

**NUFFIELD  
COUNCIL ON  
BIOETHICS**

**Human Tissue  
Ethical and Legal Issues**

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COUNCIL ON  
BIOETHICS**

**Human Tissue  
Ethical and Legal Issues**



## Nuffield Council on Bioethics

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### **The terms of reference are as follows:**

- 1 to identify and define ethical questions raised by recent advances in biological and medical research in order to respond to, and to anticipate, public concern;
- 2 to make arrangements for examining and reporting on such questions with a view to promoting public understanding and discussion; this may lead, where needed, to the formulation of new guidelines by the appropriate regulatory or other body; and
- 3 in the light of the outcome of its work, to publish reports; and to make representations, as the Council may judge appropriate.

### **Secretariat**

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Dr Rachel Bartlett  
Mr MAT Otton-Goulder  
Mrs Jill Batty

## Preface

This is a timely report; public concern has increased its importance. The report deals with the ethical and associated legal questions raised by the medical and scientific uses of human tissue. It is of direct concern to those professionally engaged in health care and medical research who are concerned with human tissue – in particular, in hospitals, blood transfusion centres, tissue banks and research units. But the report also addresses issues of concern to us all, notably consent to treatment and the relationship between doctor and patient.

The subject is complex. Its several and varied aspects have to be clarified in some detail. The wider uses of tissue are presenting more, and more difficult, problems of ethics and law. There are, for example, the ethical implications of making human tissue available for clinical treatment and research. Lawyers are still discussing a cause célèbre – the case of *Moore v Regents of the University of California*, which raised key questions of consent and ownership. The European Parliament has recently debated the ethical aspects of proposals to patent life forms.

Against this background the Council decided to establish a working party, under the chairmanship of Professor Dame Rosalinde Hurley, which has now completed its report. The report has been carefully considered and endorsed by the Council.

The report has not, and cannot, provide answers to every question it raises; but it examines the subject of human tissue with great care:

- ▶ providing a guide to the sources and uses of tissue
- ▶ defining the ethical principles which should govern the treatment of the human body with respect and dignity;
- ▶ outlining the ethical implications of the uses of tissue;
- ▶ clarifying the current provisions of the law, and indicating where further statutory provision or regulation may be required;
- ▶ and, finally, outlining the patenting problems which await resolution.

The conclusions and recommendations of the report present an agenda for both discussion and action including:

- ▶ guidelines for consent procedures;
- ▶ guidance relating to constraints on commercial transactions;
- ▶ the responsibilities of medical intermediaries such as tissue banks that supply human tissue;
- ▶ the need for the Government, with other member states, to seek the adoption of a protocol to the European Patent Convention relating to patents in the area of human and animal tissue.

The Council will welcome views and comments on the report. It also hopes that the report will stimulate public discussion; and that its recommendations will lead to early action by the Government and authorities concerned.

A handwritten signature in black ink that reads "Patrick Nairne". The signature is written in a cursive style and is underlined with a single horizontal stroke.

Rt Hon **Sir Patrick Nairne** GCB MC  
Chairman  
Nuffield Council on Bioethics

## **Working Party on human tissue**

**Professor Dame Rosalinde Hurley** *Chairman*

Professor of Microbiology, Institute of Obstetrics and Gynaecology, Royal Postgraduate Medical School. Chairman of the Medicines Commission 1982-1994.

**Mrs Kathleen Baker** is a writer and a counsellor and is Vice President of Greater Manchester Relate

**Professor Sir Colin Berry** is Professor of Morbid Anatomy and Dean of the London Hospital Medical College

**Professor Gerald Dworkin** is Herbert Smith Professor of European Law, King's College, London

**Professor Trevor M Jones** is Director-General of the Association of the British Pharmaceutical Industry, and was formerly R&D Director of the Wellcome Foundation

**Professor Ian Kennedy** is Professor of Medical Law and Ethics, Head of the School of Law and President of the Centre of Medical Law and Ethics, King's College, London

**Mr Kevin Mooney** is a solicitor with Simmons & Simmons specialising in biotechnology and patents issues

**Dr Onora O'Neill** is Principal of Newnham College, Cambridge



## Working Party on human tissue

### Terms of reference

#### The terms of reference were as follows:

- 1 to survey and report on the current and prospective medical and scientific uses made of sub-cellular structures, cells and their products, tissue and organs hereinafter referred to as human tissue;
- 2 to give some account of developments in research and exploitation of tissue, identifying current and potential benefits and current and potential difficulties;
- 3 to identify and define ethical issues and questions of public policy and current practices arising from the use and exploitation of human tissue, including such matters as:
  - a the source of the tissue, eg patient, healthy volunteer, cadaver, fetus;
  - b the relationship between the person using the tissue for research or therapeutic purposes and the source from which it derives;
  - c consent, particularly as regards the potential foreseeable consequences flowing from the intended use;
  - d rights in and exploitation of knowledge acquired from research:
    - ▶ particularly claims to exclusive use of such knowledge through use of intellectual property rights;
    - ▶ and generally the notion of regarding human tissue as a commodity, in particular as a commodity in some cases of significant commercial value.

### Summary of recommendations

#### I Removal of tissue

##### **Where tissue is removed in the course of medical treatment:**

- 1 Consent to treatment should be taken to include consent to disposal, storage and any other ethically acceptable use of removed tissue (paragraph 13.12).
- 2 Current consent procedures should be reviewed to consider whether any additions to consent forms and explanations are required (paragraph 13.13).
- 3 Handling and disposal of tissue should be in a manner that shows respect for the human body (paragraph 13.15).

##### **Where tissue is removed from volunteers:**

- 4 Information must be explicit about the range of intended uses of the tissue and about any risks to the donor (paragraph 13.16).
- 5 The legality of the removal of tissue from children or from legally incompetent adults is uncertain. Any removal should be exceptional and limited to procedures that pose negligible risk and minimal burden (paragraphs 13.17 -13.21). We recommend that the Law Commission's proposals, which would allow non-therapeutic research on incompetent adults subject to strict safeguards, should be enacted (paragraph 13.22).
- 6 Removal of tissue from the dead is largely governed by statute. This should not prevent the removal of tissue for archiving, banking and other ethically acceptable purposes that may not be expressly provided for by statute (paragraph 13.23).
- 7 Payment to donors of tissue should cover only reasonable expenses and should not act as an inducement (paragraph 13.24). Rewarded gifting is unacceptable (paragraph 13.25).

##### **Claims of people from whom tissue is removed:**

- 8 Whether a person from whom tissue is removed retains any claim over the tissue is unclear in law. We recommend that the law should proceed on any claim by examining the basis of the consent given by the person to the procedure that resulted in the removal of tissue (paragraph 13.26).

#### II Acquisition and supply of tissue

- 9 Tissue, including blood and blood components, should be supplied on a cost recovery basis (paragraphs 13.29 and 13.30).
- 10 Professional bodies should ensure that their guidelines reflect their members' responsibilities in the acquisition and supply of human tissue (paragraph 13.29).
- 11 Tissue banks should operate as professional organisations on a non-profit making basis and not as commercial organisations (paragraph 13.31).

- 12 The Department of Health should establish a central register of tissue banks approved for supplying human tissue for medical treatment and research (paragraph 13.32).
- 13 The Department of Health in its current review of confidentiality in the NHS should provide for confidentiality and traceability in the storage and use of human tissue (paragraph 13.33).

### **III Uses of tissue**

- 14 Human tissue used in the development of therapeutic products should be obtained only from sources governed by recognised codes of professional practice that operate on a non-commercial basis (paragraph 13.36).
- 15 Research ethics committees should normally be consulted about the ethical acceptability of proposals involving research on human tissue. This report offers preliminary guidance on recourse to research ethics committees (Appendix 6). The Department of Health and the appropriate medical Royal Colleges should give further consideration and issue guidance (paragraph 13.37).
- 16 Where tissue removed during treatment might prove of significant research interest, the proposal should be referred to a research ethics committee (paragraph 13.38).
- 17 Human body parts should not be displayed in connection with public entertainment or art (paragraph 13.39).

### **IV Patents**

- 18 The Government should press for a protocol to the European Patent Convention setting out in some detail the criteria for applying the immorality exclusion to patents in the area of human and animal tissue (paragraph 13.43).

### **V Safety and quality**

- 19 The proposed EU Directive on In Vitro Diagnostic Medical Devices should include those devices incorporating human tissue (paragraph 13.45).
- 20 On completion of its review of tissue banks, the Department of Health should consult widely and issue guidance taking account of concerns raised by increasingly strict safety precautions for tissue donation (paragraph 13.46).
- 21 Research funding bodies should standardise arrangements for the compensation of patients and healthy volunteers who suffer injury in the course of research (paragraph 13.47).

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# **Section I**

## **Background to the study**

**Chapter 1      Introduction**

**Chapter 2      Public concerns**





## Chapter 1

# Introduction

- 1.1 We are entering a new age of biotechnology and genetic engineering. Medical procedures that were pure science fiction a generation ago are a reality today. One aspect of the recent and rapid advances in biological and medical research is that human tissue is being used in an increasing variety of new ways. Many of these developments, such as advances in transplantation therapy, have unquestionable benefits; but using human tissue in different ways also raises questions of law and presents new ethical dilemmas. The importance of these issues is reflected in the high level of public interest they stimulate. This report examines the ethical and legal questions raised by new and more traditional uses of human tissue and, where possible, suggests a way forward.
- 1.2 The most familiar and widespread use of human tissue is in the diagnosis and treatment of illness. For example, blood or biopsy tissue is removed from patients so that diagnostic tests can be performed. Modern therapy may involve blood transfusion, bone marrow transplants or organ transplants. Already there are ethical issues here that are of justified public concern. The shortage of tissue for transplantation has led to instances in which payment has been made for tissue. Is it ethical to buy and sell human tissue? Are there safeguards in place to ensure that people are not subjected to undue pressure to donate tissue? How should the confidentiality of donors be protected? Are the supplies of tissue properly stored and tested for safety and quality before they are used?
- 1.3 Human tissue is also used for medical and biological research, and for medical education and training. Current research is developing artificial tissue that should alleviate the shortage of tissue available for transplantation. Human cells may be used to produce continuously reproducing cell lines: these can be used in the development and production of vaccines and new medicines. DNA, which contains the genetic information of a cell, may be extracted and used to study the underlying mechanisms of biological processes. Research is continuing into gene therapy techniques which involve the introduction of DNA into human cells to correct specific disorders. Here too, there are important ethical issues to consider. Once tissue has been removed from a person, does that person have any claim over it? What if the tissue is used to develop a product that has commercial value? Should anyone benefit commercially from tissue that was freely donated? Might this jeopardise the goodwill of donors? Is it ethical to patent products derived from human tissue?

## Background to the study

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- 1.4 Tissue specimens taken during diagnosis, treatment or at autopsy are stored in pathological archives. The tissue stored in an archive becomes part of a patient's records, and it can be consulted as part of the therapy of the patient. Occasionally the tissue stored in archives is examined during studies of the natural history of diseases. It was this approach that confirmed the link between asbestos and lung disease. In such a case, the use of the tissue does not contribute directly to the therapy of the patient from whom the tissue came, but it can be of immense importance to the understanding of disease and thus to public health. Here again, ethical questions arise. If the tissue is used for research, are there mechanisms to protect the confidentiality of the individual patients? At the same time, if the research produces information of relevance to their treatment can, and should, the patients be traced?
- 1.5 The uses of human tissue described above contribute to medical and scientific knowledge and may lead ultimately to new therapies. Human bodies or tissue may also be studied for forensic purposes connected with the detection of crime. It is possible to conceive of other uses of human tissue that do not involve medical treatment, research or training; on rare occasions, the lawfulness of non-therapeutic uses of human tissue has been examined in legal cases in the UK, for example, its use in art exhibitions. An important question is whether certain uses of human tissue are unacceptable and should never be countenanced, and on what grounds that view is held.
- 1.6 The expansion of the uses to which human tissue is put has been matched by increasing public interest and sometimes by concern. On the one hand, there is the view that the use of human tissue clinically, and for medical research, leads to benefits in diagnosis and treatment, and should be encouraged. On the other hand, there is concern to safeguard the individuals from whom tissue comes, and to ensure that tissue is used for acceptable purposes. In this report we have tried to maintain a balance between these positions.
- 1.7 Section I of the report, which provides the background to the study, continues with Chapter 2. We survey the historical and current settings in which questions about the uses of human tissue have arisen, and the ways in which the law, and society in general, have responded. Issues raising concern have included trafficking in human organs, advances in reproductive technology and the safety of blood transfusions and transplantation procedures. We describe the American legal case of John Moore which raises important ethical issues. In brief, while physicians treated John Moore for a type of leukaemia, they obtained tissue that enabled them to develop a potentially valuable commercial product. Moore alleges that he was not asked for his consent to this use of his tissue. Should Moore have been asked if he wished to donate tissue for research and development purposes? Should he have had a share in any commercial gains? Did the potential commercial gains foreseen by the physicians

and their associated institutions, compromise their relationship with the patient? If so, what safeguards can prevent this happening in other, similar situations?

### Scientific matters

- 1.8 Section II of the report is intended to provide the relevant scientific background to human tissue and its uses, before the ethical and legal issues are discussed. In Chapter 3 we explain what we mean by human tissue and give a general introduction to the types of tissue found in the body. The type of human tissue that is required will vary, depending on its intended use. A whole organ may be required, or part of an organ, or a quantity of blood. Alternatively, only a small quantity of tissue, a few cells, or even sub-cellular components may be used. One issue here is the perception that special respect should be afforded to corpses and large, identifiable pieces of tissue. A brain or a limb, for example, will be perceived differently from a vial of blood.
- 1.9 The different sources of human tissue, and current good professional practice for its procurement, are described in Chapter 4. Tissue may be removed from a patient for diagnosis or therapy, or from a corpse during post-mortem examination to establish the cause of death. Human tissue may also be donated. The donation of blood by healthy volunteers, of organs for transplantation or of one's body for anatomical studies after death are familiar examples. Pathological archives serve as a source of preserved tissue for teaching and research purposes. Tissue banks storing and supplying fresh human tissue have developed largely in response to the increasing demand for supplies of human tissue for therapy and research. One concern is whether, given the shortage of tissue and organs for transplantation and research, the arrangements for storing and supplying tissue are so organised as to optimise its use. On the other hand, are there sufficient safeguards regulating the procurement of tissue, and its safety? Is it ethical for tissue banks to operate on a commercial basis?
- 1.10 The many present and developing uses of human tissue are surveyed in Chapter 5. These range from routine blood transfusion to the latest advances in creating cell lines for medical research and to produce therapeutic products.

### Ethical principles

1.11 Section III examines the fundamental ethical questions about human tissue and its uses. These questions include:

- ▶ Are there any uses of human tissue which are unacceptable, even if the donors freely consent to those uses of the tissue?
- ▶ How can procedures for gaining consent provide the necessary safeguards for people from whom tissue is removed? What differences in the consent procedures are required to reflect the ethical differences between removal of tissue as part of a person's therapy, and the donation of tissue? What are the appropriate safeguards for people who are unable to give consent because they are too young, too ill or too disturbed?
- ▶ Should human tissue be treated as property? Should a person from whom tissue has been removed be able to make any claim of ownership? Indeed, should anyone make such claims? If so, in what circumstances?
- ▶ Are there any circumstances in which a commercial market in human tissue is acceptable?

1.12 In Chapter 6 we examine these questions and present the ethical arguments. We consider the respect which should be accorded to human beings and human bodies, the unacceptability of some acts involving human tissue, and issues concerned with consent to the removal of human tissue. We discuss different aspects of the commercialisation of human tissue, looking first at the potential benefits and drawbacks of organising the procurement of tissue on a commercial basis. Then we look at the extent to which the development of products derived from tissue should be commercially organised. This chapter provides an ethical basis both for examining the existing law and professional guidance in the following chapters and also for formulating our recommendations.

### Legal matters

1.13 In Section IV we examine the existing law, and the regulations embodied in professional standards, relating to the use of human tissue. There are areas where legislation or regulation has not kept pace with rapidly advancing scientific and medical developments. For example, nineteenth century legal cases concerned with body-snatching established the principle that a body cannot be considered property. Does this legal principle apply equally to parts of the body which may have been removed from a living person? Legal principles from other areas of law have had to

be applied to cases involving human tissue. The area is both complicated and confused, with many uncertainties about the legal basis of the different uses of human tissue. We have examined the current state of the law in some detail. We have highlighted areas of uncertainty and suggested ways in which these areas may be clarified.

- 1.14 We start in Chapter 7 by describing the law regulating the removal of tissue, both from the living and the dead. We look at the requirements for obtaining agreement to the removal of tissue, and the position of those who are legally incompetent to consent.
- 1.15 In Chapter 8 we look at the law concerned with the use of tissue once it has been removed, either from the living or the dead. One use of human tissue is for medical and scientific research and in some instances this may ultimately lead to the development of a commercially valuable therapeutic product. The development of valuable products using tissue removed from John Moore is an example of such a use. This case highlighted the fact that a person from whom tissue is removed may claim an interest in the tissue or products derived from it. There have been other similar cases. A recent legal case in France examined whether a widow has any right to her deceased husband's frozen sperm. In Chapter 9 we examine whether human tissue can be treated as property and whether a person from whom tissue has been removed can have any claim over that tissue.
- 1.16 A separate question is whether a body, or part of a body, can be viewed as the property of the user. In Chapter 10 we ask whether people who use human tissue have any claim over it once it is removed from the human body, and if so, in what circumstances. Then we examine whether the law recognises any limits on the use that may be made of human tissue. In particular, we examine the legality of commercial dealings in human tissue.
- 1.17 In Chapter 11 we consider patent law, and its implications for inventions arising from research using human tissue. This area involves European law. For an invention to be patentable it must both satisfy certain requirements and escape certain exclusions to patentability. We assess how these requirements and exclusions relate to inventions involving human tissue. In particular, we look at the exclusion from patentability on the basis of immorality and how this has been applied in the context of patenting inventions derived from human tissue. We describe the difficulties that have been encountered with the draft Directive on Patent Protection for Biotechnological Inventions. This Directive had been intended to clarify the European Patent Convention covering patents granted by the European Patent Office.

- 1.18 In Chapter 12 we examine the regulation of the safety and quality of human tissue for different uses. The regulatory regime is extremely complicated: both law and professional practice, and national and international guidelines, need to be considered. We survey the general health and safety requirements that may apply to human tissue. We consider the regulation of medicines and medical devices insofar as they involve human tissue, and the specific safety requirements for tissue used for medical treatment, such as blood for transfusion and tissue for transplantation. Finally, we look at the legal claims that may be brought if it is thought that standards of safety or quality have not been met.

## **Conclusions and recommendations**

- 1.19 Finally, in Chapter 13, we give our conclusions and recommendations. We use the ethical principles developed in Chapter 6, and the examination of the law in Chapters 7 - 12, to make recommendations designed to alleviate the current uncertainties in the use of human tissue. Our recommendations will not necessarily require legislation. If the ethical principles expounded in this report command general acceptance, they should be incorporated into good professional practice. In that case, it may well be that some of the legal uncertainties can be adequately covered by the common law presumption that good professional practice sets standards that the courts would not be disposed to set aside lightly. At the same time, we recognise that it may, in the future, be found advisable to incorporate acceptable principles into legislation.

## Chapter 2

# Public concerns

### Introduction

- 2.1 Throughout history special respect has been professed for the human body. This is apparent above all in the protection afforded living people by law and by custom. It is also manifested in the treatment of dead bodies. Quite apart from public health considerations, all known societies prescribe social, religious and legal obligations to dispose of the dead with dignity; and to ensure, save in the most extreme situations, that their remains are left undisturbed. Similar respect is often accorded to parts of the human body, varying of course with different parts: the public attitude towards human tissue differs from its attitude towards other objects. There is a reluctance to talk in terms of ownership of the body or of its parts, and many view with distaste attempts to make money out of the transfer of 'rights' in the body or its parts.
- 2.2 This special respect for the human body has not been seen as an absolute barrier to all uses of the human body and its parts. Society and individuals can benefit from using cadavers and human tissue; for example, for medical treatment, for scientific research or for education. It has long been accepted that corpses donated for dissection are used for the training of medical students; blood from healthy individuals is used for the benefit of patients; organs from living or dead donors are used in transplantation to save, or improve the quality of, the lives of others; human tissue is used in scientific and medical research, which may lead to the development of therapeutic products which become available commercially.
- 2.3 Thus, on the one hand, society demands a general respect for the body and its parts; human tissue should not be used at will, or abused. On the other hand, there are situations where most people are prepared to sanction certain uses of human tissue, provided that the underlying respect due to such material is not abandoned. To safeguard such respect, ethical and legal standards must be formulated which determine when, and for what purposes, the human body and human tissue can be used.
- 2.4 The ethical and legal bases for such uses have rarely been explored properly and systematically. What tends to happen is that, from time to time, particular matters exercise public attention; and if it appears that the law is unclear, or inappropriate, and the matter is sufficiently compelling, specific legislation or professional codes of practice, or both, are introduced to deal with particular problems. Public concern and outcry sometimes hasten legislative or other regulatory activity. Some of these developments have resulted in legislation that has a significant bearing on the medical and scientific uses of human tissue.

### The supply of dead bodies and organs

- 2.5 As an example, the uncertainties, scandals and crimes surrounding the acquisition of bodies by procurers for medical schools in the early part of the nineteenth century led to the introduction of the Anatomy Act 1832. This Act laid down rules regulating the acquisition and use of bodies for teaching and research.
- 2.6 Provisions permitting the removal of organs from a dead body for transplantation purposes have been in existence for many years. The Human Tissue Act 1961 provides for an ‘opting-in’ system, whereby permission must be given, based either on the express consent of the deceased or subject to the veto of relatives, before organs can be taken for such use. Compliance with these strict conditions, it has been argued, means that insufficient organs become available to supply all the patients who might benefit from transplants. There has been a continuing debate as to whether the Act should be amended to provide for an ‘opting-out’ system; one which empowers medical authorities to take organs from bodies for transplantation unless objection has been expressed to such a procedure in advance. Public and medical opinion has not yet accepted this approach, and the Act remains unamended.
- 2.7 Until very recently there was no equivalent legislation dealing with the removal of organs from living donors. The acceptability of such practices depended upon general legal principles and professional ethical opinion based upon criteria such as minimal risks, consent and *bona fide* therapeutic intent. Public concern, however, was aroused a few years ago when media attention focused on various practices involving trafficking in human organs: it was alleged, for example, that impoverished foreigners were being persuaded to come to London for the purpose of selling organs for transplantation. This led to the passage of the Human Organ Transplants Act 1989 which made such activities illegal. Under its provisions the Unrelated Live Transplant Regulatory Authority (ULTRA) was established to review any proposed transplantation of an organ from a live donor genetically unrelated to the recipient.
- 2.8 There has been understandable concern about shortages of organs for transplantation (paragraph 5.8). A recent report has examined different options for improving the supply of organs for transplantation.<sup>1</sup> In this report we have made a more general survey of the ethical and legal issues raised by the increasing use of human tissue for many different purposes. Nevertheless we hope that our conclusions and recommendations will contribute to the debate about organ supply.

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<sup>1</sup> New, B *et al* (1994) **A Question of Give and Take: Improving the supply of donor organs for transplantation** King’s Fund Institute



## Fetal and reproductive tissue

- 2.9 Another concern has been the use of fetal tissue. Although the 1972 Peel Report had recommended a code of practice, renewed concern arose in the 1980s in connection with the possible use of fetal tissue for treatment of Parkinson's disease (paragraph 5.10). The response to this expression of concern was the Polkinghorne Committee which produced a **Review on the Guidance on the Research Use of Fetuses and Fetal Material** and recommended a code of practice on the use of fetuses and fetal material in research and treatment.<sup>2</sup> A key recommendation was that an intermediary should prevent decisions about the management of pregnancy and abortion being influenced by any intended use of the fetal tissue.
- 2.10 The use of eggs, sperm and embryos for reproduction comes within the remit of the Human Fertilisation and Embryology Authority (HFEA). This Authority was established by the Human Fertilisation and Embryology Act 1990, to keep under review, monitor and license various kinds of research and medical practices in these morally, socially and medically sensitive areas.
- 2.11 New developments continue to give rise to new concerns. Thus, in 1994, the possible use for infertility treatment of eggs matured from fetal ovarian tissue became an issue. The HFEA issued a consultation document **Donated Ovarian Tissue in Embryo Research and Assisted Conception** on the implications of using ovarian tissue from live donors, from women or girls who have died, or from fetuses.<sup>3</sup> After consultation and deliberation it was decided that, in the case of fetal ovarian tissue, its use for research was acceptable, but its use in treatment of infertility was not.
- 2.12 Understandably, the sensitive issues surrounding reproduction call for particular care, as demonstrated recently by the concern of some of those opposed to abortion about the use of rubella vaccines produced in a human fetal cell line. Since questions concerning reproductive and fetal tissues fall within the remit of the HFEA, and the guidance issued by the Polkinghorne Committee, the report of this Working Party does not deal specifically with these tissues. Our recommendations are, however, consistent with the recommendations made by those two bodies.

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<sup>2</sup> Polkinghorne, J. *et al* (1989) **Review of the Guidance on the Research Use of Fetuses and Fetal Material** London: HMSO

<sup>3</sup> Human Fertilisation and Embryology Authority (1994) **Donated Ovarian Tissue in Embryo Research and Assisted Conception** London

### Wider concerns

- 2.13 In other areas, too, the use of human tissue and its derivatives is increasing, chiefly as a result of rapid developments in biotechnology and genetic engineering. We are all familiar with the benefits promised from new biotechnological developments: examples include more effective medicines, gene therapy to help avert the incidence of human diseases, and improved or disease-resistant crops and animals. Many groups, however, are increasingly voicing concerns about the environmental and physical risks which these developments create and about their ethical and social implications. Increasing manipulation of reproductive processes and of the genetic composition of organisms has given rise to accusations that some research scientists are exceeding, or abusing, their appropriate role. Passions have been aroused, and are not yet exhausted, in connection with the attempts to obtain patent rights over strains of mice bred with cancer-inducing genes for medical research purposes (paragraph 11.18). There has been protracted controversy in the European Commission and the European Parliament over a proposed Directive on the patentability of biotechnological inventions which raises questions about the patentability of inventions derived from living things (paragraphs 11.6 - 11.7).
- 2.14 The recent concern of some Catholics about the use of a human fetal cell line to produce rubella vaccine highlights the special concerns that religious organisations may have about certain issues. The Working Party has contacted a number of religious bodies. The only specific concern was raised by the medical ethics adviser to the Chief Rabbi. This contribution is reflected in paragraph 4.4.

### The John Moore case

- 2.15 One focus of concern about the medical and scientific uses of human tissue in recent years has been the issues raised by the case of **Moore v Regents of the University of California**.<sup>4</sup> (A summary of the account given in the judgement of the Supreme Court of California in 1990 will be found in Appendix 1).
- 2.16 Moore had a rare form of leukaemia: hairy cell leukaemia. The nub of the case was that, before Moore was operated on, his physicians were fully aware that certain of his tissue could be of great potential value to a number of scientific and commercial efforts. They realised that the patient's tissue could provide "*competitive, commercial, and scientific advantages*". But, notwithstanding what they knew, the physicians did not inform Moore of the potential value of his tissue. Nor, it was alleged, did they seek Moore's consent to the use of his tissue for these purposes.

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<sup>4</sup> *Moore v Regents of the University of California* (1990) 793 P 2d 479

## The general issues

- 2.17 The John Moore case was exceptional and atypical of the general use of human tissue for medical and scientific purposes. It is rare for human tissue removed during medical treatment to be of any interest for medical or scientific research; it is even more unusual for such tissue to be quickly recognised as of tremendous scientific interest and potential commercial value. There are, however, more common situations that may raise questions of ownership and, consequently, of exploitation. The John Moore case raised questions about the law, regulations and professional guidelines that might be necessary in such situations. Tissue, removed during an operation, may be used for research; alternatively, a researcher may obtain tissue from a tissue bank or some other source. The person from whom the tissue is removed may be dead or alive. If the person is alive, the researcher may also be the doctor, with whom the person should have a close and trusting relationship; but equally the researcher may be some remote and unknown member of the hospital staff or a scientist far removed, working for a university, a research institute or a commercial enterprise. In any case, it is largely a matter of chance whether a patient is treated in a specialised or teaching hospital where tissue is more likely to be used for research. Finally, if tissue is used for research, only rarely will this lead to the eventual development of a product which can be commercially exploited.
- 2.18 The issues which arise are both ethical and legal. For example, what relationship exists between the person who was the source of the tissue and the tissue removed? Does tissue remain part of the person in any sense, whether symbolically or in some proprietary sense? Does the person retain any right of control over it or is the consent to removal to be regarded as implying abandonment of the tissue?
- 2.19 Further legal issues follow: if human tissue is abandoned, is it abandoned absolutely or only on terms, for example, that it be destroyed? If on terms and these terms are not complied with, does any sort of dominion revert to the person from whom the tissue was removed? Does the answer to this depend on the circumstances, for example, the context in which tissue is obtained or the nature of the tissue?
- 2.20 There might be complications if it were decided that, before tissue was used, explicit permission was needed from the person from whom it originated. This approach raises several difficulties. For example, it might no longer be possible to locate the person. The person might be dead: in such a case should the permission of a proxy be sought? The user of the tissue might be so far removed from the person that it is not practicable for permission to be sought. Or the tissue might have undergone changes, or have been changed in such a way, that it could be argued that it had lost its original character.

### Commercialisation

2.21 In addition, there is widespread concern about what is often described as commercialisation of the human body. General worries have been expressed about the effect of what is seen as commercialisation in the supply and use of human tissue. There has been specific concern about trafficking in human organs. Such activity, as noted in paragraph 2.7, was made illegal in the UK by the Human Organ Transplants Act 1989. Some 60 countries have enacted similar legislation.<sup>5</sup> On the other hand, some have been worried that a person's tissue may be used without that person gaining any financial reward. The John Moore case, however exceptional it may have been, has understandably increased that concern. We have addressed in this report the ethics of whether financial reward is appropriate to the provision of tissue for medical and scientific use (paragraphs 6.32 - 6.40).

