, 16.

removed tissues, such as for organ transplantation and for research. On this view, then, the act of work should not create property rights in tissue, then, as this is only allowable under labour theory if the object is originally owned in common.

This argument is supported by the evidence presented in some of the case studies, and the examples given in Part I generally, which demonstrate that the person from whom tissue is taken does regard themselves as having a greater right to control that tissue. John Moore's attitude to his tissue, outlined in Case Study 14: John Moore's Spleen, is a good example—Moore clearly considered that the tissue was his or at least that he, above all others, had the best claim to direct how it could be used. Similarly, Orlan treats her tissue as her own once excised, as noted in Case Study 18: Orlan and Manipulation of the Flesh.

A second problematic issue arises if Locke's labour theory is applied to human tissue. Locke's theory rests on the assertion that all people have property in their own bodies and that this is why they own the labour of those bodies. Given this, a person should logically continue to own his or her body parts even once severed unless there is some compelling reason why the act of excision would deny this ownership right or change the tissue into something not owned. For those who accept that the living body is the property of the person, there is little logical problem—tissue once excised would already have property status and belong to the person from whom it was taken. However if, as is the case in this thesis, this view is rejected then Locke's theory is wholly problematic because the assumption on which it rests—that people own their bodies and hence their labour—is rejected.

This thesis does not engage with the debate over whether the living body is property, largely for reasons of scope. However, it can be said this view is rejected also because it is legally illogical (the subject of the law is also its own object); because it may have highly problematic legal consequences (such as allowing slavery) and because it undermines the notion of autonomy and the capacity of individuals to be self-directing to allow them to the object of property rights.¹⁰ For these reasons, as a general point,

¹⁰ See also Skene, L, 'Arguments against People Legally 'Owning' Their Own Bodies, Body Parts and Tissue' (2002) 2 *Macquarie Law Journal* 165, 167. This thesis also does not consider it necessary to derive property rights in excised tissue from a property right in the living body; it is considered sufficient that if tissue is capable of being property once excised, the source of that tissue at excision has the greatest claim to ownership: see main Introduction. This concept will be developed in general Conclusion. For a good discussion of whether the living body should be property see Harris, 'Who Owns My Body?'.

Locke's labour theory is rejected in this thesis.

However, if the theory were accepted, despite its problems, there are instances where it might further admit tissue within the notion of property. Some excised tissue may have no defined owner, such as discarded hair at a hairdresser or anonymised research samples. For example, the anonymised samples used in Case Study 6: Tissue in Australian Research might fall into this category. Where there is no owner, it may be that tissue can be regarded as not owned, or conversely, owned in common. Labour theory would permit that tissue to be property once worked on. Processing the tissue, preserving it in wax or spirits, or using it to create a test kit all might equate to work for the purposes of the theory.

Despite its flaws, labour theory seems to underpin to some degree the way the law has treated tissue. As demonstrated in Part III, the case law appear to support the view that human tissue can become property through some act of work or skill, and that the person who undertakes it will become the owner. The exception to the rule against property in a corpse, as upheld in both *Doodeward v Spence*¹¹ and *R v Kelly*,¹² explicitly allows for body parts to become property. Once preserved, tissue may be treated as any other item of property. The only differences between the holdings in these cases and a purely Lockean approach, is that the case law adds the extra proviso that the act of work be directed at preserving the tissue; and that the law views tissue as having no property status rather than as common property. The case law appears to assume that tissue has no legal status at the time of excision, and therefore has no owner.

The approach taken by the courts highlights what makes labour theory attractive, despite its flaws generally and in relation to tissue particularly. Acquiring property rights over tissue through working on it may serve a societal need. For example, consider the tissue samples taken in Case Study 6: Tissue in Australian Research. A section of skin tissue is taken and anonymised so that there is no clear owner (as the person from whom it was taken can no longer be identified). The researcher has preserved the tissue on a slide and conducts research on it. Should it then be allowable for any other researcher to enter the hospital and take possession of those slides without authority? No, because this would undermine the security that the original researcher would need to rely on to bother undertaking the work in the first place. In fact, this is the very kind

¹¹ (1908) 6 CLR 406.

¹² [1998] 3 All ER 741.

of instance that labour theory is directed as—by allowing property rights, and hence creating security, the researcher has the incentive to conduct the research knowing that he or she will be able to take it to conclusion and reap any benefits of doing so. In such a situation, the act of work probably does accord with acceptable treatment of tissue and also demonstrates how a Lockean approach could fit the needs of society in some instances. The same thinking could be applied to the acquisition of unidentified tissue samples at a crime scene (such as in Case Study 10: Forensic DNA Testing) to ensure samples are secure from intervention; to body parts preserved in museum that cannot be linked to an individual to protect collections with scientific value (as in Case Study 1: Collecting Aboriginal Remains); and to tissue used in diagnostic test kits that are produced and sold.

There are clearly problems with applying Lockean theory to human tissue. It is logically problematic to hold that labour can be mixed with a material object and it is unclear why doing so is enough to create rights not simply to the labour that is mixed, but to the whole. The theory is particularly problematic if all tissue upon excision is regarded as lacking an owner, and hence capable of being made property through work, as this would exclude the inherent interest of the person from whom it was taken. If the theory's basic tenet were accepted—that people own their own bodies—then it would suggest that excised parts are owned by the source individual, and not open to be worked on to acquire property rights. But because this view is rejected in this thesis, then the basis of the theory is essentially rejected and it should be concluded that labour theory itself should not be used to justify property rights in tissue.

2. FIRST OCCUPANCY THEORY

During the 19th century philosophical, justifications for property rights of a more metaphysical nature were considered. Immanuel Kant and Georg Hegel, among others, rejected Locke's labour theory in favour of a general justification for property rights based on the idea that the first individual to occupy or appropriate an object acquired rights of ownership in that object. Under this theory, private property only exists in an object once a person has exercised their will over it.

According to Kant, an asserted right would be just or moral if it were both universalisable and accompanied by the will of the community as represented by the

public legislature.¹³ Such recognition could occur when the individual's assertion of a right was regarded as in some way beneficial to the community. If property rights could be shown to be so, then despite their acting to exclude one person from the objects held by another, they would be just.

Against these background requirements, Kant argued that an individual acquired property rights in an object by the transcendental act of directing his or her will over it.¹⁴ To deny this right to appropriate or occupy objects and to continue in one's use of them would restrict freedom of action. In so arguing, Kant was in fact arguing for some natural liberty to appropriate, as his argument must presuppose an ability to appropriate.¹⁵ Without such a presupposition, any object which could be used (for which appropriation would be necessary) would become unusable as no one would have the right to take it for their use. Thus there must be a power to use and the object must be capable of use such that it may be made the object of will. The essential justification for a property rights system given by first occupancy theory is hence that property rights are an expression of freedom, and freedom itself should be promoted and protected.

The Hegelian conception of first occupancy theory differs slightly. Hegel argued that an object has no end in itself, that it derived its 'destiny and soul' from a person's will.¹⁶ A person had the right to put their will into the external world and consequently into any and every external object which is not owned. With this came an absolute right to appropriation over all things. In putting one's will into an object, it became one's own for it had no destiny until that point. In effect, individuals could express their freedom through the direction of will by appropriating something.¹⁷ By this reasoning, Hegel concluded that ownership was a crucial requirement for the realisation of freedom as a goal of existence. Like Kant, he believed that consent for this appropriation derived from the general will, though in his case this was expressed in the State. This State was formed from the collective will of the people and therefore would always override individual claims and the State would also always have a higher claim to property itself. Yet, this power could not be exercised arbitrarily, but only in cases where individual

¹³ By Kant's reasoning, justice was 'the aggregate of those conditions under which the will of one person can be conjoined with the will of another in accordance with a universal law of freedom': I Kant, *The Metaphysical Elements of Justice*, being Part I of *The Metaphysics of Morals* (trans. J Ladd), Bobbs-Merrill, Indianapolis, 34 as cited in Carter, *Philosophical Foundations of Property Rights*, 80.

¹⁴ See Hepburn, *Principles of Property Law*, 7.

¹⁵ Carter, *Philosophical Foundations of Property Rights*, 81.

¹⁶ Becker, *Property Rights*, 29.

¹⁷ See Ibid, 29.

rights did not serve the aims of the community. The inequality created by property rights was justified, in Hegel's view, by the inequality in the human spirit as different people would require different amounts of property to achieve happiness and fulfilment.

For first occupancy theory to be workable, four major requirements must be met. These are that:

1. The object must not be owned already.
2. The occupancy which occurs must be actual, not declaratory or intentional.
3. Actual occupation must be defined with sufficient clarity to make it clear how much can be occupied.
4. The occupier must assert a claim only to as much of the object as their actual occupation defines.¹⁸

Of these requirements, it is self-evidently crucial to the working of the theory that the object not be owned already, as first occupation is impossible if the thing is already owned. While in a theoretical sense a lack of occupation appears to be a clear enough requirement, to find something to which no claim of occupation can be found is a less simple exercise. Often, things not owned have been deemed things owned in common, such as common land or the air. Such a thing may or may not be appropriated to an individual dependant on the nature of this common ownership.

It is possible that excised tissue could be regarded as not owned already.¹⁹ Where de-identified, a sample may have no clear owner and could be subject to appropriation. The same could be said of tissue that is abandoned (such as medical waste) or taken from the deceased. In these cases, at least, the first requirement might be met.

In addition, ethics guidelines governing research in Australia appear to take a first occupancy approach to anonymised samples where no clear owner is can be found. For example, the National Health and Medical Research Council *National Statement on Ethical Conduct in Research Involving Humans* allows a researcher to appropriate such samples to a degree, allowing use and possession of them for research purposes.²⁰ In such a case, the appropriation does fit within first occupancy theory because it is a direction of will that

¹⁸ Ibid, 24.

¹⁹ If it was accepted that individuals owned their living bodies, then it would be difficult to accept that they did not own their excised parts, but this view has already been rejected in this thesis (see note 8).

²⁰ National Health and Medical Research Council, *National Statement*. See further Chapter Five, section 2.

accords with the common good, that is, the community benefit of scientific research. By contrast, the case law suggests that work or skill must be exercised over tissue for it to be property and that mere possession will only create a better claim to possession over that of others.²¹ However, the case law has also upheld rights to possession where there appears to have been little work or skill applied, such as the samples retained by police in *R v Rothery*²² and *R v Welsh*.²³

However, for the most part, both legal and ethical regulations, not to mention societal convention, require that consent be given to the taking and use of excised body parts. This may not equate to recognition of a property right in tissue, but it does suggest that there is some form of interest that others will violate if they attempt to occupy those body parts. Hence, ownership via appropriation for tissue (if not for other, unowned objects) is likely to be considered highly objectionable. Tissue differs in this case from other objects because of its inherent link to the person from whom it was taken which, as discussed above and in Part I, creates an interest in it that is greater than anyone else's at the point of excision and until someone gains a greater right. As long as the sample is identifiable, this interest means there will never be so little interest in it for it to be considered 'unowned' as one could consider other items. For these reasons, first occupancy probably cannot reasonably admit tissue as property in most cases because the first requirement is not met. However, the remaining requirements of the theory will be considered because there may be instances where the first requirement is met, namely de-identified samples with no defined owner.

The second requirement of first occupancy theory is that a person can occupy no more than he or she can use.²⁴ The rationale for this lies in the need to determine how mere occupation can equate to appropriation. If mere declaration of occupation were sufficient, the results would be absurd, as anyone could assert ownership of an object simply by stating that they occupied it, without taking any action to effect that occupation and possession. Debate over ownership would become a tussle over who first thought to say they owned something. For occupation to be regarded as appropriation it must therefore be more than physical; it must also be accompanied by purpose. Purpose in this sense means a reason for taking possession, such as to cultivate

²¹ Factual possession, aside from questions of lawful possession, has been deemed sufficient to ground a claim of theft. See *R v Kelly*, 750 per Rose LJ.

²² [1976] Crim LR 691.

²³ [1974] RTR 478.

²⁴ Becker, *Property Rights*, 26.

land or to shape a piece of wood into a chair. This purpose must also be implemented at the time of occupation. Without this second requirement, occupation would be intentional only and the individual would have done nothing more than take possession.

If possession alone were enough to create rights, then the simple act of wandering onto unowned land would transform it into one's own property. Such a state of affairs would be untenable, as it would lead to confusion and further would prevent claims more beneficial to the community (as required by first occupancy theory) being made on land so acquired. While this restriction may appear reasonable, it does beg the question of what will constitute actual occupation? It is not clear whether this aspect will be fulfilled by standing on land, or perhaps building a fence around a certain area rather than taking some action that actively excludes all others from entering onto land or taking possession of an object. These problems are related to the greater difficulties presented by the third requirement, that actual occupation must clearly define how much is occupied.

Human tissue once excised is most often quite containable, small in size and therefore capable of being actually and clearly appropriated. A block of tissue can be placed in a laboratory fridge or held in a researcher's hand and it is clear how much is possessed. Thus, both the second and third requirements could be satisfied. For example, where a genetic sample is taken and stored for research as in Case Study 9: The Menzies Centre for Population Research, the Centre has taken a discreet portion of tissue and placed it within their control for the purpose of research, making possession actual and defining the ambit of possession with clarity. The same holds true for samples held on newborn screening cards (as in Case Study 5: Newborn Screening Card Collection), as they are contained on the card, they are actually held and are kept for the purpose of testing. It seems, then, that appropriate of human tissue could meet these two requirements of the theory. Hence, at least for de-identified samples appropriated for a research purpose, the first three could be met and the theory applied.

The final requirement is that an individual lays claim only to so much of that object as their actual occupation defines. This is also not problematic in terms of tissue use and possession. Having taken possession of a defined portion of tissue, aiming to implement the purpose for which it was appropriated, this requirement is met simply when the possessor does not seek to claim more than that defined portion. From this analysis, first occupancy theory would admit tissue as property, and would provide quite a sound

basis for acquiring property rights in tissue samples that are unowned, such as de-identified tissue and perhaps also discarded or abandoned tissue. So applied, this theory would still allow the interests of individuals in their tissue to hold, if they were deemed sufficient to prevent tissue being regarded as 'unowned' (if not actually owned). It would also allow, however, people to use tissue that was not being used by others (such as unidentified samples) for useful purposes that meet community needs. Research use of discarded tissue is the primary example of this kind of situation.

However, there are a number of problems with this analysis. First, in general terms, first occupancy has a significant internal flaw. A leap is made under the second requirement from appropriation to permanent possession. Appropriation, under first occupancy theory, produces all the incidents of ownership Honoré outlined as the components of full, liberal ownership. How this leap can be justified is far from clear. Possession does not equate to a claim-right to possession. One may possess but have no actual right against others to do so, for a claim-right will place duties on others not to prevent that right being exercised. Mere possession does not impose such duties and one with a claim-right to possession would therefore have greater right to actual possession than one merely in possession, as the latter would be under a duty to the former not to prevent exercise of that right to possession.

First occupancy theory is also problematic when applied to tissue specifically. First, for the tissue to meet the first requirement by being unowned, it must be either de-identified or abandoned. What constitutes abandonment may not always be clear, and someone may appear to abandon tissue when not actually wishing to relinquish all interest in it. This is particularly so because of the emotional value of tissue to people, and the genetic link between the tissue and its source. For example, when Mary has her hair cut at the hairdressers, she may be happy for the hair to be consigned to the rubbish. She probably considers this abandonment, and for many purposes it is. But in doing so, it is unlikely that she is discarding all interest in the hair. She might not mind it being thrown away, but she may object to it being taken and genetically tested, or sold to a wigmakers. Hence, it may be difficult to show in many cases that tissue is sufficiently abandoned for it to be acceptable for another person to gain full ownership rights over it to the exclusion of the source individual.

A second criticism that can be made of first occupancy theory in general, and specifically in relation to human tissue, is that its most basic tenet, that whoever acquires

something first has the best claim to it, is fundamentally unjust. While Kant argued that there was justice in allowing a person to exercise their free will to appropriate, there is justice also in giving rights to the more deserving or to those who will make the best and most efficient use of materials, such that they will be used to the greatest benefit for the entire community. Further, where one person lacks something and another has plenty, it would seem more unjust to allow the person with plenty to acquire more simply because they have the ability to exercise possession over objects before the more needy. Finally, there is a community need to give ownership rights to those who will use tissue to achieve societal aims such as the reduction of crime through forensic use or to increase medical knowledge through researcher use, rather than simply the first person to grab the tissue once discarded.

When applied to human tissue, first occupancy theory fails to account for bodily autonomy and respect for persons—values upheld by the legal system in relation to living bodies, which should not be ignored once parts of those living bodies are removed. The unique link between an individual and his or her body parts has been mentioned many times in the course of this thesis, and it is appropriate to mention it once more here. The few laws that do regulate how excised tissue may be dealt with, as well as the ethical guidelines that apply, reflect the belief that an individual should in most cases have some say in the fate of parts removed from their bodies.

Finally, first occupancy theory is problematic in relation to tissue because of the inherent link that people have to their tissue, which de-identification cannot fully extinguish. Two issues arise. First, the tissue will always contain DNA from the person from whom it was taken. Genetic science makes it possible, however, to link a de-identified sample to a person by DNA comparison—this is the basis of forensic DNA testing used by police to match unidentified samples from crime scenes to identified samples from suspects. Hence, it is arguable that the tissue is never fully de-identified and so never fully ‘unowned’, on the analysis above. Therefore, if de-identified tissue is appropriated and owned by another, privacy and control issues may arise if the tissue is subsequently identified. For these reasons, as well as its inherent flaws, first occupancy theory is probably not acceptable as a general basis for admitting tissue as property, although it appears possible for it to do so.

Despite this long list of criticisms, the theory may have some use in justifying ownership in the very limited case of clearly abandoned tissue where the source individual will not

be found, such as the ancient remains or tissue from a deceased person. In such a limited case, this would mean that full ownership rights would be given to any person who possessed this tissue. The criticism that first occupancy is not a sound basis for acquisition still applies. However, as a pragmatic solution to the question of who may control unclaimed tissue, the theory may be a useful starting point.

3. UTILITARIANISM

Utility theory had its roots in the 18th century work of David Hume, but came to prominence in the 19th century following the work of Jeremy Bentham and John Stuart Mill. At its most basic, utility theory argues that property rights are a necessary condition for human happiness. Traditionally, this happiness was a broad notion encompassing human satisfaction in its entirety, although the theory has in some cases been refined to encompass only happiness that may be obtained through economic means.

Utilitarianism is a positive law theory, that is, it holds that laws are made by people rather than derived from nature.²⁵ Further, to achieve happiness, social institutions that are governed by these rules are required.²⁶ Which institutions should exist and the rules that are to govern them will be determinable by reference to the definition of utility. Laws that accord with utility are laws that will increase social happiness. For the early utilitarians, the making of laws was, as Alan Harding has put it, 'an exercise neither in moral philosophy nor in history, but in psychology, a problem of how to give the greatest happiness to the greatest number'.²⁷

The theory's first major proponent, Jeremy Bentham, based the need to make laws which increased social happiness on the rationale that each person's actions are directed by the pleasure or pain that will result from them. Pleasure and pain, according to Bentham, 'govern us in all we do'.²⁸ As society is made up of individuals, laws should be directed at maximising the happiness of the greatest number of those individuals. This belief led Bentham to conclude that if a law is to be moral and serve the community, it should have maintaining the happiness of that society as its goal.

A law would conform to this principle if it tended to promote, on balance, greater

²⁵ J Bentham, *The Theory of Legislation*, Kegan Paul, London, 1931, 113.

²⁶ Becker, *Property Rights*, 57.

²⁷ A Harding, *A Social History of English Law*, Penguin, Harmondsworth, 1966, 297.

²⁸ J Bentham, *An Introduction to the Principles of Morals and Legislation*, Althone Press, London, 1970, 11–12.

happiness than pain.²⁹ Bentham's model required a law act to be judged according to the intensity, duration, certainty and nearness of the pleasure it caused; its likelihood of causing greater subsequent pleasures; whether it might have the opposite effect of producing pain as well;³⁰ and the number of people it would affect.³¹ These effects had to be valued and tallied for each affected party, and the balance of them determined whether a law was sound according to utility theory.³² This form of utilitarianism focuses on the consequences of actions and the happiness they will produce not for the individual, but collectively for all concerned.

Happiness could be achieved, following the Benthamite model, if four ends subordinate to happiness were secured: subsistence, abundance, equality and security. Of these, security was the most important, for without it the other ends would not be achievable. Bentham reasoned that no one would work to achieve the other ends (such as by producing food to ensure subsistence) if the fruits of their labour were not protected because otherwise there would be no incentive to work. Rather, one could simply take what one needed from others. By protecting production, amongst other things, each person would be encouraged to increase their personal happiness by work from which they would be able to reap the benefits without fear of interference from others. Therefore, people needed individually to acquire, possess, use, and consume some things in order to achieve (the means to) a reasonable degree of happiness.³³ Bentham considered that due to inherently selfish nature of human beings, this security could only be upheld through the medium of some social institution to govern their actions.

Property laws are one such institution that may achieve this necessary security by determining how objects are to be acquired, and subsequently how they may be used and how possession of them is to be protected. The theory assumes that some people will always try to take something used by another or to a lesser extent will be disinclined to share at all times. This is due to the enjoyment they receive from using an object; an

²⁹ J Bentham, *Introduction to the Principles of Morals and Legislation*, Hafner, New York, 1948, 1–7.

³⁰ The same calculation was to be made for acts causing pain, which might produce more subsequent pain or produce pleasure as well.

³¹ Bentham, *Introduction to the Principles of Morals and Legislation*, 1–7.

³² John Stuart Mill later summed up the principle by stating that 'the ultimate end, with reference to and for the sake of which all other things are desirable...is an existence exempt as free as possible from pain, and as rich as possible in enjoyments'. See J S Mill, *Utilitarianism*, Bobbs-Merrill, Indianapolis, 1956, 16 as cited in J Rachels, *The Elements of Moral Philosophy*, 4th edn, McGraw-Hill, New York, 2003, 92.

³³ Lawrence Becker outlines three main lines of argument which build on this fundamental requirement. The first of these asserts that rights to possession and use are necessary for happiness to ensure that one may be certain of having one's possession for a particular length of time. Thus, one is able to carry out one's purpose with them without the frustration of their being unavailable at certain points: Becker, *Property Rights*, 61–64.

enjoyment that will be diminished if shared. Knowledge of this directs people to protect what they possess and to be less willing to work on objects to generate happiness when they are aware that others may simply take the products of their labour. Private property rights promote security and hence stability by clearly defining rights that exclude others from one's property. This in turn creates an incentive to labour.³⁴

Does this explanation of property law systems admit human tissue as an object over which property rights could be exercised? The first question to be answered is whether human tissue is an object that people wish to use securely. This can clearly be answered in the affirmative. For instance, in Case Study 13: Bionomics, tissue is used for research that eventually leads to the development of saleable services and products, such as genetic testing kits. Investment in the venture would not be profitable unless the materials used were secure from others taking and using them. If the tissue and materials produced could be arbitrarily taken, they could be sold by anyone and the investors could not reap the profits of their investment. Allowing property rights in this instance protects the fruits of labour and promotes production, which in turn promotes abundance of the products created. The same holds true for samples used in other commercial contexts, such as Case Study 16: Ted Slavin and Diagnosing Hepatitis and Case Study 17: StarGene.

In addition, tissue is also an object over which people want a secure interest outside the commercial sphere. For example, in Case Study 9: The Menzies Centre for Population Research, the Menzies Centre relies on access and control of the large collections of samples it has painstakingly amassed. The samples as a collection are important, as well as individually, and its research involves examining these samples in conjunction with one another and other information. If some of the samples are taken, the entire project may be affected. Hence, it needs to know its collection is secure from being taken by others. The same holds for other research examples, such as Case Study 6: Tissue in Australian Research.

As another example, it is important that police can keep samples taken from crime scenes and from suspects secure to enable them to undertake investigations (Case Study 10: Forensic DNA Testing); and organs for transplantation must be transferred securely to ensure they are given to the person who is determined to be the best recipient (Case

³⁴ A Ryan, *Property*, Open University Press, Milton Keynes, 1987, 63.

Study 3: Organ Transplantation). There are clearly many other examples.

The second question is whether allowing property rights to be exercised over human tissue does promote social happiness. If by property we mean the security provided by property-like rights in the examples above, then the answer is probably yes. Police investigations may reduce crime and promote community stability and security; ensuring organs are provided to the most appropriate recipient best promotes community health; and research, as noted in Part I, helps to develop new tests and treatments that improve community health. However, as the following criticisms suggest, many of these goals might be achieved through promoting the security of tissue without deeming it property (and particularly by not deeming it property that can be commercially exchanged).

One objection to utilitarian arguments for allowing tissue to be property, which will be explored in more detail in Part V, is that altruistic donations of tissue (that is, not property-based exchanges) better promote community happiness. They do so by creating social cohesion and a sense of community; and they allow for organs to be donated free of charge to those in need. Free exchange of tissue promotes research by removing some of the financial costs that would hinder many projects if tissue were expensive to procure.

One response is that this is a rather narrow view of what allowing property rights to be held in tissue achieves. Having property rights in tissue and commercially exploiting that tissue are not one in the same. Instead, property rights give those who hold them the rights to continued possession, to use and to give. They do not prevent altruism; they may simply create a different incentive for acting which those with truly altruistic motives would eschew regardless. Allowing property rights on a utilitarian basis would still promote social happiness—a museum that possesses human skeletons, as in Case Study 1: Collecting Aboriginal Remains, could display them for anyone to see as educational displays for the entire community to benefit from. Similarly, in Case Study 18: Orlan and the Manipulation of the Flesh, body parts are possessed and used to create works of art that have cultural significance, which in itself benefits the entire community through enriching its culture through creativity. In addition, collections of tissue held in banks provide a source of material for research and for transplantation (as in Case Study 7: Donor Tissue Bank of Victoria). Use of this resource provides benefits to society when medical treatments result or when tissue is successfully transplanted to treat an injury. In this case, as in those outlined above, were possession insecure, tissue

could be taken and used by others, who could variously take displays, destroy Orlan's art or prevent others from using banked tissue for research or treatment. It would certainly be impossible to run a museum if members of the public could take anything that they found particularly interesting. On this analysis, utilitarianism does appear to provide some good justification for admitting human tissue as property.

Despite this, five general criticisms can be levelled at utility theory and these considerably undermine its acceptability as a justification for allowing tissue to be property. These are: that it does not explain the justification for a property system; that it relies on a view of human nature as lacking in altruism or the ability to divide objects fairly without recourse to rules; that the requirement of maximising 'happiness' is vague; that it does not distinguish between a need for property and a need for private property; and that the actual rights to be accorded, beyond those of possession and use, are not clearly defined.

As to the first criticism, the utilitarian justification for a property system can be traced only so far back as the existence of law and then may only be argued to exist as a result of human laws and the chosen system of security, that being property itself. Utility can explain the need for a system of property as one solution to certain problems, but it fails to explain why that system must be a property system in the first place.³⁵ Secondly, that utilitarianism assumes individuals rarely act wholly and always with altruism first in their minds is a somewhat bleak view that does not always accord with actuality. While there is an element of truth in the utilitarian view of human nature, it is somewhat one-dimensional. If one takes the Benthamite position, this view becomes even more untenable. According to Bentham, human nature is inherently grasping and happiness can be measured by possessions and wealth while people are inclined towards theft and idleness unless prevented from these evils by laws upholding property rights. Hence, an individual's actions must be controlled by rules of law.

In the context of human tissue Bentham's (and also David Hume's) view of human nature does not wholly accord with current practice. Many people currently agree to donate their organs upon death without any need of recompense, and others freely consent to the use of their tissue in research.³⁶ As seen in Case Study 9: The Menzies Centre for Population Research, members of families with genetic conditions regularly

³⁵ Becker, *Property Rights*, 59.

³⁶ See further Case Study 2: Organ Transplantation and Case Study 6: Tissue in Australian Research.

provide their tissue for the benefit of research that will aid the community. The same is true of the families who provided samples from their deceased children to Reuben Matalon in Case Study 15: Canavan Disease Research, and Ted Slavin in Case Study 16: Ted Slavin and Diagnosing Hepatitis. This view can be countered by the fact that there is currently no other alternative. Australia does not have a market for organs nor can researchers pay for tissue samples, so one must question how far this is pure altruism. Were tissue an object for which researchers could bid, perhaps individuals would be more inclined to protect it and give it only in certain circumstances. At present, for most people their tissue has no real commercial value and hence they are prepared to give it freely. But it should be safe to assume that often people's motives are altruistic, for often people express feelings that donating their deceased relative's tissue brought meaning to their death, and they are happy that others can be saved. Hence one of the assumptions underlying utilitarianism may be flawed.