### Safety

2.22 Safety concerns have been emphasised by the transmission both of HIV and of hepatitis through blood transfusion. Before the development of satisfactory HIV testing, haemophiliacs, and others depending on treatment with blood components or products, had been put at risk. It had been hoped that the problems of possible HIV transmission had been solved by the mid-1980s. Recently, however, a German firm, UB Plasma, apparently failed adequately to screen blood products. It was alleged that 400 patients had been infected with HIV.<sup>6</sup> Hepatitis transmission has continued to be a major problem. In the UK, screening of blood donors for hepatitis C began in September 1991, when testing was judged to be sufficiently developed to be effective. This was roughly two years after the identification of the hepatitis C virus.<sup>7</sup>

### International reports, guidance and legislation

2.23 Concern about the medical and scientific use of human tissue has become general in advanced industrial countries. In the USA much attention has been given to the implications of the John Moore case (paragraphs 2.15 - 2.16). The United States Congressional Office of Technology Assessment in 1987 reviewed the uncertainty of

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<sup>5</sup> WHO (Geneva) in its Health Legislation Unit maintains a database on Organ Transplantation Legislation

<sup>6</sup> Gedye, R (1993) **British Medical Journal**, 307:1229

<sup>7</sup> For a review of the development of research on hepatitis C and of the antibody screening tests, see van der Poel, C *et al*, (1994) **Lancet**, 344:1475-9

US law and the uses of human tissue.<sup>8</sup> Further work, on which this report draws, was done by the Law Reform Commission of Canada.<sup>9</sup>

### French legislation

- 2.24 In France the Inspection Générale des Affaires Sociales (IGAS) has enquired into and reported on **Human Tissue Banks**<sup>10</sup> and on **Growth Hormone and Creutzfeldt-Jakob disease (CJD)**.<sup>11</sup> The report on **Human Tissue Banks** noted that in France there had been no legal framework prescribed for tissue banks (paragraph 1.3.2 of that report) and that the procurement of tissue, by contrast with that of organs, was carried out by a variety of professionals and paramedics (paragraph 2.3). The report concluded that the safety of tissue offered was an absolute requirement (paragraph 5.4.1); this required a pilot evaluation of technical processes (paragraph 5.4.2) and procedures for accreditation and authorisation (paragraph 5.4.3). The report on CJD demonstrates how the international cross-border supply of, and sometimes trade in, human tissue create the need for regulation (paragraph 4.4 of that report).
- 2.25 Some of these concerns were addressed by the French legislation concerning bioethics of July 1994. The law on respect due to the human body<sup>12</sup> provided by Article 3 that no remuneration may be made for body parts. It is interpreted as putting the supply of tissue almost exclusively in the hands of public health authorities or non-profit making organisations. Exceptions may be made, by special permission, for commercial companies to operate where the activity is highly technical.<sup>13</sup>

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<sup>8</sup> Office of Technology Assessment (1987) **New Developments in Biotechnology. 1: Ownership of human tissues and cells.** (OTA-BA-377) Washington, DC : United States Congress

<sup>9</sup> Law Reform Commission of Canada (1992) **Procurement and Transfer of Human Tissues and Organs** Working Paper 66

<sup>10</sup> Inspection Générale des Affaires Sociales (IGAS) (1993) **Rapport d'étape sur les banques de tissus d'origine humaine.** SA23, N° 93011. Paris

<sup>11</sup> Inspection Générale des Affaires Sociales (IGAS) (1992) **Rapport sur l'hormone de croissance et la maladie de Creutzfeldt-Jakob** N° 92145. Paris

<sup>12</sup> Loi N° 94-653 du 29 Juillet 1994 relative au respect du corps humain (1994) **Journal Officiel de la République française** pp 11056-9

<sup>13</sup> See the report in **New Scientist**, 2 July 1994, p 6

### Health Council of the Netherlands

- 2.26 The report of the Health Council of the Netherlands on the **Proper Use of Human Tissue** (1994)<sup>14</sup> found in the Netherlands many of the features that characterise the situation in the UK : rapidly expanding use of human tissue, legal uncertainties about procedures for its use and a need to establish procedures to ensure the safety and quality of the tissue used. The Health Council's Committee was able to secure a full response to a very detailed questionnaire on tissue collection, storage and use in the Netherlands.<sup>15</sup> The statistical data are a valuable demonstration of the wide range of human tissue that is now used in medical practice. We have not been able to assemble comparably detailed data for the UK, but the Department of Health's current enquiry into tissue banks may provide more detailed data than our report.
- 2.27 The Health Council's report formulated a number of principles to be observed in the further use of human tissue which are broadly consistent with our arguments and conclusions. These principles are set out in Appendix 2, together with our comments and our reservations about the mechanisms recommended for controlling the further use of human tissue.

### Council of Europe

- 2.28 The Council of Europe has issued guidelines on Human Tissue Banks.<sup>16</sup> It recommended to governments of Member states that the banking of human tissue "*be carried out by non-profit making institutions that are officially licensed by national health administrations, or recognised by the competent authorities.*" But "*. . . in the case of a public health need, the activities . . . may be carried out by a duly authorised profit making body.*" The Recommendation also covers testing for transmissible diseases, safety, record keeping and equity in distribution.
- 2.29 For several years now, the Council of Europe, through the work of the Parliamentary Assembly and of the *ad hoc* Committee of Experts on Bioethics (CAHBI), later renamed the Steering Committee on Bioethics (CDBI), has concerned itself with the problems confronting humanity as a result of advances in medicine and biology. In June 1991 the Parliamentary Assembly recommended that the Committee of Ministers "*envisage a framework convention comprising a main text with general*

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<sup>14</sup> Health Council of the Netherlands (1994) **Proper Use of Human Tissue** Publication N° 1994/01E The Hague

<sup>15</sup> Annexes C and D, pp 113-38 of the Health Council of the Netherlands report *op.cit.*

<sup>16</sup> Recommendation N° R(94)1 adopted on 14 March 1994

*principles and additional protocols on specific aspects”*.<sup>17</sup> In September of the same year the Committee of Ministers instructed the CAHBI “*to prepare, in close co-operation with the Steering Committee for Human Rights (CDDH) and the European Health Committee (CDSP) . . . a framework Convention, open to non-member States, setting out common general standards for the protection of the human person in the context of the biomedical sciences and Protocols to this Convention, relating to, in a preliminary phase: organ transplants and the use of substances of human origin; medical research on human beings*”.

- 2.30 The Convention is therefore devoted to the enunciation of general principles. The protocols that will be attached to it deal with particular fields of biology and medicine. The draft Convention was published in July 1994.<sup>18</sup> The first two protocols are concerned with organ transplantation and medical research respectively.
- 2.31 Two articles in the draft Convention apply to human tissue and its uses. Draft Article 11 states: “*The human body and its parts shall not, as such, give rise to financial gain.*” Draft Article 13 states: “*When in the course of an intervention any part of the human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures.*”
- 2.32 The Council of Europe draft Bioethics Convention is still the subject of anxious debate. The sense of that debate has been well conveyed in specialist journals.<sup>19</sup> Some of the difficulties merely reflect at the international level issues that we found difficult to resolve in the context of this report. For example, Article 6 on the “*protection of persons lacking capacity*” suggests tentatively two situations in which “*interventions with no direct individual benefit*” may be carried out on “*an incapacitated person*”. We too found this issue complex and difficult to reach a final view on, not least because of the current lack of clarity in the UK law (paragraphs 6.25 – 6.28 and 7.8 – 7.10).

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<sup>17</sup> In its Recommendation 1160 (Rapporteur: Mr Marcelo Palacios)

<sup>18</sup> Council of Europe, Directorate of Legal Affairs (1994) **Draft Convention for the protection of Human Rights and the Dignity of the Human Being with regard to the application of biology and medicine : Bioethics Convention, and explanatory report**

<sup>19</sup> See, for example, Butler, D (1995) **Nature** 373:466





## **Section II**

### **Scientific matters**

**Chapter 3            What is human tissue?**

**Chapter 4            The sources of human tissue**

**Chapter 5            Uses of human tissue**



## Chapter 3

# Scientific matters : What is human tissue?

### Introduction

- 3.1 In this chapter, we explain what we mean by human tissue. We start with a brief, general account of biological structures and their organisation. We then go on to consider the different types of tissue in the human body.

### Biological structures

- 3.2 The basic unit of every living organism is the cell. Individual human cells are far too small to be visible to the naked eye. The human body contains around 100,000,000,000,000 cells. We show in Diagram 3.1 several types of cell against the background of a human hair magnified around a thousand times. Cells have different functions and this affects both their size and shape; red blood cells, for example, are smaller and very different in appearance from the nerve cell shown. In addition we have included in Diagram 3.1 some other types of cell which are not part of the human body, but are usually present on body surfaces, for example in the digestive tract: these are bacteria and yeasts.
- 3.3 Cells contain organelles. These are specialised structures which perform different functions in the cell. One important cell organelle is the nucleus which controls the development and activities of the cell. The nucleus contains thread-like structures called chromosomes which are made of DNA. The chromosomes bear the genes which contain the genetic information needed to make all the proteins a cell requires. Proteins perform many important functions within cells. Other proteins are released from cells: the insulin released by pancreatic cells helps to control the level of sugar in the blood.
- 3.4 Some simple organisms are nothing more than free-living, single cells; yeasts and bacteria are examples. Slightly more complex life forms, like the sponges, are organised into masses or aggregates of similar cells with little evidence of cell specialisation. In higher life forms, such as humans, cells are specialised to perform different functions. Strictly speaking, a tissue is a collection of similar cells that are specialised to perform a particular function; examples are muscular, skeletal and nervous tissue. The cells lie in a supporting framework called a matrix which is made of materials produced by surrounding cells. Bone is a tissue where the matrix is extensive and very hard. Circulating blood is different from other tissue in that the cells are not embedded in a solid matrix but are separated each from the other in a fluid called plasma.

## Scientific matters

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- 3.5 Groups of different tissues can be organised further into complex organs like the liver, brain and kidneys, which perform specialised functions. The body's organs are supported and covered by other tissue familiar to us as bone, muscle, connective tissue sheaths and skin.
- 3.6 In Diagram 3.2 we show a human liver at ever increasing magnifications from the whole organ down to an individual protein molecule. At each stage of the diagram a human structure with potentially valuable uses is shown.
- ▶ The whole liver, or part of it, may be used for transplantation.
  - ▶ A section or block of the liver tissue may be used for research, for example to study how potential medicines affect the tissue.
  - ▶ Liver cells may be maintained in culture and used for research, for example in looking at the toxicity of potential medicines.
  - ▶ DNA can be extracted from the nucleus of a cell and may be used in testing for the presence of a gene defect associated with an illness.
  - ▶ In the final part of the diagram, a protein molecule is being made. Some proteins, for example insulin and human growth hormone, are very valuable in the treatment of disease.

## Body wastes

- 3.7 In our report we have defined the body's **wastes** as products that are ordinarily abandoned, such as urine, faeces, sweat, shorn hair, shed epithelial scales, nail clippings and the like. Hair, of course, although it is normally regarded as waste, may be sold for use in wigs. Some waste products may be made use of in medical treatment or research. Urine, for example, was used to isolate the substance erythropoietin, which stimulates the bone marrow to produce red blood cells (paragraph 5.5). Waste products, which are customarily discarded or abandoned, do not usually give rise to the ethical or legal considerations posed by the acquisition or use of the tissue or organs proper and we have excluded them from further consideration.
- 3.8 Unlike most of the waste products described above, the placenta is, of course, an example of a human tissue with a specialised function in the body. Once the placenta has completed its function and has been expelled from the body after birth, however, it is usually abandoned by mothers without more ado and is generally regarded as clinical waste and incinerated. Occasionally, however, the placenta may be used to extract proteins of therapeutic value, such as albumin which is used for treating burns. Some mothers may wish to ingest portions or infusions of the placenta in the belief that it wards off postnatal depression or is otherwise beneficial in the lying-in period.

## **Conclusions**

3.9 This report is concerned with human tissue organised at the different levels of complexity illustrated in Diagram 3.2. We offer, in Appendix 3, a survey of the many types of human tissue used therapeutically. A more general list of human tissue with uses discussed in this report would include:

- Organs and parts of organs
- Cells and tissue
- Sub-cellular structures and cell products
- Blood
- Gametes (sperm and ova)
- Embryos and fetal tissue

Diagram 3.1: An illustration of the relative sizes of different types of cell, shown against the background of a human hair (all structures are shown at a magnification of about  $\times 1000$ ).

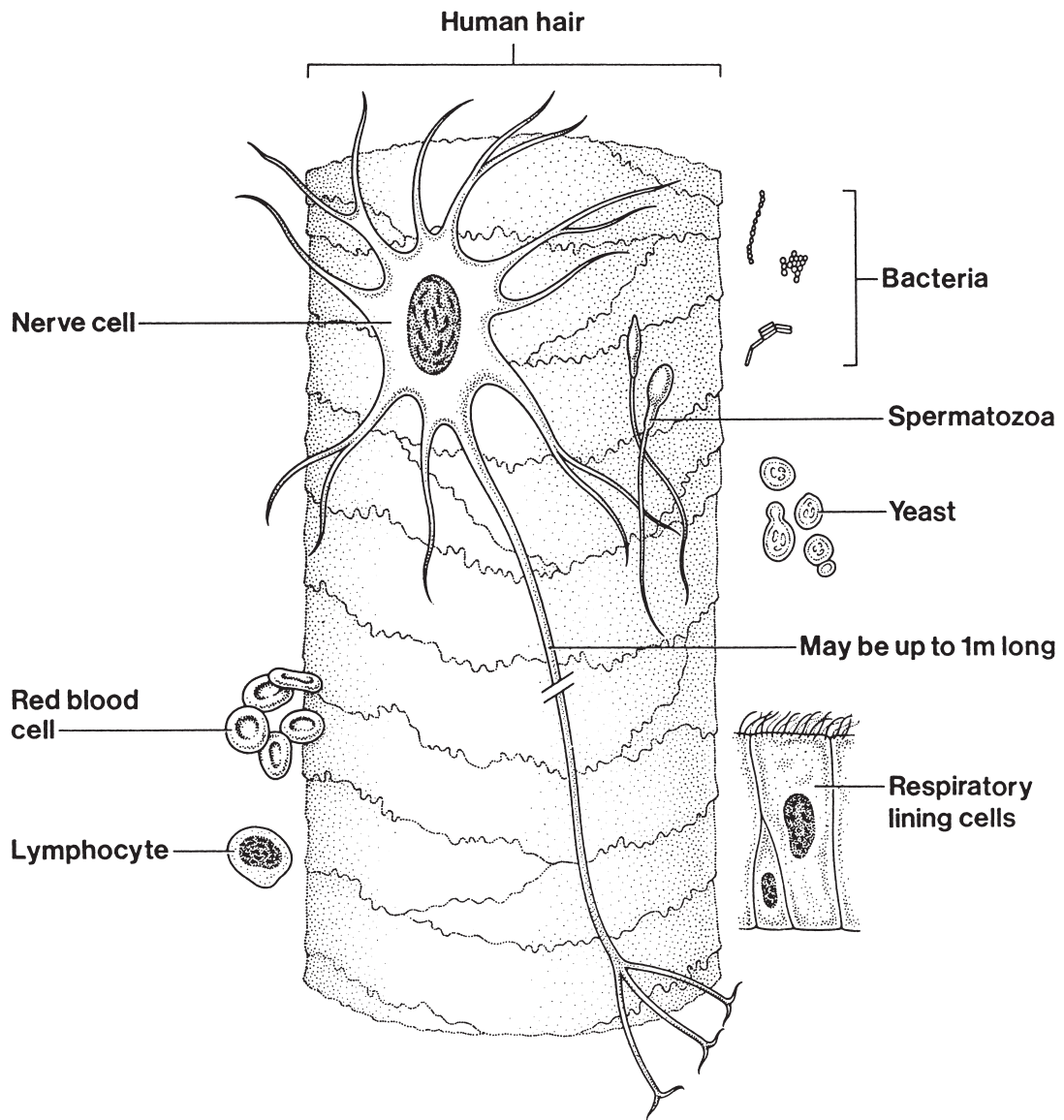
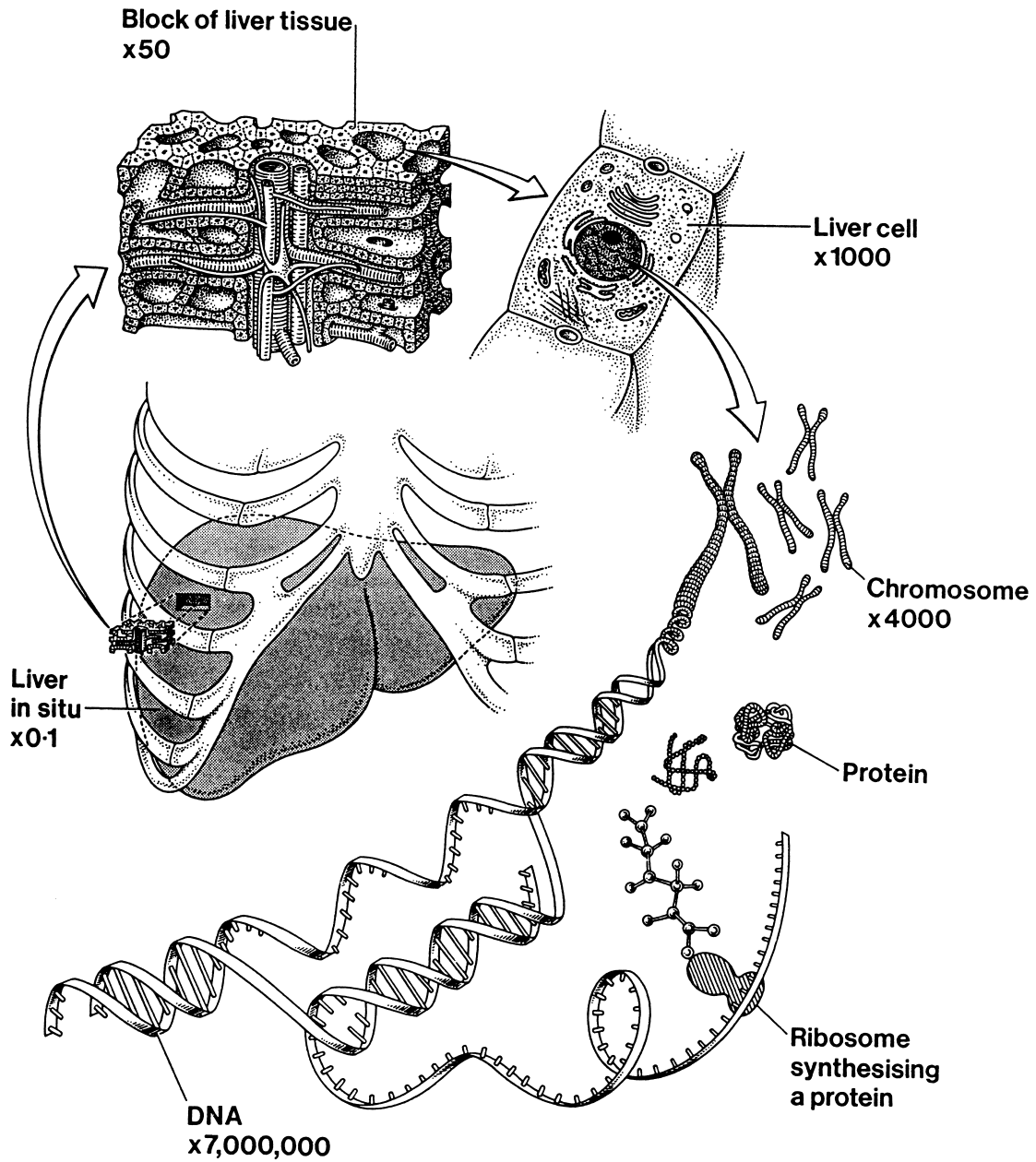


Diagram 3.2: A schematic view of the human liver, shown at progressively increasing magnifications, starting with the whole organ and ending with the DNA and proteins found in a single cell (approximate relative scales are indicated).







## Chapter 4

# Scientific matters : The sources of human tissue

## Introduction

- 4.1 In this chapter we look at the different sources of human tissue and describe some of the safeguards incorporated into current working practice to regulate the removal and acquisition of human tissue. The legal framework relating to procedures for removing human tissue is discussed in Chapter 7. Table 4.2 on p 30 gives examples of tissue from different sources and the uses to which the tissue may be put.

## Left-over tissue obtained during diagnosis or treatment

- 4.2 Most commonly, human tissue is removed from the body in the course of diagnosis or treatment. Blood or bone marrow may be drawn for diagnostic examination. Amniotic fluid or pieces of chorion villus (part of the placenta) may be taken for cytogenetic or other diagnostic tests during pregnancy. Small pieces of tissue may be taken by biopsy for pathological examination and diagnosis, and larger amounts of tissue may be removed surgically during operation for malignant or other disease. Inevitably, prudence dictates some over-collection, and there may be tissue left over after sampling or surgery once sufficient has been assured for diagnosis and therapy. This surplus is ordinarily discarded and destroyed as clinical waste. Such left-over tissue, and also material archived during the course of diagnosis and therapy may, however, be made available for scientific research, medical training and scholarship, and evaluation and review of medical procedures. The Royal College of Physicians has advised that the use of anonymised left-over tissue for research is a traditional and ethically acceptable practice that does not need consent from patients or relatives, and need not be submitted to a research ethics committee.<sup>1</sup>
- 4.3 An example of left-over tissue is the excised foreskin after circumcision, which can be used as a source of cells. Over-collection of very small amounts of blood or tissue such as chorionic villi also occurs in the course of diagnosis performed on the fetus *in utero*. Serum or plasma that has proved to be in excess of diagnostic requirements can be used, often pooled, in standardisation of tests or in quality assurance programmes.

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<sup>1</sup> Royal College of Physicians (1990) **Guidelines on the practice of ethics committees in medical research involving human subjects** Second edition, p 29

- 4.4 It must be emphasised here that there are underlying principles of professional conduct that govern such uses of left-over tissue or samples. There must be no intention to collect surpluses of tissue, not required for diagnosis or treatment, for which specific consent should be sought. The user must be a respectable, *bona fide* scientist and the use must be ethical and inoffensive. Respectful disposal of any tissue remaining after research should be afforded, with ritual burial of material from ritual circumcision (the arlot). Incidents in which human tissue is not thought to have been handled or disposed of appropriately have given rise to much concern. We recommend that bodies such as NHS trusts and independent hospitals review their practices on all handling and disposal of human parts, excised tissue and abortuses to ensure that they meet the requirements both of law and of professional standards and also to ensure that major body parts (for example, limbs, hands), and tissue subject to special public concern or scrutiny (for example, fetal tissue), are handled and disposed of in ways which show respect.

### **Autopsy material**

- 4.5 Autopsies are carried out to determine the cause of death. Parts of organs and tissue are taken by the pathologist for section and study, and whole or cut organs may be removed if they illustrate particular pathological processes. The thorough dissection and examination required during any autopsy examination provides invaluable opportunities to add to the body of medical knowledge through demonstration, teaching and training. Opportunities to study tissue from dead bodies are vital to medical research and scholarship and to the development of greater understanding of disease and the effects of treatment. An autopsy is often witnessed by and demonstrated to medical students and practitioners. Bodies may also be dissected by surgeons seeking new approaches to surgical problems.

### **Cadavers donated for anatomical studies**

- 4.6 Cadavers may be donated, by arrangements made before death, for anatomical study and teaching and, as such, are available for demonstration by dissection. Bodies donated for anatomical purposes are fixed and dissected by medical students in the course of their training. The tissue of such cadavers is not available for purposes unconnected with anatomical examination.

### Donated tissue

- 4.7 Subject to certain safeguards and some statutory control (Chapter 7), volunteers may donate, both during life and after death, organs or tissue for 'spare part' or replacement surgery. The supply of organs, and also of corneas and heart valves, for transplants is co-ordinated by the United Kingdom Transplant Support Service Authority (UKTSSA), a Special Health Authority established in 1991.<sup>2</sup> The NHS Organ Donor Register, a national register of people who wish to donate organs after their death, administered by the UKTSSA, came into effect in 1994.<sup>3</sup> Healthy volunteers may also donate tissue for research purposes. Tissue, usually blood, but sometimes biopsy specimens, may be donated during the initial trials of new medicines or therapeutic agents. Blood collected from donors (see below) that has become outdated and can no longer be used therapeutically may also be made available for research.
- 4.8 In the United Kingdom, whole blood used therapeutically comes from volunteer donors. The provision of blood and blood products in England is the responsibility of the National Blood Authority, which manages the National Blood Service and the Bio Products Laboratory. The National Blood Service organises the donation of blood and the quality assurance, storage and transport of blood and blood components. Whole blood is usually separated to produce three components of therapeutic importance: red blood cells, platelets and plasma. Plasma may be processed further by the Bio Products Laboratory to produce therapeutic products such as Factor VIII used by haemophiliacs and albumin for burns patients.
- 4.9 There has been increasing debate about the ethics of commercial transactions involving blood and blood products. One recent focus for concern was the basis on which private hospitals obtain blood (Fig 4.1). The current situation is that about 1% of all donated blood is supplied to private hospitals. This arrangement permits the central regulation of all blood donation in the UK and is seen as preferable to a situation where private hospitals would have to set up alternative systems for collecting blood. Such systems might involve payment of donors, which is widely seen as carrying the risk of affecting the safety and quality of blood donated. In the present arrangement, the same cost-recovery fees (approximately £35/unit of blood) are charged to NHS and private hospitals alike.<sup>4</sup> It is a condition of supply that private hospitals should make no profit on blood supplied to them. It has been

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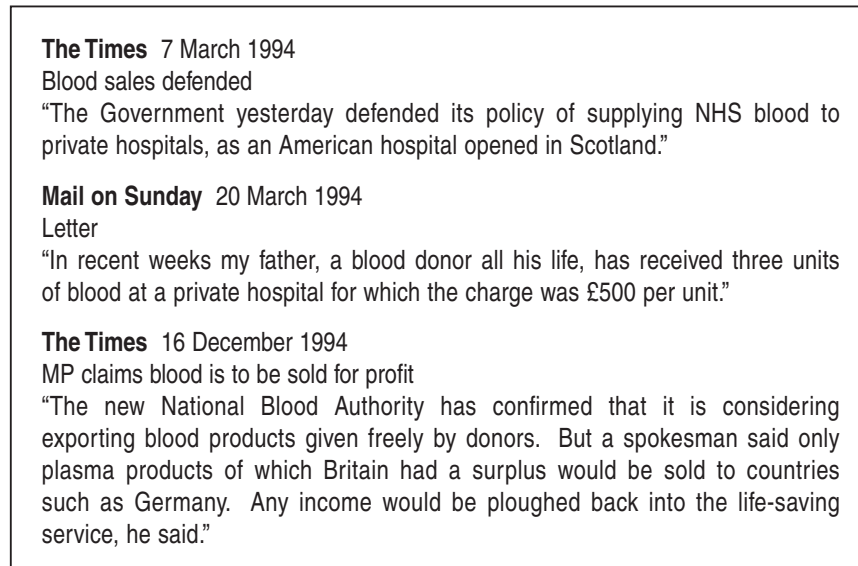
<sup>2</sup> United Kingdom Transplant Support Service Authority (1992) **The First Annual Report of the Special Health Authority 1991/2**, Bristol

<sup>3</sup> Registration forms can be obtained from Post Offices, or write to NHS Organ Donor Register, FREEPOST (BS8793), PO Box 14, Patchway, Bristol BS12 6BR

<sup>4</sup> Department of Health Circular HC(85)8

alleged, however, that a private hospital had been charging patients up to £500/unit for transfused blood (Fig 4.1).

Fig 4.1



- 4.10 The basis on which blood products are supplied to users outside the NHS has also become an issue. It has been alleged that blood products produced by the Bio Products Laboratory are being sold abroad (Fig 4.1). The policy of the National Blood Authority is to collect only enough blood from donors to satisfy therapeutic needs in the UK. This results in a surplus of some blood products, such as albumin, and these products may be sold to foreign countries. Money earned on exporting products helps the Bio Products Laboratory to recover its costs over its range of products.

## Fetal tissue and embryos

- 4.11 As we mentioned in Chapter 2, these sensitive tissues enjoy special safeguards (paragraphs 2.9 - 2.12). Research on human embryos up to 14 days old is permitted, for certain limited reasons, subject to strict licensing conditions imposed by the Human Fertilisation and Embryology Act 1990 and supervised by the Human Fertilisation and Embryology Authority, and subject also to the explicit consent of the donors. The code of practice on the use of fetuses and fetal material in research and treatment produced by the Polkinghorne Committee recommends that fetal material, which may be the result of death *in utero* or of spontaneous or induced abortion, may be used for research and also for therapy such as transplantation or

reconstructive surgery. There are recommended safeguards to prevent the management of pregnancy and decisions about abortion being influenced by the potential use of the fetal tissue. The key recommendation is that an intermediary should eliminate contact between the source and the users of fetal tissue.

### Tissue banks

4.12 Tissue used for medical treatment or research is often procured through local and informal arrangements with individual practitioners or with particular hospital departments. As the pace and scope of reconstructive and transplantation surgery and of research accelerates, it has become clear that *ad hoc* arrangements of this sort do not suffice to meet the needs of modern medicine. This has led to the development of tissue banks, which procure and store human tissue and make it available for further use (Fig 4.2), and of coordinating bodies such as the United Kingdom Transplant Support Service Authority (UKTSSA) (paragraph 4.7).