In addition, one of the premises of utility theory is that human nature is such that social and political institutions are necessary to achieve the greatest happiness for the greatest number within a community. By David Hume's reckoning, this need stemmed from the 'numberless wants and necessities' of human beings which must be met by the 'slender means' available to fulfil them.³⁷ From this perspective, the utilitarian view is more acceptable, for rather than the problem being one of the flaws in human nature; it is actually one of distribution where demand exceeds supply. Utility theory relies on the premise that some institution is necessary to ensure security of possession and use, and arguably this cannot be so unless all means of acquisition are controlled. Conflicts between individuals as to ownership clearly occur currently and it is unlikely that they can be resolved without some social institution. Utilitarianism seeks simply to solve this problem by creating a criterion for allocating those resources, and thus it is this criterion, rather than the fact that people will compete for scarce resources that should be accepted or rejected. This factor may partially address the flaw in one of the assumptions of utilitarianism noted above.

In the case of human tissue, this fact is particularly relevant. As Chapter Three discussed, tissue is now a resource. Many of the case studies, most particularly Case Study 14: John Moore's Spleen and Case Study 15: Canavan Disease Research, show

³⁷ D Hume, '*A Treatise of Human Nature* (1739) reprinted from the Original Edition in three volumes and edited, with an analytical index, by L A Selby-Bigge, Clarendon Press, Oxford, 1896' *The Online Library of Liberty*, <oll.libertyfund.org/Texts/Hume0129/HumanNature/HTMLs/0213_Pt03_Book3.html> at 26 October 2004, Part II, Section II.

that there are competing interests in some tissues. Utility theory may have some success in determining to whom rights in these tissues are accorded, and hence may be supportable as a justification for allowing tissue to be property. For example, it may be that it is best that public researchers are able to possess and use tissue samples for it is they who will produce treatments to benefit the entire community. Similarly, organs for donation are best possessed and managed by hospital networks that can distribute them to those most in need, rather than allowing ad hoc distribution in accordance with the wishes of the donor, who will not be able to see the wider picture of need. Some legal commentators, such as Loane Skene, seem to have taken this approach in arguing the hospitals and researchers are best placed to hold ownership interests in tissue samples—that is, the ownership should be accorded where it will promote social happiness.³⁸

However, the final problem with utility theory is difficult to overcome, despite these benefits. The theory does not necessarily define what constitutes happiness with sufficient clarity. On one view, by according ownership in objects to individuals, each is more likely to use their possessions more efficiently and take better care of them than they would if each were allowed individual use of common property.³⁹ While this makes a certain amount of sense, Lawrence Becker has noted two major criticisms of this position, the first being that in an economic sense objects are only used with the greatest efficiency where competition is perfect. Monopolies and interference with *laissez-faire* market mechanisms mean that this is not often the case and objects will not always be best used by individuals. Further to this, Becker rightly points out that there is an important distinction between each object being used in the best interests of the individual within the community and being used in the best interests of the that community as a collection of interests.⁴⁰ Given this, it must be accepted that in the current social and economic climate, private property rights do not necessarily promote the greatest happiness to the greatest number, or at least as a justification of *laissez-faire* private property rights, utility theory is unconvincing.

In particular, the theory does not adequately address complex situations where there is debate over how the community best benefits. For example, it may not provide a clear answer to conflicts over ownership such as in Case Study 1: Collecting Aboriginal Remains, as it may not be able to answer whether the community's happiness is best

³⁸ See, eg, Skene, 'Arguments against People Legally 'Owning' Their Own Bodies, Body Parts and Tissue', especially 173.

³⁹ Becker, *Property Rights*, 62, n 7.

⁴⁰ *Ibid*, 63.

promoted by collections being maintained by museums to educate the population, or by allowing Aboriginal communities to lay their ancestors to rest. But this is not a fatal flaw, because it does at least introduce this as an issue to be dealt with, and provides a framework for thinking about how this can be done.

Despite these concerns, on balance, utility theory as an explanation for property law institutions can admit human tissue, at least in many cases and in a general sense. While the theory is subject to a number of criticisms, these are not necessarily fatal. Further, the theory does provide a pragmatic way of addressing the problem of who should control human tissue within the already accepted social institution of property. It provides a means of determining who should own and control tissue based on whether this ownership will best promote social goals. Some of these goals are easy to determine—the community interest in new treatments, in access to tissue for therapies, in police being able to run investigations effectively, in museum collections that educate the public. Property rights in researchers, tissue banks, the police and museums respectively can promote these goals, and utility theory would support each of these bodies having property rights on this basis.

Further, compared to first occupancy and labour theories, the basic justification for gaining property rights given by utility theory is more sound. It also accords, to an extent, with current practice where actual possession and the capacity to control tissue is already upheld, though not through property rights, in many of the contexts noted above and for apparently utilitarian reasons. As such, while utility theory may not address fully the issue of how happiness is best promoted, it does provide a good basis for initially justifying property rights in human tissue. It also provides scope for altering these rights where adverse consequences result, which in the context of tissue is vital to ensuring that each of the interests identified in Part I are balanced best against one another.

4. CONCLUSION

There are clearly difficulties with using any of the philosophical justifications for property systems described above to support admitting tissue as property. However, both first occupancy and utilitarianism go some way to providing a basis for doing so in limited contexts. First occupancy may be a good means of according ownership where tissue has no owner, such as abandoned tissue. Utilitarian concerns might be applied generally in determining who, among a number of potential owners, should gain rights

over tissue. These two theories might also be used in conjunction where there are a number of parties seeking rights over unowned tissue. If a fully Utilitarian approach were accepted, leaving aside its failure to take account of the personal interest in the tissue of the person from whom it was taken, this would also support the position of commentators like Skene, who suggest that tissue should be owned, or at least possessed, by those who will use it to promote social welfare, such as institutions conducting research.

Both theories have their limitations, and if applied fully could produce problematic results. For example, there may be cases where the community's interests are best served by a hospital owning tissue, but this could leave out the highly emotional, personal concerns of individuals. The retention of organs by hospitals in the Alder Hey incidence and similar retentions in Australia as outlined in Case Study 2: Organ and Tissue Retention following Post-Mortem, is a good example of where it may be important to put individual interests before those of the collective. But these concerns can be met by using first occupancy or utilitarian justifications to admit tissue where it is judicious to do so, and where the best solution to a conflict of interests can be achieved.

Lockean Labour theory is open to a range of criticisms, particularly the internal inconsistency that people own their own bodies, yet would not necessarily own their excised tissue unless they were able to work on it. However, at one level Labour theory does provide a starting point for admitting tissue as property where there is clearly no owner, that is, where it is abandoned and hence while the theory is rejected in this thesis, it is still possible that arguments using this theory could be made to support property rights in tissue if its premises are accepted. It also provides a starting point for a pragmatic approach to ownership of tissue, like that taken by the courts.

For these reasons, each these theories provide a reasonable basis for admitting tissue as property in some cases, as well as demonstrating that there is some philosophical basis for doing so. Therefore, we can take these explanations for property systems and use them to inform our thinking about the question of whether human tissue should be property, if not wholly direct it. This question will be considered in Part V.

CONCLUSION

Common law legal systems have long regarded human tissue as a substance somehow deserving rarefied, special status. There is good reason for this, because tissue is unique and does hold special significance within Western societies. Genetic science has also allowed us to uncover intimate information about an individual from his or her tissue, creating an ongoing link (and attendant privacy issues) that differentiate tissue from other objects. However, as tissue has come to take on other statuses—as commercial resource, as donation, as research subject, as evidence, as art—a need to recognise this legally has developed.

Property law has gradually begun to emerge as a possible legal mechanism for dealing with tissue. The foregoing discussion in this Part has demonstrated that there are rather fewer practical legal problems with using property law to regulate human tissue than has perhaps been generally considered. The analysis of the concept of property has demonstrated that human tissue is aptly suited to having property status. The various property rights, such as rights to use, to possess, to manage and to the income can all be applied to tissue without legal absurdity. In fact, Chapter Nine demonstrated that in many cases rights akin to these property rights are effectively already exercised over tissue, even if they are not called ‘property rights’. People, and the law, do already deal with tissue like they deal with property in many instances, and hence conceptually it is certainly possible to deem tissue property.

Philosophically, labour theory, first occupancy theory and utilitarian explanations of property law each go some way to admitting tissue within the gamut of what may be property. In particular, first occupancy theory and utilitarianism can provide good direction for our thinking about how we should with tissue by giving good grounds for deeming tissue property in some situations.

The analysis in the preceding three chapters has shown that tissue can be property in a legal sense. The trend in the case law outlined in Part III has shown that the courts, too, have begun to shift towards admitting a property status for human tissue. Part II showed that many of the rights already exercised over tissue under the legislation and ethics guidelines mirror to a limited extent the kinds of rights that property law would allow to be exercised over tissue. What has been established is that regardless of

whether tissue should be property, it certainly can fit within the legal notion of property and in many instances, it already does.

Given that we can conclude that tissue can be property, the further question is whether it should be. There may be moral, social or practical reasons why human tissue should not be subject to property rights. Applying property law may produce adverse legal results, or work in opposition to some of the social goals we seek to achieve through our use of tissue. However, alternatively property law may provide a highly workable, practical solution to many of the issues and conflicts in interests outlined in Part I. This Part considered whether tissue could be property, and concluded in the affirmative. Part V will consider the second merits of deeming tissue legal property to answer the second question of whether it should be.

Part V

*Should Human Tissue Be
Property?*

Contents

INTRODUCTION	325
<i>Chapter Eleven</i>	
CAN PROPERTY LAW MEET THE CHALLENGES OF TISSUE USE?	328
1. Lack of Clear Status	329
2. Gaps in the Current Framework	336
3. Insufficient Control	340
4. Lack of Recognition of Other Interests	348
5. Lack of Adequate Remedies and Protections	351
6. Inability to Respond to Novel Uses	358
7. Adverse Implications of a Property Approach	359
8. Establishing Property Rights in Tissue	363
8.1 <i>Creation of Property through Work or Skill</i>	364
8.2 <i>Creation of Property at the Moment of Excision</i>	365
8.3 <i>Property arises from Authority of the Donor</i>	367
8.4 <i>Community Property</i>	369
8.5 <i>An Inalienable Property Interest</i>	370
9. Conclusion	372
<i>Chapter Twelve</i>	
THE COMMERCIALISATION DEBATE	373
1. Arguments in Favour of Commercialisation and Some Responses	374
1.1 <i>Clarification and Regulation of Current Practices</i>	374
1.2 <i>Promotion of Individual Autonomy</i>	376
1.3 <i>Benefit-Sharing and Justice</i>	378
1.4 <i>Increased Supply of Tissue and Organs</i>	379
2. General Objections to Commercialisation and Some Responses	382
2.1 <i>The Importance of Altruism</i>	382
2.2 <i>Human Tissue Is Not a Fit Object for Sale</i>	385
2.3 <i>Dangers of Commodification</i>	387
2.4 <i>Disincentive to Research</i>	393
2.5 <i>Self-Harming and Coercion</i>	395
2.6 <i>Promotion of Greater Social Division</i>	399
2.7 <i>Negative Effects on the Doctor/Patient Relationship</i>	400
3. Conclusion	401
CONCLUSION	404

INTRODUCTION

...all the societal pressures which a century ago pointed away from lawfully possessing and using human tissue now point towards it. The non-property solutions of yesterday are inadequate to the task of today. That does not mean that a property analysis is the only—or even the best—way to deal with that task, but it at least invites the inquiry. If the answer is favourable, property law could certainly be developed to the right level.

*Paul Matthews*⁹¹¹

This thesis has been framed around the idea that human tissue sits at the nexus of a range of sometimes conflicting interests. As outlined in Part I, these range from individual interests in controlling tissue and protecting the privacy of the information it contains; to Aboriginal community interest in the spiritual value of remains; to law enforcement organisations' interests in tissue for forensic purposes; and to the interest of both the community and researchers in having an adequate supply of tissue for medical and scientific research to produce tests and treatments.

Part I outlined many of the problems that arise when these interests conflict, and the concerns that certain uses of tissue raise. These included, among many, conflicts between hospitals retaining tissue and the interests of families who wish to access that tissue or to have it returned for burial; the value of altruism for the community and an individual's desire to sell his or her tissue; and the current conflict between museums seeking to retain their collections of specimens and the Aboriginal communities who want them returned so that they can be laid to rest. Part I also demonstrated that there are a range of novel uses for tissue that were previously unthought of, such as the use of tissue to make commercial items (as in Case Study 17: StarGene) or to make artistic works (Case Study 18: Orlan and Manipulation of the Flesh).

Parts II and III examined the legal approaches that have been developed to regulate the use of human tissue and in some cases to address these conflicts. These Parts analysed how successful these approaches have been, and how effectively they might deal with some of the issues identified in Part I through applying the law to the case studies. These Parts demonstrated that to date, the law has taken a piecemeal approach to the regulation of human tissue, ranging from ethical guidelines to legislation that applies in

⁹¹¹ P Matthews, 'The Man of Property' (1995) 3 *Medical Law Review* 251, 256.

only very limited contexts to a body of somewhat inconclusive case law.

It emerged from this analysis that the law has largely failed to keep up with the ever increasing uses that have been found for human tissue. It also emerged that the law has also failed to develop a consistent approach to tissue, treating it differently in different instances. While the legislation and ethical guidelines have taken a consent-based approach, the courts have begun to accept that tissue could be dealt with through the laws of property, though the debate over the ageing rule against property in corpses continues. In doing so, uncertainty about how tissue may be used in instances that have not yet been dealt with by the legislature or the courts has emerged. In failing to develop a principled, uniform approach, the law further provides no guidance for how novel uses of tissue will be regulated.

Part IV introduced the argument, taken up by many legal commentators, that the challenges presented by the use of human tissue use could be met by deeming it property. That Part divided the debate into two major questions—can human tissue fit within the common law notion of property; and should it in fact be deemed property. Part IV addressed the first question and, following an analysis of the concept of property and a range of philosophical justifications for property systems, concluded that tissue could fit within the common law notion of property. It also found, by applying the incidents of property to the case studies and to current laws, that in many ways we already treat tissue like property and that this is often legally sanctioned.

This Part addresses the second question of whether tissue should be property. The answer to this question is not only complex, it also varies greatly between contexts and depending on the values and interests the community seeks to protect and promote. Any legal approach to the acquisition and use of human tissue must be based on what is thought to be the best balance that can be struck between these interests. This balance will be determined by the moral and ethical standards within a community, the types of behaviour that community seeks to promote, the value it places on both human life and liberty, and the means by which this balance can be created and maintained. In Chapter Eleven, the efficacy of using property law to address these concerns and balance these interests is examined.

Within the debate over the property status of tissue, a parallel debate over whether tissue should be commercialised has emerged. Often these debates are intertwined, as it

is sometimes argued that allowing tissue to be property will necessarily mean it can be sold or commodified. Chapter Twelve examines this debate and the arguments for and against commercialising tissue. It does not seek to come to a hard conclusion on whether sale is tenable, but rather to provide an overview of this aspect of the general property debate. It also draws some brief conclusions about whether our stance on commercialisation precludes using property law to regulate human tissue use.

Chapter Eleven

CAN PROPERTY LAW MEET THE CHALLENGES OF TISSUE USE?

This chapter considers the efficacy of using property law to regulate tissue. It does so by drawing together the major concerns about the current framework and examines whether property law could be an effective solution to them. It is structured around six general concerns: tissue's lack of clear legal status; the gaps in the legal framework; that the current law provides inadequate control of tissue for the source and others; the current lack of recognition of other interests; that there is a dearth of suitable remedies and protections in relation to misuse of tissue; and that the current legal approach is unable to effectively respond to novel uses.

Each section will examine whether property law would be an effective solution to the problems of tissue use and some of the responses that have or can be made. The case studies will be used to highlight the specific concerns to be examined and to test the effectiveness of a property approach to particular issues. It should be noted that some problems manifest differently in different contexts and for different tissue, and that the efficacy of property as a solution may vary. For example, arguments about the sale of human organs for transplant differ markedly from those about trading in excised tumour samples for research. With this in mind, each section will examine a particular concern within different contexts and consider how property may or may not provide a solution. The overall goal is to balance arguments for and against the property approach to determine whether it can provide a workable solution to tissue use that is worth further consideration, not to take a definitive stance on one side of the debate.

There are also a variety of problematic consequences that may flow more generally from a property approach, such as the consequences of tissue being abandoned. These will be examined at the end of this chapter, and possible ways of limiting the adverse effects of a property approach will be briefly considered. In addition, a number of possible means for deriving property rights in human tissue will be outlined to consider how a property system might be developed. The goal of this section will be demonstrate how a workable property system for tissue might be introduced, again addressing the central

question of whether property law could provide an effective means of regulating tissue use.

Throughout this analysis, a number of fundamental criteria for an effective and successful system for regulating the use of human tissue will be borne in mind. Such a system would be able to deal adequately with possible misuse of excised body parts and protect the interests of all who are involved in dealings with tissue. It should also uphold community values and comply with accepted ethical standards. Though it may be based on a variety of philosophical and ethical principles, most particularly the system should:

- not create undue disincentives to research and investment in the biomedical sciences;
- protect the interests of individuals in their own body parts, including upholding the right to self-determination;
- protect the wider interests of the community and correspond to ethical standards;
- provide remedies and sanctions for misuse; and
- be legally sound and workable.

1. LACK OF CLEAR LEGAL STATUS FOR TISSUE

The foregoing chapters have demonstrated that there is no legal consensus about the status of excised body parts. Neither the legislation nor any ethical guidelines make a statement on the general status of tissue, while the case law view is disjointed to say the least.⁹¹² The Australian Law Reform Commission regarded this lack of status as satisfactory in its 1977 report, *Human Tissue Transplants*.⁹¹³ However in the twenty-six years since that statement was made, advances in genetic technologies, the growth of the biotechnology industry and expanding uses of tissue have profoundly changed the world and this approach is no longer tenable.

This lack of clear status presents a number of problems. First, it has produced unpredictability, because without any basic principles about what tissue is at law, the case law and legislation have developed in a piecemeal fashion. When presented with

⁹¹² The situation in the United States is somewhat comparable. Radhika Rao has described the law governing the body in that country as being 'in a state of confusion and chaos. Sometimes the body is characterized as property, sometimes it is classified as quasi-property, and sometimes it is not regarded as property at all, but instead as the subject of privacy rights'. See R Rao, 'Property, Privacy and the Human Body' (2000) 80 *Boston University Law Review* 359, 363.

⁹¹³ Australian Law Reform Commission, *Human Tissue Transplants*, ALRC 7, ALRC, Sydney, 1977, [13].

problems with tissue use that are not addressed by legislation, the courts have had no fundamental view of tissue on which to draw in determining how the law should deal with this use, nor any status and rules on which to base analogous approaches to similar tissues in similar situations. Lack of clear status also means it is sometimes unclear which branch of law should cover a particular use of tissue. For example, it is not clear whether misuse of tissue might be open to an action in conversion, or if the information in the DNA contained in each cell renders it subject to the principles of intellectual property law? This is particularly problematic because the courts have dealt with this lack of status by building on an aged common law rule, rather than moving into line with the consent-based legislative approach. As a result, tissue is dealt with differently in different situations not because the issues are always markedly different, but because the legislature and courts have taken divergent approaches.⁹¹⁴

Similarly, the lack of status has generated unnecessary technical difficulties for courts faced with the theft of tissue and body parts, as in *R v Rothery*,⁹¹⁵ *R v Welsh*⁹¹⁶ and *R v Kelly*.⁹¹⁷ From a commonsense perspective it seems absurd that if excised human tissue is taken without authority, it may not be subject to the law of theft and the culprit allowed to walk free or charged under a legal fiction, simply because the court is dubious as to whether the tissue can be property.⁹¹⁸

Second, as the status of tissue is unclear, it is also neither clear what occurs in a variety of transactions and uses of tissue. For example, when tissue is donated for research, as in Case Study 6: Tissue in Australian Research, what rights over the tissue have passed to the researcher? As the person from whom the tissue was taken has no defined legal rights it—as it is not property, they have not made it property through preservation, and once excised it is no longer part of them and subject to legal protections of individual bodily integrity—in fact they could pass no rights. Yet, the researcher possesses and uses it, perhaps undertakes profitable research and generates income from it, and may

⁹¹⁴ In addition, the Nuffield Council on Bioethics in its 1995 report on human tissue use, essentially rejected property rights in tissue. Paul Matthews has suggested that these differing approaches may have resulted from the 'diverse sources in which the problems [of tissue use] locate themselves' but that such a diverse approach had a variety of disadvantages. See Matthews, 'The Man of Property', 256. See also Nuffield Council on Bioethics, *Human Tissue: Ethical and Legal Issues*, Nuffield Council on Bioethics, London, 1995, Ch 9.

⁹¹⁵ [1976] Crim LR 691.

⁹¹⁶ [1974] RTR 478.

⁹¹⁷ [1998] 3 All ER 741.

⁹¹⁸ This conclusion is supported in G Dworkin and I Kennedy, 'Human Tissue: Rights in the Body and its Parts' (1993) 1 *Medical Law Review* 291, 294. Lori Andrews has also suggested that it might be similarly difficult to prosecute for theft of tissue under United States law. See L B Andrews, 'My Body, My Property' (1986) 16 *Hastings Center Report* 28, 29.

eventually transfer or destroy it. This possession is sanctioned by the Human Tissue Acts, and therefore lawful, but as the Acts are silent on future uses, storage, retention, transfer, destruction and profit generation, the remaining rights are in fact not legally supported. Were the individual to allege misuse of the tissue, they could point to no breach of their own rights, but then neither could the researcher assert rights as the law apparently affords her none in the first place.

The same is true of organs donated for transplantation after death, as outlined in Case Study 3: Organ Transplantation. Organs can be transferred under the Human Tissue Acts, and used for transplantation in accordance with the consent given, however the Acts are silent on what may be done with the organ if it is not so used—perhaps where it is not fit for transplant or is somehow damaged. Has the person to whom it was transferred for transplantation, such as a surgeon, gained a right to continued possession and to later use it in experimental research? Must he or she return it to the relatives for burial? Can he or she sell it to another researcher or commercial biotechnology firm to be used in product development? Again, the law remains unclear because the organ has no status and there is no other law that determines what may be done in such a situation.

Of greater concern are transfers of tissue that fall outside the ambit of the Human Tissue Acts. As noted in Chapter Four, tissue removed during surgery is not covered by the Human Tissue Acts. Therefore, if the tissue in Case Study 6 had been obtained from this source, there would be no legal guidance on the rights that passed in the transfer, on what the researcher might lawfully do with the tissue, nor on the donor individual's rights. The transfer would, of course, be covered by ethical guidelines, but as noted in Chapter Five these do not have binding legal force and hence may fail to prevent misuse. These problems would be even more acute if the transfer occurred in a wholly commercial setting, as the Human Tissue Acts provide no guidance on how tissue that is sold may be stored and subsequently dealt with and commercial ventures are not necessarily subject to ethical guidelines. A case in point would be Case Study 18: Orlan and Manipulation of the Flesh, where Orlan's rights over her own body parts are unclear unless she can be said to have preserved them gained property rights through the *Doodeward v Spence* exception based on work and skill.⁹¹⁹ Analysis of these gaps and their implications are considered further in following sections

⁹¹⁹ *Doodeward v Spence* (1908) 6 CLR 406. See further Chapter Seven, sections 1–4.

Three main arguments can be made in favour of according excised human tissue property status as a solution to its lack of legal status. First, it would provide a legal foundation on which both the courts and the legislature could build to develop a consistent, unified and comprehensive approach to current and future uses of tissue. In the absence of specific legislation, the courts would have a starting point from which to extrapolate how to deal with novel problems with tissue use, and also a clear body of legal rules on which to draw. Where necessary, the legislature could add to this body of rules, or proscribe the exercise of certain property rights where necessary or ethical. This argument is considered further in section 2 in relation to gaps in the current framework.

Second, it would lend clarity to how tissue is and can be legally dealt with. It could be subject to the proprietary rights as listed in Chapter Nine, such as rights to possession, use, transfer and income. Who might hold these rights and how they could be exercised could be legislatively or judicially determined, as appropriate, based both on the principles of property law and policy considerations. Such determination could take into account ethical standards, for example as embodied in the National Health and Medical Research Council (NHMRC) *National Statement on Ethical Conduct in Research Involving Humans* (National Statement).⁹²⁰

Third, as Roger Magnusson has rightly pointed out that

to categorically hold 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.⁹²¹

According property status to tissue would provide legal recognition for the manner in which tissue is already treated. By applying the indicia of property to human tissue it was demonstrated in Chapter Nine that tissue is already treated like property under the law and in common transactions. Body ownership rhetoric also suggests that people often think of tissue and body parts in terms of property. In fact, the treatment of many types of tissue so resembles property treatment that Paul Matthews has suggested that the law's response to a lay person's question whether things such as wigs, transplanted

⁹²⁰ National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans*, NHMRC, Canberra, 1999.

⁹²¹ R S Magnusson, 'Proprietary Rights in Tissue', 25. See also H ten Have and J Welie, 'Medicine, Ownership, and the Human Body' in H ten Have and J Welie, (eds) *Ownership of the Human Body: Philosophical Considerations on the Use of the Human Body and Its Parts in Healthcare*, Kluwer Academic Publishers, London, 1998, 1.

organs, preserved specimens and teaching skeletons are property, is one of embarrassment, 'for it has many times been stated by commentators and learned writers that the body and its parts are not property at all, let alone belonging to anyone'.⁹²²

This approach would also lend support to the rights already provided through legislation. For example, the Human Tissue Acts give an individual the right to transfer tissue and to consent to certain uses, while the researcher or doctor to whom it is given may use it in a variety of legally determined ways. The similarity of these rights to those accorded by property means that deeming tissue property need not materially alter how tissue is treated in this instance, but rather further support it.⁹²³ As an example, the transfer of a blood sample to a pathology laboratory for testing, as in Case Study 4: Hobart Pathology, in addition to being regulated by testing and laboratory guidelines, could be regarded as a bailment. The individual from whom it is taken would have proprietary rights over the sample, but would transfer the right to possession as part of a bailment agreement, under which the laboratory has possessory rights to enable testing. The sample would be transferred for a limited purpose, but title would not pass, and the bailment agreement would preclude the laboratory from using the sample beyond its terms, thereby prohibiting the laboratory from transferring it (including selling the sample) and using it in research without consent. Were the laboratory to do so, property actions and remedies would be available to the individual.

The same could be said of a donation for research. If tissue were property, donation of tissue could be constructed as a bailment between the donor and the researcher. This would have two positive implications. First, the donor would have a basis on which to claim the return of the tissue (or restrain further use) if the researcher misuses it. Second, the researcher would also gain a right to immediate possession to the tissue within the terms of the bailment. He or she would then also have a claim for its return if a third party gains unauthorised possession.⁹²⁴ This approach would therefore protect the interests of the donor individual, provide the researcher with a clear right to possess and use the tissue, and protect regulate access to the tissue by the donor and third

⁹²² P Matthews, 'Whose Body: People as Property' (1983) 36 *Current Legal Problems* 193, 193.

⁹²³ Roger Magnusson has given a good account of how the legal uses of tissue reflect property law principles. See Magnusson, 'Proprietary Rights in Tissue', 25, 43–44. See also R Atherton, 'Claims on the Deceased: The Corpse as Property' (2000) 7 *Journal of Law and Medicine* 361, 374. The right to possession of a corpse for the purpose of burial is also akin to a property interest. See further P Skegg, 'Medical Uses of Corpses and the "No Property" Rule' (1992) 32 *Medicine, Science and the Law* 311, 315.

⁹²⁴ Although a bailment for term will bar the bailor from suing in conversion during the term of the bailment unless the bailment is terminated by an act by the bailee that is repugnant to its terms.

parties while held by the researcher, protecting its security. The terms of the bailment could mirror the kinds of limitations already provided under the Human Tissue Acts or applicable ethics guidelines, and hence work in tandem with the current framework while providing added clarity, security and legal protection. Where either party breaches the terms of the bailment, the general remedies for such breach would be available. The availability of actions and remedies for misuse is discussed further in section 6.