Fig 4.2

After Stephen Kirkby suffered burns to 95% of his body in an accident at a camping site, an appeal was launched to find live skin donors. Although donors were found and the operation was successful, he later died of a kidney infection. This incident highlighted the importance of having a national skin bank. As a result, a skin bank will open at Queen Mary's University Hospital, Roehampton, in 1995. People will be asked if they want to donate skin removed during cosmetic operations and skin will also be removed from people who donate it after their death. The skin, which can be stored for up to three years in refrigerators, will be used to treat burn victims and cancer patients.  
(Source: **Independent** 19 October 1994)

4.13 Many tissue banks operate within the NHS, holding fresh tissue at hospital sites chiefly for the therapeutic purposes of transplantation and reconstructive surgery. Bone, heart valves, corneas and skin are the most commonly banked tissues, since they are relatively straightforward to handle. Bone, which is removed during hip replacements and used for limb reconstruction after accidents or bone cancer, can be frozen and stored for up to five years and does not require matching to the recipient's tissue. In Scotland, and in some areas of England, bone banks have been established under the auspices of blood transfusion centres. Table 4.1 offers a survey of tissue banks supplying tissue for transplantation in the UK.

Table 4.1: The number of tissue banks in the UK, which are members of the British Association of Tissue Banks, supplying different types of fresh human tissue for transplantation.<sup>5</sup>

Tissue	Number of Tissue Banks
Cornea	5
Heart Valve	6
Bone	5
Skin	2
Brain (research)	1
Cornea/heart valve	1
Heart valve/bone	2
Heart valve/bone/skin	1
In addition to the bone banks included above, several blood transfusion centres in Scotland and England store bone	

4.14 Medical and biological research using human tissue may be undertaken in hospitals and in the laboratories of universities, medical research charities or pharmaceutical and biotechnology companies. As we describe in Chapter 5, liver tissue is especially important for researching the effects of potential new medicines and their fate in the body (paragraph 5.12). Much of this research occurs in the laboratories of pharmaceutical companies and it has been argued that dependence on informal links with hospitals for supplies of human tissue particularly hampers pharmaceutical companies and can hold back such research. The use of human tissue for research is also seen as a way of reducing the use of animals in research. For some purposes, if human tissue is available its use may be more appropriate than the use of animals (paragraph 5.14). Thus, there are reasons to improve the availability of human tissue for research.

4.15 The Medical Research Council (MRC) administers several banks which supply tissue for research purposes. Various brain banks store fixed or frozen material obtained by biopsy or post-mortem from those with disorders such as Alzheimer's disease. An MRC Fetal Tissue Bank makes fresh material available for research, acting as an intermediary organisation separating decisions about abortion from those relating to the subsequent use of the tissue as recommended by the Polkinghorne Committee (paragraph 4.11). Further guidance on the use of fetal tissue for research, diagnosis and therapy has been prepared jointly by the Department of Health and the MRC.<sup>6</sup>

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<sup>5</sup> Information supplied by the British Association of Tissue Banks

<sup>6</sup> Department of Health (1995) **Guidance on the use of fetal tissue for research, diagnosis and therapy** HMSO

4.16 Thus, the term tissue bank encompasses both institutions that handle primarily fresh tissue and those that maintain collections of preserved tissue. Pathological archives also serve as a source of preserved tissue, and we describe the important uses of such archives, in Chapter 5 (paragraphs 5.19 - 5.25). There is also a distinction to be drawn between tissue banks that supply tissue primarily for therapy, and those that supply it for research purposes. It is widely recognised that sensitive handling is required so that requests for donation of tissue for research do not undermine the motivation to donate tissue for therapy. Finally, tissue banks may operate simply as central stores, providing research workers or surgeons with access to certain tissue, or those who organise them may pursue a more active policy of organising collection and distribution. In the UK at present, tissue banks are non-profit making bodies established, funded and administered by the NHS, the Medical Research Council or medical research charities. Elsewhere, some tissue banks appear to operate on a more commercial basis. A number of foreign organisations advertise the availability of a variety of tissue and organs which can be supplied for research purposes or clinical applications.

### Conclusions

4.17 As we have seen, the source of human tissue may be tissue left over after surgery once diagnosis and therapy have been provided for. Volunteers may donate blood or other tissue for transplantation or research, or their organs or bodies after death. The people from whom tissue is removed are protected and safeguarded in a variety of ways which include professional practice arising from long established custom, specific codes of guidance for conduct, and statute and common law (Chapter 7).

Table 4.2 Sources and uses of human tissue

Source	Examples	Actual or Potential Uses
From patients following diagnostic or therapeutic procedures (includes left-over-tissue) a) minimally invasive procedures (usually healthy tissue)  b) invasive procedures (biopsy or surgery: usually diseased tissue)	Blood or blood serum Scrapes of surface cells  Many organs or tissues	Diagnosis, archiving, research and teaching  Diagnosis, archiving, research and teaching
Autopsy specimens	Many organs or tissues	Diagnosis, archiving, research and teaching
Donations of organs or tissue from living or dead, related or unrelated volunteers	Kidney, liver, heart, bone marrow, cornea, gametes Blood Tissue (for example small skin biopsies)	Transplantation  Transfusion, manufacture of blood products Fundamental or pharmaceutical research
Fetal tissue	Many organs or tissues	Research or therapy
Body wastes	Urine, faeces, sweat Hair, nail clippings	Usually disposed of Direct commercial value (hair) Extraction of substances for therapy or research (for example erythropoietin from urine)
Abandoned tissue	Placenta	Usually disposed of Extraction of therapeutic substances (for example albumin)



## Chapter 5

# Scientific matters : Uses of human tissue

## Introduction

5.1 Once removed, human tissue may serve many beneficial purposes: in the diagnosis and medical management of individuals and in medical research, teaching, training, review and scholarship. These latter activities contribute to the public health and the public good. For example, research using human tissue may yield products which then become widely available for diagnosis or therapy. Appendix 4 lists examples of such products which are either being developed or are licensed for clinical use in the UK.

5.2 In this chapter we look at the following uses of human tissue:

- ▶ Blood transfusion
- ▶ Bone marrow transplantation
- ▶ Organ transplantation and reconstructive surgery
- ▶ Tissue replacement
- ▶ Studies of human tissue
- ▶ Diagnosis using cells
- ▶ The use of cell lines
- ▶ Pathological examination, archiving and storage
- ▶ Non-therapeutic applications

## Blood transfusion

5.3 The transfusion of blood is the longest established and most familiar of the life saving therapeutic uses of human tissue. Whole blood from compatible donors, and blood components, are used routinely for the benefit of others. Whole blood may be used to replace that lost through haemorrhage and its use makes cardiac or vascular operations (bypass surgery) possible.

5.4 Blood contains red cells, white cells and platelets that circulate in the fluid plasma. Plasma is a rich mixture of nutrients and many different proteins including protective antibodies and factors that promote or inhibit blood clotting. In modern medicine, component therapy using cells or substances separated from whole blood is widely used. Fresh red blood cells can be combined with fresh frozen plasma and used to replace lost blood. Separated platelet concentrates are used to treat specific disorders, such as some leukaemias. Plasma is the starting point for a number of therapeutic

products. Blood clotting factors, such as Factor VIII, are used in the treatment of haemophilia. Albumin is used to treat burns patients. Protective antibodies are used to prevent infectious disease such as tetanus or hepatitis in individuals at high risk and in the management of immune disorders.

- 5.5 Treatment with recombinant human erythropoietin, a genetically engineered substance that stimulates the bone marrow to produce red blood cells, has replaced the use of transfused blood in many who have anaemia caused by chronic renal failure. Artificial blood is in the early stages of clinical evaluation with the development of cell free haemoglobin. Haemoglobin, the substance contained in red blood cells that carries oxygen around the body, is either prepared from outdated human donor blood or produced by genetic engineering. The advantage of cell free haemoglobin is that it will not require cross matching with the recipient before transfusion. Current research is focused on preventing the rapid break down of the haemoglobin once it is in the body.

### **Bone marrow transplantation**

- 5.6 Bone marrow transplantation is used to treat leukaemias and specific inherited diseases. It is familiar to all from newspaper accounts and appeals for donors. Donors must be carefully matched to recipients according to the genetic constitution of their cell types. The practice of culturing and transplanting stem cells, the precursor cells of the blood, is being developed. If successful, this will minimise the need for complete marrow donation.

### **Organ transplantation and reconstructive surgery**

- 5.7 Organ and tissue transplantation are now well established in modern surgery. Tissue from a deceased or living donor is used for replacement or repair in the recipient. Tissue may also be transplanted from one site to another in the same patient during grafting or reconstructive surgery of damaged organs.
- 5.8 Tissue loss or end stage organ failure affects millions of people worldwide. In the UK alone, about 5,000 organ and corneal transplant operations are carried out annually.<sup>1</sup> The body part used during surgical replacement may be a complete organ (for example kidney), groups of organs (for example heart/lung), or portions of organs (for example sections of liver). Large sheets of tissue (for example portions of bone) or small pieces of tissue (for example bone chips) may be used in surgical repair. Appendix 3 offers a more complete list of the types of tissue and organs used

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<sup>1</sup> Figures from the United Kingdom Transplant Support Service Authority

in organ transplantation and reconstructive surgery. All these procedures rely on donors; demand has long outstripped supply and waiting lists continue to rise. At the end of 1993, about 4,800 patients were waiting for kidney transplants in the UK.<sup>1</sup> We share the general concern at the unmet need for donor transplants, especially kidney transplants. We therefore welcome the Government's recent initiative in establishing the NHS Organ Donor Register (paragraph 4.7), but note that further measures may be required (paragraph 2.8). In the next section we discuss advances in the development of tissue substitutes that may alleviate the shortage of organs and tissue for transplantation.

### Tissue replacement

- 5.9 Tissue engineering is an advancing science that unites the principles of biology and engineering in the development of tissue substitutes that restore, maintain or improve anatomical or physiological function. Research investigators have already attempted to develop substitutes for almost every mammalian tissue. Many of the components used in tissue engineering are of human origin, although some are artificial. Appendix 5, while not exhaustive, lists some of these developments.
- 5.10 Strategies for tissue replacement as an alternative to tissue transplantation include the use of:
- ▶ tissue inducing substances, such as human growth factors, to stimulate the growth of replacement cells or tissue. An example is the use of erythropoietin to stimulate the production of red blood cells as an alternative to blood transfusion (paragraph 5.5).
  - ▶ isolated cells or cell substitutes. Fetal nerve cells, for example, may be transplanted into the brains of patients suffering from Parkinson's disease. The fetal cells release the neurotransmitter dopamine that is deficient in Parkinson's disease patients. The use of cell free haemoglobin as a substitute for blood transfusion is another example (paragraph 5.5).
  - ▶ cells placed on or within artificial supporting matrices to form tissue masses or constructs which can be implanted. Techniques are being developed in which liver cells are contained within an artificial matrix. If successful, such artificial tissue could provide an alternative to liver transplants. For skin grafts, a supporting matrix alone can be used to stimulate the growth of the patient's own blood vessels and cells.

### Research studies of human tissue and cells

- 5.11 Excised organs, tissue slices or snips and isolated cells may be kept viable for a limited time under experimental conditions and used for research purposes. The research may involve fundamental studies of tissue function: of gaseous exchange in the lung, for example, or the transport of substances across the placenta. Applied research may make use of infected or diseased tissue: studies of white blood cells infected with the HIV virus, or of blood vessels affected by atherosclerosis are examples.
- 5.12 Human tissue is used in the discovery and the development of medicines. Much of this research is performed by pharmaceutical companies. Isolated tissue may be exposed to potential medicines intended to exert a specific effect and the response of the tissue measured. The liver has an important function in breaking down drugs and toxic substances and eliminating them from the body. So studies of sections of human liver, or of isolated liver cells, are important for determining the fate of a new medicine in the liver, its toxicity and how fast it is eliminated from the body, before the medicine is tried on healthy volunteers.

### Diagnosis using cells

- 5.13 Cells of the blood, bone marrow, amniotic fluid and chorionic villi may be cultured for analysis of the chromosomes or DNA for diagnosis of disorders such as Down's syndrome, cystic fibrosis and leukaemia.

### The use of cell lines

- 5.14 Unmodified human cells survive under artificial conditions for only a few generations. If modified by chemical treatment or incorporation of tumorigenic viruses, cells can be made to grow continuously as 'immortal' cell lines. Some cell lines of human origin originated many years ago from the cells of malignant tumours. Some cell lines are commercially available, others are prepared by individual laboratories for specific purposes. One advantage of cell lines is that they can be used to produce large numbers of cells, and their various components. This reduces the need to collect quantities of fresh tissue. Examples of the increasing use of human cell lines for the production of therapeutic products and in medical research include:
- ▶ fundamental studies of cell behaviour and function. An example is the use of cell lines for researching the mechanisms by which cells repair the DNA damage caused by radiation;

- ▶ applied research to develop new therapeutic agents such as antiviral or anticancer medicines and to study their effects and their possible interactions with other medicines. An important element of such research is the toxicity testing of new medicines. This is one situation where the use of human cell lines may be more appropriate than the use of animals. The human lymphocyte assay, for example, is used in measuring the mutagenic potential of new medicines;
- ▶ the production of therapeutically active substances on exposure to toxins or infectious agents. These substances can be collected and manufactured as medicines. For example, the interferons produced by cells when they are exposed to viruses can be used to treat leukaemia or hepatitis;
- ▶ the propagation of human viruses that are then used to make vaccines. The production of rubella vaccine from human fetal cell lines is an example.

### Studying subcellular components

- 5.15 Human tissue and cells can be used to isolate subcellular components for medical or biological research. Microsomes, for example, are small subcellular structures that, when isolated from liver cells, can be used to investigate the breakdown of new medicines. Perhaps the most important subcellular component, however, is the genetic material of cells, which is being used increasingly for research.
- 5.16 The isolation of genes coding for specific proteins has proved a powerful method for investigating the basic mechanisms underlying different biological processes, whether normal or diseased. Isolation and study of the cystic fibrosis gene, for example, indicated that it codes for a protein required for the transport of chloride ions across cell membranes. The absence of this transport in the lungs of cystic fibrosis patients accounts for the accumulation of sticky mucus in the lungs. Current research is working towards treating inherited disorders of this kind by somatic cell gene therapy which involves delivering corrective DNA to the affected tissue.
- 5.17 The insertion of foreign genes, which may be of human origin, into animals produces so-called transgenic animals. Transgenic animals can provide models for the study of some human diseases. Transgenic mouse strains which develop cystic fibrosis, for example, are used to test the use of gene therapy as a potential new treatment for the disease. Transgenic animals producing human proteins may eventually form a source of animal organs and tissue for transplantation or reconstructive surgery which are less susceptible to rejection than tissue from unmodified animals.

- 5.18 Human genes may be isolated and incorporated into microbial cells such as bacteria or yeast which are then grown in large scale biotechnology facilities to produce important medicines such as insulin, growth hormone, and erythropoietin.

### **Pathological examination, archiving and storage**

- 5.19 The importance of this range of uses of human tissue is difficult to over estimate in modern biomedical practice. Almost all human tissue removed during surgical intervention or taken at autopsy is examined diagnostically by a pathologist.
- 5.20 The tissue, which may be fresh or fixed, is first examined macroscopically. Then representative blocks are taken, embedded in wax, cut into thin sections, mounted on glass slides, stained and examined using the microscope. The primary purpose of this histopathological examination is to establish or to confirm the diagnosis. In the case of malignant disease, the degree of spread can be ascertained. Progress, either of disease or its treatment, can be measured in certain conditions by examination and comparison of serial biopsy specimens.
- 5.21 These stained microscope slides and the blocks from which they were made, together with stained slides from cytological examinations (for example, for cervical cytology) must be stored so that they are available for re-examination or review as part of good practice in histopathology laboratories. Some stained blood or bone marrow films for haematological examination are also stored in this way, as are some slides made in the course of cytogenetic diagnosis. The collection, with its attendant documentation, forms the pathological archive and is a cardinal resource, not only in diagnosis and management of individual patients, but in undergraduate and postgraduate teaching and education, research, review and scholarship. Pathological archives are large; a hospital dealing with 10,000 specimens of tissue a year will generate around 25,000 blocks and some 40,000 slides. The University Department of Morbid Anatomy at the Royal London Hospital has around 4,500,000 slides, 1,500,000 blocks and 10,000 wet specimens in store.
- 5.22 By study of the archive, pathologists can arrive at conclusions about the natural history of a disease by obtaining a view of how it behaves in many individuals. Such study of pathological archives confirmed the link between exposure to asbestos and lung disease. By this method new varieties of tumours within a particular classification have been identified behaving either less or more aggressively. This information will, in turn, inform therapeutic choice when a new patient presents; it may minimise the extent of surgery if experience has shown that radical procedures are unnecessary or ineffective, or it may indicate the need for more radical intervention if the prognosis has proved poor with conservative therapy in the past. This approach also allows the evaluation of the effectiveness of different medicines used to treat diseases. Molecular biological methods applied to material stored many

decades previously may provide genetic information and historical evidence of early occurrence of particular viral infections (Fig 5.1).

Fig 5.1

In 1959, a 25-year old man died of unexplained causes in Manchester Royal Infirmary. The unusual symptoms included weight loss, fever, night sweats, ulcers and infections. After the autopsy, tissue samples were routinely stored and the case was reported in *The Lancet*. Many years later, when AIDS had been defined, the doctors who had seen the case realised that the patient's symptoms had been consistent with HIV infection. In 1987, modern PCR technology was used to test the tissue samples stored in the archive revealing that the patient's cells had indeed been infected with HIV.

This use of archived tissue resulted in the earliest documented case of HIV infection in Britain. The HIV strain from the late 1950s was compared with strains prevalent today and with related chimpanzee viruses. This comparison suggested that the human form of the HIV virus arose about 100 years ago when it diverged from the chimpanzee virus. This argues against theories that the HIV virus arose as the result of activities by research scientists using new techniques of genetic manipulation, for instance, during the development of polio vaccines in the Congo in 1957.

(Source: **Independent on Sunday** 6 November 1994)

- 5.23 The archive is essential in quality control and assurance. The slides are a permanent record that can be checked by independent experts in the interests of peer audit review and quality assurance. The archive may be reviewed when individual diagnoses are queried, as has proved necessary, for example, in the difficult area of cervical screening of women. Large sections of the pathological archive are occasionally reviewed where mistakes are thought to have occurred. In the United Kingdom, for instance, reviews of diseased bone samples have recently been performed.
- 5.24 Thus, collectively and for individual patients, careful record keeping relevant to the histopathological archive allows definition of the natural history of disease, permits identification of new disease entities, establishes the efficacy, or sometimes, the failure of treatment and permits reassessment of management if unexpected features are encountered.
- 5.25 In all pathological archives the material is stored anonymously, being identified by laboratory number. Thus, if the material is to be used for research purposes anonymity is readily assured, but patient identity can be established by the pathologist from the confidential diagnostic records, if the research reveals information of relevance to the treatment of the patient.

### Non-therapeutic applications

- 5.26 The human tissues or products described so far have been used for diagnosis or therapy, for medical training and review or for research leading to therapy or adding to scientific knowledge. Use is also made of human tissue for forensic purposes, that is, connected with the detection of crime. Post-mortem examination may be performed in order to establish the cause of sudden, unnatural or violent death. The taking of blood samples for matching purposes has been practised for 50 years. To a large extent such activities are regulated by statute. The Coroners Act 1988 regulates the removal and use of tissue from the dead (paragraph 7.11.4). The Police and Criminal Evidence Act 1984, subject to changes under the Criminal Justice and Public Order Act 1994, regulates removal and use of tissue from the living. Recently, the ability to characterise DNA samples from individuals has led to the use of DNA fingerprinting in forensic science and for other purposes, such as paternity suits. The vigorous debate about the validity of using DNA fingerprinting for such purposes, its reliability, and the confidentiality that should be afforded to genetic information, is outside the scope of this report.<sup>2</sup>
- 5.27 A few legal cases have arisen because human tissue has been used for non-therapeutic purposes. In Chapter 8, we discuss a case involving the display of freeze-dried aborted fetuses as earrings (paragraph 8.3). We have made enquiries to discover whether human tissue is used in the UK in the manufacture of any non-therapeutic product, but have found no instance of such use. We know that human placenta has been used in the manufacture of face creams imported from overseas and sold in the UK, although this use has decreased substantially and is expected to cease. As we discussed in Chapter 3, the human placenta is generally treated as clinical waste (paragraph 3.8).

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<sup>2</sup> But see the report of the US National Research Council Committee on DNA Technology in Forensic Science (1992) **DNA Technology in Forensic Science** National Academy of Sciences.



## **Section III**

### **Ethical principles**

#### **Chapter 6      Respect for human lives and the human body**



## Chapter 6

### Ethical principles : respect for human lives and the human body

#### Introduction

- 6.1 A central task of this report is to identify the ethical principles that should govern the uses of human tissue. Chapter 5 demonstrated that there are many possible uses of human tissue. Advances in the biomedical sciences will undoubtedly create new uses. In this chapter, therefore, we have attempted to elaborate relevant basic ethical principles, which are sufficiently general to apply not only to existing uses but also to future developments.
- 6.2 We need first to consider what makes a use of human tissue ethically acceptable. Some uses can, it seems, easily be judged unacceptable: cannibalism (except *in extremis*) or the production of human leather or soap (even in abnormal circumstances) are uses that can seemingly be judged unacceptable without detailed ethical argument. Other uses are more difficult to evaluate. Would it be proper to buy and sell human tissue? Do those from whom tissue has been removed have any rights or say relating to its further use?
- 6.3 Philosophers have found these issues difficult to resolve. Much valuable theoretical writing in moral philosophy has approached issues to do with human bodies and tissue either from the perspective of human rights or from the perspective of utilitarianism (or more broadly consequentialism). Neither of these two approaches has reached incontrovertible conclusions on the practical issues that we are concerned with.<sup>1</sup> We have therefore thought it best to take a more practical ethical stance. We set out below ethical principles that are intended to command general support and that can be clearly and effectively applied to the laws and professional codes of conduct.

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<sup>1</sup> Some consequentialists, including John Harris (**Wonderwoman and Superman : the ethics of human biotechnology**, 1992, pp 118 ff), argue for the commercialisation of human body parts; others, including R E Goodin (as cited in Harris, J, *op.cit.*, pp 121 ff), argue against it. Some proponents of human rights, particularly in the US have argued that individuals' rights over their body parts include rights to sell them and to control their future use. Others, particularly in Europe, have argued that human rights are better respected by relying on non-commercial forms of organisation.

## Ethical principles

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- 6.4 We identify the **avoidance and limitation of injury** as a basic requirement for any type of use of human tissue to be ethically acceptable. Avoidance and limitation of injury can be seen as expressing a central element of the undefined, yet widely endorsed, demand for respect for the human body and for respect for human dignity. In paragraphs 6.7 - 6.16 we identify and elaborate this basic requirement which makes types of use of human tissue ethically acceptable.
- 6.5 We note, however, that the avoidance and limitation of injury is a complex requirement, and that in certain circumstances, injury can be avoided or limited only by inflicting injury. In our view, the only circumstance in which inflicting injury is acceptable is when it is done to avoid greater injury. It is this that justifies much medical treatment, and action taken in self defence and in other situations. This principle is also useful in evaluating proposed uses of human tissue.<sup>2</sup>
- 6.6 Although we identify the avoidance and limitation of injury as basic to acceptable use of human tissue, there are other important considerations. For example, **consent** of those from whom tissue is taken (patient, donor) or of relatives (post-mortem) is important. Consent, however, is not the primary consideration. In particular, consent cannot justify injury: for example, killing or maiming cannot be justified by the victim being willing. The law, and most people, regard assisting suicide as wrong and repugnant: although some might distinguish a narrow range of cases, such as terminal and painful illness, for which they would make an exception. Many people are ambivalent about the acceptability of certain sorts of cosmetic surgery, even though they are undergone willingly.

### Avoidance and limitation of injury

- 6.7 It is not easy to state the underlying rationale for viewing these and other sorts of action as unacceptable. The difficulty is in part that many people see these actions as wrong, repugnant or repellent for multiple reasons, about some of which there is no agreement. The most widely accepted reasons, however, often stress that these sorts of action fail to respect others or to accord them dignity, that they injure human beings by treating them as things, as less than human, as objects for use. Although all these phrases are vague, there is considerable agreement about a central range of injurious activity that would constitute disrespect for human beings and for human

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<sup>2</sup> The avoidance and limitation of injury to human bodies and their parts would generally be seen as acceptable both by utilitarians (consequentialists) and by theorists of rights. However, their more ambitious theories aim to show when injury should be traded off against other goods, or when rights not to be injured should be overridden by other rights. Our more limited claim is that injury is permissible if, and only if, undertaken to avoid or limit injury. We make no general claims about trading off goods or rights against one another. Nor do we discuss the full range of legitimate injury, for example self defence, but we hope to have said enough for the purposes of this report.

dignity. Conversely, lack of respect for human beings and their bodies is often expressed in action that injures.

- 6.8 **Injury** may be inflicted on human bodies and their parts by action that **destroys** or **damages** (whether by impairing function or by causing pain or both) or **degrades**. Very often injury destroys, damages or degrades the body or its parts. The strong reasons we have for thinking that forms of violence, killing, mutilation, torture, disfigurement and the like, impermissible injury are in the end based on the view that they are all unacceptable ways of treating human beings, and in particular human bodies, in that they destroy, damage or degrade. Such injury cannot be rendered ethically acceptable by securing the consent of its victims.
- 6.9 Of the various forms of injury, destruction is the most serious in that it is irreparable. Damage, whether considered objectively (impairing function) or subjectively (causing pain) may be reversible or amenable to alleviation, but it can constitute serious harm. Both destruction and damage are to a large extent independent of cultural and personal differences; degradation is not. For example, persons from different cultures (sometimes even different members of a single culture) may have very different views of what would constitute degrading forms of medical treatment or degrading ways of treating dead bodies. Thus, degradation may be defined in different or even contradictory terms as between societies, over time or even at any one time within a single society, especially when that society draws on a variety of different cultural traditions. Particular acts that one society may consider of ritual importance, for example, display of the dead, may be seen as degrading by another society. But this variation in what is found to be degrading does not entitle us to disregard bodily degradation or to argue that it may not be a serious form of injury. While the boundary may be difficult to draw, what is often significant is whether the purpose is purely entertainment or whether there are deeper religious, ritual or other purposes.

### Injury and therapy

- 6.10 Therapy and above all the practice of medicine, have always been seen as ethically special because they license action that might, **if taken out of context**, be seen as injury: without that therapeutic context they might be judged to destroy, damage or degrade human beings, their bodies, or parts of their bodies. Medical practice is special because limited action that would otherwise count as injurious is undertaken as a way of minimising or repairing injury. Thus therapy, which limits injury or avoids it, does not fail to respect human life and dignity. Therapy may legitimately:

- 1 destroy a bodily part when doing so is necessary for the preservation of that patient's life, or proper bodily functioning;

## Ethical principles

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- 2 damage the functioning of a patient's body or its parts when this is necessary for the preservation of that patient's life or proper bodily functioning;
  - 3 cause suffering and discomfort to patients when doing so is necessary for the preservation of that patient's life or proper bodily functioning;
  - 4 inflict procedures that would otherwise be experienced as degrading by that patient when doing so is necessary to preserve that patient's life or proper bodily functioning.
- 6.11 Medical practice therefore permits what would otherwise be injury in order to avoid or limit injury. But it does not license gratuitous destruction, damage or degradation. The primary tenet of the Hippocratic oath, *non nocere: not to injure*, can be understood as encapsulating this fundamental requirement. The medical practitioner's special licence to do things to patients' bodies which would otherwise be injury is granted **only** on the condition that what is done is, in each case, believed to be indispensable for avoiding more serious injury to the person so treated.

## Therapeutic context and therapeutic intent

- 6.12 Gratuitous injury, that is injury that is not undertaken in order to avoid destruction, damage or degradation, remains unacceptable. This point is sometimes blurred by an assumption that it is the **therapeutic context** which licenses what would otherwise be injury. In fact it is more precisely the **therapeutic intent** rather than the therapeutic context that justifies action that otherwise would be seen as injury. In most cases the intentions followed in a therapeutic context are themselves therapeutic. There may, however, be examples of action in therapeutic contexts by health care professionals which were not clearly and unambiguously guided by a therapeutic intention. There have also been rare cases of malicious injury in therapeutic contexts. Gratuitous and in particular malicious injury of human beings, and specifically human tissue, will always be unacceptable, especially when inflicted in a therapeutic context. Because such ambiguities and abuses have occurred and are always possible, there can be no simple institutional way of demarcating therapeutic action. Treatment given by those who are medical practitioners will be acceptable only if guided by a therapeutic intention (no doubt other non-therapeutic intentions are also often present and are wholly legitimate). Equally, treatment given by others not medically qualified may be ethically acceptable if guided by such an intention. (For example, the activities of unqualified persons who rescue, give emergency treatment or care for the sick may be ethically acceptable, indeed admirable.)

### Direct and indirect therapeutic action

- 6.13 Many activities that are not themselves therapeutic contribute to therapeutic ends. Educational and scientific activities can often do so, and so in particular can the use of tissue taken from the human body. The underlying criterion for determining whether an action that would otherwise constitute injury is ethically acceptable would be whether it could make a **direct or indirect** contribution to therapeutic activity. Uses of human tissue that contribute directly to therapy would include transfusing blood or transplanting organs. Uses of human tissue that contribute indirectly to therapy would include archiving human tissue, with the understanding that archived tissue might later be used for followup treatment of the same patient, for followup studies, for medical training, for medical audit purposes, for scientific education or for certain sorts of medical and scientific research.
- 6.14 The findings of research cannot be known in advance. It is, therefore, not feasible to set tight limits on the types of scientific research that may lead to deeper understanding. Since such research could be a stepping stone to therapeutic advances, it should be viewed as ethically acceptable. We draw attention to the requirement, in certain circumstances, to seek specific approval from local research ethics committees or other research ethics committees for research proposals. Appendix 6 sets out our preliminary guidance on the circumstances in which proposals involving human tissue should be submitted to research ethics committees.
- 6.15 Certain uses, however, of human tissue, including certain sorts of research, cannot be regarded as ways of limiting or repairing injury and are therefore unacceptable. In particular, any use of human tissue as foodstuffs, as raw materials for manufacturing products with no direct or indirect therapeutic purposes or for entertainment or for display (other than for educational or ritual purposes) is unacceptable, since none of these uses is directly or indirectly therapeutic. By contrast the collection of human blood, and the consequent manufacture of many blood products, contributes to therapy, and is thus acceptable. So too is research whose central purpose is to develop such uses of human tissue. It is never acceptable, however, to use human bodies or their parts as raw materials for products that have no foreseen therapeutic value.
- 6.16 The conclusion of this section is that using human tissue without any therapeutic intent, direct or indirect, will be unacceptable. For example, uses of human tissue as food (cannibalism), as raw materials for products without therapeutic purpose (for example, human leather), or for entertainment (for example, at least in contemporary British society, making and displaying fetal earrings) would all of them count as injurious. They treat human beings or their bodies in ways that are destructive, damaging or experienced as degrading, without any therapeutic intent which outweighs the destruction, damage or degradation inflicted in obtaining the tissue in the case of living sources, or the degradation inflicted in the case of human remains.