Some argue, however, that it is right that human tissue should have no legal status. It is argued that human tissue has a unique and sanctified status, which makes it unfit to be classed with the other sorts of things we regard as property, like cars and houses and tables—things which have no intrinsic moral value.⁹²⁵ This argument is sometimes grounded on the premise that a clear distinction should be made between people and things—people are differentiated from things because they possess free will, and recognition of this free will is crucial to ensuring that people receive respect for their human dignity.⁹²⁶ On this view, allowing the human body to be owned by the person it embodies means it becomes a subordinate object having less than human dignity.⁹²⁷ This view is often extended into an objection that deeming tissue property treats the human body as a commodity, however this particular argument will be addressed in the context of commercialisation of tissue in Chapter Twelve.

This is not a convincing argument for rejecting property status for tissue because it is not clear that placing tissue in the same legal class as objects will result in tissue being treated without respect. The qualities of tissue that engender this respect are not altered by this legal classification. Its emotional significance as something once part of a person is not altered, because the classification itself does not change the basis of that significance. For example, property-like rights were exercised over the organs retained in Case Study 2: Organ and Tissue Retention following Post-Mortem, and the remains held by museums in Case Study 1: Collecting Aboriginal Remains, but for the parents of

⁹²⁵ See, eg, the discussion of religious attitudes to property and the body in C S Campbell, 'Religion and the Body in Medical Research' (1998) 8 *Kennedy Institute of Ethics Journal* 275. See also F Illhardt, 'Ownership of the Body: Deontological Approaches' in ten Have and Welie, (eds) *Ownership of the Human Body*, 187, 189ff on the Kantian conception of people as having a dignity, rather than a worth, which sets them apart from 'things'.

⁹²⁶ This perspective is supported in R W Marusyk and M S Swain, 'An Alternative to Property Rights in Human Tissue' (1990) 20 *Hastings Center Report* 12, 13.

⁹²⁷ C Heyer, 'Moore v Regents of the University of California: The Right of Property in Human Tissue and Its Effect on Medical Research' (1990) 16 *Rutgers Computer and Technology Law Journal* 629, 650. See also A B Wagner, 'Human Tissue Research: Who Owns the Results?' (1987) 69 *Journal of the Patent and Trademark Office Society* 329, 338–9. See further on this view of excised tissue J Lavoie, 'Ownership of Human Tissue: Life after Moore v Regents of the University of California' (1989) 75 *Virginia Law Review* 1363, 1387.

the children whose hearts were possessed, used and transferred, and the community whose relatives' remains were preserved and displayed, these body parts had lost none of their moral, emotional or spiritual value. Further, though we use tissue, clearly we believe there is a need to treat it sensitively, as the high level of compliance with the National Statement demonstrates. Objections to according tissue property status on the grounds that it will promote commodification of human tissue are analysed further in Chapter Twelve, sections 2.2 and 2.3.

As a second objection, Loane Skene has rejected the idea that the lack of status of tissue makes gifts and donations problematic gaps in the legal framework. She has argued that there it is not necessary for something to be property for it to be donated or gifted. She has stated that she could 'give [her] time or [her] talents (which are not property) as readily as [her] possessions'. She has also argued that the gifting could instead be seen as exercising a personal right to consent to removal and use of tissue.⁹²⁸

Two responses can be made to this objection. First, the analogy between giving one's time or talents and giving an object is flawed. Though linguistically we say we 'give our time', we are not actually giving a thing in the sense of an item of property, but actually *doing* something. This differs from the transfer of an object between persons, hence the argument is not convincing.

Second, while it would be possible to see a gift as consent to remove and use, the argument does not explain why this approach is more favourable than simply calling the transfer of tissue a property transfer and classing it in the same way that we class other transfers of objects. Unless tissue is so special or different that it should not be treated like a commodity (arguments which are rejected below in Chapter Twelve), then it is not clear why on this argument alone it cannot be transferred. This is particularly the case given that a transfer of tissue could still be subject to the constraints that apply to tissue donations under the Human Tissue Acts, or could be conceived of as a bailment providing the bailee with only limited rights to use and possess it. This approach, as opposed to the consent approach, has the same effect in this instance while also allowing the donor to retain an interest that enables him or her to regain possession of the tissue or restrain further use (which the Human Tissue Acts' consent approach does not). It also gives both the donor and the bailee security against unlawful taking (which

⁹²⁸ L Skene, 'Arguments against People Legally 'Owning' Their Own Bodies, Body Parts and Tissue' (2002) 2 *Macquarie Law Journal* 163, 170–1.

again, the Human Tissue Acts do not).

Others, such as Christopher Heyer, have argued that human tissue actually lacks the traditional characteristics of property, and hence its use is better regulated through legislation.⁹²⁹ However, the analysis of the incidents of property in Chapter Nine demonstrated that in many ways tissue actually does have the characteristics of property, as well as already being treated in a property-like manner by the legal system. Property is characterised as something that can be possessed, used, managed, destroyed and transferred. As Chapter Nine demonstrated, tissue can be possessed and it already is used, managed, destroyed and transferred in many contexts.

2. GAPS IN THE CURRENT LEGAL FRAMEWORK

Part I outlined a great range of uses to which tissue can be and is put. It also outlined an array of groups with varied interests in that tissue. Despite this multiplicity of uses and interests, the current legal and ethical framework that governs tissue use applies to only a portion of these uses, and protects only some of these valid interests. Some of these gaps were highlighted above in relation to tissue's lack of legal status. This section looks at a number of these gaps in more detail and examines how property law might fill them.

In Australia, legislative guidance on the use of human tissue extends only to the Human Tissue Acts, legislation dealing with post-mortems and anatomical specimens, and the taking of samples for certain police purposes. The case law is limited to a small group of highly specific fact situations. As a result, there are many instances in which the law is entirely silent on how tissue may be treated. Four areas in which the law is lacking will be discussed here, however as the previous chapters have shown, there are many more instances in which the legal system does not provide rules for tissue use.

First, in the medical and scientific context, the Human Tissue Acts cover only a small area of tissue use, as they exclude tissue removed during therapy and deal only with tissue expressly donated for transplantation, therapeutic or research use.⁹³⁰ Chapter One, particularly, Case Study 6: Tissue in Australian Research demonstrated that research

⁹²⁹ Heyer, *Moore v Regents of the University of California*, 650.

⁹³⁰ *Human Tissue Act 1983* (NSW) s 34(1); *Human Tissue Act 1982* (Vic) s 42; *Transplantation and Anatomy Act 1983* (SA) s 37; *Transplantation and Anatomy Act 1979* (Qld) s 47(1); *Human Tissue and Transplant Act 1982* (WA) s 32; *Human Tissue Act 1985* (Tas) s 28; *Transplantation and Anatomy Act 1978* (ACT) s 46; *Human Tissue Transplant Act 1979* (NT) s 26.

tissue is often tissue removed for therapeutic reasons which would otherwise have been discarded. In effect, all donations and research use of this type of tissue are not covered by the same consent requirements as specifically donated tissue, and are subject only to ethics guidelines without legal force.

Second, the legislation and case law are also limited to very few fact situations. The cases are probably only applicable to disputes over pathology samples and preserved tissue, while the Human Tissue Acts focus only on research and medical use of tissue. But as Chapter One demonstrated, tissue use has expanded beyond these arenas. The law provides little guidance on artistic and commercial use of tissue (save the limited prohibitions on tissue sale in the Human Tissue Acts).⁹³¹ Hence, uses such as Case Study 18: Orlan and Manipulation of the Flesh, or Gunther von Hagens' *Bodyworlds* probably exist in a legal vacuum.⁹³² Where tissue is used to generate profit, such as through the production of therapeutics or as in Case Study 13: Bionomics, it forms the basis of lucrative research however there is no legal direction on benefit sharing arrangements for the use of tissue.

Third, the Human Tissue Acts are also silent on what may be done with tissue beyond the use allowed in the original consent. The Acts only outline how consent may be given for one use, but do not specify the wider rights that consent provides. It is unclear whether the researcher or physician receiving the tissue may store it, later re-use it in other projects, derive income from selling or producing therapeutic products from it or transfer it to others. Hence, for example, if the samples donated in Case Study 9: The Menzies Centre for Population Research were transferred elsewhere and used in another research project, it might be that this was a use outside the original consent agreement and therefore not authorised. The Human Tissue Acts approach is inadequate in two ways, first because it does not provide for more detailed consent such as future uses, storage and transfer, and second because it is at odds with the general ethical approach that allows that samples may be de-identified and later used. The blunt approach of the Human Tissue Act has gaps because it provides a very basic consent model to deal with the various and complex consent arrangements and subsequent uses to which tissue may be subject. It also does not clarify the rights of the receiving researcher in relation to the tissue, nor provide remedies for misuse or deal with uses outside the initial

⁹³¹ See Chapter Four, section 4.

⁹³² Unless, as discussed in Chapter Seven, section 4, Orlan's use could be brought within the *Doodeward v Spence* work and skill exception.

consent relationship.

As discussed in Chapter Five, section 2, these uses will often be covered by NHMRC guidelines, which lay down guidance for subsequent research use and storage of samples. However, as noted in that chapter, these guidelines have no legal force and do not provide individuals with any remedies for misuse. They also do not enable individuals to restrain or seek compensation for misuse by third parties not subject to the guidelines.

Fourth, the Human Tissue Acts, ethics guidelines and case law do not provide guidance where third parties who gain access to tissue outside a consent relationship. For example, it is arguable that tissue cannot necessarily be stolen, although there are some limited English cases where theft of tissue has been found to have occurred.⁹³³ That tissue cannot be stolen means that the security of tissue in collections, in museums, held by testing laboratories and a range of other institutions is not protected. It leaves this tissue open to unlawful taking and subsequent misuse. The major response to this argument, given by Loane Skene, is that other areas of law will protect against the real harm that is done, namely the subsequent misuse. This view, and responses to it, are considered below in section 5.

Finally, the legal framework does little to cover other interests in tissue, such as indigenous community interests or those of family members who seek access to stored tissue. This gap came to fore in the case of *Roche v Douglas*,⁹³⁴ as discussed in Chapter Seven (and see also Case Study 11: *Roche v Douglas*), where the court was faced with a lack of clear guidance on whether preserved tissue from one family member could be accessed by another.

Property law could provide a solution to these gaps. First, by according individuals or institutions property rights over tissue, their rights to use it could be more clearly defined, particularly in relation to storage and future use. Casting the donation as a property transfer would require the rights that pass to be made clear, particularly if constructed as a bailment, where the rights would be defined by the terms of the agreement. As discussed in Chapter Nine, in many ways the law already allows people to deal with tissue in a property-like manner. We can donate it, gift it, it can be stolen (as

⁹³³ See Chapter Seven, section 2.

⁹³⁴ *Roche v Douglas as Administrator of the Estate of Edward Rowan (dec'd)* (2000) WASC 146.

the case law demonstrates), and it can be possessed and used. Lori Andrews has commented, 'the legal treatment of bodies and body parts sounds suspiciously like property treatment'.⁹³⁵ In support of this view, Magnusson has also suggested that some transfers of property resemble bailment, such as blood donations.⁹³⁶

Similarly, Courtney S Campbell has suggested that biomedical ethical approaches, as well as legal approaches to the body reflect aspects of the 'property paradigm'. He argues that the right people have to bodily integrity (protected at law by prohibitions on surgery without consent, rape and assault) demonstrates that people are considered to own and possess their bodies. In addition, body parts can be removed and transferred, allowing alienation and acquisition, which also are reflective of a property-like treatment of tissue.⁹³⁷ Campbell's analysis comes, therefore, to conclusions like those reached by the application of the incidents of property to tissue in Chapter Nine, which also demonstrated that body parts are amenable to be treated like property.

Others have disputed this argument. Henk ten Have and Jos Welie have rejected this approach to arguing in favour of property rights in the body, asserting that the fact that the property paradigm may be reflected in how body parts are treated is not in itself a justification for applying property law to tissue.⁹³⁸ Alone it may not be a sufficient justification. However, the point is that it suggests that it would not be difficult in a practical sense to shift the law towards a property approach. As this shift is not great, it further suggests that the current approach already operates as though tissue is property, demonstrating that property-like concepts can be applied to tissue in a workable manner. Therefore, it would not be a particularly difficult transition to construct donations of tissue as property transfers.

Second, if tissue were deemed property, then other uses and transfers not covered by specific legislation would be subject to the basic principles of property law (and if sold, sale of goods regulations). This would provide a basic structure by which to regulate any conceived use of tissue, rather than relying on the legislature or courts to develop a

⁹³⁵ See, eg, Andrews, 'My Body, My Property', 29.

⁹³⁶ R Magnusson, 'The Recognition of Proprietary Rights in Human Tissue in Common Law Jurisdictions' (1992) 18 *Melbourne University Law Review* 601, 616; Magnusson, 'Proprietary Rights in Tissue' in N Palmer and E McKendrick, (eds) *Interests in Goods*, 2nd edn, LLP Reference Publishing, Hong Kong and London, 1998, 25, 25.

⁹³⁷ C S Campbell, 'Body, Self and the Property Paradigm' (1992) 22 *Hastings Center Report* 34, 34ff.

⁹³⁸ H ten Have and J Welie, 'Medicine, Ownership and the Human Body' in ten Have and Welie, (eds) *Ownership of the Human Body*, 1, 6.

specific approach to a use once it becomes problematic. This would also provide a definitive answer the vexed question of whether tissue can be stolen. Problematic consequences of using property law could be addressed through legislation. This issue is discussed below in section 7.

Third, property law provides for overlapping interests in the same object. This flexibility could be used to take account of some other interests in tissue, such as familial interests or indigenous concerns. This is discussed further in section 4.

3. INSUFFICIENT CONTROL

A concern that cuts across many of the areas covered in the previous chapters, and which became apparent in the analysis of the Human Tissue Acts and ethics guidelines is that the law does not always provide individuals with sufficient means to control how their tissue is used. For example, the law does not provide individuals with the ability to direct the use of their tissue in a range of contexts, such as selling it, using it in artworks, or in managing its use after it has been donated for research.

It has also become apparent that in some cases, researchers, families and indigenous groups lack the ability to control tissue where they should be able to. Families and indigenous groups do not have many rights to manage how their relatives' remains are used, even though they may have a valid interest in doing so. Researchers also lack clear legal rights to define how they may manage some tissue (such as tissue obtained following surgery) or to fully control tissue samples lawfully in their possession.

Property law may provide a means to afford individuals and others with this kind of control where appropriate. One way of looking at this question, and the question of who owns one's body in particular, has been raised by Rosalind Atherton. She has suggested that the question of who owns your body should be approached by first considering some key ideas that are fundamental within both medical ethics and legal and political theory—autonomy and justice. Autonomy and notions of free will and self-determination reflect, she has written, 'the 'person-ness' of the body' while justice is bound up with ideas of altruism and utility, that is, the common good.⁹³⁹

The first of these ideas, autonomy, is promoted by respecting an individual's right to

⁹³⁹ R Atherton, 'Who Owns Your Body?' (2003) 77 *Australian Law Journal* 178, 179.

control over his or her own body which acknowledges that person's intrinsic value as an autonomous agent. The legal system, for the most part, supports respecting individual choice.⁹⁴⁰ Psychologically, too, self-agency—the ability to control what is done to one's body—has been cited as a factor in maintaining emotional and mental well-being⁹⁴¹. As a community we show respect for a person's relationship to his or her body and his or her desire to choose how it is dealt with in a variety of ways, such as through burial and cremation rituals and through ethical guidance on the use of tissue, organs and other body parts in medicine and research. We also require that the donation of organs for transplant be consensual, placing individual choice above community need, through requiring people to opt-in, rather than opt-out of organ donation.⁹⁴²

It is therefore important that the law ensures individuals have sufficient control over their excised body parts. Even apart from any possible harm that may be done, respect for autonomy is an approach to human dealings that is desirable in and of itself, because people's well-being is promoted by enabling them to choose how best to maximise their own interests. Affording them the greatest control possible over their bodies is one way of doing so.⁹⁴³

In addition, as Sue Huynen has argued, according tissue property status is consistent with protecting the integrity of individuals, in that it extends the rights the law already gives people over their own living bodies. Given that the law provides such strong rights over our living bodies, it is, she has argued, anomalous to give this level of protection to living bodies and yet give people no rights over parts of that body once detached.⁹⁴⁴

The unique qualities of human tissue as an object are a further reason for affording the individual from whom it was taken substantial control over it. Where other objects are

⁹⁴⁰ Gerald Dworkin and Ian Kennedy have noted in support of this view that the law provides us with strong personal rights in our own bodies and their parts, at least until they are removed. See Dworkin and Kennedy, 'Human Tissue', 298.

⁹⁴¹ L Andrews and D Nelkin, 'Whose Body is it Anyway? Disputes over Body Tissue in a Biotechnology Age' (1998) 351 *Lancet* 53, 54ff (citing the work of Daniel Stern).

⁹⁴² Compare the views of Joel Feinberg, who rejects the emotional and psychological harm of non-consensual organ-taking. See J Feinberg, 'The Moral Trap of Sentimentality: The Mistreatment of Dead Bodies' (1985) 15 *Hastings Center Report* 31, 36.

⁹⁴³ A Buchanan, 'An Ethical Framework for Biological Samples Policy' in National Bioethics Advisory Commission, *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance: Commissioned Papers*, vol II, NBAC, Rockville, MD, 1999, B-1, B-11, B-12.

⁹⁴⁴ S Huynen, 'Biotechnology—A Challenge for Hippocrates' (1990) 6 *Auckland Law Review* 534, 539. This view is also supported in Andrews, 'My Body, My Property', 33. Bernard Dickens has made a similar point. See B M Dickens, 'The Control of Living Body Materials' (1967) 27 *University of Toronto Law Journal* 142.

concerned, later use in a manner that is detrimental to the original possessor may not be so in need of legal redress. But human tissue is different, for as has been noted many times in this thesis, it has special significance for the individual. Full respect of this, and individual ability to direct how one's body is dealt with require greater promotion of individual control. Further, almost all excised tissue also contains genetic material, and hence while identified remains a source of intimate information about the person regardless of how and where it is transferred. Good protection of individual control of tissue is therefore needed more than for other objects because of the repercussions misuse may have and the strong links that remains between people and their body parts.

Allen Buchanan has suggested a list of additional reasons to afford individuals substantial control of removed body tissue, which includes:

- avoiding insurance and employment discrimination where tissue is tested by others;
- avoiding stigmatisation and breaches of privacy and confidentiality where sensitive information is derived from the sample (or even from the fact of its existence, as in the case of a biopsied tumour which suggests the individual may have cancer) and made available to others;
- avoiding group-identity-based harms, for example where tissue is used for research into the role of genotype in criminal behaviour or intelligence, that promote the reinforcement of harmful group stereotypes;
- avoiding familial conflict; where the sample is used to reveal information that has sensitivities for others, such as parentage and disease status; and
- avoiding uses that the source of the sample would find objectionable or distressing.⁹⁴⁵

Despite these kinds of needs, beyond the specific instances noted above, one of the most particular failings of the current legal regulation of human tissue is that it does not extend the respect it has for persons and their right to choose how their bodies are treated, to protect their excised body parts. The law often excludes individuals from possessing legal rights to determine how their tissue and body parts are dealt with once removed from the body, and in doing so fails to promote autonomous choice about how one's body is treated by others and to protect against the types of harms noted by Buchanan.

What are some examples? Imagine your leg is severely injured in a motorcycle accident,

⁹⁴⁵ Buchanan, 'An Ethical Framework for Biological Samples Policy', B-6 – B-12.

and later amputated. You wish to have the leg buried, because to you it is a part of you and should be laid to rest. But when you request its return from the hospital, you discover that it has been incinerated as hospital waste. Under the present law, there is little basis on which you could bring a claim against the hospital,⁹⁴⁶ because tissue discarded during surgery is not subject to the Human Tissue Act consent requirements. Or imagine that the hospital had preserved your leg as an anatomical specimen and put it on display in its teaching museum. As the hospital was in lawful possession of the discarded leg, and has preserved it by the application of work or skill, if you bring a claim, the court might well determine that the leg has become the property of the hospital in accordance with the exception in *Doodeward v Spence*.⁹⁴⁷

The same failure would be seen if the facts of Case Study 14: John Moore's Spleen or Case Study 15: Canavan Disease Research played themselves out in Australia. Moore would have a claim for breach of fiduciary duty against Golde, but no basis on which to bring an action against the others who profited from his tissue. David Greenberg and the others who donated tissue to Reuben Matalon for research would also have no legal grounds to bring actions against the Hospital for commercialised research based on use of their tissue, as there was no consent relationship between them and the Hospital. They would also have had no legal means to constrain what they perceived as the adverse results of that use, that is, once one's tissue has been transferred beyond the consent relationship in which it was originally given, its use and the consequences of that use would be outside the control of the person from whom it was taken.

Families also they lack much capacity to control tissue from their deceased relatives. Chapter Four demonstrated that while their wishes may be taken into account, they lack any real rights to control what happens. They can lodge objections to post-mortems, but it is not clear that this will necessarily have much effect. Where samples or tissue is retained from their relatives by hospitals, the law does not provide any basis on which they may seek to have it returned; they must rely on the goodwill of the hospital to return it. In many cases it is likely that a hospital would be sympathetic to the wishes of bereaved families, but if not, the family may be left with few if any remedies for the

⁹⁴⁶ An action has been brought for nervous distress in a similar situation in the United States, and although the action failed (and the court also found there was no negligence by the hospital in disposing of the leg), the court did note that patients have a right to express objections to the disposal of their tissue, or make requests in relation to its disposal. See *Browning v Norton Children's Hospital* (1974 Ky) 504 SW 2d 713, 714 per Warren (special commissioner).

⁹⁴⁷ (1908) 6 CLR 406.

harm they may suffer. The same holds true for Aboriginal communities seeking to lay their ancestors' remains to rest. The Human Tissue Acts contain no provisions that would assist them, and in fact the courts are more likely to uphold the possessory rights of the museum if *R v Kelly* is followed.

If we accept that individuals should have the greatest claim to control of their body parts, then according tissue property status of some form is an effective way of giving it to them. According individuals property rights over their tissue is consistent with protecting the integrity of individuals, and would extend the strong protections the law provides the intact person to tissues and body parts removed from that person.⁹⁴⁸ It would also recognise their interest in directing what happens to their bodies, promoting their autonomy.⁹⁴⁹

Property law could be used to give individuals control in a variety of ways. The individual could be afforded a mere proprietary interest, which would provide them with a better claim to possess or control tissue in relation to others who may seek to deal with it. Or we might choose to allow only some tissues to be property, such as renewable tissue or tissue removed during surgery, or if all tissue is property, give individuals more extensive property rights over these kinds of tissues.

Particularly in relation to renewable and discarded tissue, we could provide even greater control by vesting some or all of the rights of property in the individual. He or she could be given all the rights property provides. He or she would have a present right to possession and any interference with the tissue would be a breach of this right. He or she might also have rights to possess, use, manage, alienate and so on, which would prevail against all other claimants. He or she would be the person who could determine how her tissue would be used in any given circumstance through the rights to use and manage, not only those situations in which the legislature and courts had developed rules. He or she would be able to bring actions to reclaim possession were tissue stolen or retained without consent; to gain access to stored tissue such as newborn screening cards as in Case Study 5: Newborn Screening Card Collection; or to bring an action in

⁹⁴⁸ This view has also been expressed in Huynen, 'Biotechnology'.

⁹⁴⁹ See, eg, D M Wagner, 'Property Rights in the Human Body: The Commercialization of Organ Transplantation and Biotechnology' (1995) 33 *Duquesne Law Review* 931, 955. See also Andrews, 'My Body, My Property', 29. Lori Andrews argues that enabling individuals to determine what happens to their body parts provides a significant psychological benefit. Andrews cites the significant emotional and psychological harms that people have reportedly suffered when bodies or body parts have been mistreated in support of this argument.

conversion where tissue was used in an unauthorised manner, which might afford some control in situations like Case Study 15: Canavan Disease Research and John Moore's case. This would also give the individual control over tissue removed for therapeutic purposes and later used in research. The research use could be construed as a bailment, and if the tissue use was inconsistent with the terms of the bailment agreement, the right to immediate possession would revert to the individual. He or she would then be able to seek its return, or seek damages.

As the bundle of property rights is divisible, not all rights need to be accorded, and instead differing rights could be available over different tissues in different circumstances. Objectionable rights could be excluded. Further, such rights could be shared between individuals and groups, for example by allowing researchers a present right to possession and a right to use tissue, while the individual from whom it was taken held a management right to direct what kind of research it might be used in. This approach would clarify the rights of researchers, hospitals and museums that hold tissue collections, while providing an avenue for according individuals and other interested groups with proprietary rights where appropriate.

Legislation could also be created to deal with particular situations where it might be inappropriate for individuals to exert control, or to exert it to the full extent that property law might allow. For example, for public health reasons organs and tissue should probably not be able to be returned directly to private individuals. Claims in detinue for the return of tissue might be legislatively prohibited, and replaced by a mechanism for organs to be returned to a funeral home for burial in accordance with public health requirements. The need to make such provision does not, however, mean that enabling individuals to choose what is done with their tissue in other contexts through property rules should be precluded. Property is sufficiently adaptable to also take account of other interests by dividing rights between different groups and limiting or denying rights in certain circumstances, while the option remains to legislatively overcome the unwanted implications of property where necessary.

Using property law to give individuals control of their tissue has been criticised as unnecessary, because the interests of individuals are already adequately protected by other areas of the law.⁹⁵⁰ For example, Jennifer Lavoie has argued that

⁹⁵⁰ See, eg, the majority decision in *Moore v The Regents of the University of California and others* (1990) 51 Cal 3d 347

A right of self-determination need not be synonymous with property rights; it is merely the right of control over choices regarding one's own body. Laws in other areas have adequately protected this right of control without recognizing full property rights.⁹⁵¹

Skene has made similar arguments, however as these focus on the protections against harm, they are discussed below in relation to the protections and remedies provided by the current law.⁹⁵²

Lavoie is incorrect in stating that the law provides individuals with adequate control over their body parts. In Australia, the only legal controls provided are those under the Human Tissue Acts (beyond what limited controls might exist if the English common law cases are applied in this country). These only deal with how the individual may control the use of his or her tissue in research and therapy. As the examples given above demonstrate, the current legal framework defines no rights for individuals to use their tissue in almost all other situations, and even the ethical framework deals largely with research and testing uses. The law provides no guidance on whether individuals may seek the return of their tissue once it is possessed by others, including insurance companies, employers or commercial ventures. It also gives no clear rights to prevent the theft of tissue, beyond the limited case law which has been applied in only very specific circumstances. As privacy law generally does not apply to tissue, the law further provides individuals with no rights in relation to the privacy of their samples. At present, due to a lack of support from the Federal Privacy Commissioner, it also appears unlikely that privacy law protection will be extended to samples.

Aside from providing individuals with sufficient control of tissue, applying property law to body parts would also afford those with legitimate rights to possess and use tissue with legal protection of these rights. Without a legal right to possession, researchers, genetic testing laboratories and companies all actually have no better legal right to possess tissue than any other person. Therefore, if the tissue is misappropriated, they do not necessarily have a legal basis to require its return, though other remedies may be open to them. For example, in Case Study 7: Donor Tissue Bank of Victoria, the Bank stores tissue to be used for treatment. Were these samples taken, as the Bank does not clearly have a possessory right to them it therefore may not have a basis on which to require their return. Similarly, were a pathology laboratory (as in Case Study 4: Hobart

120, 164 per Panelli J.

⁹⁵¹ Lavoie, 'Ownership of Human Tissue', 1385.

⁹⁵² Skene, 'Arguments against People Legally "Owning" Their Own Bodies', 167-8.

Pathology), to discover that one of its employees had taken identified samples and supplied these to an insurance company or an employer, the laboratory would have no possessory right to hold out against either the employee or the third parties to whom the samples were transferred. If the laboratory were afforded a proprietary right to possession, however, they would have a clear right on which to base a legal claim for the return of the samples. It should be noted, however, that if *R v Kelly* were followed, some possessory right might be accepted, but this would require acceptance that the tissue is property, hence further demonstrating the efficacy of a property approach.

Paul Matthews has argued that the view that these organisations would not have a right to present possession ignores the common law doctrine of relative title, where the common law may recognise that one party has a better relative title to the tissue without having to determine the absolute validity of that title itself.⁹⁵³ It is arguable that this would be a means by which the researcher or laboratory could claim the return of stolen tissue. However, this approach lacks the certainty and security that a property approach could provide, which coupled with the promotion of individual interests the property approach gives and its accordance with recent case law, makes this latter mechanism preferable to relying on the common law doctrine cited by Matthews.