At the same time it is recognised that not all non-therapeutic uses of human body parts or products are unacceptable. Some body parts or products may be obtainable without action that would constitute any sort of injury; these are commonly waste products that are customarily discarded (paragraph 3.7). For example, human hair may be obtained for use in wigs, and night soil for use as fertiliser, without injury of any sort being suffered.<sup>3</sup>

## Consent considerations

### General

- 6.17 So far we have discussed **types of ethically acceptable action**. However, not every act of an acceptable type of action will be ethically permissible. A particular act of an acceptable type of action involving the removal of tissue may be wrong if the person from whom tissue is removed does not consent, since its removal without consent in these conditions would constitute impermissible injury. For example, use of some persons as organ banks for others without their knowledge or consent, or the removal of a person's tissue for experimental purposes without his or her consent, or body-snatching for medical research would all be seen as ethically impermissible. Such acts do grave injury by treating one person's life or body or body parts as means to others' therapy or well being without the relevant consent. The ethical failing here is not that every use of organs, tissue or cadavers is unacceptable, but that these particular ways of procuring them violate consent considerations.
- 6.18 The basic idea behind the notion of consent is captured in the old adage: *volenti non fit iniuria* - *no wrong is done to one who is willing*. The basic considerations are common in all domains of life: if you take my bicycle, and I lent or gave it you, then I am willing, so am not injured, by your riding off. On the other hand, if I neither lent nor gave, indeed am unwilling, then I am wronged when you ride off on my bike. This ancient principle has proved of great value in medical ethics, and is constantly invoked: if a surgeon operates on a willing patient, then the operation is legitimate and the patient is not wronged (even if things turn out badly); if a surgeon operates on an unwilling, ie unconsenting, patient then the patient is wronged (even if no physical harm is done). In general, action that is clearly guided by a therapeutic intention must also be consented to by the particular patient or volunteer if it is to be ethically permissible.

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<sup>3</sup> There is, however, a historical caveat concerning the use of hair which should serve as a caution. In Victorian times the practice of maidservants selling their hair was controversial: there were fears of exploitation, and it was argued that they were degraded by being deprived of a crucial badge of womanhood, flowing tresses.



### Caveat on consent

- 6.19 Expressions such as ‘informed consent’ and ‘fully informed consent’ are often used in discussions of medical ethics. They are somewhat misleading. Consent can be given to some course of action (for example, an operation, other therapy, donation, participation in medical or scientific research) only **as described in a specific way**. Since description can never be exhaustive, consent will always be to action that is incompletely described; moreover the descriptions offered are often incompletely understood. This incompleteness cannot be remedied by the devising of more elaborate consent forms and procedures for patients, donors and relatives. ‘Fully informed consent’ is therefore an unattainable ideal.
- 6.20 The ethically significant requirement is not that consent be **complete**, but that it be **genuine**. Ensuring that consent is genuine is mainly a matter of care in detecting and eliminating lack of consent. Both in law and in ethics, consent requirements are not met wherever anything rebuts or defeats the presumption of consent. The ascription of consent is **defeasible**: the presumption of consent can be defeated by any of numerous circumstances, including violence, coercion, deception, manipulation, tendentious misdescription of action, lack of disclosure of material facts or of conflicts of interest and the like. A complete list of the circumstances that would defeat a presumption of consent is not feasible.
- 6.21 Evidently in medical and scientific practice involving human volunteers or the removal of tissue from cadavers, there are well developed (if necessarily incomplete) understandings of circumstances that defeat the presumption that proper consent has been granted. These will include failure to require patients, volunteers or relatives to read and sign the usual consent forms. However, such forms are only evidential, and signatures on forms, however carefully obtained, will not prove that consent is ‘fully informed’. Obtaining genuine consent requires medical practitioners to do their best to communicate accurately as much as patients, volunteers or relatives can understand about procedures and risks, and to respect the limits of their understanding, and of their capacities to deal with difficult information. If all reasonable care is exercised, adequate and genuine consent may be established, although it will necessarily fall short of fully informed consent.

### Alternatives to consent where consent is impossible

- 6.22 It is well known that the principle of requiring consent if treatment is to be ethically permissible is sometimes difficult to apply in medical practice because patients may be unable to consent. They may be too young or too ill or too disturbed. In all such cases other, more paternalistic, criteria have to be used to justify medical intervention. There has been considerable discussion of possible courses of action – for example, the giving of proxy consent by parents or relatives, the need for

## Ethical principles

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emergency treatment when the consent of the patient cannot be sought, and the resort to procedures for compulsorily committing disturbed patients. Such cases show that consent is not always possible, and demonstrate that consent is not an absolute requirement for medical treatment to be permissible. The most that could plausibly be claimed is that consent is necessary for ethically permissible treatment of those capable of consenting – ie, for those who are, in John Stuart Mill’s phrase, “*in the maturity of their faculties*”. In other cases some procedures which provide equivalent protection for patients’ interests have to be devised and followed.

- 6.23 Just as this point applies to all areas of medical treatment, it also applies to activities such as medical research and tissue donation involving those unable to consent. These issues have stimulated considerable discussion (paragraphs 6.26 and 6.28). The more specific case of the medical and scientific uses of human tissue in these circumstances does not raise distinctive ethical issues. It does, however, require systematic review of the cases where consent is impossible, and examination of the scope for creating procedures that offer children and incompetent adults the equivalent of the safeguards normally provided by the requirement for consent.
- 6.24 Where tissue is removed **in the course of medical treatment**, the consent of the person with parental responsibility should be and, under law, must be obtained for the medical treatment of a child deemed legally incompetent. In the case of incompetent adults the action of the responsible physician, often in consultation with relatives, may be treated as providing protection equivalent to that given by consent procedures both for medical treatment and for subsequent uses of any tissue removed. It is, however, important in such cases to ensure that medical treatment is genuinely needed, and not a pretext for obtaining tissue for some further purpose. Where a further purpose predominates, the considerations in paragraphs 6.25 – 6.28 are relevant.
- 6.25 Where the removal of tissue is **not integral to medical treatment** the situation is different because there is no therapeutic benefit for the donor. Where **children** are concerned, a cautious view should be taken of the quality of their understanding of the explanation of any procedure. With the exception of trivial procedures, we question whether children under the age of 18 should be regarded as competent to consent to the donation of tissue where this is not part of their medical treatment. The consent of the person with parental responsibility, therefore, must be obtained but this may not be a sufficient safeguard. Difficult conflicts of interest may arise for a parent where the welfare of other members of the family may be involved. Consider the case where a child may be the only compatible donor for another member of the family in need of a kidney transplant. On the other hand, a complete prohibition of tissue donation by children is also inappropriate. Consider a genetic study of a family that requires a blood sample from a child. For such reasons, our view is that it is ethically permissible to take tissue from children, other than in the course of medical treatment, only on the following conditions:

- 1 the procedures should be of negligible risk and minimal burden;
- 2 the consent of the person with parental responsibility should be obtained;
- 3 the children themselves, where appropriate, should be consulted and their agreement obtained. They should not object, or appear to object, to the procedures.

As we discuss in Chapter 7, however, the current law in the UK may not entirely coincide with this view (paragraph 7.8).

- 6.26 We draw attention to guidance on the wider issues raised by **research involving children** available from the Royal College of Physicians<sup>4</sup>, from the Medical Research Council<sup>5</sup>, and from the British Paediatric Association.<sup>6</sup> Additional safeguards include recommendations that children should be involved in research only if the relevant knowledge could not be obtained from research on adults and if the research is approved by a research ethics committee.
- 6.27 Incompetent adults cannot consent to the removal of tissue on their own behalf, and in law there is no-one who can consent for them. Whereas with children the consent of the person with parental responsibility provides a necessary but incomplete safeguard, in the UK there is no legal procedure that provides the equivalent safeguard for incompetent adults. We consider that incompetent adults should be afforded protection equivalent to, but not exceeding, that afforded children. We consider that non-therapeutic removal of tissue from incompetent adults should be ethically permissible only if the procedures are of negligible risk and minimal burden. The person should not object or appear to object to the procedure. As is the situation with children, however, current UK law may not entirely coincide with this view (paragraphs 7.9 - 7.10).

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<sup>4</sup> Royal College of Physicians (1990) **Guidelines on the practice of ethics committees in medical research involving human subjects** (2nd Edition) London

<sup>5</sup> Medical Research Council, MRC Ethics Series (1991) **The ethical conduct of research on children** London

<sup>6</sup> British Paediatric Association (1992) **Guidelines for the Ethical Conduct of Medical Research Involving Children**

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- 6.28 We draw attention to guidance on the wider issues raised by **research involving legally incompetent adults** available from the Royal College of Physicians<sup>4</sup> and the Medical Research Council.<sup>7</sup> Additional safeguards include recommendations that incompetent adults should be included in research if the relevant knowledge could be obtained only from such persons and only if the research is approved by a research ethics committee.

## Uses of human tissue

- 6.29 These general considerations about consent are relevant both to the removal and to the subsequent use of human tissue. The conditions under which tissue is originally removed bear on the uses to which it may properly be put. Various cases may be distinguished:

- 1 Cases in which removal of tissue from a patient is integral to medical treatment of that patient and is therefore covered by a direct therapeutic intention: here the most common uses to which the tissue may be put are diagnostic tests and routine archiving with subsequent disposal of any surplus tissue. Here the patient consents to the treatment, and in so doing can be asked to consent to all incidental aspects of the treatment in so far as these are acceptable and to any other acceptable use of the tissue. Everything done to the patient would be done anyhow, so there is no otherwise injurious action which is not legitimated by its therapeutic intent; assuming that the intended use of the tissue is acceptable, all that is needed is the patient's consent to treatment or the equivalent procedure for patients who cannot consent. Patients at present may commonly assume that removed tissue is put to no further uses than diagnosis and treatment and that all surplus tissue is destroyed. Thus, to ensure that consent is properly informed, explanations offered to patients should mention the possibility that tissue, if stored, may at some time be used for diagnosis, further treatment, research, teaching or study. Some examples of consent forms can be found in the Department of Health document *A Guide to Consent for Examination or Treatment*.<sup>8</sup>
- 2 Cases in which removal of tissue from a patient or volunteer is not integral to medical treatment, but the tissue is explicitly donated for a specified range of purposes, which have been properly explained to the donor. An intention in donating may be either directly therapeutic (donation of blood and bone

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<sup>7</sup> Medical Research Council, MRC Ethics Series (1991) **The ethical conduct of research on the mentally incapacitated** London

<sup>8</sup> NHS Management Executive (1990) **A guide to consent for examination or treatment** Department of Health London

marrow) or indirectly therapeutic (donation for use in basic or medical research). In every case the uses to which the tissue may be put are determined by the terms of the consent given by the donor. Where the tissue is taken from somebody who is either temporarily or permanently incompetent to consent, the considerations under paragraphs 6.25 - 6.28 would apply.

- 3 Cases in which removal of tissue is from a dead body, in which there can be donation by prior bequest (including prior bequest by those who at the time of death were no longer competent) or by next-of-kin, provided that their consent to the removal is governed by a directly or indirectly therapeutic intention. Removal of tissue from a corpse may constitute degradation unless it is **either** governed by a direct or indirect therapeutic intention **or** part of accepted funerary rites (hence a way, within a given culture, of according dignity rather than of inflicting degradation).

6.30 Where subsequent research reveals other possible uses of derivatives of the tissue, these are acceptable **only** if they do not use human tissue as raw material for non-therapeutic products (paragraphs 6.15 - 6.16).

6.31 These considerations can be summarised as requiring affirmative answers to the following questions:

- 1 is the removal of tissue governed by intentions which respect human beings and their bodies, in that gratuitous injury is avoided?
- 2 if the removal of tissue was in the course of medical treatment, was consent given by the patient?
- 3 if the tissue was donated either by a healthy volunteer or post-mortem, was the appropriate consent procedure followed? In the case of children or incompetent adults were the appropriate safeguards observed (paragraphs 6.25 - 6.28)?

## Consent and commercialisation

### Consent and markets

6.32 One way of institutionalising consent procedures for all uses of human tissue would be to organise it along conventional market principles: market transactions, such as buying, selling and contracting, all incorporate consent requirements. However, many types of non-commercial transaction, including giving and bequeathing, are also consensual forms of interaction. Hence the need to secure consent for particular uses

of human tissue determines neither whether, nor in which contexts, it would be acceptable or advisable to permit such transactions to be organised according to market principles. On the contrary, there are vigorous disagreements both in the UK and elsewhere about the rights and wrongs of permitting the ‘commercialisation of the human body’.<sup>9</sup> The question may be addressed by considering separately the merits of a commercial structure for organising the **procurement** (removal), the **development of products derived from** and the **intermediate handling** (archiving, storage and allocation of human tissue).

### Procuring human tissue on commercial principles

6.33 Several reasons have been given in favour of a market system for procuring human tissue. Such a market:

- 1 would provide financial incentives that could match supply of organs and other tissue to effective demand, so addressing the shortage of transplantable organs;
- 2 would reward those whose tissue was scarce and so in strong demand as sources for treatment or products;
- 3 would be helpful for certain businesses investing in some sorts of biotechnology which could operate on standard commercial lines. Such businesses, which might then include commercial tissue banks, could then go about procuring human tissue more efficiently. This would promote medical and scientific advances and the development of therapeutic products and of new methods for testing the safety and efficacy of products.

6.34 However, there are also reasons against organising the procurement of human tissue on commercial lines. A market for procuring human tissue:

- 1 may obstruct rather than secure genuine consent: life and death choices and deep conflicts of interest often arise when difficult choices about procurement of tissue have to be addressed. The forms of risk assessment needed for consent to be genuine are hard to achieve even in orderly and impersonal circumstances and may fail entirely when vulnerable people find themselves in a tempting situation where risks may not be understood and are too easily brushed aside;

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<sup>9</sup> A recent review that reports the academic literature is Sells, R.A. “Transplants” in Gillon, R (ed) (1994) **Principles of Health Care Ethics**, particularly at pp 1013-20

- 2 may undermine altruistic desires to give tissue, and may reduce the quality and even the quantity of tissue available under non-commercial systems. Those who would give if this were seen as noble or public spirited may be deterred by a commercial system;<sup>10</sup>
- 3 might distort rather than merely encourage supply. Those most eager to sell body parts (their own or those of dead relatives) may not be the most suitable, but only the most desperate, suppliers, who may have infected or damaged tissue. Experience with paid blood donation has demonstrated the risk that monetary reward induces ‘donors’ to conceal matters that compromise the safety of the blood product;<sup>11</sup>
- 4 might encourage criminal or morally reprehensible methods of procuring human tissue, and would certainly have to be hedged with many restrictions to prevent unacceptable use being made of the tissue collected. It would be necessary to apply restrictions to ensure that purchasers did not use such tissue for unacceptable purposes, and necessary to exclude would-be purchasers whose aim might be to purchase tissue for non-therapeutic purposes of various kinds. Even if an apparently robust and reliable regulatory system could be put in place, this objection would be a matter for concern since many regulatory systems tend, as time passes, to favour the interests of those being regulated over the original regulatory intention;
- 5 may provide large payments to some whose tissue happens to play a prominent part in profitable scientific or technological advance, while ignoring the contribution of many others whose tissue is also collected and studied. The Moore case is exceptional and thus misleads: what is normally important to scientific and medical advance is the reliable collection of tissue from many thousands rather than a system that offers large incentives for a few whose tissue happens to play a particularly central role in developing profitable therapeutic products.

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<sup>10</sup> See R.M. Titmuss (1970), **The Gift Relationship From Human Blood to Social Policy**. Allen and Unwin, London. For more recent literature, see Sells, R.A. *op. cit.*

<sup>11</sup> International Forum: “How far shall we go in the predonation selection of blood donors . . .?” **Vox Sang** 1993:65:1-9; Dodd, R.Y. “Donor screening and epidemiology” in Dodd R.Y., Barker L.F. (eds) (1985) **Infection, Immunity and Blood Transfusion** pp 389-405; Barbara, J.A.J. “Transfusion-transmitted infections and their impact on virology” **Current Medical Literature :Virology** 1993:2:67-73

### Conclusions on commercial organisation of the procurement of human tissue

- 6.35 There are strong reasons against organising the procurement of human tissue for acceptable medical and scientific purposes along commercial lines. The reasons are strongest where difficult medical decisions are being made at vulnerable times in patients' and donors' lives. The concerns about the supply of certain urgently needed tissues are serious, but could perhaps be improved by other means which do not threaten the gift relationship or risk impairing the quality of tissue provided or the quality of consent of those who provide it. The altruistic motivation of patients, donors and relatives should be respected and encouraged rather than eroded. This is not to say that current methods of procuring organs are the best available. There are several possible social policies other than commercialisation that might improve the supply of human tissue. These have been reviewed in a recent report.<sup>12</sup> There is, moreover, a growing body of international regulation and guidance prohibiting commercial dealings in organs and other human tissue (paragraph 2.21 and 10.8).
- 6.36 *Rewarded gifting* is a term that has come into use to describe the offer of incentives for donation where the rewards are in kind, not money. Examples have been the offer of lifetime medical treatment in exchange for kidney donation or of free infertility treatment in return for the donation of ova.<sup>13</sup> We consider that *rewarded gifting* arrangements should be viewed as commercial transactions in that they offer inducements for permitting removal of human tissue. As such, reasons against procuring tissue along commercial lines apply equally to *rewarded gifting* arrangements.

### Commercial organisation of the development of products derived from human tissue

- 6.37 Organisations which do not collect human tissue directly from patients or from those who donate them, but develop therapeutic products derived from human tissue, are in a different position and may have substantial reasons for adopting standard market practices. The products so derived may be conventional pharmaceutical products whose development requires major investment over a long period and which will best be distributed through market structures. Non-market structures might have difficulty in generating the capital or securing the distribution such products normally

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<sup>12</sup> See New, B *et al* (1994) **A Question of Give and Take : Improving the supply of donor organs for transplantation**, King's Fund Institute

<sup>13</sup> The Human Fertilisation and Embryology Authority is reviewing the issue of rewarded gifting in relation to the donation of ova.



require. It is important, however, that human tissue used for the development of, or used in products for, direct or indirect therapeutic use, should be obtained only from sources that are subject to, and governed by, recognised codes of professional practice and which operate on a non-commercial basis (paragraph 6.35 and see below, paragraphs 6.38 - 6.40).

### The medical intermediary

- 6.38 If human tissue is procured by non-market procedures, and the products derived from human tissue are manufactured and distributed by commercial organisations, there must be some intermediate institution, guided by professional codes and practices, which connects the market and the non-market structures. At present in the UK doctors, hospitals and tissue banks discharge this function as what we have termed *medical intermediaries* that separate the non-commercial procurement and the commercially organised uses of human tissue. Thus a hospital which archives, stores and allocates human tissue may allocate some tissue to research use, and products may be derived from the tissue so allocated. Tissue banks, which procure human tissue and make it available for further uses, are in the same role as medical intermediaries. A tissue bank will control the storage, quality assurance and allocation of the tissue it collects.
- 6.39 We have concluded that the medical intermediary should not enter any commercial relations with patients, donors or their relatives (paragraph 6.35). This would not in itself preclude medical intermediaries from entering commercial relations with those to whom they supply human tissue. If, however, this were permitted without restriction, medical intermediaries would be able to profit from selling donated tissue. This would be unacceptable to many donors and relatives and might well compromise willingness to donate. It could also generate conflicts of interest if procuring tissue were profitable for hospitals or doctors.
- 6.40 We have concluded therefore that medical intermediaries should continue to provide tissue for acceptable purposes on a non-profit making basis. However, since storing human tissue either in hospitals, pathology archives or in tissue banks is costly, there can be no objection to a scale of charges by which the operating costs of the medical intermediary are passed on to organisations that use human tissue, whether they are charitable, academic or commercial. Such charges would give rise to a limited inter-institutional market in human tissue, but would not offer incentives for procurement for profit. This suggests that tissue banks in the UK should be required to operate on a professional rather than a commercial basis. Hospitals, archives and tissue banks cannot expect to sustain the altruism of donors unless they supply those with a legitimate reason for seeking human tissue on a non-profit making basis.



## **Section IV**

### **Legal matters**

- Chapter 7      Removal of tissue**
- Chapter 8      Uses of tissue**
- Chapter 9      Claims of people from  
whom tissue is removed**
- Chapter 10     Claims of users**
- Chapter 11     Patent issues**
- Chapter 12     Safety and quality**



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## Introduction to Section IV : Legal matters

In Chapters 4 and 5 we have set out the various ways in which tissue may be acquired and subsequently used. Some of the practices are of longstanding and have become commonplace; some are very recent, the product of rapid developments in medical technology. None of these new developments, as far as is known, has been the object of examination by the courts in the UK so as to determine its legality. This reflects the climate in which scientific research is carried out, the integrity of researchers and, until recently, the previous apparent lack of widespread and systematic concern on the part of the public (but see Chapter 2). Such a situation may not, of course, persist for a variety of reasons. It is desirable, therefore, to seek to clarify the law and, where necessary, put practices involving the use of human tissue on a sound legal basis.<sup>1</sup> We have used the ethical principles set out in Chapter 6 as the basis for examining existing regulation and formulating our recommendations.

As the Working Party of the Law Reform Commission of Canada pointed out, adopting with approval the words of the Court of Appeal in California in *Moore v the Regents of the University of California*:<sup>2</sup>

*“Until recently, the physical human body, as distinguished from the mental and spiritual, was believed to have little value, other than as a source of labor. In recent history, we have seen the human body assume astonishing respects of monetary value . . . For better or worse, we have irretrievably entered an age that requires examination of our understanding of the legal rights and the relationships in the human body and the human cell.”*

Six major areas of legal concern are considered in the following chapters. Each chapter is preceded by a short summary.

- ▶ the removal of tissue Chapter 7
- ▶ the use to which tissue may be put Chapter 8
- ▶ any claim which a person from whom tissue is removed may have to that tissue, or what is subsequently derived from it Chapter 9
- ▶ the claim which users of tissue may have to tissue once it has been removed Chapter 10
- ▶ intellectual property rights and the implications of patent law for inventions arising from research using human tissue Chapter 11
- ▶ the safety and quality of tissue once removed, and of products derived from it. Chapter 12

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<sup>1</sup> This section of the report draws extensively on the material in Kennedy, I and Grubb, A (1994) **Medical Law: Text with Materials**

<sup>2</sup> *Moore v the Regents of the University of California* (1988) 249 Cal.Rptr.494

## **Chapter 7**

# **Legal matters : removal of tissue**

### **Summary**

For the living, case law establishes that a person must consent to the removal of tissue. It is appropriate to distinguish between the removal of tissue in the course of medical treatment, and non-therapeutic removal which requires more rigorous safeguards, whether the purpose is a donation for transplantation or for research. Thus, the removal of organs from donors is covered by statute which makes the requirement for consent explicit. There are a few exceptions to the requirement for consent:

- 1 Children between the ages of 16 and 18 must, like adults, consent to medical treatment. Children younger than this must be asked for their consent if they are judged competent. For children who are not considered competent, the consent of the person with parental responsibility must be obtained for removal in the course of treatment. For non-therapeutic removal, the law is complicated and unclear. The important legal principles would seem to be that any child under 18 would be deemed incompetent to consent, as a matter of public policy, to anything other than a trivial intervention, for example, perhaps, the taking of a blood sample; the consent of the person with parental responsibility must therefore be obtained; such consent could then only validly be given if the removal of tissue were not against the child's interests, that is, if it posed no more than negligible risk and minimal burden, and the tissue could not equally well be taken from an adult.
- 2 Some adults may be legally incompetent to give consent: they may be too disturbed or they may be unconscious. In such cases, tissue may be removed if it is in the patient's best interests to do so. The law is unclear on whether tissue may be removed from such adults for non-therapeutic purposes.

Statutes regulate the removal of tissue from the dead for the purposes of donation for therapeutic purposes, anatomical examination as part of medical training, and autopsy to establish the cause of death. Certain activities, such as archiving and tissue banking, may lie outside these statutes. The precise legality of such activities is unclear although, being accepted as common practices, they are also probably lawful.

### Introduction

7.1 We have noted the useful analysis of the US Office of Technology Assessment (OTA) in its 1987 study.<sup>3</sup> We use the term removal to include:

- ▶ *“aspiration of bodily fluids (for example, blood) through a needle*
- ▶ *scraping of cells from a surface (for example, skin or cervix)*
- ▶ *surgical removal of tissue*
- ▶ *collection of body substances by non-invasive procedure (for example, semen . . .)”*

7.2 Consent considerations are at the heart of the law relating to the removal of tissue. The considerations depend on whether tissue is removed from the living or from the dead and if from the living, whether the person is competent or not to give consent, and on the intended purpose for the removed tissue, whether therapeutic or non-therapeutic.

### Removal of tissue from the living : general principles

7.3 The Human Organ Transplants Act 1989 regulates the removal of organs (as defined in s.7(2) of the Act) from living donors. In particular the Act makes it a crime to deal commercially in organs and, in the case of donors unrelated to the intended recipient, established a statutory Unrelated Live Transplant Regulatory Authority (ULTRA) with responsibility to authorise each donation in accordance with strict rules on consent. Thus, the Act permits removal subject to the observance of at least two moral principles; that commerce in organs is wrong and, secondly, that in the case of unrelated donors, donation is not wrong but special care to avoid exploitation must be taken, and procedures for securing explicit consent are to serve as one of the principal means of protecting potential donors. ULTRA must be satisfied *“that the donor **understands** the nature of the medical procedure and the risks, **as explained** by the registered medical practitioner, and consents to the removal of the organ in question”* (our emphasis).<sup>3</sup> To require that the donor “understands” goes further than the common law, which requires as regards medical intervention generally only that a person be capable of understanding not that he understood, which is a much more demanding standard. Equally the requirement that the doctor explain the nature and risks of the procedure<sup>4</sup> allows no room for the discretion available to doctors at common law of not informing a patient about certain risks associated with a particular treatment, if, for example, the patient is extremely anxious.

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<sup>3</sup> Office of Technology Assessment (1987) **New Developments in Biotechnology: Ownership of human cells and tissues**, Washington DC, reviews examples of the use of tissue and the uncertainty of US law which in this context is not dissimilar to English law.

<sup>4</sup> By Regulation 3(2)(b) of the Human Organ Transplants (Unrelated Persons) Regulations 1989 (SI 1989/2480)

- 7.4 A donor of reproductive tissue, ie eggs, must as a matter of common law consent to the procedure involved. (No consent would be required for the donation of sperm). Additionally, the Human Fertilisation and Embryology Act 1990, establishes a framework of specific consents. Donors of gametes (and embryos) must explicitly consent to the use of such tissue before it may be stored or used for treatment or research, the only uses of reproductive tissue which are licensed under the Act.
- 7.5 Apart from these Acts, there is little or no law specifically concerned with the removal of tissue from the living. Clearly, as a general legal principle, unconsented interference with bodily integrity is unlawful. To remove human tissue against the consent of a competent person would ordinarily constitute both a crime and a civil wrong. In the frequently quoted dictum of the distinguished American judge, Cardozo J: “*Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient’s consent commits a [wrong] for which he is liable in damages.*”<sup>5</sup>

### Removal of tissue from the competent

- 7.6 The fact that there may be urgent need for certain tissue cannot legally justify its being taken without consent; the law’s commitment to the absolute right to ‘bodily security’ of one person cannot be abandoned in order to save the life of another person. Thus, in another US case<sup>6</sup> a court refused to order a man to donate compatible bone marrow to his cousin and so save the cousin’s life. Although the court expressed the view that the refusal was morally indefensible, “*to compel the defendant to submit to an intrusion of his body would change every concept and principle upon which our society is founded. To do so would defeat the sanctity of the individual and would impose a rule which would know no limits and one could not imagine where the line would be drawn. . .*” It is likely that these general principles would be followed in English law. (One situation where a departure from this rule was held to be justified in law was in the **very** special circumstances where a pregnant woman was said to have put the life of her unborn child at risk by refusing a caesarean section.<sup>7</sup>)

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<sup>5</sup> *Schloendorff v Society of New York Hospital* (1914) 105 NE 92

<sup>6</sup> *McFall v Shimp* 10 Pa D&C 3d 90 (1978) Pennsylvania

<sup>7</sup> In the case of *Re S* [1992] 4 All ER 671, the High Court decided that a woman should be required to undergo a caesarean section despite her objection, to prevent the death of her unborn child. Mrs S was in labour with her third pregnancy. Although the fetus was 6 days overdue and she had been in labour for several days, she refused to submit to a caesarean section on religious grounds. The fetus was in a “transverse lie” with the elbow projecting through the cervix and the head on the right side. There was a grave danger of the uterus rupturing if the caesarean section was not carried out. The medical opinion was that the fetus could not be born alive unless the operation were performed. To the extent that the fetus could be regarded as tissue, this is an example



7.7 Thus, where a person is legally competent, explicit consent, whether for therapeutic or non-therapeutic procedures, is the rule. The legal requirements necessary for a valid consent may vary between the two types of procedure. As regards therapeutic procedures, there are two levels of consent. There must be explicit consent to the nature and purpose of any proposed intervention. Thereafter, the degree of information concerning possible risks associated with the treatment, which the doctor must disclose, so as to make the consent informed and thus valid, is currently determined in English law by reference to what a reasonable doctor would disclose. In certain circumstances, for example, if a patient is extremely anxious, a doctor may decide not to inform the patient about certain risks associated with a particular treatment. Where the procedure is non-therapeutic, there are not two levels of consent and thus there is no scope for medical discretion. Consent must be explicit and all relevant information must be provided. Thus, when removal of tissue takes place in a non-therapeutic context, for example from a volunteer in a research project, not only must the removal be for a purpose which the law permits, that is, it must be in the public interest (paragraph 8.3), but it must also be consented to explicitly and on the basis of all appropriate information.

### Removal of tissue from the incompetent

#### 7.8 Children

By s.8(1) of the Family Law Reform Act 1969, children aged 16 - 18 years are deemed competent in law to consent to medical **treatment**, in the absence of evidence to the contrary. This section does not, however, apply to non-therapeutic interventions.<sup>8</sup> Children under 16 may also be deemed competent to consent to medical **treatment** if of sufficient maturity and understanding.<sup>9</sup> In the case of a **child deemed incompetent** to consent, as regards removal **in the course of treatment**, the tissue may be removed if the person with parental responsibility judges it to be in the child's best interests. If removal takes place during the course of *bona fide* treatment, it will ordinarily be in the child's best interests. If **removal of tissue is not during the course of treatment**, the legal principles regulating non-therapeutic research in the past would have suggested that a child under 18 will be deemed to be incompetent to consent, as a matter of public policy, to anything other than a trivial intervention, for example, perhaps, the taking of a blood sample. Removal may be lawful, however, and therefore may be consented to by someone with parental

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of the removal of tissue without consent. This case has been widely criticised. It could well be that future courts will overrule the principle it states.

<sup>8</sup> See dicta in *Re W* [1992] 4 All ER 627

<sup>9</sup> *Gillick v West Norfolk and Wisbech HA*, [1985] 3 All ER 402

responsibility, **if it is not against the child's interests, that is, if it poses no more than negligible risk and minimal burden, and the tissue could not equally well be taken from an adult.**<sup>10</sup> Those principles relating to research have apparently been overtaken, however, by the European Code of Good Clinical Practice which regulates the conduct of research into pharmaceutical products and which provides that **non-therapeutic research** may be conducted only on those able to consent for themselves, ie only on the competent. The European Directive 91/507/EEC, which, on one reading, appears to incorporate the Code of Good Clinical Practice, is now part of UK law by virtue of the Medicines (Applications for Grant of Product Licences - Products for Human Use) Regulation 1993 (SI 1993/2538). Thus, if the analogy with research is employed, removal in a non-therapeutic context would be unlawful. The situation is further complicated, however, by the fact that the new Regulations apply only to research done with a view to making an application for a product licence for a medicine. Thus, arguably, the legal principles argued for earlier may still apply in all other non-therapeutic contexts. The law, as a consequence, appears to be excessively complex. At least, however, research on the incompetent child involving the removal of tissue would be lawful provided that it met all relevant ethical requirements, conformed to these legal principles and was not being carried out with a view to applying for a product licence.

### 7.9 Adults

In the case of an incompetent **adult**, no-one has legal authority to consent to removal. During the course of **treatment**, the attending doctor may remove tissue if it is in the patient's best interests to do so. Whether tissue can be removed in a **non-therapeutic** context from such a person is an unresolved question. The analysis drawing on non-therapeutic research on children may seem relevant. But, in the absence of anyone with authority to consent, it is debateable whether this analogy is appropriate. The lawfulness of any removal would depend on whether the law would countenance the dilution of the concept of best interests, by adopting the test of "*not against the interests*" as in the case of a child. But in the case of a child, there is, in law, someone to make that decision and to be held accountable for it. In the case of an adult, there is no such person.<sup>11</sup> Furthermore, what was said earlier about the new Medicines Regulation (SI 1993/2538) would apply equally here to the incompetent adult. The issue of medical treatment and research involving mentally incapacitated adults has been considered by the Law Commission in a report on

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<sup>10</sup> Nolan LJ in *Re W* [1992] 4 All ER 627 suggested that it may also be desirable to apply to the court for authorisation where what is contemplated is the "donation" of an organ.

<sup>11</sup> There are dicta in *Re F* [1990] 2 AC 1 per Lord Bridge (HL) and Neill LJ (CA) that the involvement of the court may be necessary, at least where the removal of tissue for transplantation was contemplated.

mental incapacity.<sup>12</sup> The report reached the conclusion that research of no therapeutic benefit to the participants would currently be unlawful. The new legislative scheme proposed by the Law Commission recommends that “*research which is unlikely to benefit a participant, or whose benefit is likely to be long delayed, should be lawful in relation to a person without capacity to consent . . .*” subject to strict safeguards. Research would be contemplated only if it would provide knowledge of the incapacitating condition with which any participant is affected; if the research could not be achieved without such persons; and if the procedure were of negligible risk and were not unduly invasive. A new statutory Mental Incapacity Research Committee is proposed that would be required to approve non-therapeutic research procedures. In addition, procedures for approving the participation of each individual in the research project are recommended.

- 7.10 The above discussion of removal of tissue for non-therapeutic purposes has been concerned with its use for research. What of the donation of tissue for the treatment of others? The requirement of ULTRA that there must be explicit consent to organ donation means that an incompetent person, whether child or adult, who is not genetically related to the recipient cannot be an organ donor. It may well be that a court would apply this principle equally in the case of the proposed removal of an organ from an incompetent person for transplantation into someone who was genetically related.

## Removal of tissue from the dead : statute law

- 7.11 At least four statutes regulate the removal of tissue from the dead:

1 **The Human Tissue Act 1961** provides by s.1 that:

- (1) *If any person, either in writing at any time or orally in the presence of two or more witnesses during his last illness, has expressed a request that his body or any specified part of his body be used after his death for therapeutic purposes or for purposes of medical education or research, the person lawfully in possession of his body after his death may, unless he has reason to believe that the request was subsequently withdrawn, authorise the removal from the body or any part or, as the case may be, the specified part, for use in accordance with the request.*
- (2) *Without prejudice to the foregoing subsection, the person lawfully in possession of the body of a deceased person may authorise the removal or any part from the body for use for the said purposes if, having made such reasonable enquiry as may be practicable, he has no reason to believe -*

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<sup>12</sup> Law Commission Report No 231 (1995) **Mental Incapacity** HMSO. See, in particular, pp 96-102 and Clause 11 of the draft Bill (p 228)

- (a) *that the deceased had expressed an objection to his body being so dealt with after his death, and had not withdrawn it; or*
  - (b) *that the surviving spouse or any surviving relative of the deceased objects to the body being so dealt with.*
- (3) *Subject to subsections (4) and (5) of this section, the removal and use of any part of a body in accordance with an authority given in pursuance of this section shall be lawful.*
- (4) *No such removal shall be effected except by a fully registered medical practitioner, who must have satisfied himself by personal examination of the body that life is extinct.*
- (4A) *No such removal of an eye or part of an eye shall be effected except by -*
  - (a) *a registered medical practitioner who must have satisfied himself by personal examination of the body that life is extinct; or*
  - (b) *a person in the employment of a health authority or NHS trust acting on the instructions of a registered medical practitioner who must, before giving those instructions, be satisfied that the person in question is sufficiently qualified and trained to perform the removal competently and must also either -*
    - (i) *have satisfied himself by personal examination of the body that life is extinct, or*
    - (ii) *be satisfied that life is extinct on the basis of a statement to that effect by a registered medical practitioner who has satisfied himself by personal examination of the body that life is extinct.*
- (5) *Where a person has reason to believe that an inquest may be required to be held on any body or that a post-mortem examination of any body may be required by the coroner, he shall not, except with the consent of the coroner,*
  - (a) *give an authority under this section in respect of the body; or*
  - (b) *act on such an authority given by any other person.*
- (6) *No authority shall be given under this section in respect of any body by a person entrusted with the body for the purpose only of its interment or cremation.*
- (7) *In the case of a body lying in a hospital, nursing home or other institution, any authority under this section may be given on behalf of the person having the control and management thereof by any officer or person designated for that purpose by the first-mentioned person.*
- (8) *Nothing in this section shall be construed as rendering unlawful any dealing with, or with any part of, the body of a deceased person which is lawful apart from the Act.*
- (9) *In the application of this section to Scotland, for subsection (5) there shall be substituted the following subsection -*
  - (5) *Nothing in this section shall authorise the removal of any part from a body in any case where the procurator fiscal has objected to such removal.*

The Act makes lawful the removal of parts of the body “for therapeutic purposes or for the purposes of medical education or research” (s.1(1)). Provided that the terms of the Act set out above are complied with, any part may be removed (save where the deceased has specified a particular part, in which case it appears that only that part may be removed). The part may then be used for the purposes indicated by the deceased or the person lawfully in possession of the body. Any removal must be by a registered medical practitioner (unless, exceptionally, in respect of the removal of an eye or part of an eye where s.1(4A) applies). Where an inquest or post-mortem may be required, the consent of the coroner is required before any authority may be given under the Act for the removal of any part.

- 2 **The Human Organ Transplants Act 1989** extends the prohibition on commercial dealing in organs noticed earlier (paragraph 7.3) to organs removed from the dead.
- 3 **The Anatomy Act 1984** regulates the conduct of an “*anatomical examination*” in circumstances where a deceased person has bequeathed his body for such a purpose. Such an examination is relevant here since it involves the removal of tissue in that an “*anatomical examination*” is defined (in s.1(1)) as “*the examination by dissection of a body . . . and where parts of a body are separated in the course of its anatomical examination . . . examination by dissection of parts.*” It should be noted:
  - a an examination under the Act must be carried out on licensed premises by someone licensed to do so (not, it seems, necessarily a registered medical practitioner) or by someone in “*the course of teaching or studying or researching*” (s.3(3)) who has permission from a licensed person; and
  - b if an anatomical examination is carried out in accordance with the terms of the Act, removal of tissue is lawful.
- 4 **The Coroners Act 1988.** By this Act, coroners, or, at their request, registered medical practitioners, are authorised to carry out post-mortem examinations. A necessary feature of such examinations is the removal of parts of the body if this is necessary to ascertain the cause of death.

### Removal of tissue from the dead : common law

- 7.12 These statutes do not cover all the circumstances in which tissue might be removed from a dead body: they address certain intended uses and stipulate what must be done if tissue **for those purposes** is to be removed. Is there any residual power **at common law** to remove tissue **for other purposes**?

- 7.13 There is certainly a range of criminal law offences which have been employed over the years to convict persons who have dealt ‘improperly’ with corpses. Older common law prosecutions were for “*exhuming corpses for indecent display*” or “*with intent to dissect*” and “*unlawfully and indecently mutilating corpses*”. More recent prosecutions have been for “*unlawfully removing a corpse from a grave*”, “*interfering with and offering indignities to the remains of a body*”, “*conspiracy to prevent burial*” and for “*preventing a burial and obstructing a coroner*”. In 1985 a clergyman was convicted of the common law offence of mutilating a corpse: for sexual gratification he had cut off the genitals of corpses awaiting burial in his chapel.<sup>13</sup> Clearly, in most of these cases, the defendants acted for “*improper purposes*”; although in one or two of them, even though the motives of the defendants were worthy, they were regarded as irrelevant.
- 7.14 Could it be argued, though, that the common law today might react differently if some conduct relating to a corpse was carried out for some “*good reason*”? There is no clear law on this point. It is open for the courts to accept that removal of parts of a body, outside the terms of the various statutes, can be justified at common law where such removal is for the advancement of the public good. This would be of importance, for example, in the case of tissue removed for retention in an archive: unless archiving can be regarded as “*teaching or studying or researching*” within the terms of s.3(3) and s.6 and of the Anatomy Act 1984 and its statutory regulations (and, on one reading of the Act it may be so regarded), it could be unlawful to remove tissue for these purposes in the absence of a common law justification. The same consideration would appear to apply to tissue banks. Another example may be the removal for examination of parts of the body by a pathologist during the course of a post-mortem examination requested by the deceased’s relatives (rather than ordered by a coroner). This matter is crucial in every situation when removal of tissue from the dead cannot be brought within the statutory language. Clarification of the law, or the acceptance of a common law justification, would be desirable. We have described in Chapter 6 how the scope of that justification might be delimited (paragraphs 6.13 – 6.16). Clearly, in any such clarification of the law, attention will have to be given to the need for consent by the deceased or next-of-kin. Bearing in mind the importance attached to consent in, for example, the Human Tissue Act 1961, it would undoubtedly be regarded as a requirement also at common law.

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<sup>13</sup> For a detailed and scholarly discussion of this area of law, see White, (1993) “An End to D-I-Y Cremation?” 33 *Med.Sci.Law* 151.

## Chapter 8

# Legal matters : uses of tissue

## Summary

Statute law provides the framework within which the use of tissue from the living for the purposes of transplantation or infertility treatment is permitted. There is also comprehensive legislation covering the use of tissue from the dead for therapeutic purposes and for the purposes of medical education and research. The lawfulness of all other uses of tissue would depend on a common law justification that it was in the public interest and did not offend public decency.

## Introduction

- 8.1 It is clear that there is a close relationship between the lawfulness of the removal of tissue and the lawfulness of any subsequent use of the tissue: the propriety of the use largely determines the legality of the removal.

## Use of tissue removed from the living

- 8.2 As has been seen, the Human Organ Transplants Act 1989 makes removal of an organ lawful if it is to be used for the purpose of transplantation (paragraph 7.3). This is the only use contemplated by the Act. Removal for other uses is outside the Act. The Human Fertilisation and Embryology Act 1990 makes the use of gametes or embryos for infertility treatment or research lawful provided that the necessary consents, under schedule 3 of the Act, have been given, all other uses being outside the Act.
- 8.3 So, the legality of all other uses of tissue becomes a matter of common law. Our concern in this report is with the use of tissue for five general purposes: treatment, archiving, banking, study/research and teaching. Each of these uses is one which in general terms can be described as being in the public interest. This is the criterion which a court would be most likely to employ if the legality of any particular use of tissue were challenged. It reflects the ethical analysis which we offered earlier (paragraphs 6.13 - 6.16). Put another way, the test would be whether any proposed use offended public decency or order as understood and previously determined by the courts. If treatment, archiving, banking, study/research and teaching are in the public interest, the question then becomes how far these general terms extend and

what are their proper limits? The common law at present is silent on these specific questions. Notions of public decency would guide the court if a case arose. Although not directly related on its facts, the case of *R v Gibson*<sup>1</sup> supports this view of the principle which would be applied. Freeze-dried aborted fetuses were put on display as earrings attached to a sculpted head. Strictly speaking, it was the public nature of the display rather than the use (if these can be separated) which was the basis of the prosecution. The conviction of the artist and the gallery owner of the crime of outraging public decency demonstrates the residual power of the common law to condemn that which “*goes too far*”. Of course, the vagueness of the terms also leaves the person who intends to use the tissue in a novel way which could offend others in some difficulty as to whether the (indeterminate) line has been crossed.

### Use of tissue removed from the dead

- 8.4 We have already seen that the statutes regulating removal of tissue from the dead also stipulate the use to which this tissue may be put. The Human Tissue Act 1961 refers to “*medical education and research*” in addition to “*therapeutic purposes*”, and the Anatomy Act 1984 refers to “*teaching or studying or researching*”. With the exception of archiving and banking, these statutes clearly embrace all the intended uses which are our concern (as well as allowing, under the Coroners Act 1988, for the proper investigation of cause of death). We have already suggested the way in which archiving, if indeed it is a separate purpose, can be dealt with (paragraph 7.14). As regards the banking of tissue, since the purpose of such banking is to facilitate treatment, research or teaching in the future, it may also be brought within the general scheme of permitted uses.
- 8.5 What if it is intended to use the tissue in such a way as to exploit it commercially or to develop ways of doing so? It could be objected that commercial exploitation is not mentioned and thus falls outside the permitted range of uses. The response may be that commercial development and exploitation are not themselves uses but ways of organising uses that appeal to standard commercial motivation. Since research is a use authorised by statute, it could be argued that the motive for such research, which might be commercial exploitation, is irrelevant. Where, however, tissue is removed without any intention of using it for research but merely so as to be used immediately in some process of commercial development or manufacture, then such a use would appear to be outwith the terms of the Acts referred to. It must find its legality in the kind of common law justification referred to earlier, reflecting as it must our prior view of what is ethically acceptable (paragraphs 6.13 – 6.16).

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<sup>1</sup> *R v Gibson* [1991] 1 All ER 439



**Chapter 9**

**Legal matters : claims of people from  
whom tissue is removed**

**Summary**

In general, a person from whom tissue is removed has no interest in making any claim to the removed tissue. There have, however, been recent exceptions. The most celebrated is the Californian case of John Moore. Moore attempted to claim an interest in products developed by using tissue from his body on the basis that he had a property right in the tissue. The court decided that Moore had no such property rights. It left open the question whether he could claim on the basis that he had not consented to his tissue being used in this way.

English law is silent on the issue of whether a person can claim a property right in tissue which has been removed. The traditional view has been that a body is not property. This view has been the subject of recent debate, however, especially when parts of the body are concerned. The Polkinghorne Committee took the view in its report on the use of fetal tissue, that a woman having an abortion must give express and unconditional consent to the use of the tissue of the aborted fetus. The effect of the consent was that if there were any claim to the tissue, it was thereby abandoned. The Human Fertilisation and Embryology Act equally adopted a scheme of consents so as to avoid addressing the issue of property. Donors of gametes and embryos must consent to the storage and licensed use and disposal of those gametes and embryos.

The question remains open, therefore, whether in certain circumstances the English courts would uphold the claim of someone from whom tissue had been removed. Any such claim should, however, proceed on the basis of the consent given to the removal rather than any claim in property. The likely approach would be that where tissue is removed in the course of treatment, consent to the treatment will entail the abandonment of any claim to the tissue. Where tissue is voluntarily donated any claim will be based on the terms of the donation. There is one problem, however, with this approach; the case of the incompetent adult. Such a person cannot give consent whether to treatment or to any donation. A scheme based on consent cannot apply and special consideration needs to be given to the circumstances under which tissue may be removed and what claims may be made to it once removed.

### Introduction

- 9.1 In this chapter we examine the question whether someone has or retains any claim over tissue removed from his body. There is no need here to deal with the living separately from the dead since any claim, if it exists, would be the same though enforceable in the latter case by the deceased's estate.
- 9.2 By way of introduction, it should be noticed that the **traditional** view is that the common law does not recognise any right of property **in a body**. This traditional view is derived from a number of nineteenth century (and earlier) cases having to do with the disposal of and interference with dead bodies. The cases refer to a dead body but the principle is thought to be equally true as regards a living body, hence slavery is unlawful. Even if these cases represent the law, it is important to analyse the scope of the traditional view and its relevance here, not least because our concern is with parts of the body rather than the body as a whole, and with claims made by the person from whom the tissue is removed rather than by others. In particular, we are anxious to determine the legal basis on which any claim could or should be based.
- 9.3 No claim by statute is available to the person from whom tissue is removed. Indeed, the implication of the Human Tissue Act 1961, the Human Organ Transplants Act 1989 and the Anatomy Act 1984, though it is not expressly stated, is that the tissue removed pursuant to these Acts is given free of all claims, ie is an unconditional gift. The Human Fertilisation and Embryology Act 1990 is less straightforward. Donors of gametes or embryos may impose conditions on use and may vary or withdraw any consent given. By adopting a scheme of consents, however, the Act avoids vesting any property claim in the donor.
- 9.4 At common law, the issue has not been tested in English law. It is instructive to enquire why the question of a claim over tissue once removed has not received legal attention. The answer seems simple. In the general run of things a person from whom tissue is removed has not the slightest interest in making any claim to it once it is removed. This is obviously the case as regards tissue removed as a consequence of treatment. It is equally true in the case of the donation of tissue whether, for example, blood, bone marrow or an organ. The word donation clearly indicates that what is involved is a gift.
- 9.5 It is certainly true, of course, that an appendix or gallstone may be returned to a patient who may refer to it as **her** appendix or gallstone. But this says nothing about any legal claim she may have to the appendix. In fact, in the case of the returned appendix, one view of the legal position may be as follows: the patient consents to the operation which involves the removal of her appendix; by her consent to the operation she **abandons** any claim to the appendix; on removal the appendix acquires the status of a *res* (a thing) and comes into the possession of the hospital authority prior to disposal; in response to a request by the patient that it be

returned, the hospital gives the appendix to the patient as a gift; the appendix then becomes the property of the patient.

- 9.6 While what has been said about the lack of interest of the patient in the fate of tissue removed from him may be true, some have enquired whether a claim to tissue which has been removed can be advanced in certain circumstances. One such circumstance is the use of fetal tissue subsequent to an abortion. Does a mother, it may be asked, have any claim to the tissue? The report of the Polkinghorne Committee did not claim to resolve the question.<sup>1</sup> Instead, it provided for a scheme whereby the woman has to give explicit and unconditional consent to the use of the fetal tissue before it may be used. The same scheme of consents, circumventing the need to resolve questions of property and ownership, was employed in the Human Fertilisation and Embryology Act.
- 9.7 But there are other circumstances in which the question posed in paragraph 9.6 may arise. In some circumstances, it could be argued, and has been by a number of commentators,<sup>2</sup> that tissue once removed becomes the property of the person from whom it is removed. This is to say that consent to removal does not **entail** an intention to abandon. The tissue may well, in fact, be abandoned or donated, but these imply a prior coming into existence of a *res* and the exercise of rights over it. Indeed, such an analysis is logically essential, it is argued, even if the resulting property (ie a person's assertion of a property right over the new *res*), exists merely for a moment (a *scintilla temporis*). On this view the person from whom tissue is removed must have a property right in the tissue which expressly or by implication he could waive on removal so that the property passes to another. The consequence is, of course, that if the property right were not waived, it would be retained. To return to the example in paragraph 9.5, the appendix would have become (and remained) the patient's property had she not by implication waived any right to it.
- 9.8 The case of *Venner v State of Maryland*<sup>3</sup>, decided by the Court of Special Appeals in Maryland, USA, may be of assistance. Powers J held that, "*By the force of social custom . . . when a person **does nothing and says nothing to indicate an intent to assert his right of ownership, possession, or control over [bodily] material, the only rational inference is that he intends to abandon the material***" (our emphasis). The implication of this approach is clear.

1 The legal presumption is in favour of abandonment.

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<sup>1</sup> Polkinghorne, J *et al* (1989) **Review of the Guidance on the Research Use of Fetuses and Fetal Material** London: HMSO

<sup>2</sup> See, for example, B Dickens, (1992) **Living Tissue and Organ Donors and Property Law**, 8 *The Journal of Contemporary Health Law and Policy*, p 73 and material cited therein.

<sup>3</sup> *Venner v State of Maryland* (1976) 354 A 2d 483 (Md CA)

- 2 Abandonment may be prospective.
- 3 Where, however, the circumstances are such that abandonment may not be presumed, it must follow that if no consent were given, or a consent expressed to be 'on terms', were given, property rights over the tissue **would not necessarily** pass but would be retained by the person from whom the tissue was removed.

9.9 It is fair to say that some support for this property approach can be derived from the various statutes already referred to. While we have seen (in paragraph 9.3) that no claim arises by reference to these statutes, the approach to tissue adopted by them may assist in understanding the current state of the common law. While the Human Tissue Act 1961 is of no assistance, both the Human Organ Transplants Act 1989 and the Human Fertilisation and Embryology Act 1990 appear to endorse a property approach. Indeed, the latter, although relying upon a scheme of consents so as to avoid the need to decide the issue of property, contemplates that the control and disposal of gametes and embryos rest with the donor(s) and allows for the transfer of the reproductive material between those having a licence to deal with them. A final statutory provision, s.25 of the National Health Service Act 1977 also seems implicitly to adopt a property approach. The section provides that:

*where the Secretary of State has acquired:*

- (a) *supplies of human blood . . . or*
- (b) *any part of a human body . . .*

*he may arrange to make such supplies or that part available (on such terms, including terms as to charges, as he thinks fit) to any person . . .*

The statutory language is, therefore, that of things, of property, of the reification of blood and body parts.

9.10 The Working Party of the Law Reform Commission of Canada<sup>4</sup> outlines this conflict between the traditional view that there is no property in a body and the view that those from whom tissue has been removed may have some claim to it:

*Does the no-property rule encompass living donors? In Canada [and for our purposes English law can be taken to be the same] there appears to be no case that specifically addresses the issue. In cases in the United States, the courts have tended to apply the no-property rule to tissue disputes involving living donors, although there are recent trends to the contrary. . . .*

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<sup>4</sup> Law Reform Commission of Canada (1992) **Procurement and Transfer of Human Tissues and Organs** Working Paper 66

Cases in the United States have arisen over the discarding of donated or deposited human tissue without the consent of the patient-depositor. In two cases, one involving lost eye tissue that was being examined for cancer and another involving the disposal without consent of reproductive matter in an infertility clinic, courts have avoided resolving patients' damages claims in terms of property. Instead, they have preferred to analyse them in terms of mental shock or distress to the patient. Those cases seem to suggest that some courts in the United States have extended the no-property-in-a-corpse rule to a no-property-in-bodily-parts rule.

Commentators have critiqued the no-property-in-bodily-parts tendency for living donors. Some jurisdictions significantly limit nervous shock claims. It is argued that even when nervous shock claims and damages are available, they do not address instances when the return of valuable human tissue or material is sought. The suggestion is that property concepts would better protect an individual's autonomy and person, in addition to clarifying legal rights and duties regarding the control of human tissue in particular circumstances. For example, when an institution destroys valuable human tissue without consent in a jurisdiction that limits mental damages, common law property principles concerning the destruction or spoilage of materials rightfully in one's possession might prove helpful in defining legal rights, duties and grounds of recovery.

The issue of rights and duties regarding the control and transfer of human tissues has arisen most acutely in some recent cases involving human reproductive material. While there are no reported Canadian cases on this point, an American couple was recently successful in litigating the control of and right to transfer their frozen embryo from an east-coast infertility clinic to a west-coast clinic.<sup>5</sup> In France, the wife of a deceased sperm depositor argued that she had a right to her husband's frozen sperm, which he had deposited for preservation after learning that he would undergo cancer treatments that risked making him sterile.<sup>6</sup> The court expressly rejected the argument that frozen semen was property, on grounds that human reproductive material was neither inheritable nor an object of commerce. Nevertheless, it ruled that the sperm bank must return the frozen semen to the wife of the depositor, as a result of an understanding between the depositor and the sperm bank. That decision suggests that agreements between tissue banks and depositors, as reflected in well-drafted informed consent forms, might help to minimize disputes over the control of deposited tissues, in the absence of legislation or professional standards that sufficiently address the issue.

Disputes over reproductive substances are helpful in identifying concerns and values at issue in potential disputes over other human tissue and substances. For example, the growth in tissue banking may make the rights and duties in controlling other deposited, valuable human tissue a more prominent medical-legal issue. Consent forms for autologous blood banking in Canada have referred to deposited blood in terms of property, as have professional protocols for the banking of reproductive and genetic materials in the United States.

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<sup>5</sup> *York and Jones* (1989) 717 F S Supp 421 (ED Va)

<sup>6</sup> *Parpalaix v CECOS* Gaz.Pal.1984.2e sem.jur.560

9.11 So far, we have noticed the following as possible legal approaches to any claims made by the person from whom tissue is removed: either

- 1 consent to removal entails abandonment; or
- 2 on removal, property rights vest in the person from whom it is removed.  
It is presumed that these are abandoned, but they can be retained.

A further legal approach is to argue that tissue once removed becomes property, but at the time of its removal it is *res nullius*, ie that it belongs to no-one until it is brought under dominion (the traditional legal example is the wild animal or plant). This would reflect the traditional view of “*no property in the body*”. It would also mean that a person could not prospectively donate “his” tissue, once removed from his body. All he could do would be to consent to the removal. If this analysis were adopted, the tissue would be the property of the person who removed it or subsequently came into possession of it. The person from whom it was removed would not, however, have any property claim to it.

9.12 The current state of English law makes it unclear (at best) which of these approaches (or another) represents the law. Interest in the validity of property claims over removed tissue has, however, been rekindled because of an awareness of circumstances in which tissue has been removed and then developed in some way so as to serve as the basis for a commercial product. The *locus classicus* is the well known *Moore* case,<sup>7</sup> which has already been referred to (paragraphs 2.15 – 2.16 and Appendix 1). In *Moore*, the Supreme Court of California, trying a preliminary point of law, decided that Moore had no property rights in the tissue taken from his body. Although not expressed in such a way, if we impose the language that we have employed, the court appears to have found that Moore’s consent to the operation entailed an abandonment of any claims over the removed tissue. Thus, he could not assert a claim in property as the basis either for objecting to the removal of his tissue or for having a share in whatever profit was gained through its use. The issue of the validity of the consent he gave to the operation and subsequent procedures then became the focus of the case.

9.13 It is not easy to predict whether an English court would adopt the Supreme Court of California’s conclusion. Certainly, the reasons advanced by the majority of the court for rejecting Moore’s property claim are somewhat unconvincing. The majority found that there were three “*reasons to doubt*” Moore’s claim, all of which Mosk J sharply criticised in his dissenting judgment. The first was the absence of precedent. Mosk J’s response was that the Supreme Court was there precisely to make law when necessary. The second was that the matter was more appropriately for the legislature, a view which Mosk J said was out of place in a decision of the

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<sup>7</sup> *Moore v Regents of the University of California* (1990) 13P 2d 479)

highest court, one of whose roles was to develop the law. The third was that the patent granted to the University of California preempted any claim Moore might have. But, the grant of the patent did not mean, according to Mosk J, that Moore could not share in any profits arising from it. Notwithstanding these weaknesses, the **conclusion** of the Supreme Court, if not the reasoning, may recommend itself, not least because of the consequences of adopting the alternative. For, if the alternative approach were adopted, and a potential property claim recognised, the consequences could be far-reaching. Consent to even the most minor procedures would have to refer to possible property rights in removed tissue and seek a waiver of such rights. Patients might be encouraged to bargain over tissue (if thought to be unusually valuable, for example, for research). Agencies to negotiate such bargains might appear and research may be impeded in a welter of contractual arrangements.