Further, property concepts could be used to define more accurately what institutions are doing when they use tissue. They need not be afforded full ownership, but only some form of quasi-ownership, where their possession is protected by trespassory rules, but does not provide them with full rights to exploit the tissue they hold. James Harris has referred to this approach as one which excludes the 'crucial feature of ownership interests, namely, authorized self-seekingness'.⁹⁵⁴ This approach would enable them to protect their legitimate interest in possessing tissue, while preventing them from using it in a manner that offends the interests of the individual from whom it was taken. The rights to use and possess would rest on the social function served by the institution, such as using tissue for research that promotes the development of medical treatments, and also limit those rights based to uses directed at this function.

4. LACK OF RECOGNITION OF OTHER INTERESTS

As Chapter One discussed, there are a great many other interests in human tissue that

⁹⁵³ Matthews, 'Whose Body: People as Property', 215–6.

⁹⁵⁴ J W Harris, 'Who Owns My Body?' (1996) 161 *Oxford Journal of Legal Studies* 55, 61.

need to be balanced against individual interests. To name but a few, these include community interests like those of the Aboriginal community; familial interests in access to samples such as to aid their own treatment or to test for paternity where acceptable; researchers' need of tissue to study the causes of disease and the general community's interest in the tests and treatments this might lead to; commercial need for tissue to produce therapeutics, which again are also beneficial to the community; and more specific interests like the police's need to access tissue for forensic purposes.

By basing regulation of human tissue around a consent relationship between donor and researcher or hospital, both the Human Tissue Acts and the ethical framework do not always allow for other valid interests to affect how tissue may be used. As an example, the consent approach to research use in the Human Tissue Acts gives little direction on how testing facilities should deal with reasonable requests for access to samples where testing may be necessary for a family member's diagnosis and treatment. Such a situation might arise if a genetic disorder is suspected, and it is necessary to trace the disease history within a family. As the Acts are based only on a consent relationship between donor and researcher, they do not provide guidance on how to deal with the interests of others.

Property law could provide a solution to this issue by allowing for overlapping rights in particular tissue, or by burdening some rights with the interests of others. For example, while an individual may have proprietary rights to use tissue and to manage it, family members might be provided with a proprietary interest that allows access for certain purposes, such as health testing, which burdens these rights.

A property approach in this instance might be preferable to the current lack of guidance on what should be done in such a situation. Take, as an example, newborn screening cards stored as in Case Study 5: Newborn Screening Card Collection. A parent seeks to have her child's newborn screening card destroyed because she fears it might later be misused if it is tested to generate information that might be used in a discriminatory manner or if it is accessed by a relative and tested for paternity. She would find that the law presented her with no clear statement of her position or the rights of the hospital holding the card. At present, the security of these cards relies on health department and hospital policy. The parent and the child appear to have no legal right of access.⁹⁵⁵ Were

⁹⁵⁵ See L. Skene, 'Access to and Ownership of Blood Samples for Genetic Tests: Guthrie Spots' (1997) 5

the child to go missing, and the police sought to access the card for a sample to identify her suspected remains, again the law would provide no regulation, rather this form of access is dealt with solely on a case-by-case basis by the hospitals and police, or through a memorandum of understanding which has no legal force.⁹⁵⁶

What should be recalled is that property provides a set of rights that can be distributed in line with the balance of interests that is regarded most appropriate. The divisibility of property rights could be exploited to give rights where appropriate. For example, individual control could be limited to management power to direct how tissue is used, but doctors and researchers could acquire rights to possession and use for research purposes. Alternatively, the tissue could be deemed *res nullius* on excision, but be transformed into property through the exercise of work and skill, in line with the common law view. Hence, only those who lawfully take and use the tissue in certain ways will be able to exercise property rights over it. Once tissue becomes property, however, the person from whom it was taken might also acquire some form of management power to require consent to certain uses and give them scope to object to uses and transfer they regard as unacceptable. This would ensure research collections and pathology samples could be protected against theft, and allow lawful possession for legitimate purposes, while maintaining some individual control.

By deeming the tissue in question property, and determining a division of rights over it, the situation described above might be clarified and the valid interests of the parties promoted. For example, legislation might outline circumstances in which the police have a right to access cards, such as for forensic purposes, and this might also require the consent of the parent. However, this would not clarify the hospital's position to the card, nor the parent's rights in other circumstances. Relying on property law, the hospital could be deemed to have a present right to possession for certain purposes, and perhaps holds the card in the form of a bailment. In recognition of the sensitive nature of the blood sample on the card, and the intimate information it contains, the child might be deemed to retain other rights, such as a management. Were the card misused by the hospital, this proprietary right plus the limits of the implicit bailment could found an action. Further, were the card taken and misused by a third party, the child and parent could seek its return in detinue, or bring an action for trespass to chattels. They would have rights against the third party that could be clearly defined by applying

Journal of Law and Medicine 137, 140.

⁹⁵⁶ See Case Study 5: Newborn Screening Card Collection and Chapter Two, note 37.

property laws, rather than being denied a remedy because the law had made no statement on other party's rights in relation to the card. The application of property law could be guided by ethics to ensure both that human dignity was preserved, socially worthwhile uses of tissue promoted, while still developing a workable solution from a well-formed body of legal principles.⁹⁵⁷ A similar approach could be taken in any other situation where there was no legislative or common law rule about tissue use.

However, a criticism of using property law to afford individuals rights is that it does exclude the rights and interests of others from protection. As Magnusson has argued, property is 'a fairly blunt instrument through which to analyse the use and control of human tissue samples, because it fails to accommodate the variety of competing interests that may exist in relation to the tissue'.⁹⁵⁸ By affording individuals (and institutions in possession of tissue) strong rights to control that tissue, deeming tissue property could exclude others from using tissue despite their reasonable claims to do so. For example, it might be considered reasonable to allow a family member access to samples to trace the genetic history of a disorder in their family to better determine which genetic mutation may cause them to have the disorder. If an individual has strong proprietary rights to that tissue, they may be able to exclude the family member from doing so.

This is a valid concern, however it can be met by developing a framework of property rights that builds on the divisibility of those rights and also takes advantage of the different types and levels of interests property can afford. Just as an ownership interest in land might be burdened by an easement that provides people with a right to use a path across it, so we could consider an individual's ownership of tissue open to an analogous burden that allows family members access in reasonable circumstances. The point is that though applying property bluntly might be problematic, drawing on its complexities and subtleties might enable us to benefit from its useful elements while offsetting potentially problematic implications.

It is arguable that applying the privacy framework described in Chapter Four might better deal with situations of the kind described above.⁹⁵⁹ However, to date this framework does not apply to tissue samples and hence the gap remains. Further, if

⁹⁵⁷ Magnusson, 'Proprietary Rights in Tissue' in Palmer and McKendrick, (eds) *Interests in Goods*, 25, 62.

⁹⁵⁸ R Magnusson, 'The Use of Human Tissue Samples in Medical Research: Legal Issues for Human Research Ethics Committees' (2000) 7 *Journal of Law and Medicine* 390, 391.

⁹⁵⁹ See Chapter Four, section 5.1.

privacy law were applied to tissue, in many ways it would resemble the kind of scheme described above that might be achieved using property principles. Therefore, it appears that there are some good reasons to use property law to address this problem in the absence of privacy laws which do so. Further, the property approach may be preferable for the other benefits it achieves, such as the provision of remedies and stronger control over the use of tissue, as described in other sections in this chapter.

5. LACK OF ADEQUATE REMEDIES AND PROTECTIONS

The analysis of the regulatory framework in Chapters Four and Five demonstrated that there are few remedies available to individuals whose tissue is misused. The Human Tissue Acts do not provide personal remedies for misuse of tissue nor for uses that go outside the original consent to the use of tissue. The ethical framework developed by the National Health and Medical Research Council may have sanctions to compel compliance, but does nothing to remedy harms done to individuals. The same can be said of the pathology and other guidelines examined in that chapter. This, coupled with the gaps in the general framework, means that it covers few other situations where tissue is used, leave those whose tissue is misused with no legal actions through which to seek remedies for the harms they have suffered. In addition, rightful possessors of tissue have little basis on which to seek compensatory remedies, or the return of tissue that is misused or misappropriated.

A major reason cited for allowing tissue to be property is that property law can provide more appropriate remedies for the kinds of harm that are suffered where tissue is misused.⁹⁶⁰ This section examines some of the remedies that would be available if misused tissue were deemed property. It also examines how the application of property law principles can better protect the interests individuals and institutions have in tissue.

The first argument in favour of a property approach in this context is that interests in property can be held out against anyone.⁹⁶¹ In particular, where tissue is taken and misused by people who are not party to the donation relationship established through the Human Tissue Acts, there is no clear means by which the source of the tissue can seek for it to be returned or, in some cases, for the misuse to be restrained. Were the tissue property, however, for the most part any person using that tissue without

⁹⁶⁰ See, eg, Huynen, 'Biotechnology', 539.

⁹⁶¹ Magnusson, 'The Recognition of Proprietary Rights in Human Tissue', 609–10.

authorisation from the owner would have breached the owner's rights over it and would be liable to an action for unlawful use.

The value of this lies in the ability of individuals and rightful possessors to bring actions where third parties interfere with tissue. For example, it would enable an individual to bring an action if an insurer unlawfully accesses samples for testing, or where a hospital retains possession of tissue without good reason and the individual wishes it returned to prevent uses to which he or she objects, or to have it interred.

A second argument is that if tissue were property, then the available remedies would be more appropriate to redress the sorts of harms people suffer when their tissue is misused. For example, Magnusson argues that where personal rights are breached, the law generally provides compensatory remedies, whereas proprietary rights can give rise to remedies that enable the interest to be recovered.⁹⁶²

If tissue were property, under tort law, actions would be open for trespass to chattels, conversion and detinue. Trespass to goods would institutions in possession of samples to bring an action where an individual directly interferes with its lawful possession of the sample, as trespass is a wrong to possession.⁹⁶³ This would provide remedies for pathology laboratories where samples have been misappropriated, and similarly assist commercial companies if valuable tissue-based resources are stolen (and that theft may also be open to criminal sanctions).

In situations where an individual wishes to restrain unwanted use of their samples in research, an action in detinue might be open to prevent continued unlawful retention of a sample of tissue. If the individual had property rights over the sample, and the researcher refused to return it but instead continued to use it in research to which the individual objected, detinue could be used to enforce the individual's right to possession. If successful, the court may order the return of the tissue or award damages,

⁹⁶² Ibid, 609–10. See also Andrews, 'My Body, My Property', 29.

⁹⁶³ *Penfold's Wines Pty Ltd v Elliott* (1946) 74 CLR 204, 224. The act may be intentional or negligent and is actionable *per se*. For an action in trespass to goods to succeed, the plaintiff must have been in actual or constructive possession of the good, or a right to immediate possession of it, at the time of the defendant's interference (see *Johnson v Diprose* [1893] 1 QB 512, 515). That interference must have been directly caused by the act of the defendant. The act itself must have been voluntary and either intentional or negligent. It is generally agreed that there is no requirement for actual damage to be demonstrated (*Demers v Desrozier* [1929] 3 DLR 401, 405 per Ford J; *William Leitch & Co v Leydon* [1931] AC 90, 106 per Lord Blaneburgh, but in relation to negligent trespass to goods compare *Everitt v Martin* [1953] NZLR 298, 302–3 per FB Adams J).

and the defendant may have the option of returning the object or paying damages.⁹⁶⁴ However, the court is not required to allow the option of payment, particularly where the object is unique.⁹⁶⁵ Therefore, given the uniqueness of tissue, the individual would likely be able to have it returned. As detinue and trespass may also give rise to a right to request a prohibitory injunction to prevent unauthorised dealing with the object,⁹⁶⁶ these actions could also be used simply to prevent uses of the tissue that the individual has not authorised.

Applied to the case studies, these actions might bring relief where samples are used in a way that the individual not longer agrees to (or did not in fact agree to), as in Case Study 15: Canavan Disease Research. The Greenbergs and others in the instance might have been able to use detinue to prevent further use of their samples in the research once they learned that the projected outcomes and future uses of the results were objectionable to them, if they had learned early enough before the research was complete and the test developed (at which point the tissue was no longer needed). John Moore, similarly, might have required the return of his tissue to prevent further research (see Case Study 14: John Moore's Spleen). Had he learned early on of the proposed use of his tissue, before the research had been conducted and the cell line created, this option might have been open to him. Alternatively, they might have sought an injunction to prevent further research using the samples.

These actions might also bring relief to families where organs or tissue have been retained following treatment or autopsy, if the proprietary interest in tissue can be said to pass to relatives upon death. This would have given the families of children whose organs were retained in Case Study 2: Organ and Tissue Retention following Post Mortem a means to compel the return of their children's tissue. The same could be said for Case Study 1: Collecting Aboriginal Remains, if the proprietary interest passed down the family line.

Alternatively, an action in conversion might be available. Conversion may be open where an individual destroys or uses up an object owned by another to the extent that

⁹⁶⁴ See, eg, *General Motors Acceptance Corporation of Australia v Davis* [1971] VR 734, 738–39 per McInerney J.

⁹⁶⁵ See *General & Finance Facilities Ltd v Cooks Cars (Romford) Ltd* [1963] 2 All ER 314 (CA), 650 per Diplock LJ.

⁹⁶⁶ See, eg, *Stanford v Hurlstone* (1873) LR 9 Ch App 116; *Petromin SA v Secnav Marine Ltd* [1995] 1 Lloyd's Rep 603.

the owner's right to possession is denied.⁹⁶⁷ Therefore, someone who takes tissue and refuses to return it to the rightful possessor may have converted it,⁹⁶⁸ as may someone who changes the nature of the tissue such as by preserving it.⁹⁶⁹ The source individual may sue for damages as well as request that the object is returned. The option of bringing such an action might be useful where tissue has been taken, preserved and retained (as in Case Study 2: Organ and Tissue Retention following Post Mortem), or where it has been misappropriated and used in a way such that its nature is changed (for example, unauthorised use of samples for commercial research).

A further benefit of allowing tissue to be property is that it may open up claims to unjust enrichment if the tissue is used to generate income without the individual's authority. This would allow the individual to claim a restitutionary remedy in equity, and might therefore aid those whose tissue is used to create valuable products without consent to such use.⁹⁷⁰

Finally, in the absence of privacy legislation covering tissue samples, the availability of actions that enable the return of samples, or injunctions to prevent further misuse, may be a useful means of protecting the samples' privacy. For example, if an individual learns that his or samples have been appropriated by an employer or a family member (who may seek to have them paternity tested), these actions could be used to prevent testing. This would prevent the generation of information, rather than requiring the individual to seek remedies only once personal information has been generated and the harm has occurred.

However, it has been argued that there is no need to resort to proprietary rights in tissue to ensure individuals and users of tissue are adequately protected. Skene has countered arguments that the law provides insufficient protections for people's rights over their bodies by arguing that one need not resort to property law, but rather strengthen the

⁹⁶⁷ *Penfolds Wines Pty Ltd v Elliott* (1946) 74 CLR 204, 229 per Dixon J. Ownership, as well as mere possession, may give rise to title to bring an action in conversion (although a right to future possession will not). Conversion is a tort of strict liability, therefore there is no requirement that the defendant should intend to deny the plaintiff's right to possession, only that he or she intentionally deal with the object in a way that does so. Conversion also requires that the person who takes the object must intend to make some use of them, or that by his or her acts, they are destroyed or consumed, in manner that denies the right of possession person who claims conversion (see *Fouldes v Willoughby* (1841) 151 ER 1153, 547 per Lord Abinger CB).

⁹⁶⁸ See, eg, *Upton v TVW Enterprises Ltd* (1984) 4 FCR 121.

⁹⁶⁹ See, eg, *Hollins v Fowler* (1875) LR 7 HL 757, 764, 768 per Blackburn J.

⁹⁷⁰ Huynen, 'Biotechnology', 548.

areas of law that already apply.⁹⁷¹ Her argument rests on a number of assertions about how the current framework already provides adequate protection. Tort law, she has suggested, protects the living body from interference through the tort of battery (as well as the criminal offence). Negligence requires medical practitioners to inform patients about the purposes for which tissue is removed, protecting them from unauthorised removals.⁹⁷²

To an extent, Skene is correct in this. There may be other areas of law that can be used to regulate misuse. However, two objections can be made. First, using a range of other laws to prevent misuse may exacerbate the current problem that the law dealing with tissue is piecemeal, with different approaches already taken in the legislation and case law. Turning to other areas of law is less effective than developing one, consistent and comprehensive approach like that which property law might provide.

The second response relates to the law of battery providing protection against unauthorised removal. While it would do so, it would not apply where the tissue was removed with consent, but later used for purposes to which the source did not consent, or by individuals not party to the consent relationship.⁹⁷³ In the absence of personal remedies provided under the Human Tissue Acts, there appears to be little remedy at law for such subsequent misuse, particularly where the tissue is later transferred to a person not involved in the removal. If the tissue were the property of the person from whom it was taken, however, actions would remain open against the third party misuser, for example in detinue or conversion.

In response to claims that the law does not protect against unlawful taking, and the desirability of individuals being able to bring actions in detinue and conversion, Skene has argued that it is in fact the wrongful use, rather than the taking that is the crux of the offence. The person from whom the tissue is taken does not, she has suggested, wish for it to be returned, but rather wants the misuse to stop and perhaps to gain some compensation. Hence, privacy law, rather than property law, provides a better solution to such misuse.⁹⁷⁴

⁹⁷¹ Skene, 'Arguments against People Legally "Owning" Their Own Bodies', 167.

⁹⁷² Ibid, 167–8.

⁹⁷³ See, eg, Magnusson, 'Proprietary Rights in Tissue' in Palmer and McKendrick, (eds) *Interests in Goods*, 25, 44.

⁹⁷⁴ Skene, 'Arguments against People Legally "Owning" Their Own Bodies', 168.

However, as noted previously, in some cases people actually do want the return of the tissue. For example, the parents in Case Study 2: Organ and Tissue Retention following Post-Mortem were more concerned to have their children's organs returned so that they can bury them decently, than they were with gaining some money to make up for the emotional distress they have suffered. The same applies to the Aboriginal communities seeking the return of remains in Case Study 1: Collecting Aboriginal Remains. Imagine also that tissue samples are stolen from the researchers in Case Study 6: Tissue in Australian Research. The samples are an integral part of research into which many hours of labour have been put, and perhaps are quite rare. These researchers would wish for the return of the samples to carry on the research, not simply monetary compensation. The same could be said for Orlan, as in Case Study 18: Orlan and Manipulation of the Flesh. Were a relic stolen, it is possible she would want it returned because of its uniqueness and perhaps particular emotional importance to her, rather than be paid out its potential market value.⁹⁷⁵

Skene has further argued that privacy and anti-discrimination law specifically could be used to deal with concerns about the misuse of genetic information derived from tissue testing.⁹⁷⁶ While this is true, such laws only work once the information has been generated and then protect its privacy. By contrast, a property approach that prevents the use of the tissue in the first place might in some instances work to prevent the generation of the information at all. It might therefore be possible to prevent the misuse occurring at all, rather than later punishing the misuse once the harm is done. For example, imagine that an employer unlawfully takes samples from employees and plans to have them genetically tested and determine whether to terminate some individuals' employment. If this act is learned about prior to testing, an individual might seek an injunction to prevent his or her personal information being revealed through the testing and hence better protect his or her privacy. This would also prevent possible leakage of information, whereas discrimination law would only operate once the employer generated and used the information unlawfully.

Allowing tissue to be property to make actions for unauthorised dealing with goods available may also be criticised as this might give rise to a raft of cases where individuals bring actions against researchers or companies that use their tissue to make profits

⁹⁷⁵ Skene does, however, concede that there are instances where the individual may prefer the return of tissue which would be possible only if the tissue were property. See *Ibid*, 168, note 15.

⁹⁷⁶ *Ibid*, 168.

without consent. This might undermine research and medical advancements by requiring researchers or companies to pay large sums in damages, potentially also driving up the price of therapeutics. This would of course be counter the community's interest in accessing affordable therapeutics.

It is, however, unlikely that this would occur because the courts, particularly in Australia, are not likely to award large sums in damages unless the tissue in question is rare, or unless significant actual harm is suffered by the individual (rather than simply a sense of injustice at not sharing in profits). Jeffrey Potts notes that most tissue has little intrinsic value, and hence compensatory damages will generally be low.⁹⁷⁷ That is, generally each tissue sample used in research is not in itself valuable because most research does not rely on rare tissue that the market would value tissue highly if it were saleable. Therefore, as Potts argues, the possibility of according tissue property status leading to cases of individuals successfully suing researchers or companies for large monetary sums is not a strong policy argument for rejecting pro-property arguments.

This section demonstrates that there may be instances in which deeming tissue property will provide harmed individuals with greater options for legal redress. There are also valid arguments that the law already protects individuals sufficiently. However, in some instances individuals do wish to gain access to their tissue, as the examples given above demonstrate. The personal remedies currently available, such as for the emotional distress they may suffer, would provide only damages to compensate the harm. This would not give them the solution they want, whereas the actions open if tissue were property would. Further, in the absence of a comprehensive privacy regime that also covers samples (which might form a solution in many of the instances raised in this section) there is a need for individuals to have access to injunctive relief to prevent unwanted uses of tissue. Property law, unlike the current framework, could provide this and therefore on balance is preferable to the present dearth of options for those seeking legal solutions to their concerns.

6. INABILITY TO RESPOND TO NOVEL USES

One particular point that can be drawn from the analysis of the case law in Chapters Six and Seven is that the courts have struggled to deal with new uses of tissue that are not

⁹⁷⁷ J A Potts, 'Moore v Regents of the University of California: Expanded Disclosure, Limited Property Rights' (1992) 86 *Northwestern University Law Review* 453, 492.

regulated. For example, in both *R v Kelly* and *Roche v Douglas* the courts were presented with situations not contemplated by the legislative framework in either the United Kingdom or Australia. Both resorted to property concepts to address these situations, but the point to be drawn is that they had to do so because the current framework is not amenable to developing solutions to new problems raised by tissue use.

The current framework is focused on regulating tissue use for research, transplantation and therapy, and forensic use by police. However, as Part I demonstrated, tissue is also used to develop commercial products and valuable therapeutics (as an input to research that results in saleable products, as in Case Study 13: Bionomics), to create valuable intellectual property (as in Case Study 15: Canavan Disease Research) and to create works of art or non-medical products for sale (Case Study 18: Orlan and Manipulation of the Flesh; Case Study 17; Star Gene). These uses, and particularly the possibility that it may be reasonable for individuals to require monetary compensation for tissue use or to be able to establish a benefit sharing arrangement with researchers, are not covered by the regulatory framework.

These gaps have already been discussed. This section argues that because the current framework is both specific and based on a consent model between donor and researcher, it cannot accommodate other situations outside such a consent relationship. There is no clear extrapolation to be made between the consensual donation of tissue from an individual to a hospital for transplantation, and what should be done where a family member takes a sample from a relative to have it tested for paternity. Similarly, there is not clear means to extrapolate what should be done to regulate a mutually accepted benefit sharing relationship such as that established in Case Study 16: Ted Slaving and Diagnosing Hepatitis.

This occurs because the current system is not based on a set of clear principles that can be applied regardless of the situation. Rather, it is based on directives about how tissue should be used in certain, defined cases that differ to greatly from other situations that may arise. This makes it difficult, if not impossible, for these directives to be imported across to other, dissimilar fact situations. The current framework therefore lacks the flexibility to expand to cover new uses or new issues that arise.

By contrast, property law could provide a principled basis, as it outlines rights and duties for each party involved, and allows for overlapping interests arranged hierarchically.

These rights would apply across situations, and hence in any novel situation it would be clear what rights each party would have to the tissue in question. This could form a starting point for thinking about how the tissue should be dealt with, and modified or constrained as appropriate.⁹⁷⁸

7. ADVERSE IMPLICATIONS OF A PROPERTY APPROACH

Within the debate on the body as property, an often cited objection is that according all tissue full property status once excised will lead to problematic consequences. These implications include the problems that may arise in relation to whether tissue has been abandoned and what others may do with such tissue,⁹⁷⁹ concerns about commodification,⁹⁸⁰ and concerns about the implications of tissue being passed by will or open to the same laws controlling the fitness of goods for supply.⁹⁸¹

The abandonment concern is certainly valid, and there may be a range of difficult consequences of applying property from this perspective. Where tissue is abandoned, the finder of the tissue would acquire at least possessory title sufficient to support a claim in conversion or detinue against third parties who later gain unauthorised possession of the tissue.⁹⁸² This would potentially allow finders to use tissue as they chose, including testing it in a manner that would invade the privacy of the source individual or using it in objectionable research. Conversely, if tissue is property and is discarded, but not abandoned, unauthorised dealing with that tissue would then contravene the rights of the owner (unless it can be shown to have been legally abandoned). This could lead to absurd results, such as leaving a person cleaning the floor in a barber's shop open to an action for unauthorised dealing with the leftover hair.⁹⁸³

However, this concern is not fatal to the property approach. If a property approach

⁹⁷⁸ Similarly, a principled system like that provided by privacy legislation in Australia might also be a workable approach, though as noted previously the application of privacy law to tissue in this way might actually resemble a property system in this instance. Also, there remains considerable resistance to applying privacy law to tissue samples in Australia and this option is therefore less likely to be accepted.

⁹⁷⁹ See, eg, P Parker, 'Recognizing Property Interests in Bodily Tissues: A Need for Legislative Guidance' (1989) 10 *Journal of Legal Medicine* 357, 365.

⁹⁸⁰ See, eg, D Mortimer, 'Proprietary Rights in Body Parts: The Relevance of Moore's Case in Australia' (1993) 19 *Monash University Law Review* 217, 254.

⁹⁸¹ Skene, 'Arguments against People Legally "Owning" Their Own Bodies', 169–170.

⁹⁸² *Armory v Delamirie* (1722) 93 ER 664. Possession will create a form of possessory title that can be held out against others except those with better title. See *Russell v Wilson* (1923) 33 CLR 538, 546 per Isaacs and Rich JJ.

⁹⁸³ See, eg, Parker, 'Recognizing Property Interests in Bodily Tissues', 365.

were taken then a legal understanding of abandonment in relation to tissue could be developed that takes account of the potential harms of allowing any new possessor to gain proprietary rights over it. This might involve taking an adapted approach to notions of legal abandonment where tissue is the property in question, to offset these problems. Were tissue property, it could be argued that the courts should (and would) not infer abandonment of tissue lightly. Rather, they would take account of the particular characteristics of tissue that mean the doctrine of abandonment should apply differently to discarded tissue.

The courts are perhaps likely to do so if they take account of the fact that people have strong personal links with their tissue and it is apparent from the events at Alder Hey and the Bristol Royal Infirmary that people do care what is done with their body parts and those of others and therefore are unlikely to have abandoned them unconditionally. Further, the general populace probably understands to some extent that their tissue contains DNA which can reveal information about them. These two factors suggest that it is unlikely that people wholly intend to abandon their tissue, and probably given this the courts will not generally infer abandonment. Also, as Diana Brahams has pointed out, the courts have in the past been reluctant to infer abandonment. For example, as she notes, golf balls lost on a golf course⁹⁸⁴ and refuse in a rubbish bin were not found to have been abandoned.⁹⁸⁵

In the rubbish bin case, *Williams v Phillips*,⁹⁸⁶ it was held that although the refuse had been discarded by the householder who placed it in the bin, it was not abandoned. Instead, it remained the householder's property until removed by the garbage collectors, who then gained property rights over it. It is possible that given the strong interest of an individual in the fate of his or her tissue, and the consequent unlikelihood that he or she would completely abandon it, that the courts might follow this approach. This is particularly likely because, as Brahams has argued, when their tissue is removed people most likely expect it will be decently disposed of (such as tissue removed during surgery) and have this expectation of its fate, rather than a general intention to abandon it and hence allow it to be dealt with in any way by any person who gains possession.⁹⁸⁷

⁹⁸⁴ *Hibbert v McKiernan* [1948] 2 KB 142.

⁹⁸⁵ *Williams v Phillips* (1957) 41 Cr App Rep 5. See D Brahams, 'Bailment and Donation of Parts of the Human Body' (1989) 139 *New Law Journal* 803, 803.