9.14 Of the various approaches referred to, therefore, it may be that a preferable approach for the English courts would be the following:

- 1 It will be entailed in any consent to **treatment** that tissue removed **in the course of that treatment** will be regarded in law as having been abandoned by the person from whom it was removed;
- 2 tissue removed **in circumstances other than treatment**, which is **voluntarily donated**, will be regarded as a gift. Use for purposes other than those for which consent was given could give rise to a claim on the part of the person from whom the tissue was removed. Such a claim will depend on the terms of the original consent;
- 3 where tissue is removed voluntarily but is intended to be kept **for the donor**, for example autologous blood donations, the donor will be able to claim the tissue by virtue of the agreement under which it is kept. (The donation of gametes and embryos is subject to a specific statutory framework of consents regulating *inter alia* the giving and withdrawing of consent to use);
- 4 where tissue is removed without **explicit** knowledge and consent, any claim the person from whom it was removed may have as regards the subsequent use of that tissue will turn on the validity of any general consent which may have been given, ie as to whether removal and subsequent use of the tissue could legitimately be said to be implied.

9.15 From this summary it will be seen that, on the reasoning proposed, legal claims may be open to persons from whom tissue is removed. It is suggested they should properly proceed on the basis of the consent given to the procedure which resulted in the removal, or its absence, rather than a claim in property (see the reference in paragraph 9.10 above to the Parpalaix case by the Canadian Working Party). It may be important, however, to add a rider. It will be recalled that in the case of an

incompetent adult, no-one is authorised to consent on his behalf to treatment, let alone to subsequent use of left-over tissue, nor to any non-therapeutic removal and subsequent use of tissue. As regards removal in the course of treatment and use thereof, unless such use was in the patient's best interests, as, for example, being necessary for a proper diagnosis, it is difficult to see how a consent scheme can adequately deal with any claim that the adult himself, if he later regains competence, or someone else on the incompetent adult's behalf, may subsequently make concerning use of his tissue. (Removal of tissue in a non-therapeutic context and use thereof may not currently arise if the view prevails that such removal is outside the law) (paragraphs 7.9 - 7.10).

- 9.16 One response would be that tissue should not be removed from incompetent adults, save when it is genuinely in their therapeutic interests. Otherwise, if tissue were removed, it could be open to the adult or a "*next friend*" on his behalf to pursue a claim. The success of such a claim would depend on a court finding that there was a property right in the removed tissue which the adult, being incompetent, could not waive or abandon and which a guardian charged with acting in the incompetent adult's best interests may not be able to waive either, since to do so could be to give away something of potential value to the adult. We have earlier doubted that a court would adopt the property approach. Indeed, we would recommend that it should not. But the possibility exists. Given the legal difficulties posed by this particular situation, the optimal solution would be to legislate that no property rights inhere in a person from whom tissue is removed. This, however, would require Parliamentary time and effort.
- 9.17 A middle course may be to rely upon the ethical analysis advanced earlier (paragraphs 6.27 - 6.28) and propose that in the case of the incompetent adult, the courts should regard it as legally justified in the public interest to use tissue taken from an incompetent adult even though no consent can be obtained, provided, of course, that such use was itself a justifiable use. This would prevent the particular circumstances of the incompetent adult from serving as a means of resurrecting any property right in tissue. Any such proposal would, however, have to be attended by appropriate safeguards to ensure that there was no exploitation of this class of person. It will be recalled, however, that the Law Commission in its recent report doubted the current legality of such an approach (paragraph 7.9).
- 9.18 So far discussion of property rights has concentrated on rights over the actual tissue that is removed. It is important to recall that a person may also claim an entitlement to share in any benefits arising from the exploitation of the tissue removed and, where relevant, any consequent intellectual property rights. Abandonment and donation, however, do not ordinarily give rise to intellectual property rights. We defer a systematic examination of claims to intellectual property and patent issues until Chapter 11 (and see, in particular, paragraph 11.32).



- 9.19 Finally, it must be emphasised that these views and conclusions are advanced without any case law to rely upon. They are, therefore, tentative. If it is thought desirable that the law should be clarified in such a way as to reflect the conclusions reached, due attention must be given to the proper means of achieving this (paragraph 1.19).



## Chapter 10

# Legal matters : claims of users

## Summary

Does someone who makes use of human tissue have any claim over the tissue? More specifically, can a body, or part of a body once separated, be viewed as the property of the user? Traditionally, the law has held that human corpses are not property. There is, however, a duty to effect a decent burial and a corresponding right to possession of the corpse for that purpose. In rare cases, urine and blood samples needed for sobriety tests have been removed from police stations. These have led to convictions for theft, indicating that body waste and tissue may be treated as property. Whether anatomical specimens of human tissue can be considered property has been the subject of much debate. The law remains unclear on this issue.

Despite the lack of clarity, it is probable that the user of tissue acquires at least the right to possess, and probably a right of ownership over, the tissue. The question then arises whether the law recognises any limitations on the users of tissue as to what can be done with it. One important issue is that of commercial dealing in human tissue. Statutes restrict commercial dealing in organs, gametes and embryos. The legality of commercial dealings in other tissue is not clear, and some clarification is desirable.

## Introduction

- 10.1 In Chapter 9 we discussed whether or not the person from whom tissue is removed may have a property right in the tissue. Whatever view is taken, it does not follow that the user (broadly defined) has no such right. The tissue once removed comes into the possession of the remover and may then be passed to others. The nineteenth century doctrine that a body may not be property would suggest, however, that no possessory nor property right vests in the user of a body or, arguably, parts of a body. In this chapter we examine the claims users may have over human tissue.
- 10.2 The Canadian Working Party helpfully summarised the background to the doctrine of no property in a body as follows:

*Both the common and the civil law have traditionally maintained that the human corpse is not the subject of property. The sacrosanct nature of the dead human body understandably traces much of its origins to religious custom. The **Civil Code of Lower Canada** refers in burial matters to dead bodies as “sacred by their nature.” Similarly, the*

common law no-property rule is traced to sixteenth- and seventeenth-century English case law and Sir Edward Coke's commentary that burial matters were within the domain of the Church, and the burial of cadavers is *nullis in bonis* (among the property of no one). As the courts of England began to hear matters formerly within the jurisdiction of the courts of the Church, they imported Coke's statement into English jurisprudence concerning dead bodies.

Despite the no-property rule, the common and civil law still recognized a number of interests that continue to enjoy legal protection today. For example, although the common law did not grant an absolute right to the control of one's body after death through one's will, it and the civil law have long recognized one's right to a decent burial. To effect the deceased's right to a decent burial, the law imposed on the deceased's executor or family a duty of burial and a corresponding right to possession of the decedent's body for burial:

*In Canada [as in England], this duty of burying a dead body falls upon the executors of the deceased's estate. In the absence of a will naming executors, the right to possession for burial goes to the surviving spouse . . . If no spouse survives, the right belongs to the next of kin.*

Some courts and jurisdictions refer to the right of possession as a "quasi-property" right. It empowers spouses or the next of kin who are wronged by interference to sue for damages. The essence of such suits is damages for injury to the emotional or mental tranquillity of the next of kin, in the legal form of the wrongful infliction of emotional distress. Thus, instances of interference with the right of possession arise in diverse cases, including the negligent handling or transporting of dead bodies, the withholding of a body for payment of funeral expenses, the unauthorized removal of hair from the deceased by a funeral home, the withholding of a body for an unreasonable length of time to determine organ donor status and the mutilation of the deceased during the course of an unauthorized autopsy.

- 10.3 The early twentieth century Australian case of *Doodeward v Spence*<sup>1</sup> is often cited as authority for the no property rule. "There can be no property in a human body, dead or alive. I go further and say that if a limb or any portion of a body is removed that no person has a right of property in that portion of the body so removed", per Pring J. On appeal to the High Court of Australia the judgment of Griffith CJ in the New South Wales Court of Appeal decided that if some work was carried out on the body part, for example to preserve it, which changed the part, then it could acquire the characteristics of property and be subject to property rights.<sup>2</sup>

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<sup>1</sup> *Doodeward v Spence* (1908) 6 CLR 406

<sup>2</sup> The case is described in Skegg, P. (1976) **Human Corpses, Medical Specimens and the Law of Property** 4 *Anglo-American Law Review* 412 as follows:

*[The case of Doodeward v Spence involved an action for conversion] and detinue . . . [of] the corpse of a two-headed child. The child had died before birth in New Zealand 40 years earlier, and its mother's doctor had taken the body away with him. He preserved it in a bottle of spirits, and kept it in his surgery as a curiosity. On his death the specimen was sold by auction. The successful bidder was Doodeward's father, from whom it passed to Doodeward. The bottle and its contents were seized under warrant, for use in*

10.4 By contrast to the view of Pring J, Stephen expressed the view<sup>3</sup> that anatomical specimens could constitute personal property. More recently, as Magnusson points out<sup>4</sup> “*there are a handful of English decisions in which human tissue has been treated as property.*” He cites criminal cases where a defendant was convicted of theft (as well as assault) when he cut a quantity of hair from a woman’s head<sup>5</sup>, where a defendant poured a urine sample he had given to establish his sobriety down the sink and was convicted of theft<sup>6</sup>, and where the defendant was convicted of theft when he removed the blood sample, taken for the same reason, from the police station<sup>7</sup>. The last two cases, albeit that the point was not directly discussed in either case, suggest that property vested in the police. Admittedly, two of these cases involve hair and urine, neither of which are, strictly speaking, tissue, but if they are treated as property, *a fortiori*, so would what we define as tissue by virtue of its identification as an organised collection of cells and the tangible quality such identification

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*criminal proceedings, in which Doodeward was prosecuted for publicly exhibiting the specimen for gain, ‘to the manifest outrage of public decency’. At the conclusion of the prosecution, in which Doodeward had pleaded guilty, the judge refused to order that the corpse be handed back to him. Doodeward then commenced proceedings to recover it. He was non-suited in a District Court on the ground that there was no property in the subject matter of the action. He appealed, first to the Supreme Court of New South Wales, as the District Court of Appeal, and then to the High Court of Australia. By the time the case reached the High Court, the bottle and spirits had been returned to him. However, the corpse was retained at the University Museum, on behalf of the defendant, a Sub-Inspector of Police.*

*In the High Court, all three Judges accepted that immediately after death a corpse is not the subject of property. However, the Judgment of Griffith, CJ, with which the other judge who made up the majority expressed his agreement, can be interpreted as laying down that a corpse can be so changed that it becomes the subject of property. Griffith, CJ, took the view that, at least in Australia, it was not necessarily unlawful to retain a corpse for a purpose other than immediate burial. He laid down a proposition which applied to those cases where a person had, by the lawful exercise of work or skill, so dealt with a corpse in his lawful possession that it had acquired some attributes differentiating it from a mere corpse awaiting burial. In these cases, he said, the person acquires a right to possession of the corpse or part thereof - at least as against anyone who is not entitled to have the object delivered up to him, for the purpose of burial. Griffith, CJ, said he did not know of any definition of property which was not wide enough to include such a right of permanent possession. He said that, so far as this right constituted property, a corpse or part thereof is capable by law of becoming the subject of property. Applying his principle to the case before him, Griffith, CJ, said that the evidence showed that the body had come ‘not unlawfully’ into the doctor’s possession, that ‘some -perhaps not much - work and skill had been bestowed by him upon it’, and that it had acquired an actual pecuniary value. He allowed the appeal.*

<sup>3</sup> Stephen, J F (1883) **History of the Criminal Law of England**

<sup>4</sup> Magnusson, R S (1992) **18 Melbourne University Law Review** p 601, at 616

<sup>5</sup> *Herbert* (1961) **25 J Criminal Law** 163

<sup>6</sup> *R v Welsh* [1974] RTR 478

<sup>7</sup> *R v Rothery* [1976] RTR 550

suggests.<sup>8</sup> Finally, it must be recalled that Broussard J in his dissenting opinion in the *Moore* case (paragraphs 9.12 – 9.13), wrote that “. . . the majority’s analysis cannot rest on the broad proposition that a removed part is not property, but . . . on the proposition that a **patient** retains no ownership interest in a body part once the body part has been removed” (our emphasis).<sup>9</sup>

- 10.5 Reflecting on the lack of clarity in English law, Professor Peter Skegg examined the question of whether anatomical specimens and tissues are the subject of property. Discussing *Doodeward v Spence* nearly 20 years ago, he wrote:

*One drawback of Griffith, CJ’s principle is the difficulty of its application. If the principle were adopted in England, it would no doubt apply to Egyptian mummies in museum collections and probably also to shrunken heads, or heads which had been tattooed after death. But much more difficult would be the question of whether it would apply to anatomical specimens, and tissues and organs awaiting transplantation. If the English courts were prepared to apply the principle in the same way as the majority of the High Court of Australia in Doodeward v Spence these objects might very often be considered the subject of property. However, when dealing with an object on which no more labour or skill had been expended than was on the corpse in Doodeward v Spence, which had simply been placed in spirits, an English court might favour the approach of the dissenting Judge in Doodeward v Spence. He said that “No skill or labour has been exercised on it; and there has been no change in its character.” It would be better to find a principle which applies more naturally to parts taken from corpses for medical purposes, and indeed, in some circumstances to whole bodies. To find such a principle, it is desirable to look to Scots law.*

*Scots institutional writers, and dicta in the Court of Justiciary in Dewar v H M Advocate [1945 JC 5] support the view that in Scots law a corpse is the subject of property (and can therefore be stolen), until such time as it is buried or otherwise disposed of. Buried corpses are now perfectly adequately protected by the common law crime exemplified in R v Sharpe (1857) Dears & B 160 at 163, which is the English equivalent of the Scots crime of violation of sepulchres. Where English law is inadequate is in the rather limited protection it extends to corpses or parts of corpses prior to burial or cremation. This inadequacy could be overcome by the courts taking the view that, until such time as a corpse or part thereof is buried, cremated, or otherwise disposed of, it is the subject of property. Unburied corpses, and anatomical specimens and transplant material removed from corpses, would then be protected by, amongst other things, the crime of theft and the tort of trespass to goods.*

*It would be desirable for the English courts to go further than Scots authority yet does, and take the view that it is only while corpses or the remains of corpses are buried, or dispersed following cremation, that they are not the subject of property. This would enable the courts to extend more effective legal control, not only over corpses awaiting burial and cremation, but also over ashes which had not been buried or dispersed, and human remains which had been disinterred.*

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<sup>8</sup> See further Matthews, P. **Whose Body? People as Property** [1983] 36 Current Legal Problems 193

<sup>9</sup> *Moore v Regents of the University of California* (1990) 13P 2d 479)

- 10.6 The continued absence of clear legal authority admittedly leaves the law uncertain. It is suggested, however, that common sense as well as the common law require that the user of tissue acquires at least possessory rights and probably a right of ownership over tissue once removed. It cannot plausibly be argued that University College London does not own Bentham's skeleton. *Mutatis mutandis*, a hospital which has tissue in its possession, for example for transplant, has such property rights over the tissue as to exclude any claim of another to it, as does a coroner or pathologist who has carried out a post-mortem and retains body parts for examination. Equally, it would follow, they have the right to recover the tissue if it were taken without permission. The same must also be true of those who operate a tissue bank or an archive of specimens used for research or teaching.
- 10.7 To conclude that the user acquires property rights over removed tissue does not, of course, mean that the user can then do whatever he likes with the tissue. English law is familiar with the notion of constraints on what an owner may do to or with property. A dog is a chattel, but it cannot lawfully be harmed gratuitously. A tree is property but, if subject to a conservation order, must be dealt with in a particular way. In the case of tissue which has been removed, the question arises as to whether the law recognises any limitations on the exercise of property rights and if so, what. Perhaps the limitation of greatest concern to us has to do with commercial dealing in tissue.

### Commercial dealings

- 10.8 We have seen that the Human Organ Transplants Act 1989 (HOTA) makes commercial dealing in organs (as defined) a crime (paragraph 7.3). Internationally, there is a growing body of legislation and other guidance that prohibits commercial dealing, or trafficking, in organs (paragraph 2.21). Equally, s.12(e) of the Human Fertilisation and Embryology Act 1990 provides that "*no money or other benefit may be given or received in respect of any supply of gametes or embryos unless authorised by directions.*" By directions made by the Human Fertilisation and Embryology Authority (HFEA Directions 1991/2) individual donors of gametes may be paid up to a maximum of £15 for each donation plus any reasonable expenses incurred. Provision for the payment of donors of gametes is a reflection of existing practice when the HFEA was established. The value of any payment is limited by the HFEA, however, and the intention is eventually to phase out payment completely.<sup>10</sup> Licence-holders who supply other licence-holders with gametes or embryos may only be paid their reasonable expenses. The effect of these provisions is to prevent trade in human gametes and embryos. Directions by the Secretary of State for Health, pursuant to s.25 of the National Health Service Act 1977 (paragraph 9.9), restrict

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<sup>10</sup> Human Fertilisation & Embryology Authority (1993) **Second annual report** p 29

charges made by blood transfusion centres for blood and blood derivatives to reasonable handling charges, with no charge to be made for the blood or derivatives.<sup>11</sup>

- 10.9 Apart from these specific statutory provisions, does the common law regard tissue as something *extra commercio*, ie would commercial dealings be regarded in law as having no force? Would a court, in other words, declare any purported commercial contract to be a contract contrary to the public interest, (*contra bonos mores*). It is by no means clear whether commercial contracts dealing with, for example the purchase of blood or other tissue, are currently entered into and if they are whether, if challenged, they would be upheld in law. Thus the true question for the law is whether some line can be drawn identifying those arrangements which are acceptable and those which are not, perhaps by analogy with the prohibition of commercial dealings of HOTA or HFEA or s.25 of the NHS Act 1977. It may be noted that the Recommendation on Human Tissue Banking of the Council of Europe's Directing Committee on Public Health specifically recommends that all activities associated with the banking of human tissue "*should be carried out by non profit-making institutions*".<sup>12</sup> Arguably, in keeping with the ethical analysis offered in Chapter 6, (paragraphs 6.38 - 6.40), the distinction which suggests itself is between non-profit making arrangements involving intermediaries, such as tissue banks, which could be accepted as lawful, and profit making open-market arrangements, which could be regarded as having no legal validity. Clearly, some kind of clarification is desirable.
- 10.10 Additionally, as has been noted, there are problems, particularly in the area of intellectual property rights, which are associated with the commercial advantage which a user may derive from the use of tissue. Advances in biotechnology have increased the consequent desire to protect the commercial investment in, and potential for profit from, developments using human tissue. This makes the concern of the users of tissue for some clear guide as to their rights that much more pressing. We return to this in detail in Chapter 11.

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<sup>11</sup> National Blood Transfusion Service, National Health Service Act 1977, Directions of Handling Charges (1992)

<sup>12</sup> Recommendation N° R(94)1



## Chapter 11

# Legal matters : patent issues

## Summary

A patent is a monopoly right, granted for a limited period, given to an inventor in return for the publication to the world at large of the details of an invention. The requirements for patentability are as follows: novelty, inventiveness, industrial applicability, sufficiency of description and the absence of any feature that makes for inherent unpatentability. The exclusions to patentability are as follows: mere discoveries, immoral inventions, biological processes and animal or plant varieties.

Both the requirements for, and exclusions to, patentability are examined as they relate to inventions derived from human tissue. Exclusion on the ground of immorality is examined in detail, since it has been important in the arguments about the patentability of biotechnology inventions such as transgenic animals, and, in at least one case covering the hormone relaxin, in arguments about the patenting of inventions derived from human tissue.

We review the options for ensuring that the ethical issues are properly taken account of in the patenting of inventions derived from human tissue. We conclude that a protocol to the European Patent Convention should be devised to set out criteria for applying the immorality exclusion where patents in the area of human and animal tissue are concerned.

### Introduction

- 11.1 Recent innovations in the biological sciences have led to many difficulties in modern patent law, as a look at the newspaper headlines and introductory sentences in Fig 11.1 shows. In this chapter, we begin by defining a patent and then go on to discuss the patent issues raised by inventions derived from human tissue.

Fig 11.1

**Independent** 19 February 1992

**Breasts provoked patent conflict**

“Patent officials will have to come to a delicate decision in the coming months on how to regard an invention for secreting valuable proteins in the breast milk of women . . .”

**The Times** 13 January 1993

**Cancer mouse protest**

“Animal welfare groups have appealed to the European Patent Office against the granting of a patent to a mouse genetically engineered to develop cancer . . .”

**Independent** 14 January 1993

**Royalties demand threatens research into cystic fibrosis**

“Research and treatment of cystic fibrosis could be hamstrung because researchers are facing demands for royalty payments following the patenting of the human gene responsible for the disease . . .”

**Daily Telegraph** 22 September 1994

**Patent ends co-operation over breast cancer gene**

“Efforts to pinpoint a second defective gene responsible for breast cancer may be delayed by a row between British and American teams over patenting . . .”

### Patents and human tissue

- 11.2 A patent may be defined as a monopoly right which is granted for a limited period, extending to the territory of a state. It is given to an inventor in return for that inventor publishing details of his invention to the world at large. The monopoly is the exclusive right to use the invention. This carries with it the right to give consent to (to license) others to use the invention, usually in return for a sum of money (a royalty) and, conversely, the right to prevent others from using the invention, if necessary by means of a legal action for infringement of the patent.

- 11.3 A patent is always granted for a limited term. Currently in Europe this term is 20 years from the date the patent is applied for. However the effective monopoly period is always less than 20 years because of the period between the date of application and the date when the patent is granted. During this period, called the prosecution period, the patent application is examined by patent offices around the world to ensure that it complies with the requirements for patentability.
- 11.4 The requirements for patentability differ in certain important respects in different parts of the world. There has been harmonisation of patent law within Europe but limited progress has been made in harmonising European patent law with that which applies, for example, in the United States and Japan.
- 11.5 The European Patent Convention (EPC)<sup>1</sup>, which governs European patent law and practice, is completely silent on the patentability of inventions relating to human tissue. This is not at all surprising since, at the date of the EPC, much of the technology which has led to the making of such inventions simply did not exist. However, it has been the consistent position of the European Patent Office (EPO), which grants patents under the EPC, that the normal requirements of patentability (as set out below) apply to inventions derived from living matter, including human tissue, in just the same way as they do to non-living matter.<sup>2</sup>
- 11.6 A draft Biotechnology Directive<sup>3</sup> which aimed to “clarify” (but not to change) existing European patent law, insofar as it related to biotechnological inventions (the “draft Directive”), was recently rejected by the European Parliament, the first occasion on which the Parliament has voted to reject a Directive.

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<sup>1</sup> The EPC was ratified by the United Kingdom in March 1977 and entered into force in October 1977. The provisions of the EPC were enacted by the Patents Act 1977 which came into force in June 1978.

<sup>2</sup> In the US, it was held in the oft-quoted decision in **Diamond v Chakrabarty** (206 USPQ 193 1980), that patentable subject matter includes “. . . anything under the sun that is made by man”. This **Chakrabarty** approach is therefore similar to that which the European Patent Office has been following for many years.

<sup>3</sup> The draft European Directive on the legal protection of biotechnological inventions was first proposed by the Commission to the Council of Ministers in November 1988 (European Commission, Office for Official Publications (1988) **Proposal for a Council Directive on the legal protection of biotechnological inventions** COM(88) 496 final - SYN 159). There then followed a lengthy period of consultation, and in October 1992 the European Parliament approved the draft in its first reading, with 45 proposed amendments. The Commission then put these amendments to the Council and in February 1994 a Common Position was adopted. This received its second reading by the European Parliament in May 1994, which voted in a number of controversial amendments (although doubts existed as to whether a quorum was present). The amendments were rejected by the Council of Ministers and a Conciliation Committee began to meet on 28 November 1994 to see whether a compromise could be achieved. On 23 January 1995 a compromise was apparently achieved between the Council and the Parliament but on 1 March 1995 the Parliament rejected the draft Directive by a vote of 240 to 188 with 23 abstentions.

- 11.7 Despite the deficiencies of the draft Directive (see below) it had been hoped that some of the uncertainties in this area of law would have been resolved by its implementation by member States. It now seems unrealistic to expect further legislation in this area from the European Union within the foreseeable future. This emphasises the need for clarification of, and possible amendment of, the EPC.<sup>4</sup>

### The current position

- 11.8 Over the last decade the European Patent Office (EPO) has granted many patents relating to inventions derived from human tissue. Thus it has granted patents covering the use of, or processes for the production of, human cell lines (for example, a human lymphoblastoid cell line and a human hepatocyte culture process), human cell-derived protein products (for example, interferons) and DNA fragments (genes) for coding for useful proteins (for example, the hormone relaxin). A recent search of human tissue-related patents in the period 1982-1994 revealed 235 published patent applications covering mainly cultured human-derived cell lines, as well as techniques or substances relating thereto. Since the search only covered published applications and granted patents, the number of unpublished applications for patents pending in this field will be far greater than the above figure.
- 11.9 The patentability requirements which must be satisfied by an invention under European law are as follows:
- ▶ Novelty
  - ▶ Inventiveness
  - ▶ Industrial applicability
  - ▶ Sufficiency
  - ▶ Not inherently unpatentable (for example, discoveries, immoral inventions, essentially biological processes and animal or plant varieties are all expressly excluded from patentability).<sup>5</sup>

Each of these requirements is briefly considered below insofar as it applies to human tissue-related and/or biotechnological inventions.

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<sup>4</sup> Paragraphs 11.37 - 11.43 and 11.47

<sup>5</sup> Patents Act 1977, Section 1.

## Novelty

11.10 An invention must be new, in the sense of not having been made available to the public anywhere in the world before the filing date of the application for a patent (the “priority date”). A substance which already occurs in nature, for example in humans, will nevertheless satisfy this requirement, if what is claimed in the patent specification is something which is **not** naturally available – for example if it is highly purified. To take a specific example, tissue plasminogen activator (t-PA) is an enzyme active in humans in the dissolution of blood clots. In a patent covering the production of human t-PA by means of recombinant DNA technology, one of the claims read: “*Human tissue plasminogen activator unaccompanied by associated native glycosylation*”.<sup>6</sup> This would be regarded as satisfying the novelty requirement for a patent. Even if the identical substance is available in nature (for example, a DNA sequence in humans) the substance will be regarded as novel when identified and isolated for the first time.<sup>7</sup>

## Inventiveness

11.11 An invention must be inventive, in the sense that it would not have been obvious to a person of ordinary skill in the relevant art at the priority date. Again, for inventions derived from human tissue, this rule applies as it does to any other type of invention. Thus, for example, if the invention is a process for obtaining a given human gene, and that process was not obvious to the person skilled in the art at the priority date, then it will be inventive. Even if the process is entirely conventional, there may still be invention if the process provides a useful substance which was previously unknown.<sup>7</sup>

## Industrial applicability

11.12 An invention must be capable of industrial application. In practice, pharmaceutical or biotechnological inventions for use in treating human beings will normally satisfy this requirement.<sup>8</sup>

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<sup>6</sup> **Genentech Inc’s Patent** [1989] RPC 147

<sup>7</sup> Decision of the EPO in the Opposition to Patent No 112 149 in the name of the Howard Florey Institute of Experimental Physiology and Medicine dated 18 January 1995 (“the Relaxin Opposition”)

<sup>8</sup> This requirement would not present a problem in many cases. For example, the Genentech claim to “*Human tissue plasminogen activator as produced by recombinant DNA technology*” (paragraph 11.10) would satisfy it. However, it might have constituted a bar to two rather controversial patent applications filed in Summer 1991 and February 1992 by the US National Institutes of Health (NIH) relating to over 2,400 DNA fragments,

### Sufficiency

- 11.13 The invention must be clearly and completely described in the patent specification, sufficient to allow someone else skilled in the art to perform it.<sup>9</sup>

### Exclusions to patentability

- 11.14 Finally, certain specific exclusions to patentability exist. Thus if the invention falls within one or more of these, it is **not** patentable. The more relevant of these exceptions are noted below.

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known as Expressed Sequence Tags, or ESTs. These ESTs correspond to partial sequences of genes expressed (that is, translated into proteins) in human brain tissue. The genes in question are estimated to represent about 5% of all human genes. Any alleged industrial applicability of this invention is probably speculative, because for most of the claimed ESTs, the genes to which they correspond and the proteins for which they code remain largely unidentified.

The NIH argued the usefulness of the claimed ESTs as markers (among other things). However this was not enough to satisfy the US Patent & Trademark Office, which in August 1993 rejected one application on the ground *inter alia*, of inutility (effectively the US equivalent to the European requirement of industrial applicability). The NIH did not appeal the decision and has since withdrawn its other application and all foreign equivalents of the applications. In September 1992, Congress asked the US Office of Technology Assessment (OTA) to review the implications of NIH-like filings. That report is awaited. Meanwhile the inventor of the NIH patents is now working independently of the NIH and the US company for which he now works has filed new patents on gene sequences.

In the UK, the Medical Research Council and the Government have stated that they are in favour of an international agreement not to patent such sequences, in the interests of promoting the Human Genome Project – the 15-year international effort to sequence all human genes. However, it had felt obliged to file two patent applications similar to those of the NIH, as a “protective measure”, but these were also withdrawn in early 1994.

As regards the European Patent Office, it is not yet clear whether NIH-like patent applications will be granted. In the Relaxin Opposition (footnote 7) when distinguishing between invention and mere discovery, the European Patent Office relied upon the fact that the patentee had found a use for the protein coded by the relevant human gene.

<sup>9</sup> Rule 28 of the EPC states that for those inventions which relate to a micro-organism which is not publicly available and cannot be described, this requirement will be met by the micro-organism’s **deposit** in a recognised culture collection. Thus for many human tissue-derived inventions, a need may arise for the deposit of a sample of the human cell line in question.