⁹⁸⁶ (1957) 41 Cr App Rep 5.

⁹⁸⁷ Brahams, 'Bailment and Donation of Parts of the Human Body', 308.

In addition, in the case of tissue it may be possible to limit what may be done with tissue even if it is abandoned. Again, as tissue is unique and retains links to the person from whom it was taken that other items of property do not, it may demand an adapted and somewhat unique legal approach. Therefore, tissue that has been abandoned might only be able to be used in de-identified form for research but not for testing that may reveal information about an identified person.

A related concern raised by Skene is that allowing tissue to be property could mean that all property of an individual passes upon death, including stored tissue, organs and surgical waste. This would mean a hospital holding the material would be required to consult with the beneficiaries about how to deal with the stored material. The hospital would also have to gain consent from all patients to dispose of tissue. Denying the hospital ownership of stored tissue is inconsistent with the hospital's ownership of clinical records. Further, she has argued that a donor of tissue might then be held liable for the supply of a faulty product if it is transplanted.⁹⁸⁸

In relation to Skene's point, tissue held by the hospital could be regarded as held under the terms of a bailment, and hence its continued possession might remain lawful although a gratuitous bailment would cease upon the death of the bailor. Alternatively, the tissue might have simply been transferred as property by will but the hospital's right to possession might reasonably remain and simply affect the proprietary rights of the new owner. It should also be noted, however, that allowing tissue to pass by bequest would provide the beneficiaries with a means to ensure the property burial of any such retained organs, which particularly for Aboriginal people might actually be desirable. It should also be noted that requiring consent to continue using these organs is not necessarily to be regarded as problematic, though it may place significant administrative burdens on the hospital. Further, legislative restrictions on the passing of tissue by bequest could be created if the problematic consequences of this aspect of tissue being property outweigh the important controls they may afford the individual's relatives. specific legislative provisions dealing with tissue removed and disposed of following surgery or held by hospitals generally, could be developed to meet Skene's objection. As such, this objection is not fatal to the efficacy of a property law approach.

Second, it is not necessary that simply because tissue is treated as property, potentially

⁹⁸⁸ Skene, 'Arguments against People Legally "Owning" Their Own Bodies', 169–170.

even only limited property, that it must also be regarded as a good and subject to the same requirements. However, the property approach could be tempered by excluding this supply of some tissue, such as transplant organs, from sale of goods legislation. For example, the organ could pass as property to the hospital that transplants it (giving it a right to possession that would protect the organ from unlawful taking) but once the organ is to be transplanted it is subject only to the controls that are currently, successfully, applied as transplantation protocols.

Others, such as Debra Mortimer, have argued that 'granting proprietary rights over an object inevitably draws that object into the commercial arena as the value in granting such rights lies in the ability of the subject to transfer ownership of that object for reward'.⁹⁸⁹ This view reflects quite a subtle argument against allowing property rights in tissue that holds there are concepts which society associates with a property regime. In particular, we associate the ability to sell and earn money with the notion of property. Joan Gilmour has suggested that these concepts are so strongly associated, that categorising something as property 'imports with it market concepts ... [and] carries with it an expectation of a market model and market behaviour as the norm'. Gilmour has argued that it is therefore quite difficult to disassociate these concepts and that people perceive their entitlement to body parts as somehow diminished if the right to sell or earn money from them is precluded, that people will in fact feel that some right has been taken away from them, despite the fact that they never actually had it in the first place.⁹⁹⁰

One response is that it may in fact be reasonable that in some circumstances individuals should be able to sell their own tissue. Another is that concerns about commodification of individuals due to commodification of their tissue are unfounded, as it is difficult if not impossible to show how an attitude towards tissue will actually shift and become an attitude towards people. These arguments against allowing tissue to be property are linked with more specific concerns about commodification where tissue is sold. Therefore, they are considered in more detail in Chapter Twelve, section 2.3, which examines concerns about commodification in the wider context of issues around commercialisation of tissue.

⁹⁸⁹ Mortimer, 'Proprietary Rights in Body Parts', 254.

⁹⁹⁰ J M Gilmour, 'Our Bodies: Property Rights in Human Tissue' (1993) 82 *Canadian Journal of Law and Society* 113, 132.

While there are some valid concerns that there may be adverse implications if property law concepts are applied to tissue, they do not appear to be fatal to arguments in favour of allowing tissue to be owned. Particularly given the many benefits of applying property law to tissue outlined in the foregoing sections, it appears that on balance these concerns are not significant enough to undermine arguments in favour of deeming tissue property. Rather, they demonstrate that to some degree property law as it stands will not provide an unproblematic solution to the challenges of tissue regulation. Given the benefits of applying property concepts to tissue, they simply demand that we draw on the inherent flexibility of property law to adapt it to suit the needs of tissue regulation and that we temper its problematic implications by developing new or different ways to deal with tissue within a property framework as necessary. Where appropriate, we should limit property rights in tissue, or burden them with other requirements, but these concerns are not serious enough to justify wholly rejecting the many valuable ways in which property law might assist in regulating tissue use.

8. ESTABLISHING PROPERTY RIGHTS IN TISSUE

If we are to accept a property approach, there are a number of ways it could be implemented and property rights derived and assigned. It is not, however, the purpose of this thesis to delve into these deeply. Rather, a number of models for establishing a basic property approach are presented and appraised to demonstrate how it might be feasible to begin applying property law to tissue. Any number of approaches might be taken, based on who is best regarded as an appropriate owner and what kinds of rights are deemed applicable to tissue, including whether tissue should be saleable. These include according individuals property rights upon excision, allowing hospitals to gain rights through the application of work or skill, deeming tissue a form of community-owned property and creating an inalienable property interest in tissue that vests in the source individual.

The point of outlining these possible approaches is to show that property law can be used in a range of ways to accord rights to different parties and in different combinations. The point is also to show that it is flexible and that the rights to be accorded can be shaped to fit the most accepted approach and address commercialisation as seen fit. This will demonstrate that property law has the capacity to provide an approach adapted to the specific needs of a regulatory framework for tissue use that can take account of the range of issues and problems highlighted in this thesis. The feasibility and effectiveness of some of these approaches also further supports the

general argument in this thesis that property law could successfully be used to regulate tissue use.

8.1 Creation of Property through Work or Skill

One possible property approach would be to draw on the approach taken in the cases and hold that an act of work or skill on lawfully possessed tissue may give rise to proprietary rights in that tissue. This approach is desirable from a pragmatic perspective, as it would afford researchers and hospitals good protections for the samples they legitimately obtain.⁹⁹¹ They would gain possessory rights as well, potentially, as rights to use, transfer and so on that would enable them to use tissue for research securely. This would also promote community interests by aiding research and hence assisting the development of new tests and therapies.

The major objection, as Magnusson has argued, is that this would produce rather unjust results, as researchers would gain the benefit of possessory rights, while the donor of the tissue would not gain such benefits.⁹⁹² The work and skill approach tacitly assumes that the rights of researchers or hospitals should be placed above those of others. The cases given above in this section, as well as the many other examples of people's legitimate concerns about the use of their tissue given in Part I demonstrate that this is unjust in many situations. It is unjust to exclude the individual from directing how his or her tissue is used, given the personal connection he or she has to tissue. The rights afforded the researchers or hospital would also be greater than those of the individual, and hence may leave open situations in which the individual's capacity to restrain objectionable use of the tissue would be unreasonably limited.

The other objection is that these possessory rights could be held out against families and indigenous communities who validly seek access to tissue samples, or who want their relatives' remains interred. In the situation described in Case Study 1: Collecting Aboriginal Remains, this approach would further undermine the capacity of the Aboriginal communities seeking the return of remains, as it would give the museum a clear, strong right to possession while the community would have none. This would not only make their attempts to have remains returned more difficult, it would give legal

⁹⁹¹ For a discussion in favour of an approach of this kind see Skene, 'Arguments against People Legally "Owning" Their Own Bodies', 173. Skene has argued that 'it is possible to reconcile the recognition of a proprietary right in favour of third parties but not in favour of the person from whom a body or body parts came, or next of kin, if such a principle is found to be necessary'.

⁹⁹² Magnusson, 'The Recognition of Proprietary Rights in Human Tissue', 623.

sanction to the view it more important that the museum hold the remains to educate the public, than it is for the cultural beliefs of Aboriginal communities to be respected. The same argument would apply in relation to Case Study 2: Organ and Tissue Retention following Post-Mortem, where the hospital would be given a right to retain organs that trumps the families' need to see their loved ones' remains treated with respect and interred.

Finally, there is no clear explanation of why working on an object gives rise to proprietary rights in it. As Chapter Ten discussed, there are serious concerns with the Lockean labour approach to property creation in relation to tissue. Labour theory relies on an object initially having no owner and all people having equal rights to use it. With tissue, this is not the case as at least one person—the individual from whom it was taken—has a greater interest in that tissue because of the emotional linkages he or she has to it and the privacy concerns the DNA it contains raises. Consequently, there needs to be a better reason for work and skill application to give rise to proprietary rights.

While the work and skill approach to deriving property rights may be accepted on the basis of pragmatism, overall the model should be rejected for its failure to adequately respect and promote individual interests, for placing researcher and hospital interests over those of other who may legitimate claims to tissue and because it lacks a sufficient logical basis as a derivation of rights.

8.2 Creation of Property at the Moment of Excision

Another approach is to hold that tissue becomes property at the moment of excision, and that proprietary rights over tissue vest in the individual from whom it has been removed. This approach has a number of strengths. First, this approach takes as its fundamental starting point the recognition that upon excision, the individual has the greatest interest in tissue. This gives legal force to the idea that individual autonomy should be upheld and respected. By achieving this through property principles, the individual's initial rights will remain the strongest rights in the tissue until either the individual chooses to transfer some or all of his or her rights, or other countervailing laws vest rights in others. It also ensures that the person from whom tissue is taken has a claim against all others regardless of the circumstances in which it was removed because that claim will not be dependent on the relationship between the individual and the person who has possession of the tissue. Further, this approach accords with ethical and legal regulations on donation of tissue (for research) by giving the individual, rather

than others, the initial capacity to choose what is done with his or her tissue.

Second, it can be seen as an extension of the protections the law already accords individuals against interference with their living bodies, such as the criminalisation of rape and assault. This is particularly important given that almost all detached tissue will contain DNA that is unique to the source individual, and which can reveal personal information about that person. In the same way that rape interferes with our bodily integrity, misuse of our excised tissue can offend our psychological connection with our body and invade our privacy if it is tested to reveal personal information. These interferences are in some way analogous to interferences with bodily integrity, and hence it is rational to extend similar protections to detached tissue as the law already provides for intact living bodies.

This approach also recognises that of all parties who may have an interest in tissue, the individual has a greater inherent interest in it than others due to the intimate psychological, as well as physical, connection between the individual and his or her tissue. In addition, it protects a person's natural expectation that he or she has the 'first option' on the detached part.⁹⁹³ In this sense, allowing the individual property rights over their parts accords with the assumption people already seem to make that their body is their own.⁹⁹⁴

From a practical perspective this approach is appealing too, as it avoids the complexities of the common law approach that requires work or skill to be done before rights will arise. Determining what equates to sufficient work or skill has already challenged the courts and the question has not been decisively settled. Given the variety of uses of tissue, requiring work or skill to be applied may become a particularly vexed issue if it is made the basis of the creation of rights. Allowing individuals initial rights in tissue would avoid this difficulty.⁹⁹⁵

A major objection to this approach is that it will leave anyone dealing with abandoned tissue open to possible legal sanction, as the tissue will be property the moment it is excised and unauthorised dealing with that tissue will constitute a breach of the individual's proprietary rights. This issue has been dealt with above in relation to

⁹⁹³ Huynen, 'Biotechnology', 540.

⁹⁹⁴ This issue is explored in James Harris's work on 'body-ownership rhetoric'. See further Harris, 'Who Owns My Body?', section 3.

⁹⁹⁵ Huynen, 'Biotechnology', 540.

concerns about abandonment.⁹⁹⁶

It may also be argued that this approach would undermine research, as individuals who can sell their tissue (if they have strong individual property rights) may require researchers to bid for their valuable tissue, and hence raise the cost of research. This argument is considered and dismissed in Chapter Twelve, section 2.4, as the ability to sell tissue is unlikely to create a real obstacle to tissue use. The right to sell could also be excluded from the rights that vest in the individual upon excision of the tissue if concerns about undermining of research are regarded as serious, without rendering this model ineffective or unworkable.

Finally, it could be argued that these rights may be too strong, and may undermine free sharing of tissue for research or retention in hospitals for teaching. That is, if individuals must always be contacted for permission to use tissue then free-sharing of material will be hampered. However, this argument could be addressed by limiting individual rights as necessary, or overlaying a legal regime along the same lines as the National Statement that allows for the effective use of tissue in research. Also, tissue being the individual's property does not mean it cannot be donated and used in research, it just requires that the terms of that donation clearly define which property rights pass. In effect, it really just requires us to be clearer and more open about what occurs when tissue is donated. This kind of regulation would simply reflect the ethical guidelines already in place that require consent for all research uses, including subsequent uses, of tissue except where tissue is de-identified. Concerns about breach of proprietary rights where de-identified tissue is used could be met through legal restrictions on rights over tissue that has been consensually de-identified or abandoned.

8.3 Property arises from the Authority of the Donor

Skene has suggested an alternative to the creation of property rights that vest in the donor which takes a fairly pragmatic approach. She has argued that proprietary interests should vest in favour of third parties arising from the authority by which the body parts were acquired. This would include the authority given by consent to removal and donation, statutory authorisations (such as those provided in the Human Tissue Acts and laws regulating coronial autopsies) or legislation legalising the taking of samples for

⁹⁹⁶ See section 7.

testing for police purposes.⁹⁹⁷ Her argument is that this authority

could be regarded as converting something that was not previously property (namely body parts and tissue that are still part of the body) into something that is property, and over which the person who lawfully acquires it has property rights.⁹⁹⁸

The extent of these rights will be determined by the context. The new possessor will have full ownership of the tissue, limited by an executor's right to possession for burial. Where the tissue is obtained without consent, these proprietary rights will be limited only to the purpose for which it was lawfully obtained.⁹⁹⁹

This approach is subject to the same objections made to the work and skill approach. It ignores the individual's greater claim to the right to determine what is done with his or her body. Certainly, it allows for the excised tissue to be used as the consent provides, but it goes further than this and suggests that this consent gives rise to far greater rights to use than the original consent does. There is no clear justification for this, beyond the pragmatism of allowing hospitals, researchers and other lawful possessors greater rights to use the tissue in ways which may benefit the community. But while this is an attractive argument, it should be rejected because it does not take into account the valid interests of the individual in controlling what happens to his or her tissue; respect for the autonomy of the donor is subjugated to the need to promote medical research and other beneficial uses of tissue.

There is, however, no need for this subjugation. Instead, taking the creation of rights at the moment of excision approach, consent to use could still be given, but further consent required for future research use. This could be given at the time of donation, and if obtained, this would legitimate future uses. If withheld, then this would demonstrate that the researchers should not have such strong rights as this property approach would provide, as they would conflict with the desires of the individual. Therefore, the same goals could be achieved by the creation at excision model without the subjugation of individual interests in tissue promoted by the model posited by Skene.

Skene's approach is problematic also because it fails to provide individuals with any rights to restrict uses of tissue that are objectionable, including the use of tissue to

⁹⁹⁷ Skene, 'Arguments against People Legally "Owning" Their Own Bodies', 175.

⁹⁹⁸ *Ibid*, 175.

⁹⁹⁹ *Ibid*, 176.

invade his or her privacy. This approach is in fact worse than that provided under the Human Tissue Acts, as rather than simply leaving it open whether future use is lawful, it explicitly removes all future rights of the individual in favour of others. It also means that the lawful possessor will have greater rights than relatives and indigenous groups who, as already noted above, may have valid reasons for accessing tissue.

8.4 Common Property

Another approach, suggested by Randy Marusyk and Margaret Swain, is that tissue could be regarded as common property of all people once removed, and individual rights would vest only once tissue had been lawfully appropriated and used to produce something of value.¹⁰⁰⁰ This approach is focused on promoting the community's interest in access to tissue for research above source individual control of tissue.

There are a range of objections that can be levelled at this approach. First, it ignores the fact that one person, the person from whom the tissue was taken, has a greater interest in it than others. Second, it does not include any means to take account of the personal connection between an individual and his or her tissue that may make non-consensual use of their tissue objectionable and harmful to them. Third, it allows for widespread use of tissue without addressing the many good reasons individuals have for wanting to control what is done with their tissue.

Finally, as Harris has argued, tissue cannot properly be dealt with as common property, as it can only be used by one person at a time.¹⁰⁰¹ As Harris has put it

The consequence of refusing ownership to anyone is not, as with information in the public domain, 'common property'. Information can be used by anyone simultaneously, without treading on each other's toes. It could hardly be suggested that separated bodily parts should be permanently open to a common scramble. Trespassory rules are obviously required.¹⁰⁰²

What this approach would really entail is a community right to use tissue, which is then used on an individual basis. This approach is really no different from other approaches to property in tissue, except that it unreasonably excludes the individual from consenting to that use. Harris has, however, suggested that as an alternative there could be some form of quasi-ownership interest vesting in the community, where the source of tissue retains a 'mere property' interest and a public organisation has quasi-property

¹⁰⁰⁰ Marusyk and Swain, 'An Alternative to Property Rights in Human Tissue', 13ff.

¹⁰⁰¹ J Harris, *Property and Justice*, Clarendon Press, Oxford and New York, 1996, 351.

¹⁰⁰² *Ibid*, 351.

rights to exploit tissue to generate income for the community.¹⁰⁰³ This approach might alleviate some of the concerns with this approach, but it would still provide the individual with unacceptably little control.

8.5 An Inalienable Property Interest

However, one approach that has not been raised in the literature is that of creating some form of inalienable proprietary interest vesting in the individual to account for his or her ongoing relationship to excised tissue. Tissue would be property, and others could exercise varying rights over it, but these would remain burdened by the interest. This would clarify the status of tissue, the rights of others over it and provide a principled, comprehensive approach while always maintaining some level of protection for the individual. For these reasons, this model is favoured.

In *National Provincial Bank v Ainsworth*, Lord Wilberforce held that a property right must be definable, identifiable by third parties, have some degree of stability or permanence, and be capable of assumption by third parties.¹⁰⁰⁴ The interest proposed here is a novel interest, designed to take account of the unique aspects of tissue, most particularly the genetic link that will always remain between an individual and his or her body parts. Hence, it is suggested that this interest should be defined as an interest in the acceptable use of tissue, where notions of what is acceptable could be developed by the courts or more effectively via legislation. It should be identifiable to third parties by its clear establishment on the basis that it protects individual genetic privacy and the emotional and psychological links between people and their bodies. It would be identifiable because it would vest, inalienably, in all people in any tissue that is removed from them. However, it should not be capable of assumption by third parties, as they do not and cannot possess the relationship with the tissue that the individual has. This should also be the case because the interest is directed at providing ongoing protection to the individual's privacy and autonomy. Here, the uniqueness of human tissue should be a justification for taking a somewhat unique property approach.

The interest should give rise to limited actions that may enable the individual to seek the kinds of remedies that should be available when tissue (as property) is misused. For example, it could be used to establish a better claim to samples or remains held in hospitals or museums that are simply storing that tissue, rather than using it in

¹⁰⁰³ Ibid, 359.

¹⁰⁰⁴ *National Provincial Bank v Ainsworth* [1965] AC 1175, 1247–8 per Wilberforce L.

accordance with a defined consent relationship. It would give individuals a basis on which to claim the return of their tissue, or to prevent its further use, while still enabling others to use that tissue. The interest should be proprietary, rather than personal, so that it can be held out against all the world and also to ensure that proprietary remedies are available to ensure that the individual can seek the return of tissue. The interest should, however, be limited to enable uses that are legislatively sanctioned. It should also be constrained by some form of reasonableness requirement for the grounds on which misuse is alleged. It should allow for abandoned tissue to be used, but only within the constraints of what is determined reasonable, for example, where an HREC has given approval to the use of de-identified tissue.

Such an approach could be supported through the reasoning developed by Harris. Harris has argued that property rights cannot simply be created by the act of excision, but instead could be based on the creation-without-wrong model.¹⁰⁰⁵ On this model, a person who creates a new object of social wealth and wrongs no one should be given some property rights over that new object.¹⁰⁰⁶ For example, the creator of a literary work or piece of music acquires by that act, ownership of the copyright in it.¹⁰⁰⁷ It would be possible to make arguments that the individual, having taken care of his or her body over time, created the tissue from which a sample is removed. Alternatively, in consenting to the removal of his or her tissue, the person has acted in a way that causes the creation of the new object.

Harris has noted, however, that such an act should not give rise to the full gambit of property rights, but only make concrete those that are an extension of the protections already afforded to the living body in the form of protections from interference.¹⁰⁰⁸ This reasoning would support the creation of the interest suggested in this section, as it does not equate to full property rights, but only to those rights or interests needed to ensure that the excised tissue is treated with the same respect the law already requires to be shown to individuals' living bodies through prohibitions on rape, assault and the like.

9. CONCLUSION

Harris has suggested that one of the attractions of speaking about body parts as

¹⁰⁰⁵ Harris, *Property and Justice*, 357, 359.

¹⁰⁰⁶ *Ibid*, 357–8.

¹⁰⁰⁷ F H Lawson and B Rudden, *The Law of Property*, 2nd edn, Clarendon Press, Oxford, 1982, 46.

¹⁰⁰⁸ Harris, *Property and Justice*, 358.

property is that 'invocations of body-ownership may add pithiness and force to what would otherwise seem laboured and tame'¹⁰⁰⁹ However, property law has many other practical attractions as well. It is flexible; it can be developed through the common law to accommodate novel situations; it can be adapted to take account of the differing issues surrounding various tissues, the contexts in which they may be used and the interests that people have in them. Property law can divide rights between a number of parties, enabling it to represent a variety of intersecting interests, while still retaining the consent-based requirements of the current approach.

Deeming tissue property would create a baseline position on how tissue may be treated subject to legislative exceptions and judicial development. Such an approach is preferable to creating rules for use that apply only in specific circumstances, as is now the case. The current approach merely forces the courts to deal with novel uses and problems by drawing tenuous analogies with the circumstances contemplated in the legislation. This latter approach also forces the courts to turn to legal fictions and gloss over the legal vacuum to achieve a just and commonsensical result. That tissue is not property and hence cannot really be stolen most tellingly exemplifies this problem. Using property law to regulate the use of tissue would enable the courts to incrementally build a body of effective law in response to the ever-expanding role of excised tissue in medicine, science, industry and personal life. Where required, the legislature could constrain or alter the rights provided by property to offset problematic implications of the approach.

¹⁰⁰⁹ Ibid, 184.

Chapter Twelve

THE COMMERCIALISATION DEBATE

The biotechnology revolution has moved us, literally or figuratively, from the class room to the board room and from the New England Journal to the Wall Street Journal.

Leon Rosenberg¹

This chapter examines the issue of commercialising tissue. As noted in Chapter Four, the Human Tissue Acts generally prohibit the sale of tissue and organs, except where ministerial approval has been given, or where that tissue has been processed and is sold for therapeutic or scientific purposes in accordance with the directions of a medical practitioner.² However, despite this, both in this country and elsewhere, the question of whether human tissue should be able to be sold remains a matter of some debate. Often, this question has been considered in conjunction with whether human tissue should be property, and the commercialisation debate can be considered an important subset of the general body as property debate.

The goal of this chapter is not to enter into this debate and to take a stance on whether it is acceptable for human tissue to be saleable. Rather, this chapter examines the commercialisation debate to analyse how this issue affects the general debate about whether tissue should be property. The debate is complex, particularly because the issues surrounding the sale of tissue may differ based on the type of tissue to be sold (for example, whole organs as opposed to blood) and the context and purpose of that sale. There are also arguments for and against sale that apply generally across contexts. To impose some order on the issues to consider in relation to the debate, this chapter first considers a range of arguments in favour of selling tissue and some responses to them. These include the fact that tissue is already sold, but in a relatively unregulated manner, the promotion of individual autonomy, the possibility that sale may increase the supply of needed tissue and organs, and the desirability of allowing tissue owners the ability to share in the financial benefits of research. It then examines a number of the

¹ L Rosenberg, 'Using Patient Derived Materials for Product Development: A Dean's Perspective' (1985) 33(4) *Clinical Research* 452, 452.

² See Chapter Four, section 4.

major objections to tissue sale and again some responses. These objections include concerns about a decline in altruism, the dangers of commodification, the potential for coercion and self-harming, and the possible detrimental effects of tissue sale on the doctor/patient relationship and on research. This chapter then draws conclusions about how the debate overall affects the question of whether tissue should be dealt with as property.

1. ARGUMENTS IN FAVOUR OF COMMERCIALISATION AND SOME RESPONSES

1.1 Clarification and Regulation of Current Practices

Arguably, the current legal approach to human tissue does not adequately address the continued incursion of commercial values and treatment into the various spheres of tissue use. As already noted in Part I, tissue is sold or used to generate financial returns in many circumstances. Human tissue is entering the commercial sphere at an increasing rate, as the many examples provided in Part I demonstrated. It has become a commodity in itself in other nations, like the tissue sold by Ted Slavin to produce hepatitis tests in Case Study 16: Ted Slavin and Diagnosing Hepatitis, and it may be that Australia should take a similar approach. In the Australia context, tissue is an important resource for research that generates valuable intellectual property, as in Case Study 13: Bionomics. It also leads to medical advances, as in Case Study 6: Tissue in Australian Research, that may be translated into income-generating products. In instances of this kind, it may be that allowing researchers to offer to buy tissue will increase supply where necessary and hence increase medical advances, benefiting the community. In light of this, the general prohibition on sale in Australia may no longer be sufficient in scope or in subtlety for a number of reasons.

In addition, esoteric commercial uses are also emerging that are presently precluded, such as in Case Study 17: StarGene where celebrity DNA is sold to fans, and as in Case 18: Orlan and Manipulation of the Flesh, where artworks created from human tissues that may be sold. In many ways, income is generated from human body parts, directly and indirectly. A general prohibition may no longer reflect the value we place on tissue in different contexts, and the situations in which we do tolerate the use of human biological materials to generate income. We might well accept that Orlan may turn her own body into artworks, and if other artworks may be sold, then why not those? One might particularly argue that the emotional input into a painting bears much

resemblance to the psychological connection she has with her body parts—it appears odd, then, that she may sell one but not the other. This is particularly odd, arguably, given one may sell one's hair to make a wig—the legal approach at present seems to deal with areas in which sale is relatively unobjectionable by turning a blind eye. As more sales that do not offend general community morality emerge, it may be that this approach is insufficient.

Finally, and this reason is more specifically related to the property question, by allowing sale in some contexts (such as processed tissue for therapeutic use) but not allowing tissue to be property, that tissue sits in a legal void because its lack of property status excludes it from many of the legal rules governing sale and dealings with commercial property. Does tissue of this kind always fit within the definition of a 'good' for the purposes of sale of goods legislation? Need it be fit for purpose? Upon sale, what rights does the buyer acquire—the right to continued possession? May he or she sell it to others? Is he or she allowed to use it to make money by developing a therapy of which it forms part? If it is stolen, or misused by others or destroyed by someone else's careless mishandling, does the person who bought it have all rights in law of a person who owns property? Given that the Human Tissue Acts do allow limited sale, the failure to openly regulate these transfers of good through property law leaves buyers and sellers unprotected.

To sum up, the current approach of denying most sales of human tissue ignores the reality that human tissue is increasingly becoming an income-generating resource. This approach prevents companies, researchers and individuals from determining whether benefit-sharing arrangements might be mutually beneficial and from increasing supply where necessary by offering money to encourage people to give their discarded tissue to a good use. Finally, this approach requires the legal system to turn a blind eye to sales it actually does condone, because it has set itself such a blunt and all-encompassing rule that no longer accords with actual community views of what kinds of sales really are acceptable. Whether or not all sales of tissue are acceptable is not the issue, and that question will be dealt with below. The argument here is that the current way in which the law prevents sale results in an unacceptable failure to effectively regulate sales that are in fact tolerated.