By their nature, biotechnological inventions often cover many variants (eg. sequences, vector constructions, epitopes, etc). When it comes to obtaining patent protection, naturally the claims are drafted as broadly as possible, so as to cover as many variants as possible. However, only **some** of these may actually be disclosed in the specification – or indeed, may be workable. It was held in decision **T292/85/Genentech I/Polypeptide Expression** that the sufficiency requirement is met if at least **one way** is clearly indicated which enables the skilled person to carry out the invention. However, in 1994 this was modified in the European Patent Office and the English Court of Appeal : what is required is that the skilled person is enabled to carry out the invention across the whole range of what the patent claims (in decision **T409/91/Exxon/Fuel Oils**; *Biogen v Medeva*, CA unreported).

## Exclusions : discoveries

11.15 A discovery, scientific theory, or mathematical method, is not patentable. At first glance, it would seem that identifying a substance which occurs in nature (for example in humans) could be said to amount to a discovery, and hence to be unpatentable. However in general, if an invention is the **practical application** of a discovery, it will be patentable. Thus a natural substance may be patentable if it has first to be isolated from its surroundings in pure form, and/or if the process for doing so is patentable. To give an example, in the EPO a claimed invention to a specific human DNA sequence for use in expressing a useful polypeptide encoded therein would not be considered a discovery, and so would fall outside this exclusion.<sup>7,8</sup>

## Exclusions : immorality

11.16 Any invention which would be expected to encourage offensive, **immoral** or antisocial behaviour, is not patentable.<sup>10</sup> In June 1978, when the Patents Act 1977 came into force, biotechnology was in its infancy. Thus the “*immoral*” inventions which the legislation contemplated at that time included such things as instruments of torture and letterbombs – which were so clearly immoral as to require little detailed consideration of the meaning of the exclusion. It was only with the emergence of biotechnology and the creation of such entities as transgenic animals and attempts to patent human genes (see below) that the meaning of the immorality exclusion has begun to be tested in any depth in the EPO. It is to be expected that this exclusion will be invoked increasingly in future in cases of inventions derived from human tissue – as indeed has already been the case unsuccessfully with at least one application, covering the DNA sequence for the protein hormone relaxin (see below), derived from the human ovary.

11.17 The Guidelines for Substantive Examination in the European Patents Handbook provide that an invention is “*immoral*” if the general public would consider it so abhorrent that patenting would be inconceivable. There are no express guidelines which go beyond this general statement, and the EPO has stated that it considers it the responsibility of individual patent examiners to determine on the facts of each case whether a given invention is “*immoral*”, or not.<sup>11</sup> As mentioned above, until very recently, the morality requirement was a relatively obscure provision which was rarely invoked. It has now come to prominence in the context of patents relating to human parts and transgenic animals.

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<sup>10</sup> Patents Act 1977, Section 1(3)(a) and EPC, Article 53a

<sup>11</sup> However, the draft Directive did expand on this position as regards the patentability of human tissue (paragraphs 11.21 - 11.24)

- 11.18 In the case of **T 19/90 Harvard Mouse/OncoMouse** in the EPO, the invention concerned a mouse with a genetically inserted predisposition to cancer, for use in cancer research. In deciding that the invention was **not** immoral, and was therefore patentable, the EPO's approach was to weigh the suffering to the patented animal against the invention's usefulness to mankind. In doing so it considered such factors as the invention's benefit to mankind, the threat it posed to the environment (which, in the case in question, was regarded as controllable), and the reduction in the overall level of animal suffering which would be expected to result by decreasing the numbers of animals used in conventional testing. The **OncoMouse** patent is now being opposed in the EPO.<sup>12</sup>
- 11.19 By contrast, in the case of a patent application filed by the Upjohn company, the EPO is understood to have decided that it is immoral to patent transgenic animals for the purposes of screening agents for wool growth and hair promotion in humans. The animals in question carried a promoter from a gene coding for a hair-specific protein, linked to a reporter gene, which latter gene had an observable phenotypic effect. A specific embodiment of the gene was an oncogene - such that the animals developed cancer when used in the hair-growth tests. It was this to which the EPO

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<sup>12</sup> The **OncoMouse** patent was first granted in the US in 1988 and in the European Patent Office in 1992. In the US Patent Office, after a hiatus of four years, patents are now being granted covering transgenic animals. An estimated 180 applications for transgenic animals are pending. It is widely expected that such "animal models" will become a growth industry. However, in February 1993, the European Parliament passed a resolution (B3-0199, 0220, 0249/93) requesting the European Patent Office to revoke the **OncoMouse** patent, on the grounds of immorality, and to institute a moratorium on future patent applications covering transgenic animals. The European Parliament's resolution has of course no direct legislative effect on the European Patent Office. However, the Parliament has now exerted its influence by voting down the draft Directive.

In January 1993, a coalition of system animal welfare groups and one individual, headed by the British Union for the Abolition of Vivisection (BUAV) and Compassion in World Farming, filed an opposition to the **OncoMouse** patent. The BUAV attack, based solely on the immorality exclusion, has two limbs. It is argued that:

- (1) The European Patent Office did not weigh the merits and demerits of the **OncoMouse** patent with sufficient care, because "oncomammals":
  - (a) suffer considerably, and higher oncomammals (such as oncochimpanzees) suffer most of all;
  - (b) are not very useful - because of the doubts which exist as to the inherent unreliability of extrapolating from animal models to human beings, and because oncomammals exhibit a high "background" incidence of spontaneous tumours; and
  - (c) constitute a risk to the environment, because they may escape, breed with domestic/farm animals, and so spread the oncogene.
- (2) It is inherently immoral genetically to predispose animals to painful diseases. In other words, the end - of benefiting mankind - does not justify the means. Thus the EPO's balancing act - even if properly carried out - is wholly misconceived.

In July 1994 Harvard filed a lengthy reply brief. The opposition proceedings continue and are expected to be heard in November 1995.



objected, saying that the potential suffering to the animals was not outweighed by the invention's benefit to mankind.<sup>13</sup>

- 11.20 On 18 January 1995 the EPO published its decision in the opposition to European Patent No 112 149 in the name of the Howard Florey Institute of Experimental Physiology and Medicine, of Melbourne, Australia ("the Relaxin Opposition"). The patent covers the DNA sequence (ie the gene obtained from a human ovary) which codes for hormone relaxin, which relaxes the uterus during childbirth. An opposition to the patent was filed in January 1992 by members of the Green Party in the European Parliament on a number of grounds, including the immorality exclusion. The opponents objected specifically that, since the DNA relaxin gene could only be isolated from the tissue of a pregnant woman, the use of pregnancy for profit was an offence against human dignity. They also objected more generally on the basis that to patent human genes was patenting "life" and therefore intrinsically immoral, and also that patenting of human genes amounts to slavery contrary to the fundamental human right to self-determination.
- 11.21 The EPO, in its decision, acknowledges that it is not the right institution to decide fundamental ethical questions. It confirmed that its general approach to the immorality exclusion in Article 53(a) of the European Patent Convention (EPC) would remain that as set out in the EPO Guidelines (see paragraph 11.17 earlier) and that the exclusion would be narrowly construed and applied in only the clearest cases.
- 11.22 Applying these general principles, the EPO rejected the opposition. It noted that the original ovarian tissue had been donated during the course of necessary gynaecological operations. This use of donated tissue, according to the decision, was no more immoral than using donated blood as the source of life-saving substances, such as blood clotting factors. So far as slavery was concerned, the EPO stated that the opponents had fundamentally misunderstood the nature of a granted patent. A patent does not give the proprietor any right over a human being but merely the right to prevent another from practising the same invention **outside** the human body. Finally, the EPO rejected the argument that a patent on a DNA fragment or gene was equivalent to patenting "life". In the view of the EPO, DNA is not life but rather a chemical substance which carries genetic information to produce medically useful proteins.
- 11.23 In this rather strongly worded decision, the EPO refused to draw any distinction in principle between the patenting of genes and the patenting of other human substances that might be useful in treating humans. It also denied that such a distinction is drawn by members of the public generally. In support of this view the EPO pointed to the existence of the draft Directive which allowed for the patenting of genes. Now of course the draft Directive has been rejected by the European Parliament.

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<sup>13</sup> It is understood that Upjohn have since re-submitted revised claims, having deleted those covering oncogenes.

- 11.24 It is to be anticipated that the decision in the Relaxin Opposition will be the subject of an appeal to the relevant Technical Board of Appeal at the EPO. If the normal procedure is followed, the appeal will not be considered for approximately two years.
- 11.25 The draft Directive was until 1992 completely silent on the morality of patenting. Ultimately the draft Directive was voted down by the European Parliament precisely because agreement could not be reached between the Council and the Commission on the one hand and the Parliament on the other hand as to the extent to which the patenting of human parts should be permitted. On 23 January 1995 a Conciliation Committee comprising members of the Council and Parliament appeared to have agreed on a compromise text for the critical draft Recital 10 dealing specifically with body parts. The compromise appeared to allow the patenting of human parts provided that the ordinary technical requirements for patentability were satisfied and provided that the parts: “*are no longer directly ascribed to a specific individual.*” It was not at all clear how this wording distinguished the patentable from the non-patentable. The Council proposed to adopt a declaration to clarify its understanding of Recital 10. Regrettably the Parliament proposed to adopt a second declaration which was substantially inconsistent. In particular, the Parliamentary declaration seemed to require the part in question to be “*modified*” to some extent from the natural part as it exists in humans even though no such requirement existed in the compromise Recital 10. Perhaps with all the confusion it is not surprising that the draft Directive was voted down. Both industry and representatives of the Green Group have expressed themselves satisfied at the outcome.
- 11.26 Although the decision of the EPO in the Relaxin Opposition has clarified to some extent the patentability of human genes, a number of important questions remain. It is not clear to what extent the morality exclusion will apply to patents concerning germ-line gene therapy as distinct from somatic gene therapy. (Somatic gene therapy is one which brings about non-hereditary changes in an existing human being; germ-line gene therapy brings about hereditary changes). The draft Directive appeared to allow for patenting of germ-line gene therapy. Now that the Directive has been lost, the patentability of such therapy will be tested for the first time in the EPO during the prosecution of WO93/11228, a patent application in the name of the Trustees of the University of Pennsylvania. This application covers *inter alia* a method of germ-line gene therapy involving replacing the sperm-producing cells of a male mammal with sperm-producing cells not native to that mammal. Thus, this technique allows for the genetic manipulation of a male animal’s sperm so as to produce alterations in that animal’s progeny. Claim 27 of the application covers this method of gene therapy for use in human beings.

## Exclusions : biological process

- 11.27 Any essentially biological process for the production of animals or plants is not patentable – although a microbiological process or the product of such a process **is** patentable.<sup>14</sup> This is a difficult distinction for most to understand. There is some guidance on the meaning of “*essentially biological process*” from the EPO, namely that it is “*the routine manipulation of a known and naturally occurring biological event*” such as, for example, traditional methods of selective breeding. Thus for an invention to fall outside this exception (and hence to be patentable) there needs to be “*significant technical intervention*”, going beyond routine manipulation.<sup>15</sup>
- 11.28 “*Microbiological processes*”, which **are** patentable have in practice been construed so widely as to include, among other things, human cell lines.

## Exclusions : animal or plant variety

- 11.29 Any variety of animal or plant is prohibited from patent protection.<sup>16</sup> The meaning of “*animal variety*” remains unclear. In the **OncoMouse** decision the EPO held that although they did not understand the meaning of this term, “*rodents*” or “*mammals*” (the words used in the **OncoMouse** patent) “*constitute a taxonomic classification unit much higher than species (“Tierart”)*”.<sup>17</sup> An “*animal variety*” or “*race animale*” is a sub-unit of a species and therefore even lower ranking than a “*species*.” Therefore the claims fell outside the exception and were patentable.

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<sup>14</sup> Patents Act 1977, Section 1(3)(b)

<sup>15</sup> Decision T 320/87 Lubrizol Genetics Ltd

<sup>16</sup> The animal and plant variety exception came about as follows. In the 1950’s when the idea of plant variety rights was taking hold, a convention was signed which specifically prohibited double protection – that is, by both patents and plant variety rights – of the same plant variety (the UPOV Convention). This notion was adopted by the EPC in 1973, in respect not only of plant but also animal varieties. However, the difficulty is that the term “animal variety” does not have an unambiguous scientific meaning (which was acknowledged by the European Patent Office in the **OncoMouse** decision referred to above). Moreover, the text of the EPC exists in three languages, which are recognised by the EPC as being equally authentic. A problem arises in that the English term “animal variety” and the French “race animale” are both vague and ambiguous, compared with the more specific German term “tierarten” – which is apparently more akin to the English term “species”. This problem has so far not been resolved by the European Patent Office, and the draft Directive did nothing to assist.

<sup>17</sup> Two representative claims in the **OncoMouse** patent read as follows:

- “1. A method for producing a transgenic non-human mammalian animal having an increased probability of developing neoplasms, said method comprising introducing an activated oncogene sequence into a non-human mammalian animal at a stage no later than the 8-cell stage.
2. A transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence introduced into the 8-cell stage, said oncogene optionally being further defined according to any one of claims 3 to 10.”

### Conclusions on patentability

- 11.30 From the above it will be clear that human genes, human cells, and the products and processes derived from them, are already patentable (and patented) under European patent law and that, in the first instance, the patentability of such inventions (including the question of morality) is determined by individual examiners at the EPO on a case by case basis. The European Patent Office has for over a decade been applying the established patentability criteria to such inventions. There is a body of opinion that the immorality exclusion, at least, needs clarification. Now that the draft Directive has been rejected, the preferred course may be amendment to or clarification of the EPC itself.
- 11.31 It is also important to note that the decision of an examiner at the EPO is not necessarily the final decision on the patentability of a given invention. It is possible to oppose a patent in the EPO within nine months of its grant – and such opposition proceedings involve a review of the original examiner's decision. This review can be the subject of a further appeal within the EPO. Moreover, even after the opposition period has expired, or after an unsuccessful opposition, it is open to an interested party to apply to have the patent revoked in a relevant national court on one or more of the grounds set out earlier.

### The current position : ownership of patents derived from human tissue

11.32 Under European law, the following persons are entitled to apply for a patent:

- ▶ the inventor (or co-inventors); or
- ▶ the inventor's successors in title – that is, his assignees, licensees or heirs; or
- ▶ where the inventor is an employee, his employer may be entitled to the patent, depending on the circumstances.<sup>18</sup>

The right of ownership in a patent derives from the act of invention. In the case of inventions derived from human tissue, the act of invention is carried out by the person who extracted and purified or manipulated the human tissue by some inventive means – and it is this intervention which confers the right to apply for a patent. It follows that the owner of the monopoly is not the donor of the tissue in question; he has played no part in the intervening inventive act. Hence the donor

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<sup>18</sup> Patents Act 1977, Section 39

has no right to interfere with the lawful owner's exercise of his monopoly - irrespective of whether the tissue was obtained and/or experimented on with or without his consent.<sup>19</sup>

### **The current position : possible restrictions on the exercise of the patent monopoly**

- 11.33 As with all other patents, the effect of the grant of a patent for an invention derived from human tissue is to give its proprietor a monopoly. As stated earlier, this may be characterised as the exclusive right to practise the invention, the exclusive right to prevent others from making unauthorised use of the invention and the exclusive right to authorise others to practise the invention (usually in return for payment) by means of the grant of a licence.
- 11.34 Particular problems as regards the scope or exercise of the monopoly do not appear to have arisen in the case of inventions derived from human tissue. However it may be considered more important in the case of these inventions that the monopoly should not be exercised by the patent owner in such a way as to prevent or restrict academic research.
- 11.35 As the law stands an act done for "*experimental purposes relating to the subject-matter of the invention*" is not an infringement, ie a breach of the monopoly. However, the limits of this exception are unclear. In particular there is no statutory definition of "*experimental purposes*" (although it has been conceded that this can include testing with a commercial end in view, provided that commerce is not the **sole** end). Similarly, the meaning of "*relating to the subject-matter of the invention*" is unclear. For example, if a patented growth factor-producing cell line were used to research the production of other factors, such as a proliferation inhibitor, could it be said that such research "*relates to the subject-matter*" of the patented cell line, and hence is not an infringement by virtue of the exception? The better view is probably that such an act should be an infringement, because the exception should be narrowly construed. Proposals to clarify, and possibly to widen, this exception have received widespread support in the pharmaceutical industry, which regards the present lack of clarity as an unnecessary and undesirable fetter on research. In particular, in 1992 the International Association for the Protection of Industrial Property (AIPPI) passed a resolution on how the exception should be clarified.<sup>20</sup>

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<sup>19</sup> Patents Act 1977, Section 60(5)

<sup>20</sup> The resolution is as follows:

"1. *Experimental use comprises any use of the patented invention which is effected for purely academic purposes*

### The current position : compulsory licensing

11.36 European law allows a compulsory licence to be granted under patents in certain circumstances.<sup>21</sup> This means that if certain statutory criteria are satisfied a company or organisation can obtain the right to practise a patented invention even against the wishes of the patent owner. The question arises whether the statutory criteria need special amendment in the case of patented inventions derived from human tissue. Our view is that there is no evidence to suggest that there is a public interest in further legislation in this area.

### The way forward : possible options

11.37 We support the view that as a general rule (and subject to the major qualification in paragraph 11.38 below) the criteria for patentability laid down by the EPC should be applied to inventions relating to human tissue, just as they are applied to all other inventions.

11.38 It is however recognised that the field of human tissue-related inventions raises ethical and moral questions that have not been encountered to the same degree (or at all) with other technologies. This poses a challenge for patent law. On the one hand, there is a need to satisfy legitimate public concern about the ethics of these inventions – while on the other hand, there is a political and economic need to do so in a way that does not inhibit innovation and discourage economic investment.

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*and without commercial character.*

2. *Experimental use comprises any use of the patent invention in a manner which is suited to experimentation (and not commercial use), the aim of which is to improve the invention, to advance it or to find an alternative thereto, but not commercial exploitation of that improvement or advance.*
3. *Experimental use comprises tests which are carried out to evaluate the teaching of the patent and the validity of the patent.*
4. *Experimental use is to respect the principle that such use is to involve work on the subject of the patent and not use of the patented invention as means for other uses or subjects, even experimental.”*

This resolution is now being considered by the World Intellectual Property Organisation with a view to an eventual amendment to the Paris Convention. However, to date nothing has been implemented.

<sup>21</sup> Patents Act 1977, Section 48 *et seq.*

- 11.39 It was once hoped that the draft Directive would eventually provide some guidance on the application of the immorality exclusion, but the draft Directive has now been lost. Thus other options need to be considered.
- 11.40 One option would be to remove the immorality exclusion altogether from the patent application process – in other words, to obviate the need for patent examiners to decide complex ethical issues for which their training has left them unprepared. It would then be for national courts to resolve ethical questions. There are two principal disadvantages to this approach. First, removing the immorality exclusion would require amendments to the EPC and the harmonising national legislation such as the UK Patents Act 1977. Secondly, national courts might differ in their determination of ethical issues – just as they have already been observed to do in their approach to other patentability issues. Significant national differences in the extent to which inventions derived from human tissue are patentable within the European Union would cause ethical, political and commercial confusion.<sup>22</sup>
- 11.41 A second option would be to retain the immorality exclusion and to ensure that it continues to be invoked only in extreme cases of obviously abhorrent inventions – leaving a more considered determination of the scope of the exclusion to national courts, as occurs with other patentability issues.<sup>23</sup> This so-called “*light approach*” would have the advantage of not requiring a change in the law, but by relegating the problem to national courts it may still result in national differences in the application of the exclusion, with the concomitant disadvantages mentioned above.
- 11.42 A third option would be to retain the immorality exclusion, but to ensure that its scope and application was determined not by patent examiners, but by a specially constituted Europe-wide ethics committee concerned exclusively with the resolution of ethical issues. Such an ethics committee might either form part of the patent application process (that is, part of the EPO), or alternatively, some commentators have suggested that it should exercise some kind of post-grant “*vetting*” process,

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<sup>22</sup> The Community Patent Convention provides for the eventual grant by the European Patent Office of a single patent which would be valid for the whole of the European Community. Such a patent would in the first instance be assessed by national courts but thereafter there would be a right of appeal directly to a new Community institution, namely the Community Appeal Court – otherwise known as “COPAC”. Thus COPAC would effectively supersede national appeal courts as regards the determination of patent issues. However, it is expected to be some years before COPAC will be in place to express Community wide views on patentability issues.

<sup>23</sup> The two former Comptrollers of the UK Patent Office support this approach, based upon the history and practice of the European patent system. See their monograph; Armitage and Davis, “Patents and Morality in Perspective” (Common Law Institute of Intellectual Property 1994) which is a response to a more interventionist analysis of the morality provision by Beyleveld and Brownsword, “Mice, Morality and Patents” (Common Law Institute of Intellectual Property 1993)

examining the ethics of each attempt by industry to put a given invention into effect.<sup>24</sup> We do not regard the latter, post-grant, approach as being desirable – since this would create significant uncertainty as to the scope and effect of **granted** patents as well as delaying the exploitation of inventions – both of which would be prejudicial to industry.

- 11.43 A fourth option would be for the signatory states to the EPC to adopt a protocol to the EPC which would set out in some detail the criteria to be used by national courts when applying the immorality exclusion to patents in the area of human and animal tissue. This approach would have the advantages of: avoiding the delay inherent in bringing about changes to the EPC itself and harmonising national legislation; avoiding the uncertainty and additional bureaucracy of a separately constituted ethics committee; minimising the risk of national differences in applying the exclusion; and providing much-needed guidance to the courts. Although of necessity this approach would be time-consuming, we would regard it as the most practicable and balanced of the available options. We would in the meantime prefer the maintenance of the light approach by the EPO itself. We do not regard patent examiners as the right people to decide complex ethical issues.

## Conclusions and recommendations

- 11.44 We recognise that inventions derived from human tissue are open to patenting. Over two hundred patent applications have been published where the criteria for patentability have been met (paragraph 11.8). We accept this position as a matter of fact.
- 11.45 There is at present a major controversy about patenting in the area of human genes. The law, as it stands, discriminates between discoveries and inventions (paragraph 11.15). Fundamental to the application of the notion of invention in this area is that some technical intervention should have taken place that justifies the granting of an intellectual property right. We note that questions of fact arise in each case on whether patent applications meet the existing legal criteria.
- 11.46 The immorality exclusion, which has a long-standing existence, has now a greater influence than was originally intended (paragraphs 11.16 – 11.26). We recognise that there is a need to take account of ethical factors and sensitivities in the patenting of inventions derived from human tissue (paragraphs 11.37 – 11.43).

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<sup>24</sup> Price, R. and Cohen, S. (1994) *Nature* 369:589



11.47 We attach great importance to the fuller consideration and review of the process by which ethical issues are taken account of in relation to the question of patenting inventions derived from human tissue. We recommend that the Government joins with other member states of the European Patent Convention (EPC) in adopting a protocol to the EPC which would set out in some detail the criteria to be used by national courts when applying the immorality exclusion to patents in the area of human and animal tissue (paragraph 11.43).



## Chapter 12

# Legal matters : safety and quality

## Summary

Increased awareness of the risk of the transmission of infectious disease has highlighted the importance of ensuring the safety of human tissue. There is a large body of regulation relevant to the safety and quality of human tissue. Legislation originates both in the UK and in Europe. Professional regulation is also important.

Much general regulation, on health and safety at work, or on environmental protection, will apply to human tissue insofar as it presents a hazard to health or to the environment. Where human tissue is used for the production of medicinal products, its use will come under the provisions of the Medicines Act 1968. The regulation of medical devices, and in particular devices incorporating human tissue, such as heart valves, is less comprehensive. Other regulation applies to the use of different types of human tissue for medical treatment or for research. The Medicines Control Agency, for example, licenses and monitors centres handling or processing blood. It is equally important that effective standardised procedures are in place for institutions handling other types of human tissue, both to protect recipients of transplants and those handling the tissue.

There are a number of different legal channels open to those who consider that the protection offered by procedures regulating the safety and quality of human tissue has been unsatisfactory. Failure to comply with laws designed to promote safety can result in criminal sanctions. Civil claims for damages may be made in respect of harm caused by defective tissue. Nevertheless, an injured person faces considerable difficulties before liability can be established. There are many, in both medical and legal circles, who feel that the law is at present inadequate and requires change.

## Introduction

12.1 There is heightened public awareness today of the need to ensure the safety and quality of human tissue, for whatever purpose it is used. Increased use of tissue as a result of technological developments has led to a greater appreciation of the problems which can arise from the use of contaminated tissue and to greater attention being focused on the claims of those who suffer damage resulting from such use. All those concerned with the donation, acquisition and use of blood and all other tissue, and the public in general, must be satisfied that proper care is taken to eliminate, or reduce to an acceptable level, all risks.

- 12.2 There are many rules of general application, for example, those regulating health and safety at work, which are of relevance to those concerned with human tissue. There are also many more specific rules which regulate the use of human tissue in medicines, and for medical treatment and research activities. Taken together, the variety of laws, professional regulations and other codes concerned with ensuring the quality and safety of human tissue can be overwhelming.
- 12.3 In this chapter, we offer a survey of the existing regulation relating to the safety and quality of human tissue. We have indicated areas where there is concern that the regulatory framework may not be adequate. At the end of the chapter, we discuss the legal channels open to those who consider that the protection offered by the procedures regulating safety and quality of human tissue has been unsatisfactory. This chapter has drawn on several sources.<sup>1</sup>

### The regulatory framework

- 12.4 At the international level, there are advisory bodies, such as the World Health Organisation, which provide valuable information and advice. Initiatives in some countries, in particular the USA, can be influential elsewhere. Within Europe, there are also many bodies providing information and advice.
- 12.5 At the legislative level, the UK is now controlled from two directions. First, there is UK legislation. Secondly, laws are made by the European Community: the European Commission has been responsible for formulating a stream of relevant Directives<sup>2</sup>, which are then incorporated into UK law. In addition to legislation,

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<sup>1</sup> Barton: (1992) "Criminal Liability under the Medicines Act 1968: Private Prosecution and Personal Liability" **Pharmaceutical Medicine** 6: 121-126.  
Cash: (1993) "Quality Assurance in the Blood Transfusion Services". **Proceedings of the Royal Society of Edinburgh** 101B: 241-249  
Charlesworth: (1993) "Approving Medicines for Marketing in the European Community - Now and in the Future" in **Textbook of Pharmaceutical Medicine** eds Griffin, O'Grady and Wells Queen's University of Belfast.  
Cook, Doyle & Jabbari: (1991) **Pharmaceuticals Biotechnology and the Law**, Macmillan  
Dodds-Smith and Spencer: (1994) "Product Liability for Medicinal Products" in Powers and Harris (eds), **Medical Negligence**, 2nd ed p 502  
Goldberg: (1991) "The Development Risk Defence and Medicinal Products" **36 Jo.Law Soc.Scotland** 376  
Hodges: (1993) "Legal and Ethical Issues Concerning Pharmaceutical Products" in **Textbook of Pharmaceutical Medicine** eds Griffin, O'Grady and Wells Queen's University of Belfast  
Jones & Jeffreys: (1994) "EMA and the New Pharmaceutical Procedures for Europe" **Health Trends** 26:10-13.  
Snell and Hurley: (1993) "Quality Assurance in Medical Microbiology" **Proceedings of the Royal Society of Edinburgh**, 101B: 311-320

<sup>2</sup> For example: 89/381/EEC extending the scope of Directives of 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulations or administrative action relating to proprietary medicinal products derived from human blood or human plasma; 89/342/EEC extending the scope of Directives 65/65/EEC and 75/319/EEC and laying down additional provisions for immunological medicinal products consisting of vaccines, toxins or serums and allergens; 90/219/EEC on the contained use of genetically modified

there are professional and industrial bodies, European, national and local, laying down and monitoring standards in respect of virtually every aspect of relevant activity. All that can be done here is to give a very general picture, with some examples, of this complex area.

## Examples of general regulation that covers human tissue

### Health and safety at work

- 12.6 The Health and Safety at Work Act 1974 imposes duties upon employers to ensure, as far as practicable, *“the health, safety and welfare at work of all their employees”* and *“to conduct their undertakings in such a way .. that persons not in their employment who may be affected thereby are not exposed to risks to their health and safety.”* The Act is operated through the Health and Safety Commission and the Health and Safety Executive which monitors and enforces the detailed health and safety regulations (many of which now originate in European Community Directives).
- 12.7 For example, the Control of Substances Hazardous to Health Regulations 1994 (COSHH) impose rules and procedures in relation to employees who are exposed to hazardous substances. COSHH regulations require employers to assess the risks to health created by the use of substances such as toxic chemicals and biological agents. COSHH provisions would, therefore, cover human tissue insofar as it may be hazardous to health. It should be noted that no substance administered in the course of medical treatment is considered a substance hazardous to the health of the patient. These are subject to a separate regulatory regime outlined below (paragraphs 12.11 - 12.26).

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microorganisms; 90/220/EEC on the deliberate release into the environment of genetically modified organisms; 90/679/EEC on the protection of workers from risks related to exposure to biological agents at work; 92/59/EEC on the safety of products; 93/39/EEC in respect of medicinal products; 93/41/EEC repealing Directive 87/22/EEC on the approximation of national measures relating to the placing on the market of high technology medicinal products, particularly those derived from biotechnology. There are also Council Regulations which have immediate effect as law in each Member state, for example, Council Regulation 2309/93 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products.

Pursuant to an EC Directive on General Product Safety (92/59/EEC) there are broad framework provisions dealing with the supply of any unsafe products and giving the Commission power to take Community-wide action if necessary. However, to the extent that there are product safety provisions applicable to specific products as outlined above, they supplant the requirements of the General Directive.

### Environmental protection

12.8 There are many rules concerned with environmental matters. For example, when research work is completed, any waste materials, particularly if hazardous, must be disposed of in compliance with the terms of the Control of Pollution Act 1974 and the Environmental Protection Act 1990. Waste human tissue, body fluids, drugs, swabs or dressings, and syringes or needles are defined as clinical waste. Such waste must be appropriately contained, stored, transported and disposed of, for example by incineration by specialist commercial waste disposal contractors.