This argument in favour of sale in some instances demonstrates the need for a property approach to clarify what is actually occurring in legal sales of tissue. A property

approach would elucidate the exact rights of those who possess commercially saleable tissue, such as rights to possession, use, management, security and the like. If a person had legitimately bought processed tissue, he would have a lawful right to possess it that could be upheld against anyone who might misappropriate it. His use of the tissue would be clearly defined as lawful, and he would be entitled to keep the tissue secure from interference. Objectionable uses could be subject to legal constraints. Effectively, the rights that are usually granted over items of property would be granted to the purchaser, rectifying the current lack of clarity about what rights may be held over tissue sold under the Human Tissue Acts, which really only declares it legal to sell tissue and is silent on what may then be done with it. A property approach and retaining the current restrictions within the Human Tissue Acts are not mutually exclusive.

Applying this to the case studies, property law could be used to clarify the rights of researchers and companies that acquire tissue through the processing exception in the Human Tissue Acts. It could be used to create clear rights to possession and use. For example, if the researchers in Case Study 6: Tissue in Australian Research bought tissue, it would clarify their rights over that tissue beyond the limited consent relationship established by the Acts. It would also provide them with security in relation to the samples, as remedies would be open for unauthorised use or acquisition. It could also found benefit-sharing agreements if situations such as Case Study 16: Ted Slavin and Diagnosing Hepatitis arose, by allowing Slavin to license use of his tissue (through the right to manage) and earn income from allowing its development into a product (through the right to the income) and he would clearly be allowing others certain rights, such as rights to use and possess. The relationship between him, the researchers and the company could be more clearly outlined.

1.2 Promotion of Individual Autonomy

The promotion of autonomy is one of the major arguments cited in favour of allowing individuals to sell their tissue or organs.³ Proponents of this view generally hold that people's liberty should only be curtailed if the need to be paternalistic and protect

³ See, eg, J F Childress, 'The Body as Property: Some Philosophical Reflections' (1992) 24 *Transplantation Proceedings* 2143, 2144; Andrews, 'My Body, My Property', 32; T Wells, 'The Implications of Property Rights in One's Body' (1990) 2 *Jurimetrics Journal* 371, 373; H Horsley, 'Reconsidering Inalienability for Commercially Valuable Biological Materials' (1992) 29 *Harvard Journal on Legislation* 223, 237; Wagner, 'Property Rights in the Human Body', 955; J J O'Connor, 'The Commercialization of Human Tissue—The Source of Legal, Ethical and Social Problems: An Area Better Suited to Legislative Resolution' (1990) 24 *Loyola of Los Angeles Law Review* 115, 145.

people from their own choices can be justified.⁴ In denying people the right to sell parts of their body, we are interfering with their right to make their own decisions, so we must find good reasons why this is necessary. A number of these reasons and the arguments for and against them are outlined in other sections of this chapter.

While some commentators regard autonomy as the paramount concern and hence argue in favour of sale, others find some of the objections to sale of tissue more compelling and sufficient to trump the need to promote autonomy.⁵ For example, Thomas Murray has argued that other concerns outweigh the argument from autonomy. These include the possibility of coercion and abuse, the decline in altruism, devaluation of the sanctity of tissue and that the assumption that a market model will maximise individual good is dubious because people do not always make rational choices that will promote their own interests. He also contends that there is not always consistency between what people desire and what they need; that financial gain does not always promote human flourishing.⁶

By contrast, it can be argued that respect for individual autonomy requires us to accept people's choices about their own lives. If we accept, as we generally appear to, that people are rational agents capable of weighing choices before them, we should allow them to make such choices in relation to the sale of their tissue just as we do in other areas of life.⁷ Because we respect this ability to make choices and take risks, we already allow people to take dangerous jobs or participate in extreme sports. Particularly where selling tissue poses little risk to the individual, it seems unreasonable and out of step with the general respect we show for individual autonomy to constrain the choice to sell one's tissue. These issues are considered further in section 2.5 in relation to concerns about self-harming and coercion.

It should be noted, however, that these objections do not undermine pro-property arguments, as even if we allowed people property rights over their tissue, these rights (and consequently their autonomy) could be limited as considered appropriate. Conversely, if we agree that people should be able to sell their tissue is an aspect of

⁴ G J Annas, 'Genetic Prophecy and Genetic Privacy' (1996) 32 *Trial* 18, 22.

⁵ See, eg, T H Murray, 'On the Human Body as Property: The Meaning of Embodiment, Markets, and the Meaning of Strangers' (1987) 20 *Journal of Law Reform* 1055, 1075–7; G Annas, 'Life, Liberty and the Pursuit of Organ Sales' (1984) 14 *Hastings Center Report* 22, 22ff.

⁶ Murray, 'On the Human Body as Property', 1078.

⁷ See, eg, J Savulescu, 'Is the Sale of Body Parts Wrong?' (2003) 29 *Journal of Medical Ethics* 138.

respecting their autonomy, then property law would provide a clear means of defining and protecting their rights to do so.

1.3 Benefit-Sharing and Justice

As discussed in Chapter Three, there are a range of contexts in which human tissue is used to generate financial rewards. Most particularly, biotechnology companies that create therapeutics using tissue sell these for profit, and similarly produce and sell products that have been developed through research using tissue. Researchers and companies that patent their research results may also exploit the patent for lucrative returns.

Clearly, there are some who are currently gaining financial rewards from the use of human biological materials. Hannah Horsley has pithily summed up the issue this raises in relation to the individuals who supply this tissue, stating

The question is not whether these biological materials should be commercialized; they already are. Instead, the issue is whether the patient should share in that commercialization and how.⁸

One argument in favour of allowing individuals to sell their tissue is that will enable them to share in the financial rewards others currently enjoy as a result of using their tissue in research. At present, these individuals are precluded from doing so because in Australia tissue is supplied for research on the understanding that it is a gift that promotes the whole community's well-being by helping to create new treatments and to uncover the causes of disease.⁹

Those who favour allowing benefit sharing through the sale of tissue argue that the issue is about justice, that it is fair for those who supply tissue from which others make money to share in that financial return. For example, Danielle Wagner has argued that allowing sale is in fact a way to redress the perceived or actual injustice people feel when researchers and doctors profit from using the tissue they have freely donated.¹⁰ Others have agreed with her,¹¹ and the reasoning is convincing—it accords with our sense of

⁸ Horsley, 'Reconsidering Inalienability for Commercially Valuable Biological Materials', 229.

⁹ Individuals are also prohibited by law from selling their tissue. See further Chapter Four, section 4.

¹⁰ Wagner, 'Property Rights in the Human Body', 955. See also Magnusson, 'The Recognition of Proprietary Rights in Human Tissue', 603.

¹¹ See, eg, R Hardiman, 'Toward the Right of Commerciality: Recognizing Property Rights in the Commercial Value of Human Tissue' (1986) 34 *University of California Los Angeles Law Review* 207, 229; Horsley, 'Reconsidering Inalienability for Commercially Valuable Biological Materials', 236; M Danforth, 'Cells, Sales and Royalties: The Patient's Right to a Portion of the Profits' (1988) 6 *Yale Law and Policy Review* 179, 197.

distributive justice to allow everyone who inputs something valuable into an endeavour that reaps profits to share in those returns. Mary Taylor Danforth has further pointed out that where research could not occur without the tissue, it is a crucial input analogous to that of an inventor without whom the research breakthrough could not be made. The source of the tissue should be compensated in line with the importance of the input.¹²

The major response to this argument is that if researchers must pay donors for tissue, the already high costs of research will increase. These costs may either stymie research, or be passed on to consumers as higher prices on tests and therapies.¹³ But while this might be true in some cases, as an objection to sale it is problematic. It puts the needs of researchers and companies above considerations of fair distribution of wealth, and it draws no distinction between rare tissue and commonly available tissue. The cost of therapies may go up, but in the interests of justice perhaps these costs should be borne by the general community, rather than the individual effectively paying them while researchers and companies do not. Arguably, though, the individual has lost nothing but the opportunity to sell and improve his or her position; he or she is not materially worse off not being able to sell something that was also previously unsaleable. These arguments are developed further in section 2.4.

However, for the most part the price of tissue used in research will be minimal and the effect on costs small, because most tissue used in research is not rare. As Patricia Parker rightly notes, the price of most tissues that can be easily obtained will remain low because there will be high supply to meet demand. Individuals with ordinary tissue will have no bargaining power to drive up the price.¹⁴ Therefore, the response based on sale leading to higher prices will generally not apply.

1.4 Increased Supply of Tissue and Organs

One argument that is often made in favour of allowing people to sell their tissue is it will increase the supply of tissue and organs available for research and transplantation. Considerable empirical work has been done on this issue, which is it is beyond the scope

¹² Danforth, 'Cells, Sales and Royalties', 197.

¹³ See, eg, T P Dillon, 'Source Compensation for Tissues and Cells Used in Biotechnological Research: Why a Source Shouldn't Share in the Profits' (1989) 64 *Notre Dame Law Review* 628, 633–5; W Greenberg and D Kamin, 'Property Rights and Payment to Patients for Cell Lines Derived from Human Tissues: An Economic Analysis' (1993) 36 *Social Science and Medicine* 1071, 1073; O'Connor, 'The Commercialization of Human Tissue', 148; Heyer, '*Moore v Regents of the University of California*', 660; R W Marusyk and M S Swain, 'A Question of Property Rights in the Human Body' (1989) 21 *Ottawa Law Review* 351, 375.

¹⁴ P Parker, 'Recognizing Property Interests in Bodily Tissues: A Need for Legislative Guidance' (1989) 10 *Journal of Legal Medicine* 357, 371–2.

of this thesis to delve into.¹⁵ However, we probably cannot conclusively say whether sale will increase supply as this approach has not been tested in this country, and hence it is unclear how the Australian population would respond.

Those who take this view argue that a monetary incentive will encourage more people to provide tissue and organs.¹⁶ Some base this on the belief that there is a section of society that does not donate due to apathy, which the offer of money would inspire them to overcome.¹⁷ In response, it has been argued both that it is uncertain that supply will increase,¹⁸ and that increasing supply alone is not a good enough reason to allow sale. On this second view, put by George Annas, if increasing supply were a sufficient reason for altering how we acquire tissue, it could be used to justify taking tissue from incompetents or through coercion. If we do not accept this, then we cannot really accept increasing supply as the sole reason for allowing sale either.¹⁹

This argument in favour of sale is also sometimes opposed on the basis that while sale might increase the supply of tissue and organs, the quality of that supply would be proportionately lower.²⁰ Proponents of this view usually reason that the monetary incentive will encourage people to conceal information about their health that would exclude them from selling their tissue. For instance, a person wishing to sell blood might conceal that they have tested positive for hepatitis if they need the money, as they know that if they reveal this information the buyer will not accept their blood.

There are a number of criticisms that can be made of this view. First, some such as Arthur Caplan have pointed out that there is not always a direct relationship between

¹⁵ See particularly R Titmuss, *The Gift Relationship: From Human Blood to Social Policy*, Pantheon Books, New York, 1971.

¹⁶ See, eg, Huynen, 'Biotechnology', 542; Wagner, 'Property Rights in the Human Body', 955; Childress, 'The Body as Property: Some Philosophical Reflections', 2144. See generally also M Clay and W Block, 'A Free Market for Human Organs' (2002) 27 *The Journal of Social, Political, and Economic Studies* 227; J Harris and C Erin, 'An Ethically Defensible Market in Organs: A Single Buyer Like the NHS is an Answer' (2002) 325 *British Medical Journal* 114. Loane Skene has also noted that sale may increase the supply of tissue, but further argues that sale may also adversely affect the range of tissue that is available for research. See Skene, 'Arguments against People Legally "Owning" Their Own Bodies', 171.

¹⁷ Andrews, 'The Body as Property', 2150. Arthur Caplan has pointed out the converse that when financial incentives are removed, supply decreases. He cites, for example, the chronic shortages of sperm and plasma that resulted when some European nations stopped allowing them to be bought. See A L Caplan, 'Blood, Sweat, Tears and Profits: The Ethics of the Sale and Use of Patient Derived Materials in Biomedicine' (1985) 33 *Clinical Research* 448, 450.

¹⁸ Caplan, 'Blood, Sweat, Tears and Profits', 450.

¹⁹ Annas, 'Genetic Prophecy and Genetic Privacy', 22.

²⁰ This argument is raised in Wells, 'The Implications of Property Rights in One's Body', 337; Marusyk and Swain, 'A Question of Property Rights in the Human Body', 373; Nuffield Council on Bioethics, *Human Tissue*, [6.34]; A Lang, 'What is the Body? Exploring the Law, Philosophy and Ethics of Commerce in Human Tissue' (1999) 7 *Journal of Law and Medicine* 53, 60.

payment for tissue and the quality of supply. He cites the example of hepatitis rates in the Japanese and Swedish blood supplies. The Japanese blood supply had high rates of hepatitis, despite being acquired through altruistic donation, while in Sweden, where blood was acquired through the market, levels were low.²¹

Second, tissue used in research and therapy will not usually be sourced by advertising for donors, but be obtained from spare material removed during therapy. Money could be offered to use this tissue, and hence the offer of financial gain would not have stimulated supply and therefore have no effect on its quality.²² Finally, even if some people would try to sell tissue by concealing their health status, the quality of supply could be maintained just as the quality of donor tissue is maintained now—by testing it for disease and by screening donors.²³ Lori Andrews has suggested that people who sell tissue could also be made liable for non-disclosure of risks if they do not reveal all relevant health information.²⁴

A further objection to sale in this context is that markets for transplant organs will undermine the current system of organ donation and equitable distribution.²⁵ Arthur Caplan has suggested that a market for organs could result in ‘the ghoulish spectacle of desperately ill, and as a result, vulnerable patients bidding furiously against one another for invaluable biological materials’.²⁶ The implications of a market where people can freely buy and sell organs could easily be that the rich, who have the capacity to buy organs, receive them while the poor do not.

The main response to this argument is that legislative measures and different models for buying and selling could offset these implications. Sue Huynen has argued that legislative controls could be used to prevent this occurring.²⁷ Wagner has suggested that incentives that are financial, but not actual payments to the individual could be used to acquire organs to be distributed in accordance with the current system. These might include a tax break for an agreement during life to donate upon death.²⁸ Another

²¹ Caplan, ‘Blood, Sweat, Tears and Profits’, 450.

²² See Horsley, ‘Reconsidering Inalienability for Commercially Valuable Biological Materials’, 239.

²³ This conclusion is supported by Wagner, ‘Property Rights in the Human Body’, 955.

²⁴ Andrews, ‘My Body, My Property’, 34.

²⁵ See, eg, H Hipkens, ‘The Failed Search for the Perfect Analogy: More Reflections on the Unusual Case of John Moore’ (1992) 80 *Kentucky Law Journal* 337, 344.

²⁶ Caplan, ‘Blood, Sweat, Tears and Profits’, 449.

²⁷ Huynen, ‘Biotechnology’, 541.

²⁸ Wagner, ‘Property Rights in the Human Body’, 956. Megan Clay and Walter Block have made similar suggestions. See Clay and Block, ‘A Free Market for Human Organs’.

suggestion is to use a market to acquire organs, but not distribute them via the market.²⁹ John Harris and Charles Erin have developed a model of this kind, with the National Health Service acting as a single monopsonistic purchaser that could then distribute organs in the same manner as currently used.³⁰

This argument in support of sale of tissue clearly favours a property approach, as such an approach could be used to clarify and protect the rights and interests of buyers and sellers of tissue. It could also be used to regulate supply, and ensure goods (that is, tissue) are fit for the purpose for which they are supplied. Even if we reject this argument, and reject the sale of tissue and organs for the reasons given in this section, the property approach is not undermined—we could simply exclude the right to sell, or at least the right to sell organs and tissue where the implications of doing so are problematic in the ways discussed in this section.

2. GENERAL OBJECTIONS TO COMMERCIALISATION AND SOME RESPONSES

2.1 *The Importance of Altruism*

One of the major objections to allowing individuals to sell their own tissue is that this will reduce the level of altruistic donation of tissue. Altruistic giving is regarded as important because it psychologically rewards the giver,³¹ and because altruism benefits the community in general by promoting solidarity and a sense of social connectedness. For example, Murray has argued that

We affirm our solidarity when we give of ourselves—literally—to fellows in need. We give out of generosity and because we need community; we need to affirm our connectedness in the face of the many forces in mass society that drive us apart.³²

He has added that

Gifts of to body are one of the most significant means mass societies have to affirm the solidarity, or community, that humans need in order to mature and flourish as individuals.³³

²⁹ Andrews, 'The Body as Property', 2149; Wagner, 'Property Rights in the Human Body', 955. Thomas Murray, despite being generally opposed to markets in tissue, has also noted that a production-only market for tissue could be supportable. See Murray, 'On the Human Body as Property', 1075.

³⁰ Harris and Erin, 'An Ethically Defensible Market in Organs'.

³¹ See, eg, Andrews, 'My Body, My Property', 23.

³² Murray, 'On the Human Body as Property', 1085. See further T H Murray, 'Gifts of the Body and the Needs of Strangers' (1987) 17 *Hastings Center Report* 30.

³³ Murray, 'On the Human Body as Property', 1085. Other commentators who have raised the altruism objection to tissue sale include Andrews, 'My Body, My Property', 28; Nuffield Council on Bioethics, *Human Tissue*, [6.35], [13.24]. Hub Zwart has also pointed out that allowing a right to sell 'is to deny the community the right to shape its institutions so as best to encourage altruism among its members'. See

This argument suggests that gifts of tissue and organs, such as the donation of tissue and organs after death as described in Case Study 3: Organ Transplantation and Case Study 7: Donor Tissue Bank of Victoria, are important ways in which we develop bonds that hold us together as a community. In doing so, we create a stronger, more mutually supportive society that therefore promotes human flourishing. Altruistic giving also promotes the valuable interest the community has in participating in research.

There are a number of responses to this objection to tissue sale. First, tissue sale or simply deeming tissue property will not necessarily reduce altruistic giving.³⁴ For example, Andrews has accepted that altruism promotes social connectedness. However, she has countered the objection by arguing that allowing sale of tissue will not affect the fact that people act altruistically.³⁵ She argues that many of life's necessities are already sold, such as food and clothing and shelter, yet people still give these altruistically. Her point is that simply because something is sold, does not necessarily remove the incentive for people to also give these freely, hence even if tissue were saleable, people would still donate it.

Second, the altruism argument suggests that individuals should be encouraged to act altruistically, as this is good for society, but does not address the fact that no-one else involved in the use of tissue is expected to do so. Pharmaceutical companies are not required to sell their products at cost price, but the altruism argument suggests that individuals are expected to give up their claim over what may be a valuable resource while researchers can reasonably use it to create economically valuable intellectual property and companies can turn it into saleable therapeutics. Unless the altruism argument is actually used to suggest that anyone using tissue to create a profit should donate the researcher, intellectual property or products developed from it freely, then really the objection discriminates against individuals. They are required to give up something to promote social connectedness, but companies and researchers are not.

Much tissue used in research may go towards the production of therapeutic goods or patented genetic tests that are then supplied back to the community that donated the

Hub Zwart, 'Why Should Remunerated Blood Donation Be Unethical?' in ten Have and Welie, (eds) *Ownership of the Human Body*, 39, 41.

³⁴ See, eg, Marusyk and Swain, 'A Question of Property Rights in the Human Body', 16; Andrews, 'My Body, My Property', 34; Dillon, 'Source Compensation for Tissues and Cells Used in Biotechnological Research', 640; Andrews, 'My Body, My Property', 35.

³⁵ Andrews, 'My Body, My Property', 35.

materials—at a cost. It is true that the community benefits from the availability of treatments and developments in medical science, but the community also pays for them. In effect, the community pays twice—once with their tissue, then with their money. This is not a mutually beneficial and altruistic exchange, it is an exchange where one party is able to profit and the other is not. While it has been noted that the community has an interest in medical advances and access to therapeutics, having an interest does not equate to a reason to deny them fair compensation for their contribution in enabling those benefits to be created. To assert that the gift exchange and involvement in science is enough compensation is somewhat galling for the donor, when the other participants are not expected to take comfort simply from the positive emotions they derive from it.³⁶

Therefore, unless the objection can be applied across all who use tissue, which it cannot because it would be unfeasible to expect that companies would operate without the profit motive, then it becomes merely an assertion that people should act kindly towards others. This is a laudable sentiment, but not a convincing reason to prevent individuals acting as we already allow companies and researchers to act.³⁷

Third, the altruism objection to tissue sale actually relies on a premise that undermines its own argument. The objection suggests that giving of our bodies connects us as a society because we act to support one another, rather than in return for something. However, if we have no other choice but to give our tissue freely—that is, we cannot make a choice between selling it and giving it—then is allowing others to use tissue that we no longer need really altruism?³⁸ What actually occurs when people give their tissue is that they agree to the use of tissue they would otherwise discard—for example, in Case Study 3: Organ Transplantation, deceased persons who no longer need their organs allow others to have them. In Case Study 6: Tissue in Australian Research, donors allow tissue that has been removed during treatment to be used in research. They may give this with good motives, or it may be they have not further use for the tissue and do not care how it is used. The point is that they have no choice to gain any advantage from giving it, so they have not had to make a positive decision to act altruistically.

³⁶ See further R S Magnusson, 'The Use of Human Tissue Samples in Medical Research: Some Issues for Human Research Ethics Committees' (2000) 7 *Journal of Law and Medicine* 390, 403ff.

³⁷ This argument is supported by Joan Gilmour, who notes that producers of therapeutics are not expected to act altruistically. See Gilmour, 'Our Bodies: Property Rights in Human Tissue', 128. In support of this view see also Horsley, 'Reconsidering Inalienability for Commercially Valuable Biological Materials', 240.

³⁸ Andrews has also raised this criticism. See Andrews, 'The Body as Property', 2140.

If we believe that people give their tissue altruistically, and that it is this altruism that is so important, then we should also believe that they would donate it for free even if they could sell it. If we do believe this, then it is irrelevant if we give them the option to sell because on our reasoning they would not take the money anyway. If we do not accept this reasoning, and believe that people would not give their tissue freely if they could sell it, then we cannot have believed they were behaving altruistically in the first place, and hence their actions were not actually supportive of community bonding. Presumably if we had used the altruism argument as a reason for the need to preclude sale, we could not have believed their actions were altruistic, and basis of the argument is found to be false—there never was any altruism at all. It appears, then, that altruism should occur regardless of whether people can sell. In fact, the act of donation would be more obviously altruistic if people were able to sell but chose not to—this, more than forced giving, would reinforce social connectedness. The altruism objection therefore emerges as a rather weak objection to tissue sale, as regardless of whether we allow tissue to be sold or not (or indeed, be property or not to facilitate sale) the benefits of altruism should still occur.

This objection does not undermine a property approach, as regardless of whether tissue is gifted or sold, property law will be equally useful in clarifying what is occurring in the transfer and defining and protecting the rights that pass.³⁹ Further, tissue being property and even saleable does not prevent people from gifting it altruistically.

2.2 Human Tissue Is Not a Fit Object for Sale

Another objection to the sale of tissue is that human tissue is somehow sacrosanct and should not be dealt with as we deal with objects of commerce. Its unique qualities and the fact that it was once part of a morally valuable person should preclude it from being treated as something that can be bought and sold. For example, Murray has argued that

The body, in its significant manifestations, is not suitable for markets because our most important religions and secular traditions treat it as 'dignity-property' or 'sacra', as an integral part of the person who is the locus of moral concerns and moral worth. It should not be traded in markets because markets in body parts, like all markets, will be subject to inequities and abuses. But these inequities and abuses will have special significance in body markets, because it is the morally significant body (and health, and life) that is being traded off.⁴⁰

³⁹ See Chapter Eleven, section 1.1.

⁴⁰ Murray, 'On the Human Body as Property', 1088. See also Heyer, '*Moore v Regents of the University of California*', 653. James Harris argues that it is an affront to human dignity to commodify organs. See

Murray went on to argue that 'putting a price on the priceless, even a high price, and actually cheapens it. So we don't approve of selling out body parts; and the body isn't quite property'.⁴¹ Here Murray has extended the argument against sale to an argument against property.

This argument is subtly different to objections based on concerns about commodification, which are examined in the next section. The objection rests solely on the fact that tissue is a morally valuable substance that should be treated with particular respect because of its origins, and that selling tissue is a failure to respect this special status.

The main criticism of this objection is that it assumes that all markets in any kind of tissue constitute a failure to respect the sanctity of body parts. But this is not necessarily borne out by our experiences. Taking this argument to its logical limits, we would have to accept that selling one's hair to make a wig offended these religious and secular traditions, and yet most people seem to accept such sale as reasonable. The reason is that some uses for tissue, even those that involve sale, are not inherently disrespectful to the fact that the tissue was once part of a morally significant person. For example, selling hair for a wig probably does not offend the suggested need to demonstrate respect for a substance that was once part of a person. However, by contrast, the use of hair from Nazi prisoners at Auschwitz, Majadenk and Treblinka to stuff mattresses during the Second World War, as described in Chapter One, does offend us because it is a use of that hair that deliberately fails to respect its origins.⁴² Similarly, buying Orlan's relics (as in Case Study 18: Orlan and Manipulation of the Flesh) might be acceptable, but a trade in Aboriginal remains would not due the offence to cultural sensitivities. What we should conclude is that some sales of tissue are acceptable, and that a blanket prohibition on sale is unnecessary and out of step with actual acceptance of sales.

This objection to sale of tissue may have implications for a property approach. Property, it is asserted, is often associated with sale and usually applied to commodities. Therefore, even according tissue property status may raise similar concerns as addressed in this section. However, a number of responses can be made. First, the assumed association may not exist or at least not be as problematic as possibly assumed. This is

Harris, *Property and Justice*, 352.

⁴¹ T H Murray, 'The Gift of Life Must Always Remain a Gift' (1986) (March) *Discover* 90, 90.

⁴² See Chapter One, section 3.2.

particularly so given the second response, namely that we already can have objects of property that have especial, emotional value to us. Letters from an old lover are our property, as are culturally valuable paintings. We do not regard it as problematic that they are property and hence associated with a concept that is often linked to the sale of commodities. This is because the fact that we own them as property does not affect what it is about them that makes them important to us. In fact, allowing us to own them and hence keep them secure recognises their importance to us and the need to keep them safe for ourselves.

Finally, allowing us to treat the body as property does not require us to treat it with as little respect as we might treat other objects of property. We already treat different objects with differing levels of respect based on their value, such as the deference we show to culturally important paintings in comparison to a chocolate bar wrapper. Most probably the unique and sensitive nature of tissue would see us treat it with the respect it deserves regardless of the label we have chosen for its status.

2.3 Dangers of Commodification

A more developed objection to the sale of tissue that draws in part on similar concerns to those raised in the previous section, is the concern that allowing the sale of human tissue may have implications for how we value tissue, and consequently people. This objection suggests that the sale of tissue results in commodification of tissue, and potentially, aspects of individuals. Often the commodification objection is put in terms of the objection considered above, that tissue is not a fit object for sale.⁴³ Having examined this view above, this section explores other aspects of the commodification objection.

Some proponents of the commodification objection suggest that in allowing body parts to be bought and sold like any other commodity, our perception of these parts changes and we begin to value them not as something intimately related to the morally valuable person, but in the same way that we value other objects of commerce like books and cars and houses.⁴⁴ These latter objects derive their value solely from their usefulness to us, and hence we do not owe them any respect or special care. By contrast, we regard people as having an intrinsic moral value that derives from their ability to think and

⁴³ See, eg, L Kass, 'Organs for Sale? Propriety, Property, and the Price of Progress' (1992) 107 *Public Interest* 65.

⁴⁴ On this potential objection see, eg, Heyer, 'Moore v Regents of the University of California', 653; Annas, 'Life, Liberty and the Pursuit of Organ Sales', 28.

make decisions for themselves, that is, their autonomy. Objectification is incompatible with showing respect for people, because it precludes showing respect for their autonomy and reduces them to things to which in fact no respect is owed.⁴⁵

Commodification of tissue is also said to be ethically problematic because it may affect how we value people themselves, if we allow parts of them to be fit for sale.⁴⁶ For instance, David Resnik has suggested in relation to patenting human genetic material—a form of commercially exploitable property right—that ‘by applying market language to human DNA, we may come to hold less respect for the value of human life’.⁴⁷

One of the most convincing and sophisticated versions of the commercialisation objection to selling tissue is developed from the seminal work of Margaret Radin. Radin has noted that people think in terms of both literal markets—in which things are exchanged for money—and metaphorical markets—in which people conceive of their social interactions as a form of trade for benefits.⁴⁸ Starting with the archetype of universal commodification, in which all things that are valued and desired are commodities and can be subject to free market exchange,⁴⁹ she has argued that within this archetype

[v]aluation in terms of dollars implies that all commodities are fungible and commensurable—capable of being reduced to money without changing in value, and completely interchangeable with every other commodity in terms of exchange value ... the simplest version of universal commodification tends to presume that individual value is equivalent to exchange value.⁵⁰

On this view, all value can be expressed as a price. Radin has explicitly rejected this conception of value, arguing that all values are not commensurable and that the notion of universal commodification ‘cannot capture—and may debase—the way humans value things important to personhood’, that instead there are some values that are incommensurable. From this, her basic argument is that our belief that some values are incommensurate helps to explain why some objects are actually contested commodities, that we are not certain that they should be saleable.⁵¹

⁴⁵ T Claes, ‘Cultural Background of the Ethical and Social Debate about Biotechnology’ in S Sterckx (ed.), *Biotechnology, Patents and Morality*, Ashgate, Aldershot, 2000, 179, 182.

⁴⁶ See N Holtug, ‘Creating and Patenting New Life Forms’ in P Singer and H Kuhse (eds), *A Companion to Bioethics*, Blackwell, Oxford, 1998, 206.

⁴⁷ D Resnik, ‘DNA Patents and Human Dignity’ (2001) 29 *Journal of Law, Medicine and Ethics* 152, 152.

⁴⁸ M J Radin, *Contested Commodities*, Harvard University Press, Cambridge, Mass, 1996, 1–2.

⁴⁹ M J Radin, ‘Market-Inalienability’ (1987) 100 *Harvard Law Review* 1849, 1861.

⁵⁰ Radin, *Contested Commodities*, 2–3.

⁵¹ *Ibid.*, 9.

To this analysis, Radin has added that that when people speak of trading objects, whether in the literal or the metaphorical market, they use market rhetoric, that is, they use the language of markets to explain what they are doing. Radin has argued that when this rhetoric is applied to human interactions ‘one conceives of human attributes ... as fungible owned objects’ and that people are troubled by applying this kind of language in some metaphorical contexts because ‘they think it will be contagious and lead to literal commodification’.⁵² Radin does not accept that this slippery slope will always exist, or that the use of market rhetoric will necessarily result in the creation of a literal market. However, she argues that the division between the actual interaction—sale within a literal market—and the use of market rhetoric is not sharp and that the conceptualisation structure that we choose may be harmful in itself.

Based on this reasoning, Radin’s central argument is that the conceptualisation of personal attributes, as ‘mere’ commodities in rhetoric can ‘undermine personhood by engendering inferior understandings—conceptualizations—of what a person is’.⁵³ The conceptualisation itself is in fact harmful. She has made this point in relation to conceiving of rape and marriage in terms of market rhetoric, where personal integrity is a personal attribute conceptualised as a commodity. The conceptualisation itself is problematic because

[s]ystematically conceiving of personal attributes as fungible objects is threatening to personhood, because it detaches from the person that which is integral to the person. Such a conception makes actual loss of the attribute easier to countenance. For someone who conceives bodily integrity as ‘detached’, the same person will remain even if bodily integrity is lost; but if bodily integrity cannot be detached, the person cannot remain the same after the loss. Moreover, if my bodily integrity is an integral personal attribute, not a detachable object, then hypothetically valuing my bodily integrity in money is not far removed from valuing *me* in money ... this is inappropriate treatment of a person.⁵⁴

This argument can be translated to the physical body, which is more clearly a part of the person, and though detachable physically, certainly intimately and forever linked to the person because of its psychological significance, and the unique genetic material it contains. On this view, tissue is not fungible, because of its particular links to the person, and hence is a similarly inappropriate subject for commodification. Radin’s conclusion is that universal market rhetoric when applied to people ‘does violence to

⁵² Ibid, 13. Radin uses the illuminating example of imagining reproduction in terms of market rhetoric, where the cost of producing children is measured as an input of time and resources. She suggests that market rhetoric of this kind disturbs people because they believe that if enough people conceive of reproduction in this way, actual baby selling will result.

⁵³ Ibid, 15

⁵⁴ Radin, ‘Market-Inalienability’, 1881.

out conception of human flourishing' because

[I]n our understanding of personhood we are committed to an ideal of individual uniqueness that does not cohere with the idea that each person's attributes are fungible, that they have a monetary equivalent, and that they can be traded off against those of other people. Universal market rhetoric transforms our world of concrete persons, whose uniqueness and individuality is expressed in specific personal attributes, into a world of disembodied, fungible, attribute-less entities possessing a wealth of alienable, severable 'objects'. This rhetoric reduces the conception of a person to an abstract, fungible unit with no individuating characteristics.⁵⁵

Given that even speaking of people in market language can be damaging, those who use this reasoning to object to property rights in, and sale of, body tissue conclude that to actually do so is at least as harmful, and probably worse—we would not just speak of people as fungible commodities, we would really treat parts of them as such. For example, Michelle Bray has applied Radin's personhood analysis to the sale of body parts and concluded that treating excised body tissue as fully alienable property, that is able to be sold, 'would encourage perception of body parts as interchangeable commodities and undermine the recognition of the human body as the physical embodiment of the personality'.⁵⁶ Bray has further argued that 'people selling body parts not only would lose part of themselves, but might begin to view themselves solely as a means to someone else's physical cure, instead of as an end in themselves'.⁵⁷

Radin's view and Bray's application of it are open to the criticism that it is not necessarily clear that if we talk of blood or nail clippings or hair in market language, or even actually allow it to be sold, that this will transfer to how we regard people. Bray's view is also somewhat problematic because it accepts the body as the physical embodiment of the personality—it is again not entirely clear that we do conceive of our physical self as wholly intertwined with our psychological self, and certainly not down to the level of discarded tumours or skin samples. Finally, Bray rather overstates things when she suggests people will start to perceive themselves as something less than human. We are each of us intimately aware of our own ability to think and to feel and to choose, and regardless of what is done to parts of us, it is unlikely that in any but the most extreme cases we could achieve such a separation from our thinking selves that we no longer regard ourselves as autonomous agents, but as some form of organ farm for others. It is, therefore, difficult, if not impossible, to demonstrate that the necessary

⁵⁵ Ibid, 1895.

⁵⁶ M B Bray, 'Personalizing Personalty: Toward a Property Right in Human Bodies' (1990) 69 *Texas Law Review* 209, 241.

⁵⁷ Ibid, 243.

shift from treating excised parts of people as commodities, to treating thinking, feeling whole people as objects, will occur.⁵⁸

Consider this example. Your friend, Anne, of whom you are very fond because she is witty, clever and a good listener, sells you her old car. She has had the car all the years you've known her, she even has a name for it—Bessie—and painted it herself (red and yellow stripes). The car is strongly associated with her; she has put emotional energy into it and probably feels quite sad to sell it. Does the fact that you are able to buy this car affect how you regard Anne? If not, as one would hope, why not? So did buying Anne's car alter anything about her that was the basis of your respect for her as an autonomous agent? No, because the sale didn't change how witty or clever she is, nor whether she will listen to your problems. And if nothing has changed the basis of your respect and regard, there is no reason why your attitude toward Anne would change in this example, and hence no logical reason why the sale of her car would lead you to stop treating her as a thinking person deserving of respect.

Given all this, what would happen in the example if we exchanged Anne's car for a pint of Anne's blood. If she sold it to you, would it change how you think of Anne? For the same reasons we just considered, it very probably wouldn't, because the fact of the sale would not alter what it is that leads you to value her as a person, which is her wit and her ready shoulder to cry on. As this would not change, your attitude to her also would not logically change. The act of selling you her blood is not causative of any change in how you regard Anne as a person, and hence regardless of whether you think the blood is a commodity, there is no logical reason to suggest that in this kind of example you would start to think of Anne herself as a commodity too. We also have to ask recognise that tissue is already sold in many contexts all the time, yet we do not appear to have begun treating people as organ farms.

Applied to the case studies, the same criticism seems to hold. Imagine that individuals sell tissue to the researchers, rather than donating it, in Case Study 6: Tissue in Australian Research. The commodification objection would hold that these researchers

⁵⁸ This view is supported in Feinberg, 'The Mistreatment of Dead Bodies'. See also N Gerrand, 'Utilising Human Body Parts as Medical Resources' (1998) 7 *Res Publicae* 13, 15; Andrews, 'The Body as Property', 2150; L de Castro, 'Commodification and Exploitation: Arguments in Favour of Compensated Organ Donation' (2003) 29 *Journal of Medical Ethics* 142. De Castro suggests that the commodification objection is not rationally convincing in reality. See also Childress, 'The Body as Property: Some Philosophical Reflections', 2145. Childress does accept the commodification objection to some degree, but suggests that the concern has been overstated and may be met through legislation.

would then be more likely to lack respect for the person who sold the tissue. This would mean that they take less account of the person's feelings about what happens with their tissue, perhaps would be less inclined to worry about protecting his or her privacy, or perhaps would not take as much care to avoid using the tissue in ways that the person might find objectionable. It is arguably unlikely that the researchers would in fact do so, because in reality they are aware of the person who has sold them the tissue, and just as they are with donors, they are also aware that this person may have thoughts and feelings about how the tissue is treated. Their awareness of this does not evaporate simply because they bought the tissue, and hence the factors that drive them to treat donor tissue with respect still exist and therefore probably still have the same influence—they influence them to treat the seller with the respect they deserve due to their moral agency.

A second criticism of the commodification objection in relation to tissue sale is that we already sell many things that are arguably more intimately connected with who we are as people, yet this does not appear to have reduced the respect that society shows for people who do so. For example, Andrews has commented that the products of our mind, our intellectual property, are far more connected to the self—if I pour my heart into writing a novel, the thoughts and expression in that work are related far more intimately to what makes me me than a toenail clipping—yet we allow its sale. 'Arguably,' she has suggested, 'it commercialises me less as a person to sell my bone marrow than to sell my intellectual products'.⁵⁹

A final objection has been raised by two commentators specifically in relation to Radin's view that commodification of body parts adversely affects human flourishing. Megan Clay and Walter Block have argued that we should also consider the human flourishing of those who will die without transplant organs, as commercial markets in organs would increase supply and hence provide more life-saving organs for these people. In blunt response to Radin, they have stated

Others say that it is 'wrong' to buy and sell kidneys or other such body parts because it would be immoral for someone to make a profit from the commercialization of such items. Their argument is that this violates 'human flourishing'. Tell that to the person on a kidney dialysis machine who is reduced to the position of looking forward, ghoul-like, to holidays such as Memorial Day or July 4 weekend, since this is when motor

⁵⁹ Andrews, 'My Body, My Property', 33. On the separation of the self from the body as a response to the commodification objection see also Horsley, 'Reconsidering Inalienability for Commercially Valuable Biological Materials', 232.

vehicle accidents peak, and hence when these body parts are more available.⁶⁰

Their argument highlights that although there may be losses to human flourishing through commodification of organs, prohibiting sale can also affect that flourishing in very practical and tragic ways.

In relation to the property debate, concern about an association between property and commodities has already been discussed in the previous section and that same arguments apply to the objection considered here. Further, the weakness of the commodification objections given in this section suggests that the problems that might arise from the association are relatively unfounded. Therefore, the commodification objection does little to undermine the efficacy of the property approach.

2.4 Disincentive to Research

A more practical objection that is made to allowing tissue sale is that it will create a disincentive to research if scientists must pay for access to the tissue they need. For example, Christopher Heyer has argued that if individuals are able to sell their tissue, those with rare tissue that is valuable to research will require researchers to bid for access and sell for the highest price. This, he suggests, will 'chill valuable medical research efforts which rely on the free exchange of experimental material'.⁶¹

However, researchers and companies developing products already have to pay for many other inputs into the process, such as equipment and chemicals.⁶² They also have to pay for access to journals where the results of research are published. Paying for tissue might increase costs, but only in the way that is already accepted in relation to any other tool needed for research.⁶³ The cost to researchers, then, is not a sufficient objection on its own to allowing tissue sale. The objection only holds if we think that research is

⁶⁰ Clay and Block, 'A Free Market for Human Organs', 231.

⁶¹ Heyer, 'Moore v Regents of the University of California', 655. See also Dillon, 'Source Compensation for Tissues and Cells Used in Biotechnological Research', 634; Murray, 'On the Human Body as Property', 1081; Potts, 'Moore v Regents of the University of California', 461.

⁶² See, eg, Huynen, 'Biotechnology', 542; Andrews, 'My Body, My Property', 36. However, Huynen does note that researchers who have to pay for tissue samples may be less willing to share them with other researchers, potentially undermining the free exchange of materials that promotes research (this occurs through Materials Transfer Agreements in Australia and is regulated by the National Health and Medical Research Council).

⁶³ Roy Hardiman suggests that the current system of free donation simply allows researchers to enjoy a free supply of tissue because the public is ignorant of the commercial value of the tissue. He suggests further that because tissue has been excluded from the market, to date the biotechnology industry and users of tissue have not had to internalise one of the costs of research. See R Hardiman, 'Toward the Right of Commerciality: Recognizing Property Rights in the Commercial Value of Human Tissue' (1986) 34 *University of California Los Angeles Law Review* 207, 227–8.

sufficiently vital that all the inputs to it should be made freely available to researchers. Clearly, this is not the case nor would it be a workable approach in a market-based economy where most therapeutics developed using tissue are made because they can be sold for profit.

Further, it is unlikely that tissue will be an expensive input to research. Most tissue used in research is not rare and can be obtained from many sources. Situations like that in the John Moore case (Case Study 14: John Moore's Spleen) where the tissue needed is hard to obtain will not arise often. Therefore, individuals will not often have tissue for which researchers would be prepared to bid and pay large amounts.

A second form of this objection is that allowing the sale by individuals of tissue will actually decrease the supply of tissue for research, as altruistic donations will decrease. For example, Thomas Dillon has suggested that there is a 'fear that monetary compensation would discourage donations by eliminating the altruistic motives and encouraging sources to "hold out for the highest bidder"'.⁶⁴ This concern, however, is unconvincing. This argument, like those that suggest generally that allowing sale will decrease altruism, take little account of the fact that at present there is considerable donation of tissue without the incentive of payment, demonstrating that, at least in Australia where research relies wholly on donation, there are many people who are prepared to give their tissue to research freely. This concern is also not significant because, as noted above, in most cases the tissue used for research is not rare, and hence one individual's tissue is no more useful than another's, largely eliminating the bargaining power Dillon has argued that an individual will have.⁶⁵

This argument also fails to take account of the fact that people donate tissue not simply because they are altruistic or good-hearted, but because they want to assist community efforts to treat disease. They do so because it will aid themselves if medical care improves through research, and also often because they or someone they know has suffered from a condition and they wish to promote research that will find a cure. For all of these reasons, it is fairly unlikely that the possibility of receiving payment will drastically reduce the amount of freely donated tissue.

⁶⁴ Dillon, 'Source Compensation for Tissues and Cells Used in Biotechnological Research', 640–1. Caplan has also made this point. See Caplan, 'Blood, Sweat, Tears and Profits', 451.

⁶⁵ Magnusson has made similar arguments in response to this objection. See Magnusson, 'Proprietary Rights in Tissue' in Palmer and McKendrick, (eds) *Interests in Goods*, 25, 55. See also Huynen, 'Biotechnology', 542.

By contrast, it is also arguable that allowing sale will actually increase the supply of tissue for available for research by creating an incentive for people who would not otherwise do so to provide tissue.⁶⁶ In cases where researchers are unable to access the necessary tissue for research, this might actually aid research, and thereby promote research and the community's benefit from the development of new tests and treatments.⁶⁷

2.5 Self-Harming and Coercion

Two related objections often raised to markets in tissue, particularly in debate over whether individuals should be permitted to sell their tissue and organs for transplantation, are that such markets will result in individuals self-harming or being coerced into selling.

2.5.1 Self-Harming

Some, such as Heyer, have argued against the sale of body parts, particularly organs, as it will result in people harming themselves for money.⁶⁸ The poor may then debilitate themselves by selling non-replenishable body parts such as a kidney or corneas, which harms them and also places a burden on society when their debilitation requires them to seek medical care.

A number of responses can be made to this concern. First, as discussed above in section 1.2, preventing people from weighing risks and making choices for themselves fails to respect their autonomy as moral agents.⁶⁹ As discussed below in relation to social divisions, we should not paternalistically prevent people from undertaking risks that they calculate as reasonable, particularly as we already condone people performing dangerous jobs to earn income. As Andrews has argued, individuals should be able to sell their tissue when the risks of doing so are commensurate with the risk of other forms of accepted labour.⁷⁰

⁶⁶ See, eg, Huynen, 'Biotechnology', 542; Andrews, 'The Body as Property', 2150. Andrews cites survey information that suggests up to 20% more of the population of the United States would donate tissue if they received payment. Annas has also noted increasing supply as a reason for allowing sale, however he has also argued that it is not a sufficient reason alone to allow sale and made have the adverse consequence of leading to coercion. See Annas, 'Life, Liberty and the Pursuit of Organ Sales', 22.

⁶⁷ However, compare Caplan, 'Blood, Sweat, Tears and Profits', 450. Caplan argues that it is not clear that allowing individuals to sell would increase supply.

⁶⁸ Heyer, 'Moore v Regents of the University of California', 654. See also Dillon, 'Source Compensation for Tissues and Cells Used in Biotechnological Research', 637–8.

⁶⁹ See also section 2.6. Compare Marusyk and Swain, 'A Question of Property Rights in the Human Body', 372. Marusyk and Swain argue that individuals should not have the choice to self-harm.

⁷⁰ Andrews, 'The Body as Property', 2149.

Second, again as Andrews has argued, it is hard to justify preventing people from self-harming where they consider the risks reasonable when we allow them to harm themselves for altruistic reasons, such as live kidney donations between family members.⁷¹ Further, there are examples of what might be considered self-harming that we already accept. Donation of blood and plasma is common practice hence it appears that the slight bodily harm of these donations is also acceptable.

The question, then, is why is this allowable, where saving the life of another person is the main goal, when sale is not allowed, despite the fact that the sale will also provide an organ that will save a life, and provide the seller with financial compensation that may improve his or her life too? It may be that the self-harming argument in some cases is founded more on concerns about the monetary aspect of the exchange, rather than the actual transfer of tissue. Although not favouring a market in biological materials from human sources, Arthur Caplan has wryly commented that

For many years transplant surgeons have defended the practice of organ donation by living donors to kin on the grounds that kidneys taken from genetically related kin have a better chance of surviving than do organs obtained from cadaver sources and that the risks to the health and well-being of the donors are minimal. However, when the proposal was made to buy and sell kidneys what had historically been deemed 'minimal risks' suddenly escalated into intolerable dangers when profit became an obvious motive.⁷²

What should be recognised is that the payment itself does not harm to person who sells tissue, so there is arguably no distinction between paid self-harming and altruistic self-harming that makes one acceptable and the other not.⁷³ If we accept these harms, it seems unreasonable to argue that they are too great where individuals wish to undergo them for money.⁷⁴

The potential harms of creating a society in which people debilitate themselves can be offset through legislative controls, such as by prohibiting sales of tissue that are unacceptable debilitating.⁷⁵ In addition, as Henry Hipkens has pointed out, the rationales behind prohibiting organ sales on the basis that it will lead to self-harming do not apply

⁷¹ Andrews, 'My Body, My Property', 32.

⁷² Caplan, 'Blood, Sweat, Tears and Profits', 450.

⁷³ Andrews, 'The Body as Property', 2149.

⁷⁴ This argument is supported in Caplan, 'Blood, Sweat, Tears and Profits', 449; Horsley, 'Reconsidering Inalienability for Commercially Valuable Biological Materials', 239.

⁷⁵ Andrews, 'My Body, My Property', 34; Huynen, 'Biotechnology', 541. See also Childress, 'The Body as Property: Some Philosophical Reflections', 2145. Childress argues that the risks to the seller could be managed in the same way that risks to donors are currently managed.

to smaller samples, such as cells used to create cell-lines.⁷⁶ The same argument can be made about the sale of tissue that has already been removed, or tissue removed as part of a medical procedure. Therefore the self-harming objection to sale does not apply to these types of tissue.

There are, however, valid public policy concerns about allowing people to self-harm where this will place greater burdens on the healthcare system. If people self-harm for financial gain, it is arguable that the money they receive will later translate into money lost by the community generally through having to fund the added healthcare resources these people may need. For example, if a person sells his kidney for \$50,000 he does make this gain, but in twenty years when his remaining kidney fails the community may have to pay for his dialysis and other treatment in the form of healthcare funding.

2.5.2 Coercion concerns

Some commentators, like Heyer, have argued that allowing people to sell their own tissue may lead to exploitation and coercion.⁷⁷ Onora O'Neill has suggested that there are

quite serious concerns ... about the adequacy of ordinary commercial consent procedures to protect the more vulnerable should a market in human body parts be permitted.⁷⁸

The general argument made in response to this objection is that the potential for coercion can be met through regulation. For example, Andrews had argued that most of the problems associated with sale could be dealt with through legislatively-required cooling off periods, by limiting payments to middlemen, by precluding tissue sale from being required to meet a debt, and by allowing people to sell only their own bodies, not those of relatives.⁷⁹ Andrews has further argued that the market could be used only to acquire tissue, not distribute it, removing some of the unwanted incentives for people to coerce others to sell.⁸⁰ Similarly, Wagner has argued that coercion is more likely where there is no regulated market in organs, as is currently occurring in countries like India.⁸¹ She has argued that regulation that allows organs to be bought but not distributed via

⁷⁶ Hipkens, 'The Failed Search for the Perfect Analogy', 344.

⁷⁷ Heyer, 'Moore v Regents of the University of California', 653. See also Murray, 'On the Human Body as Property', 1078. Many others have noted these concerns, but not necessarily considered them sufficient to prohibit tissue sale. See, eg, Andrews, 'My Body, My Property', 32ff; Andrews, 'The Body as Property', 2149; Wagner, 'Property Rights in the Human Body', 954; Childress, 'The Body as Property: Some Philosophical Reflections', 2144.

⁷⁸ O'Neill, 'Medical and Scientific Uses of Human Tissue' (1996) 22 *Journal of Medical Ethics* 5, 5.

⁷⁹ Andrews, 'My Body, My Property', 33.

⁸⁰ Andrews, 'The Body as Property', 2149.

⁸¹ Wagner, 'Property Rights in the Human Body', 954.

the market could offset coercion concerns.⁸² Further options for preventing coercion have already been described above in section 1.4 in relation to increasing the supply of organs for transplantation.

Another version of this objection holds that individuals are not coerced by others, but rather that the choice to sell a body part is such a desperate action that it cannot be voluntary.⁸³ The obvious response to this argument, for example as made by James Childress, is that a hard choice is not a 'non-choice'.⁸⁴ It is, however, beyond the scope of this thesis to delve into the whether a market would remove some people's ability to make a real choice. What can be said, though, is that this argument does not apply to tissue removals that are unlikely to harm the individual, as they are not faced with a desperate choice between significant self-harming and financial gain. Therefore this objection has less force in relation to sale of tissue that has already been removed or which is replenishable.

Both of the objections to tissue sale considered in this section are valid and may be good reasons to prohibit some sales if the risks they predict would manifest. However, neither has adverse implications for a property approach, as the right to sell could be withheld as required to meet these concerns. In fact, if sale in some circumstances or by individuals of their own tissues, the flexibility of the property rights bundle could be useful in addressing these concerns. Individuals might be restricted from exercising the right to sell over some tissues but not others, or the right might only be available to persons other than the individual once tissue has been processed and is to be sold in an acceptable way. For example, individuals might not be given the right to sell their own tissue, but hospitals could have the right to sell within their bundle of rights over stored excess tissue. Alternatively, the right to sell might be available to individuals over tissue that it carries little risk to remove, but not over organs.

2.6 Promotion of Greater Social Divisions

Some argue that organ and tissue sale should not be allowed because it will lead to the poor selling parts of their bodies to the rich. This objection is most often raised in relation to organ sales, as it rests on the assumption that a person would only sell an

⁸² Ibid, 955.

⁸³ Annas, 'Life, Liberty and the Pursuit of Organ Sales', 28.

⁸⁴ Childress, 'The Body as Property: Some Philosophical Reflections', 2145.

organ if desperately poor. The predicted result is greater social division between rich and poor, and the objection is premised on the belief that it is unacceptable to broaden the divide that already exists. Those who raise this objection sometimes also argue that the idea of the rich buying life from the poor is an anathema to our notions of justice.⁸⁵

In the early 1980s the United States government undertook a re-evaluation of the laws controlling organ procurement and donation. This came as a response to the intention of one Virginia physician to set up an organ-brokering scheme. The scheme met with widespread criticism and, as Annas has noted, there was 'almost universal revulsion at the notion of a market in organs that would inevitably lead to the poor selling their body parts to the rich'.⁸⁶ For some such as Murray, it is this possibility that gives produces a sense of moral repugnance. 'Our consciences,' he has written, 'can tolerate considerable injustice, but such naked, undisguised profiteering in life would be too much for us'.⁸⁷

A variety of responses can be made. Andrews has pointed out that we allow all kinds of gaps to remain between rich and poor and do not prevent many other injustices,⁸⁸ while Wagner has suggested these injustices could be dealt with through strong regulation that prevents sale between individuals, but allows a government-controlled intermediary to facilitate sale.⁸⁹ Julian Savulescu has argued also that allowing people to sell their tissue if they consider the risks reasonable can allow them to improve their situation. Echoing Andrews' point, he further comments

If we allow people to die for their country, it seems to me we should allow them to risk death or injury for the chance to improve the quality of their lives or their children's lives or for anything else they value.⁹⁰

Finally, banning the sale of tissue will not alleviate the gap between rich and poor; if anything it will close off an avenue some might choose to end their poverty. The question is whether this avenue is so detrimental to the individual and to society generally that it should be closed off. Leon Kass has evocatively expressed this vexed issue, stating

As I read about the young healthy Indian men and women selling their kidneys to

⁸⁵ See, eg, Murray, 'On the Human Body as Property', 1088; Marusyk and Swain, 'A Question of Property Rights in the Human Body', 373; Bray, 'Personalizing Personalty', 242; D Josefson, 'Human Tissue for Sale: What Are the Costs?' (2000) 173 *Western Journal of Medicine* 302.

⁸⁶ G Annas, 'Life, Liberty and the Pursuit of Organ Sales', 22.

⁸⁷ Murray, 'The Gift of Life Must Always Remain a Gift', 90.

⁸⁸ Andrews, 'My Body, My Property', 34.

⁸⁹ Wagner, 'Property Rights in the Human Body', 954–5.

⁹⁰ Savulescu, 'Is the Sale of Body Parts Wrong?', 139.

wealthy Saudis and Kuwaitis, I can only deplore the socioeconomic system that reduces people to such a level of desperation. And yet, at the same time, when I read the personal accounts of some who have sold, I am hard-pressed simply to condemn these individuals for electing apparently the only non-criminal way open to them to provide for a decent life for their families.⁹¹

Again, for the same reasons raised in relation to the coercion and self-harming objections to sale, this objection has few problematic implications for a property approach.

2.7 Negative Effect on Doctor/Patient Relationship

The final objection to sale considered here is that allowing sale of tissue may create conflicts between patients and doctors. This objection applies where doctors are involved in recruiting research participants, as in Case Study 9: Menzies Centre for Population Research. Were recruitment to involve payment for tissue, the patient may believe, rightly or wrongly, that the doctor places monetary interests above the need to do his or her best by the patient.⁹² This may decrease his or her trust in the doctor. Trust is crucial to the relationship between healthcare professional and patient. Individuals need to be able to have faith that doctors and others are making treatment decisions with the best interests of their patient in mind. Trust between medical professionals and patients must also be promoted to ensure that patients feel confident to fully disclose the details of their medical condition. Without such full disclosure, it may be more difficult for them to be treated effectively.

Problems may also arise if doctors facilitate sale of tissue because they are in a position of unequal power with the patient.⁹³ The doctor may be likely to gain financial from his or her role in the sale, and may consequently use the power provided by the doctor/patient relationship to pressure the patient into selling, rather than helping the patient to make the best choices for his or her health. They might also perform unnecessary procedures to acquire tissue, as in Case Study 14: John Moore's Spleen.⁹⁴

These are valid concerns, although they may not be sufficient to reject commercialising tissue. Rather, they point to a need to ensure any tissue sales involving a doctor/patient

⁹¹ Kass, 'Organs for Sale? Propriety, Property, and the Price of Progress'.

⁹² This argument has been raised in D Nelkin and L B Andrews, 'The Body, Economic Power and Social Control' (1999) 75 *Chicago-Kent Law Review* 3, 36; Caplan, 'Blood, Sweat, Tears and Profits', 450; Marusyk and Swain, 'A Question of Property Rights in the Human Body', 373; Danforth, 'Cells, Sales and Royalties', 199.

⁹³ See, eg, Danforth, 'Cells, Sales and Royalties', 199.

⁹⁴ Heyer, 'Moore v Regents of the University of California', 654.

relationship are regulated in a way that prevents conflicts. This might include requiring the doctor to disclose all interests in the research, including whether he or she will gain financially from the involvement. It might also require the use of intermediaries not involved in the research to facilitate the sale to avoid patients being unwittingly pressured into participating. It has also been suggested in response to this objection that there need not always be a conflict and that commercialising tissue will actually increase patient trust in doctors. By making the commercial aspects of dealings with tissue overt, doctors will be required to fully disclose the specifics of tissue use.⁹⁵ This will also negate perceptions that doctors and researchers are profiting from the donation of tissue, increasing the community's trust in the profession.⁹⁶

This objection does not undermine the property approach for the same reasons that concerns about commercialisation generally do not. It does, however, highlight how property law might be useful whether or not sale is permitted. If tissue is sold, property law could offset some of the concerns about the implications of sale for the doctor/patient relationship by requiring more full disclosure (as part of the sale agreement). If sale is not permitted because of the problems noted in this section, property law would at least more fully clarify what is occurring in the transfer between doctor and patient, and define the exact rights that pass.

3. CONCLUSION

The multitude of arguments for and against allowing commercial dealings with human tissue reflects the depth and subtlety of the issues involved. There are good arguments on both sides. Buying body parts might provide us with more organs with which to save people's lives, and more tissue to create new drugs and tests. There may be justice in allowing individuals to share in the profits that tissue research may generate, and sale may be appropriate in many contexts where the consequences are not objectionable. But selling tissue might also adversely affect both how we view people and how we relate as a community, if the altruistic basis of tissue donation is undermined and if the poor become a source of parts for the rich.

The issue for this thesis is not whether the sale of tissue is supportable. Rather, the

⁹⁵ See, eg, Hardiman, 'Toward the Right of Commerciality', 231–232; Horsley, 'Reconsidering Inalienability for Commercially Valuable Biological Materials', 239; Annas, 'Life, Liberty and the Pursuit of Organ Sales', 36.

⁹⁶ Wagner, 'Property Rights in the Human Body', 955.

foregoing discussion demonstrates that the issues surrounding tissue commercialisation are so complex and varied that the current blanket prohibition on sale not only fails to meet deal with current tissue use, it also lacks the flexibility and subtlety to address the varying views on how we might approach the question of tissue sale. It makes no distinction between contexts or different tissues, nor does it allow for situations in which the adverse consequences on tissue sale it seeks to prevent would not manifest. It does not allow for a graduated approach to be taken, and as a blanket ban, the prohibition is not of a form that lends itself to development. Exceptions to it could be legislatively created, but this approach is less than satisfactory—it would be difficult to ensure the exceptions kept pace with changes in the use of tissue, and any changes in those exceptions would need to be achieved through the legislative process, with all its attendant delays and difficulties.

By contrast, deeming tissue property would be a more flexible approach. The prohibition could remain, excluding the right to sell from the property bundle when regarded as appropriate. For example, the right might only be able to be held over certain types of tissue or in certain circumstances. Small samples of tissue might be saleable where removal does not harm the individual, while we might exclude the right to sell from ownership of organs to promote more ethical organ distribution. Or we might allow sale in a context like Orlan's art, but not allow sale of tissue to researchers if it appears that this will increase the cost of resulting tests and treatments.

Where sale is allowed, the role of developing the legal system's position on tissue sale would be left to the courts in interpreting the scope and nature of the property rights that might be held in tissue. This would leave room for the courts to alter those rights where necessary to accord with community standards, allowing a right to sale or generate income where acceptable. Further, as noted in section 1.1, if we do allow sale, then the remedies and constraints of property law would allow us to regulate that sale better. Tissue could be classed as a good for the purposes of sale of goods legislation, and hence be subject to clear guidance and standards for fitness for purpose. Theft of valuable tissue would also give rise to property remedies for the owner who has lost an economic resource.

It is apparent from the analysis in this chapter that the objections to tissue sale do not undermine the efficacy of using property law to regulate the use of tissue. It is unlikely that according tissue property status will affect the level of altruistic donation.

Commodification concerns are not convincing reasons for prohibiting tissue from being property. Instead, the laws of property could offset some concerns, such as those where tissue already sold, by clarifying the nature of the transfer. It would also provide security for valuable resources and define more clearly what possessors of tissue can rightfully do with that tissue. Consequently, regardless of which position one takes on the commercialisation issue, a property approach could be used to either prohibit sale entirely, or its flexibility drawn upon to develop a more nuanced and pragmatic approach to current commercial dealings with tissue.⁹⁷

⁹⁷ See Chapter Nine. This view has been supported by many legal commentators. See, eg, Childress, 'The Body as Property: Some Philosophical Reflections', 2144; Andrews, 'My Body, My Property', 29; Huynen, 'Biotechnology', 541; Harris, *Property and Justice*, 356.

CONCLUSION

Parts II and III demonstrated that the current legal framework for regulating tissue use is problematic in many ways. There are gaps, there is inconsistency and there is a lack of any clear principles from which the courts can extrapolate how to deal with unregulated uses of tissue. These parts, when read in conjunction with the long list of uses and potential abuses of tissue outlined in Part I, show that the present approach requires serious reworking.

The debate over the property status of tissue has focus on how such reworking might be achieved. This Part has shown that in many ways, property can provide an effective approach for reworking the law in relation to tissue use. It has shown that property can provide strong protections for individuals and those with other legitimate interests in tissue. These protections, unlike those provided by the current framework, could be held out against all the world and so are stronger and more effective than the present consent-based model. They would also afford rights-holders with the more desirable range of proprietary remedies, which this Part has suggested may often better meet the needs of those who have been harmed. Further, adopting a property approach would improve upon the piecemeal approach currently taken and it would end the ongoing division in the courts over the status of tissue.

There are legitimate concerns about the adverse implications of a property approach, and it may be that the approach could be bluntly applied. However, this Part has shown that these concerns are not insurmountable. Rights can be constrained, or be made available only for some parties, in some circumstances and over some types of tissue. The value of a property approach is that we can start with a well-defined area of law and then address the concerns that arise, rather than continue on the present way of developing rules on an ad hoc basis as new uses and concerns arise. On balance, it should be concluded that there is at the very least a good case for continuing to examine the property approach. The next step, as will be discussed in the conclusion, is to shift the focus of the debate away from the property–no property dichotomy. Instead, the debate should begin to move towards accepting the feasibility of the property approach as a starting point for thinking about how we can draw on and modify property to create the unique legal solution that the challenges of modern tissue demand.

Conclusion

Thinking about how society should regulate the use of body parts requires not only delving into issues of law, but also into wider questions: how does society view the human body: what constitutes ethical treatment of body parts in their myriad uses; , and, what goals are to be promoted by the way of regulation. When looked at from this wider perspective, it becomes apparent that the debate about whether the body should be property has implications not only for law, but also for what kind of society we want to create. We need to ask questions not only about whether property law can regulate the use of body parts, but also how treating parts in this way will affect how we view people, how we can take account of the complex relationships people have with their body tissue and how we can balance the competing interests of individuals, families, communities, commerce and research. The debate on human body involves a complex web of interests ranging, from individual interests in autonomy and privacy, to familial interests in the body parts of deceased relatives and access to their tissue for testing, to the general community's needs for transplant organs, scientific research into new medical treatments, the promotion of security through police use of tissue in investigations. There are also the interests of the scientific community in using tissue in their research and the interests of indigenous groups in ensuring the respectful treatment of their members' remains.

This thesis has sought to locate the body as property debate within this broader context of interests by examining many of these uses for tissue, ranging from research use to forensic testing, from transplantation of organs to the sale of tissue in commercial products, and from the use of tissue for genetic testing to its incorporation in artistic works, to name but a few uses.

Often, the debate has focused on one particular type of tissue use, such as research use or organ transplantation. However, such an approach undermines the capacity of the debate to lead to a comprehensive resolution on how the uses of human tissue should be regulated. There are limits to this type of approach. By focusing on limited situations, it is difficult to develop a broad, principled regulatory framework. If only some uses, interests and goals are considered to the exclusion of others, a solution that works in one instance may fail or produce absurdity in another.

It is this kind of compartmentalised approach that has also led to the piecemeal regulatory framework currently in place, where different rules based on different principles apply to tissue in different contexts; the courts have taken one approach

(recently, the property approach), while the legislation and ethics guidelines have marked out two main areas of use for regulation via a consent approach (namely, donation for transplantation and research uses) and left other uses wholly unregulated and hence in a legal and ethical vacuum. This piecemeal approach was demonstrated through the analysis of the legislation, guidelines and case law in Parts II and III. As the uses to which tissue can be put have proliferated and the issues use raises have expanded, particularly following the developments in genetic science over the past decade, the failings of this piecemeal approach have become more and more apparent.

In locating the debate more broadly, this thesis has highlighted not only the vast and varied uses to which tissue can and is put, but also the need to develop a regulatory approach that can both encompass these uses and expand to meet others that may emerge in the future. Such an approach will need to be focused not on producing a legal solution to cover some uses in some situations, but rather rest on a comprehensive, principled basis that can be used to take a consistent legal (and ethical) approach to regulating tissue in all situations. An approach of this kind will ensure not only consistency, but provide the legal system, particularly the courts, with a foundation from which to develop regulatory approaches where no precedent for dealing with a particular use yet exists. Establishing such a foundation does not preclude differential regulation of tissue use where appropriate. Instead, it provides a starting point for thinking about how use should be regulated from which tailored legal solutions can be developed to adequately balance the interests involved in this use and meet social goals in relation to the use of tissue and more broadly.

In developing a picture of the many uses of tissue and the interests involved, and then applying the legal framework to these, this thesis has also uncovered many areas in which the current law fails to promote or protect these issues adequately. Part II demonstrated that the current framework for donation of tissue fails to protect individual autonomy by not addressing future uses of tissue and by not enabling individuals to exercise control over their tissue once donated or seek remedies when that tissue is misused. This Part also showed that individual privacy interests in tissue are largely unprotected in privacy legislation(although ethical guidelines provide many protections for tissue used in research), that the legislative scheme takes insufficient account of indigenous interests, and that families may be left without the capacity to direct how their relatives' remains are dealt with. While Part II did show that ethical guidelines in relation to research, genetic testing and pathology laboratories provide

considerable protection for individuals while promoting the needs of researchers, it also showed that where these fail, the individual is left without a legal remedy to seek compensation or prevent the continuing misuse of their tissue by parties not subject to the guidelines.

The analysis of relevant case law in Part III also highlighted the problems that arise when individuals and institutions do not have clearly defined rights to tissue where it is not directly regulated by law or covered by guidelines. For example, the lack of legal status of tissue means it is unclear what may be done where tissue is abandoned, where it is held by an institution, such as a laboratory, once it has been used for the purpose for which it was obtained, or where tissue is taken unlawfully. The analysis in this Part particularly demonstrated that the lack of a principled approach to tissue use, and the consequent failure to ascribe to it some legal status, leaves many uses unregulated. Hence the interests of both individuals and others are not protected or promoted, and many potentially objectionable uses of tissue may be free of legal sanction.

The body as property debate arose in part as a response to some of these concerns. It also arose as the courts began to examine using property law to address some of the gaps in the regulatory framework when novel cases came before them. The debate centres on whether property law can provide a solution to these problems. It also often considers whether treating tissue as property would provide individuals with other rights in relation to their tissue that should be promoted, such as the right to sell their organs and tissue. The debate is therefore wide-ranging, as some commentators focus on the ethics of ascribing tissue property status, others on whether property law would promote social goals such as medical research, while a subset of the debate focuses on the commercialisation of body parts by allowing individuals the right to sell, which could be afforded through the laws of property.

The goal of this thesis was to bring a new unifying perspective to the body as property debate by critically appraising the foundations of the debate itself. It did so first by locating the debate more broadly, but then by considering the basic questions on which the debate should rest—can the law admit tissue as property, and should it? Most often the debate has focused on this second question, that is, the merits of using property law to regulate tissue. However, in this thesis this question was secondary to the main question of whether, in fact the legal concept of property is wide enough to encompass human tissue. In focusing on the second question, often the first question had been

largely assumed to be answered in the affirmative. This thesis was premised first on the view that this might not be the case. Its second premise was that consideration of this question could both affect the efficacy of the debate and lend new insights into whether, and how, property law would provide a good legal mechanism for regulating tissue use. Therefore, this thesis sought to answer this question to draw conclusions about whether the debate rested on a supportable assumption, and hence critically appraise the debate, and to add to the general debate by providing some foundational research on feasibility of turning to property law to regulate tissue.

To achieve this, this thesis approached the question from a number of angles. First, in Part III, it analysed the body of case law precedents that has dealt with human tissue in Australian and the United Kingdom. It did so to determine whether, in fact, there was already a legal precedent for asserting that human tissue had the status of property at law. This analysis revealed two things. First, that the long established common law prohibition on corpses being property is probably based on a misinterpretation of the early cases. Secondly, that over the past century a significant precedent in favour of ascribing some limited form of property status to tissue has emerged, albeit with the caveat that, in some cases the tissue must have been preserved in some way before it is regarded as property. The case law, then, is not a significant impediment to treating tissue property. In fact, the case law supports this approach. That it does also demonstrates that property has been regarded by some courts as the best way of regulating tissue use in some circumstances.

Second, in Part IV this thesis examined the theory of property and sought to answer the question by unpacking the concept of property to determine whether it could be reasonably applied to tissue. To do so, it used the analytical rights vocabulary developed by Wesley Hohfeld and the classic exposition of the incidents of ownership given by A M Honoré. Together, these were used to examine each of the incidents of property, including the rights to possession, to use, to manage and to the income. These incidents were applied to human tissue and its uses to determine whether it would be possible to exercise them over tissue. If application was possible, this would suggest that tissue could be treated like property. This analysis found that almost all the incidents could generally be applied to tissue, demonstrating that tissue does fit within the concept of property from a theoretical standpoint.

To further support this conclusion, two other questions were considered as part of the

analysis of these incidents in relation to tissue—whether current approaches to how we use tissue suggest that we act as though we have these rights, and whether the way the law regulates tissue allows us to act as though we do. Again, in many instances the answer to both these questions was in the affirmative, demonstrating that not only could we treat tissue as property, we already do and the law sanctions this property-like treatment. This analysis therefore lends significant support to the possibility of successfully applying property law to human tissue, suggesting that the pro-property position within the debate is feasible. Part IV concluded by also examining some of the philosophical justifications for property systems to consider whether these might also support a property approach to tissue. Three major theories were considered—First Occupancy theory, Lockean Labour theory and Utilitarianism. While each theory has its flaws, and given that a full account of the foundations of property law cannot necessarily be found, this analysis did suggest that each might lend some support to the case for property.

The general conclusion to be drawn from the analyses in Parts III and IV is that from both precedential and conceptual perspectives, there is scope for admitting tissue as property. These analyses demonstrated that tissue can fit within the concept of property, that our treatment of tissue largely accords with how we would treat it were it property, and that there is case law to support taking such an approach.

Having established this, Part V turned to the secondary policy question of whether we should accord tissue property status, and examined some of the arguments for and against doing so that have been raised in the debate. This Part also considered some of the possible ways in which property may successfully address the problems in the current approach to tissue outlined earlier in the thesis. Balancing this, Part V examined some of the problems that a property approach might raise. It is not surprising, given the continuing debate on this question, and the complex ethical and legal questions it involves, that this Part did not come to a conclusion that supported one side or the other of the debate unequivocally. However, this was not the aim of either this Part, or this thesis in general. Rather, what this analysis of the varied arguments for and against property showed was that there are good reasons to treat tissue as property, and reasonable concerns about doing so. While a property approach might operate to protect individual rights by giving people the right to possess, use, manage, even sell their tissue, thus promoting their autonomy, it might also lead to significant practical problems

As one example of practical problems, once such rights were established, that anyone taking tissue that is apparently abandoned would be liable in conversion to the source individual if they use it in anyway. Hence, a hairdresser cleaning up after a haircut might be liable for throwing the hair away, which would be both absurd and leave those who have probably done nothing regarded as harmful open to legal penalties. However, establishing these rights would give the source individual some legal means of seeking compensation if the hair is misused, or if it is transferred to a third party who misuses it, such as by testing any DNA that might be found in the hair and using the information generated in a way that breaches the individual's privacy.

As another example of practical problems, if an individual has rights in his or her tissue, this might allow them to legally transfer these to someone else, such as a researcher, who might then gain full property rights in the tissue. If tissue is property, this might be the basis of donating tissue for use in research. However, should the individual then object to the use of the tissue, they may have no legal basis on which to seek a remedy as it is the researcher now who may decide how tissue is used. Such a situation may be less acceptable than the current consent model, where the donor can object if the tissue is used in manner for which consent was not given. Conversely, under the current system, the donor would have no personal remedy to seek, whereas under property law they might only transfer a right to use for certain purposes, and then have an action in conversion if the tissue is used in a manner that does not accord with this right.

What we should conclude from the analysis in Part V, then, is not that one side of the debate is correct and the other wrong. Rather, we should draw from this that the interests involved in tissue use are many, their interrelationships are complex, and there are often competing goals that need to be achieved by whatever regulatory framework we establish. In an area of this level of complexity, and which involves overlapping interests that may be equally valid, we need instead to recognise that the better answer is to develop a more nuanced approach. Instead of seeing the issue in black and white terms, we need to move on from the polarised debate over whether tissue should be property, and take a new approach that incorporates the valid strengths of the property approach and avoids some of the problematic implications of deeming tissue property in the usual legal sense.

Tasking this new integrated approach, assume that we take the property approach by

giving individuals property rights in their tissue upon excision. This approach is preferable to allowing others the first claim to property rights over the tissue for two reasons. First, the individual has would have a closer initial relationship to the newly created object than others. Second, it contains their DNA, which also establishes a strong, personal link to the tissue that others do not have. Taking this view, the property approach is good because it can provide strong protection for the individual whose tissue is excised if property rights over the tissue vest in that person at the moment it is removed. Such protection is an effective means of promoting individual autonomy, which is important to empower individuals to protect their privacy and to respect their beliefs about how their bodies should be treated. It could be used to provide them with individual remedies against anyone who misuses their tissue, and in particular, to enable them to seek cessation of that misuse or the return of tissue, rather than compensation or criminal penalties only. This in turn would enable them to prevent further misuse and to have the tissue destroyed or appropriately interred. For the same reason, property law may provide the families of deceased persons, whose tissue is held and misused, to gain possession for the purposes of burial. Similarly, this approach would allow indigenous groups to establish rights to remains as part of a deceased individual's estate. In this way, they may be able to use property law to require the return of remains held in museum collections.

Second, a property law approach could provide security for lawful possessors of tissue, such as researchers, against theft or unauthorised access and use by third parties. It would give them remedies against unauthorised interference with samples. It might also give greater security to museum collections if their possession is deemed lawful and their right to do so stronger than claims by others, such as indigenous groups. This approach can be consistent with allowing individuals to have initial property rights over the excised tissue. Some or all of the individual's property rights will be transferred when the individual donates the tissue for research or other uses.

Further, allowing an individual to hold the initial property rights over tissue once exercised is preferable to other property approaches because it clarifies which rights pass when tissue is transferred. This is preferable to the current approach taken by the courts of according rights to the individual or institution that preserves tissue. It is also preferable to the approach, favoured by some commentators, of according rights based to promote particular goals, such as allowing researchers to own tissue to promote research interests. Both latter approaches ignore the vital link between the individual

and his or her tissue by failing to provide rights over tissue to them, and unjustly placing the interests of others above those of the individual whose tissue it is. Providing the individual with the initial property rights promotes autonomy and respects this link, but can still facilitate the same goals as the other approaches, such as providing security to museums and promoting research.

However, a full property approach is not a panacea and has limitations. Such an approach may lead to a number of unwanted consequences. First, it would mean that anyone dealing with apparently abandoned tissue may be open to an action by the person from whom it was removed where there was no intention to abandon. In addition, an individual's DNA is contained in almost any discarded tissue, and that person may have special beliefs about the appropriate respectful treatment of such tissue. Many people have complex psychological relationships with their bodies. Therefore, the normal doctrine of abandonment would be problematic to apply, as it would allow anyone else who obtains the tissue once abandoned to exercise the normal, full rights that they would gain by possessing an abandoned object. They would then be able to use it that may violate the privacy or offend the important beliefs the source individual has about their body.

Second, the property approach, in providing individuals with such strong rights over their tissue would make it difficult to continue to apply the ethical framework established by the National Health and Medical Research Council that allows de-identified tissue to be used without consent to promote the important social endeavour of medical research. Therefore, by giving individuals greater power, we may decrease the capacity of others to pursue goals that promote the well-being of society.

Third, the property approach would also require that the law clarify which rights are transferred in any situation where tissue is removed, even those situations that are already lawful. For example, the Human Tissue Acts would need to be modified to reflect this, by determining whether consent to donation passes all rights, or perhaps only rights to possess and to use for limited purposes. Once that use has been completed, the fate of the tissue would also need to be determined. For example, would possession need to revert to the individual, thus creating potential public health concerns at releasing possibly hazardous material to the public? Or would the hospital need to renegotiate further rights to use the tissue? Or if we think that the transfer would involve transferring all rights, would we really be wanting the hospital to have the

right to sell that tissue or use it in any way it chose, regardless of any offence to the individual? There are many other situations in which a property approach would be problematic.

Fourth, applying a property approach would also require us to deal with many other legal implications. Would the owner of tissue therefore be able to bequeath their organs by will, potentially undermining the current system of organ donation? Would removed tissue that had value be liable to execution for a debt? Would we want to allow people to use their tissue to generate income, and if so, would we tolerate any use to which they might put that tissue to make money?

Recognising these limitations, the way forward for the debate about the body as property is to acknowledge these strengths of property, and work out how they can be incorporated in a new integrated approach to tissue regulation while avoiding some of the pitfalls of a full property approach. Rather than focusing on supporting or rejecting property, instead the debate needs to move towards considering how property law might be manipulated to achieve a regulatory framework that provides more effective individual protections while still promoting research, organ transplantation and other socially useful goals.

Importantly, this thesis has adumbrated and highlighted that of the concept of property does not have to mean full property. There are eleven incidents within the concept of property, and as Honoré himself noted, it is in fact rare for all of these to vest in one person or for all of them to apply to any one object. What we need to do is recognise the flexibility that is already built into the concept of property by developing a property-like approach to tissue that vests some of these rights in some individuals or institutions as appropriate. For example, we might allow rights to possess, to use and to transfer to be vested in individual and institutions, but not a right to the income if we consider commercial dealing with tissue to be objectionable. We can also place limits on the exercise of these rights based on context, the type of tissue and any ethical concerns that the exercise of these rights may raise.

This thesis has sought not to provide a conclusion to the debate, but rather to demonstrate that it should now take a more nuanced approach to the issues by drawing on the strengths of property law. One approach is to vest a modified property right in source individuals at the point when tissue is removed. Such a right, or perhaps only an

interest, could be inalienable to reflect the unseverable connection an individual has with their tissue, because it contains their DNA and because of the emotional and psychological importance of a person's body to them. However, this interest would not extend to full control of the tissue. Rather, it could be invoked to exert control or seek remedies where tissue is used in a manner that might be objectionable. This kind of approach, if developed fully, could recognise the ongoing interest of an individual in his or her tissue, and provide them with a basis for seeking control of it or pursuing a legal remedy, while still enabling others to use that tissue in ways that are accepted. This idea is the basis for the title of this thesis, 'A Twitch upon a Thread'

This approach could also be developed to incorporate limited rights that may vest in others, such as doctors, researchers, the police or genetic registers, which have a legitimate and authorised interest in using tissue. This highlights the other aspect of property law that the debate has often ignored, but which the analysis in this thesis has emphasised. This is that property rights can be overlapping and that a range of individuals and institutions can each have some of the rights property provides over the same object.

The courts have battled with the issue of whether to give tissue property status for over a century. The academic debate on this issue stretches back more than twenty years and remains unresolved, with little legal change having resulted. This thesis has demonstrated that the way to move forward from the current impasse is to take a more integrated approach that draws on the strong arguments for and against according tissue property status. It has shown that allowing individuals to exercise property rights over their excised tissue is defensible on precedential grounds and is theoretically justifiable. It has further demonstrated that a modified property approach can be an appropriate response to the new genetic era, and can be developed to reflect multicultural and diverse views of the body.

However, by recognising the limitations of a property approach, it has further demonstrated the need to step back from according tissue full property status. It highlighted that according tissue full property status would give individuals or institutions a problematic level of control over the tissue of others. For example, full property status could provide others with very broad usage rights over the tissue of others. This could allow them to use the tissue in ways the source finds objectionable because of the intimate connection the source will always share with their own body

parts. It may also undermine the National Health and Medical Research Council framework that promotes the ethical use of tissue in research, and potential future legislative measures to protect the privacy of tissue samples. It might also have the adverse implications of leaving tissue open to be taken in payment of a debt, bequeathed by will (undermining the system for the distribution of organs based on need) and give museums and other institutions a stronger legal basis to retain tissue against the wishes of the source, their family or their community. Finally, this thesis has also demonstrated that there are a range of valid ethical concerns about the implications of commercialising tissue by using property law to allow it to enter the market freely.

This thesis began by stating that human tissue is a unique substance. What needs to be done now is to develop a unique legal approach that can regulate tissue use. This will only provide a satisfactory outcome if the concepts of property law are unpacked and their inherent flexibility utilised so that property law is capable of adapting to the novel and evolving demands of regulating the body. The next stage for the debate should be to examine how this can be achieved through exploring an integrated approach that combines the benefits of property law and tempers them with other regulatory mechanisms where needed. In doing so, particular attention should be given to assessing some of the adapted property approaches that have been suggested.⁹⁸

In considering new models, the debate should consider the approach suggested at varying stages in this thesis, namely an inalienable right for individuals in their tissue that can provide them with a cause of action where their tissue is used by anyone in a manner the law accepts as objectionable. Such an interest should, as the title of this thesis suggests, let their tissue 'wander to the ends of the world' and still enable them to bring it back with a twitch upon the thread.

⁹⁸ For example, Loane Skene's model that allows possessory rights to vest in hospitals and researchers, but not individuals as discussed in Chapter Eleven. See L Skene, 'Arguments against People Legally 'Owning' Their Own Bodies, Body Parts and Tissue' (2002) 2 *Macquarie Law Journal* 163, 175–6. See also the community property model suggested by Randy Marusyk and Margaret Swain in R W Marusyk and M S Swain, 'A Question of Property Rights in the Human Body' (1989) 21 *Ottawa Law Review* 351; R W Marusyk and M S Swain, 'An Alternative to Property Rights in Human Tissue' (1990) 20 *Hastings Center Report* 12; and James Harris's work on a lower form of ownership for tissue based on use-privileges and control-powers rather than full ownership. See J W Harris, 'Who Owns My Body?' (1996) 161 *Oxford Journal of Legal Studies* 55; J Harris, *Property and Justice*, Clarendon Press, Oxford and New York, 1996. See also the 'cascade of possession' approach suggested by G Laurie and T Mason in J K Mason and G T Laurie, 'Consent or Property? Dealing with the Body and its Parts in the Shadow of Bristol and Alder Hey' (2001) 64 *Modern Law Review* 701. Rosalind Atherton and Roger Magnusson have also suggested beginning not with the property question, but by asking who should be given control of tissue and to what extent. See R Atherton, 'Claims on the Deceased: The Corpse as Property' (2000) 7 *Journal of Law and Medicine* 361, 363; R Magnusson, 'The Use of Human Tissue Samples in Medical Research: Legal Issues for Human Research Ethics Committees' (2000) 7 *Journal of Law and Medicine* 390, 391.

Bibliography

Contents

1. Cases	465
2. Selected Legislation	466
3. Guidelines, Codes and Standards	467
4. Parliamentary Debates	468
5. Legal Commentaries and Pleas	468
6. Books	469
7. Articles	471
8. Reports	480
9. Newspapers, News Broadcasts and Documentaries	482
10. Media Releases	484
11. Internet Sources	484
12. Pamphlets	486
13. Miscellaneous	486
14. Interviews	486

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