### Genetically modified organisms

12.9 Particular attention has been paid to the deliberate release of genetically engineered organisms into the environment. These are defined as micro-organisms “*in which the genetic material has been altered in a way that does not occur naturally by mating and/or recombination*”. This could therefore cover micro-injection of human or other DNA into cells, and genetic manipulation of DNA sequences in viruses. The Contained Use Directive<sup>3</sup> and the Deliberate Release Directive<sup>4</sup> and, in the UK, the UK Genetically Modified Organisms (Contained Uses) Regulations 1992, regulate all aspects of the deliberate release of genetically modified organisms.

12.10 These laws and procedures are thought to be effective, but are criticised by some as being too rigid and putting European industry to much greater expense than its competitors elsewhere. The European Commission is aware of this concern and is anxious to ensure that, without prejudicing public confidence in biotechnology, regulatory control is sufficiently flexible to enable some rules to be relaxed where, in the light of improved knowledge, the risks are seen to be lower than previously thought.

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<sup>3</sup> The **Contained Use Directive (90/219)** imposes minimum standards (which can be increased by Member States if they so wish) for all aspects of the production, development and use of genetically modified organisms under containment. Commercial use is treated slightly differently to basic research: the former requires prior approval, even though the same genetic manipulation for academic purposes does not. All work involving human pathogens must be notified to a national Competent Authority before it can proceed.

<sup>4</sup> The **Deliberate Release Directive (90/220)** deals with the regulation of releases in the European Union. In the main it applies to new plants.

## Use of human tissue in medicines and medical devices

- 12.11 Much research, especially industrial research, on human tissues or their naturally occurring products has as its purpose the development of therapeutic medicines, implantable devices or diagnostic agents intended after development to be manufactured on a commercial scale and sold.

## The Medicines Act

- 12.12 The main catalyst for strengthening controls over the production and use of medicines was the Thalidomide tragedy. The first response in the UK was the setting up in 1964 of a voluntary system for monitoring the results of clinical trials and adverse drug reactions. This Committee on the Safety of Drugs (the Dunlop Committee) was replaced by a much more detailed statutory regime under the umbrella of the Medicines Act 1968. The parallel European response, starting with Directive 65/65, was to develop a comprehensive and harmonised Community regulatory system, which has been incorporated into UK law.<sup>5</sup>
- 12.13 Thus, in the UK, it is the Medicines Act 1968 and its accompanying Regulations, which provide the legislative control over virtually all aspects of the manufacture, sale, supply and use of medicines for human and veterinary purposes. Both the Medicines Act and its European counterpart, Directive 65/65, are concerned with “*medicinal products*”. These comprise, very broadly, any substance or combination of substances used for treating or for preventing disease in human beings and animals.
- 12.14 The Medicines Act is administered and enforced by the Medicines Control Agency acting on behalf of the Licensing Authority who are the Ministers of Health and Agriculture of the United Kingdom. Guidance documents relevant to the assurance of safety and quality are regularly issued and updated by the Medicines Control Agency. There is also a global move towards international harmonisation of safety and quality requirements and inspection procedures.

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<sup>5</sup> The most recent regulations implementing Community provisions concerning the marketing of medicinal products are The Medicines for Human Use (Marketing Authorisation etc) Regulations 1994, SI 1994/3144. For a commentary on this see Medicines Control Agency (1995) **The Medicines for Human Use (Marketing Authorisations etc) Regulations 1994** Medicines Act Leaflet MAL 81

- 12.15 Licences are of three sorts: **product**, **manufacturing** and **wholesale**. Thus the Medicines Act regulates not only the granting of product licences, but also all those in the chain of supply, from manufacturer to ultimate user. The granting or denial of **product licences** is based on expert assessments of safety (of each description to which the licence relates), efficacy (for the purposes of which the medicines are to be administered) and quality (according to the specification and proposed method of manufacture of the products and the provisions proposed for securing that the product as sold or supplied will be of that quality). The granting of **manufacturing** and **wholesale licences** turn on assessments of the operations proposed to be carried out in pursuance of the licence, the premises, the equipment, the qualifications of those under whose supervision the operations will be carried out and the arrangements for securing the safekeeping and maintenance of adequate records. Premises and processes are subject to regular inspections and reports.<sup>6</sup>
- 12.16 Although trials of medicinal products in patients are generally subject to the provisions of the Medicines Act, trials on healthy volunteers are not. Substances used in tests on volunteers are not normally considered “*medicinal products*” for the purposes of the Medicines Act. However, all proposals involving human subjects are reviewed by research ethics committees.

## Medical devices

- 12.17 Until recently most medical devices fell outside the ambit of the Medicines Act.<sup>7</sup> Medical devices, broadly speaking, are appliances or products used for diagnosis or medical treatment that, in contrast to medicinal products, do not act principally by pharmacological means. Examples are diagnostic kits and heart pacemakers.<sup>8</sup> In borderline cases, where it is not clear whether or not something should be submitted for licensing as a medicinal product, guidance is provided.<sup>9</sup> Also, Orders have been made under s.104 of the Medicines Act extending the provisions of the Act to cover a range of devices which are not medicinal products, but are made wholly or partly for medicinal purposes.

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<sup>6</sup> There are also provisions under subordinate legislation for granting licences for the parallel importation of medicines.

<sup>7</sup> Although evaluation of some has been effected by the Medicines Device Agency of the Department of Health and of others by medical professional organisations.

<sup>8</sup> A more detailed definition of a medical device can be found in EC Directive 93/42/EEC.

<sup>9</sup> Medicines Control Agency (1990) **A Guide to the Status Under the Medicines Act of Borderline Products for Human Use** Medicines Act Leaflet MAL 8



- 12.18 The exclusion of many medical devices from the strict controls of the Medicines Act has called into question whether their safety, quality and efficacy are adequately safeguarded. Whereas strict quality control laws apply to diagnostic laboratory reagents in the USA, this has not been the case in Europe. Guidelines are in place in respect of some devices, for example, bone chips, corneas and heart valves, but there does not appear to be comprehensive coverage.<sup>10</sup> The European Commission has now become more active in this matter. Two harmonisation Directives, the Active Implantable Medical Device Directive (90/385/EEC) and the Medical Devices Directive (93/42/EEC) have been adopted. However, because there appears to be considerable diversity in practice in Member states, human tissue and devices which incorporate such tissue were deliberately excluded from the provisions of the Directives.
- 12.19 The Commission's advisory European Committee for Standards is currently considering standards for "*Tissues for use in medical devices*". The extent to which a third Directive, proposed for In Vitro Diagnostic Medical Devices, will apply to devices involving the use of human tissue is not yet clear. In any event, there appears to be no intention to include devices used for medical or pharmaceutical research. Research ethics committees, however, are requested to take these matters into account when formulating opinions on research proposals.
- 12.20 In our view, it would be undesirable to allow human tissue related devices to fall through a gap in the regulatory coverage, and we support those who believe that not only should there be comprehensive guidelines laid down in respect of the manufacture and use of all human tissue related medical devices but also that the proposed Directive concerned with In-Vitro Diagnostic Medical Devices should extend coverage to all such devices.

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<sup>10</sup> The Medical Devices Agency (formerly the Medical Devices Directorate) is the competent UK authority for introducing and enforcing statutory controls on medical devices under European Directives and is also responsible for auditing the quality assurance systems of medical devices manufacturers supplying the NHS from overseas, for investigating adverse incidents involving medical devices and for managing a programme to evaluate medical devices and publish reports. It has also adopted a Code of Practice on enforcement.

## Examples of other regulations applying to medicinal products and medical devices

### European Medicines Evaluation Agency<sup>11</sup>

- 12.21 The European Union is moving towards a single pan-European system to regulate all procedures including safety, quality, efficacy, and information handling that affect medicinal products. A major step towards this objective has been the recent establishment of the European Medicines Evaluation Agency in London. It will be responsible for the co-ordination of the registration procedures for medicines in the Community. Centralised procedures are now compulsory for the licensing of biotechnological medicines involving recombinant DNA technology, controlled expression of genes coding for biologically active proteins and hybridoma and monoclonal antibody methods. The procedures are optional for other high technology medicines and new active substances.
- 12.22 The Agency will also be responsible for the coordination of national monitoring and inspection and other controls in order to guarantee the safety of medicinal products available in the Community. A decentralised procedure will enable a marketing authorisation issued by one Member state to be extended to one or more other Member states as a result of the recognition of the original authorisation. There are also moves towards a broad international harmonisation of technical and other aspects of product registration through the International Conference on Harmonisation.

### Biological standards

- 12.23 The National Biological Standards Board, set up under the Biological Standards Act 1975, manages the National Institute for Biological Standards and Control (NIBSC). The NIBSC monitors the safety and quality of biological substances used in medicine such as vaccines, hormones and blood products, whose purity or potency cannot be adequately tested by chemical or physical means.<sup>12</sup>

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<sup>11</sup> See, Jones & Jeffreys: **EMEA and the New Pharmaceutical Procedures for Europe** Health Trends 1994. 26. 10-13.

<sup>12</sup> National Institute for Biological Standards and Control (1993/4)4 **Annual Report 1993/94**, Potters Bar

## Records

12.24 There are obligations to maintain records relating to medicinal products. Persons responsible for placing medicinal products on the market have a duty to make arrangements for archiving of documentation; the investigator must arrange for the retention of the patient identification codes for at least 15 years after the completion or discontinuation of trials; any changes of ownership of all data must be documented; and all such data and documents must be made available if requested by relevant authorities.<sup>13</sup>

## Audit

12.25 Independent audits of organisations or hospital departments handling blood or other human tissue are now often required. For example, Clinical Pathology Accreditation (UK) Ltd, provides an external audit of the quality of service provided by pathology departments.<sup>14</sup> It defines, reviews and monitors standards for the organisation and performance of clinical pathology and it provides accreditation for pathology departments. Detailed standards and guidelines are set out relating to all aspects of pathology work.<sup>15</sup> Thus, when blood and blood products are stored, it is necessary to ensure that facilities are adequate and secure; when they are moved, for example when blood is transferred between hospitals, the recipient must request written confirmation of satisfactory prior storage conditions; there are also written procedures relating to specimen collection, handling and disposal.

## Good laboratory practice

12.26 Underpinning all this detail are requirements to comply with “*Good Laboratory Practice*” and to provide evidence of compliance; this must be done, for example, by pharmaceutical companies when applying for marketing authorisation for a medicinal product; and by laboratories which carry out tests on chemical and biological products to determine their safety for man.<sup>16</sup>

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<sup>13</sup> See EC Directive 91/507/EEC (Updated Standards and Protocols for the Testing of Medicines for Human Use).

<sup>14</sup> This is a non-profit making company incorporating as shareholders *inter alia* the Royal College of Pathologists, the Association of Clinical Pathologists and the Association of Clinical Biochemists.

<sup>15</sup> These relate, *inter alia*, to organisation, administration, staffing, facilities and equipment, policies and procedures, staff development and education and evaluation. All equipment has to be appropriate for service demands and properly checked; and adequate storage facilities must be provided for specimens, reagents and records.

<sup>16</sup> There are two EC Directives (87/18/EEC and 88/320/EEC) which harmonise principles of Good Laboratory Practice (GLP) to ensure that there is compliance with all relevant Regulations. The detailed information requirements are set out in the Annex to Directive 87/21/EEC as amended by Directive 91/507/EEC. Member

# Regulations applying to specific tissue

## Blood and blood products

12.27 Products derived from human blood and plasma can be considered in two main groups:

- 1 Whole blood or blood products derived from single donations, or from pools of source material deriving from fewer than 12 donors, collected and distributed by blood centres. Whole blood is unprocessed and blood products such as cell concentrates are subjected to only one or a few separation procedures. Thus safety and quality is largely dependent on careful selection and control of donors, on microbiological screening of donations and on measures taken to minimise contamination during processing.
- 2 Blood products derived from plasma, produced on an industrial scale from pools of source material, and by various manufacturing procedures. These products are covered by the Medicines Act. Their quality and safety are assured not only by selection and screening of source materials, but also by the choice and control of manufacturing process. The products include albumin, immunoglobulins, plasma protein solutions, coagulation factors and antiproteases or other plasma fractions.

12.28 All national centres concerned with handling or processing blood, and the processing procedures involved, are licensed by the Medicines Control Agency. The Agency issues detailed guidelines: for example, “*Validation of virus removal and inactivation procedures*” and “*Medicinal products derived from human blood and plasma*”. The Medicines Control Agency also licenses imported blood products and samples are checked regularly.

12.29 When new risks arise and when knowledge improves, procedures change. The impact of more virulent or newly recognised viral infections has resulted in much higher priority being given to quality assurance programmes. Improved quality systems are being put in place in connection with blood collection programmes, donation testing and processing programmes, and the clinical use of blood and blood components. For example, donated blood is now routinely screened for hepatitis C.

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States carry out inspections to verify compliance with GLP. The UK GLP Monitoring Unit is within the remit of the Department of Health. The Guide to Good Pharmaceutical Manufacturing Practice (the Orange Guide) set out general pharmaceutical manufacturing principles to ensure that end products were fit for their intended use. More recently, the European Community has published “Rules Governing Medical Products in the European Community, Vol. IV: Guide to Good Manufacturing Practice for Medicinal Products”. Beyond these general guides are more detailed Guidelines for particular areas.

12.30 Nevertheless, there is no room for complacency. Incidents are regularly reported which call into question the effectiveness of particular procedures. When a private Germany company allegedly supplied unchecked and probably contaminated blood to many hospitals in Germany and abroad, it certainly highlighted the difficulties in calculating the risk of the medical use of imported human tissue. Another incident originated in France: it concerned one of the largest producers of blood products in the world which had specialised in collecting placentas from maternity units in some 40 countries for the production of albumin, immunoglobulins, and collagen, which were then sold worldwide. The placentas often came from countries where AIDS is common: it was alleged that the history of disease in the women sources was not sought and that serological tests had not been performed. Some experts maintained that, however thorough the inactivation processing, there was a potential risk of transmission of prion diseases such as Creutzfeldt-Jakob disease (CJD).<sup>17</sup> Clearly, legislative and professional safety and quality procedures must be strictly applied if they are to be effective.

## Human milk banking

12.31 The steps to safeguard babies from the accidental transmission of disease in donated human milk are similar to those recommended for donated tissues or organs. There is careful screening of potential milk donors to ensure that those at high risk of infection are excluded (for example, blood tests to exclude HIV, hepatitis B and C), careful testing (and, where appropriate, counselling) of donors, proper treatment of the milk and proper maintenance of records about the donors and recipients.

## Tissue for transplantation

12.32 Procedures relating to the safety and quality of material taken from donors are under regular review by, among others, the Department of Health which is currently carrying out a review of tissue banking in the UK. Donors who offer their tissue or organs for transplantation must be carefully screened to eliminate, or reduce as far as possible, the risk of transmission of infectious disease. Specific consent is required before a living donor is tested for evidence of HIV infection. In the case of cadaveric donations, careful enquiries of relatives are made to exclude donors at high risk. Testing procedures for tissue have become stricter. Recently, a bone graft recipient in the US developed AIDS from an implant from a donor who had initially tested negative for HIV but was subsequently found to be infected. As a result, recommendations have been strengthened in relation to all human organs, tissue and body fluids from living donors for transplantation and in relation to semen for artificial insemination. When tissue is stored prior to use it should not be

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<sup>17</sup> See Nau, J-Y, *Lancet* 342:1290 (1993), and for a reply, Barré-Sinoussi, F *et al.*, *Lancet* 343:178 (1994).

transplanted until a second negative test at least 90 days later is obtained.<sup>18</sup> The British Association of Tissue Banks is developing guidelines for the safe handling of different stored tissues. Clearly there is a need for standardisation and harmonisation so that best standards of practice are maintained throughout different centres in the UK.

- 12.33 Several factors make it difficult to eliminate completely the risk of transmission of infectious disease. Different tissue requires different treatment: organs must be transplanted very rapidly, whereas skin and bone may be stored before use. Whether the donor is living or dead will affect the screening procedures used. Thus, tissue banks vary in the purpose for which they store human tissue, the nature of the tissue stored, their organisational structure, and their method of operation (paragraph 4.16). This, and the need for rapid use of much tissue, make it impractical and undesirable to centralise tissue banking. There is, however, a need for the coordination and regulation of tissue banks. This would facilitate the standardisation and harmonisation of procedures for ensuring the safety and quality of human tissue. We recommend that the Department of Health establish a central register of tissue banks approved for supplying tissue for medical treatment and for research. The maintenance of such a register would serve to coordinate the activities of different tissue banks and would improve the regulation of safety and quality.

## Cadavers

- 12.34 Safety matters concern not only the ultimate recipients of human tissue. They are also imposed to safeguard those coming into contact with possible contaminated material. For example, advice has recently been given to licensed Anatomy Departments and all those involved with handling dead bodies, whether in post mortems or as part of anatomy teaching or research. The advice was to alert them to the small risk of transmission of disease posed by handling of the brains, spinal cords and eyes removed from the bodies of those who have or may have died from Creutzfeldt-Jakob disease (CJD) or Gerstmann-Straussler-Scheinker Syndrome (GSS), both rare prion diseases.<sup>19</sup> Anatomy Departments are required to make enquiries to establish whether there are such problems.

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<sup>18</sup> Chief Medical Officer (1990) **Guidance and Advice Concerning Prevention of HIV Infection by Tissue Transplantation** PL/CMO (90)2

<sup>19</sup> Chief Medical Officer (1993) **Creutzfeldt-Jakob Disease from Treatment with Human Pituitary Gonadotrophins** PL/CMO (93)11

12.35 Cases of this kind point to the desirability of preserving records for longer than the minimum statutory periods: persons may now be at risk as a result of treatment many years earlier and need to be traced. This can be seen from another, similar, example. Between 1956 and 1985, hormones from the pituitaries of cadavers had been used to induce ovulation in the treatment of some infertile women whose ovaries did not produce eggs naturally. Recently, it was discovered that a small number of such women in the UK were at risk of developing CJD as a result of this treatment. Steps were taken to trace the women now known to be at risk to advise and to counsel them.

### **Wider ethical issues**

12.36 It can be seen, therefore, that screening of donors is becoming ever more relevant. This raises issues relating to consent to the questioning of donors and their families and the nature of the obligations to such persons or their families in connection with information obtained as a result of such testing. Record-keeping, confidentiality, counselling and the ability to trace donors are other important ethical issues that have, rightly, attracted much attention. These issues, in addition to those mentioned above (paragraphs 12.32 - 12.33), will also have arisen in the review of tissue banking that is currently being carried out by the Department of Health. We recommend that, when the tissue banking review is completed, the Department of Health, in consultation with the appropriate professional bodies, should seek to take account of these concerns.

12.37 For example, confidentiality in the handling of human tissue and any records of it, is governed both by law and by professional guidelines. There are three statutes that directly touch on the confidentiality of health data. They are the Data Protection Act 1984, the Access to Medical Records Act 1988 and the Health Records Act 1990. There is also voluminous and complicated case law on confidentiality. In addition, healthcare professionals are expected to conform to professional guidelines on confidentiality. For doctors, these are set out by the General Medical Council; for the nursing professions they are set out by the UK Central Council for Nursing, Midwifery and Health Visiting. The Department of Health is currently reviewing confidentiality in the NHS. We recognise that the case law on confidentiality is complex, and that application of the professional guidelines may be difficult in borderline cases. We recommend that the Department of Health, in its current review of confidentiality in the NHS, should take account of the requirements for confidentiality and traceability in the storage and use of human tissue, including biological samples.

### Safety and quality : an evaluation

- 12.38 Anybody attempting to evaluate all the laws and procedures affecting the safety and quality of activities involving the use of human tissue cannot but be overwhelmed by the range of provisions which are involved. It is difficult to assess whether all these mechanisms are appropriate. The European Commission, the UK authorities and the relevant professional bodies have done a great deal to harmonise and strengthen procedures; and, as more information becomes available, increasing standards relating to safety and quality are imposed.
- 12.39 Some argue that the licensing of products involving the use of human tissue is not all-embracing and that gaps and weaknesses in the Medicines Act should be plugged or at least strengthened to protect the consumer.<sup>20</sup> There is a continuing need to match the rapid technological advances with the development of parallel procedures for assuring the quality of the products which are used.<sup>21</sup> Others maintain that excessive regulation is unnecessarily time-consuming and counter-productive.
- 12.40 Whilst we would urge that the monitoring of safety, quality and efficacy should be comprehensive, clearly understood, enforceable and effective, we are conscious that there is continuous activity in this area, at European and national levels, designed to achieve these objectives. The pressures of public opinion, particularly as the result of media publicity, and of litigation, to which we now turn, do much to ensure that standards are adhered to and are continually improved.

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<sup>20</sup> Brahams: "Introduction to the Legal Aspects of Pharmaceutical Medicine: A Brief Overview of Some Emerging Issues" in Griffin, O'Grady and Wells (eds), **The Textbook of Pharmaceutical Medicine** (Belfast, Queen's University of Belfast, 1993).

<sup>21</sup> "Medicinal products arising from the application of the new biologies (especially recombinant DNA and monoclonal antibody technologies) are being developed for clinical use at an ever increasing rate. Changes in a number of areas have posed unprecedented challenges to the regulatory authorities who are responsible for the licensing and quality control of such products ensuring their quality, safety and efficacy and that they reach the market without delay." Jeffcoate, Corvel, Minor, Gaines-Das and Schild: (1993) "The Control and Standardisation of Biological Medicines" **Proceedings of the Royal Society of Edinburgh**, 101B: 221



## **Criminal sanctions and compensation for injury**

### **Penalties and compensation**

- 12.41 Failure to comply with laws designed to promote safety can result in criminal sanctions. Thus, breach of many of the obligations under health and safety regulations are criminal offences. Similarly, the Medicines Act 1968 creates offences relevant to such matters as licensing, clinical trials, sales, prescriptions, quality, registration, leaflets, labelling and advertising.
- 12.42 Staff members of medical or research establishments (a medical director or clinical research officer, for example) may be personally criminally liable for offences under the Medicines Act, such as for failure to report adverse drug reactions. Prosecutions of this kind are a matter for the police and other public prosecution authorities. It has been suggested that private individuals or professional bodies might seek to use the criminal process to obtain compliance with, say, the Medicines Act (for example, with regard to false drug claims), but this is likely to be rare.

### **Civil liability**

- 12.43 Defective human tissue which causes loss or damage, can give rise to claims for compensation. Actions may be brought by victims, including those who suffer injuries before birth, against different persons or organisations: the donor; those who use or sell the tissue itself or who manufacture or import human tissue based products; and institutions or authorities, such as the Committee on the Safety of Medicines and the Department of Health, who may be responsible for the proper regulation of activities involving human tissue. Thus, in recent litigation, several of such parties have been joined as defendants. Claims may arise either in contract or, more commonly, in tort law. These will be looked at briefly in turn.

### **Contract**

- 12.44 Standard law applicable to the sale of all goods or supply of all services in the course of business is that a purchaser may have a claim against the seller should the product prove to be defective.<sup>22</sup> This would also apply where the contract is for the sale of human tissue, whether in its original form, or after treatment, or as a component of another product. We have discussed elsewhere, whether transactions involving

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<sup>22</sup> See the Sale of Goods Act 1979, the Supply of Goods and Services Act 1982 and the Sale and Supply of Goods Act 1994. At one time different consequences could have flowed depending upon whether the sale of human tissue was the sale of goods or of services, but this is no longer an issue as far as a claim in contract is concerned.

human tissue should be commercially organised and whether commercial contracts dealing with the sale of blood and other human tissue are currently entered into. It seems clear that the activities of any institution which sells human tissue, whether at cost-recovery or for profit, would be “*in the course of business*”: this would include the National Blood Service, a tissue bank, a private hospital or, indeed, an NHS institution which entered into such contracts.<sup>23</sup>

- 12.45 Such tissue must be of merchantable quality and suitable for “*all the purposes for which goods of the kind in question are commonly supplied*”. It is not necessary for the purchaser to show that the supplier has been negligent in any way; it is only necessary to show that the product which has been sold does not satisfy the terms, express or implied, of that contract. So, where a research organisation buys human tissue from a foreign supplier, that supplier (if it can be sued in the UK) may be liable for the poor quality of the product, because it would not meet the statutory requirement that it be of “*satisfactory quality*” or “*appropriate for its contemplated use.*” Even if the purchaser does not bother to test the quality of the tissue, this will not count against it in an action for breach of contract. If the tissue is bought by one person and then sold on, the parties to each contract have similar obligations, but only to the other party to their contract.
- 12.46 The donor of defective human tissue would not ordinarily be liable **in contract** for any defects, since there would no contract relating to the supply of that tissue. Nor would most medicinal products prescribed under the National Health Service: the courts have held that there is no contract between a patient and a pharmacist in connection with the drugs since a pharmacist has a statutory duty to supply the patient on presentation of a prescription.
- 12.47 In most cases, in any event, actions in respect of defective human tissue are likely to be brought under tort law, that is, where independently of any contract, a claim for damages may be brought for harm suffered.

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<sup>23</sup> The contractual situation can be quite complex. For example, in the case of the supply of blood: the National Blood Service (NBS) sells whole blood and blood components to National Health Service authorities and non-NHS, private sector, bodies. The NBS also sells plasma to the Bio Products Laboratory (BPL) for production of plasma products. BPL, in turn, charges NHS and private sector bodies for supplies of plasma products. In all these transactions, there is no charge for the whole blood, blood component or plasma itself, since it is derived from freely donated blood. The charges are intended to reflect the costs to the National Blood Service, and Bio Products Laboratory, of producing and supplying blood products.

## Actions for breach of statutory duty

12.48 We have already noticed that failure to comply with health and safety regulations often gives rise to criminal liability. In some cases, those injured as a result of such breaches may also use the offence as the basis of a civil action for breach of statutory duty. The courts will allow such actions where it is expressly provided in the relevant law or where they believe that it was the intention of Parliament to allow such a civil action. It is widely applicable for breach of health and safety at work regulations; it is less commonly available in other legislation, including the Medicines Act 1968.

## Negligence actions

12.49 There are three prerequisites to a negligence action. First, the defendant must owe a legal duty to the plaintiff to take care. Those supplying human tissue, or a product containing human tissue, would usually owe such a duty to the injured party to take reasonable care in connection with the acquisition, preparation and use of that tissue.

12.50 Secondly, the defendant must be shown to have been in breach of that duty. It is not sufficient for the plaintiff simply to demonstrate that injury has occurred. It must be shown that the defendant did not exercise the degree of care which would have been expected of a reasonable person in those circumstances. For example, a donor of tissue might be negligent if he knew or should have known that the tissue could be contaminated and fails to disclose this information; other suppliers of tissue who do not take care in handling or treating the tissue might be liable; tissue banks for failing to take care in screening or treating tissue or, indeed, in some cases, the licensing or monitoring authorities for failure to lay down, monitor or enforce appropriate standards.

12.51 Proving negligence is often difficult. Where the defendant did not carry out its statutory or, indeed, its professional obligations or did not otherwise conform with relevant standards or guidelines a presumption of negligence will normally arise, for these standards reflect what experts regard as good practice. It is worth noting, however, that the Medicine Act s.133(2) expressly declares that breach of the provisions of the Act, or Regulations made thereunder, does not amount to negligence *per se*. Nevertheless, unless some good reason can be offered for failing to comply with common practice and guidelines aimed at promoting safety a breach of duty is likely to be established.

- 12.52 Although **failure** to comply with established standards may be evidence of negligence, it does not always follow that **compliance** with standards and practice is conclusive evidence that the defendant had taken reasonable care. For example, new events may have occurred necessitating a change of practice, even though statutory standards may not have yet been amended accordingly. Nor is the fact that a product has obtained licensing approval necessarily a defence to any particular negligence action. For example, Article 9 of Directive 65/65/EEC provides that a marketing authorisation under European law “*shall not affect the civil and criminal liability of the manufacturer and where applicable, of the person responsible for placing the proprietary medicinal product on the market.*” Nevertheless, the fact that a defendant has complied with the appropriate requirements does cast a heavier burden on the plaintiff to establish that there has been a breach of the duty of care.
- 12.53 Standards of care change from time to time: what was not negligence in 1990 may well be negligence in 1995. As knowledge, and the perception of risks and their avoidance, improve, so too do the obligations imposed upon those who work in these areas. For example, at one time far less was known than today about the various contaminants in blood products: HIV, hepatitis, syphilis, malaria and toxoplasmosis; and methods of screening or heat-treating blood products were not so prevalent. There may have been no negligence liability on the supplier of defective blood had a person then been contaminated with an HIV virus. The situation would be different today, when the norm is to test for such viruses. But what of other viruses? Does an obligation to screen for all known viruses arise as soon as the risk of their presence becomes known? The view has been expressed that as “*more and more minor contaminants of recombinant DNA derived human growth hormone are being identified which are biologically active and pose no safety problem .. the effort and expense in identifying them and then measuring them on a batch-to-batch basis may be out of proportion to the public health risk*”.<sup>24</sup> As long as no adverse consequences follow, that argument may appear to be sound. But what happens if a virus which is deliberately neglected turns out to be far more potent than was anticipated? This has been an issue with hepatitis C: could it be said to be negligent to take a professional, and considered, decision not to screen for this virus even when its presence but not its full potency were known? And what of such bodies as the Committee on the Safety of Medicines and the Licensing Authority (paragraph 12.14): should they be liable for failure to act earlier to impose higher standards of care?<sup>25</sup> In the last resort, it will be for the courts to weigh up all the factors and decide whether the balance struck was reasonable.

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<sup>24</sup> Jeffcoate, Corvel, Minor, Gaines-Das and Schild: (1993) “The Control and Standardisation of Biological Medicines” **Proceedings of the Royal Society of Edinburgh, 101B**: 207-226

<sup>25</sup> Actions have been commenced against regulatory authorities for negligence in failing to implement stronger statutory requirements. For example, in *Re HIV Haemophilic Litigation* [1990] NLJR 1349 (CA) the Court of Appeal held that there was an arguable claim in negligence against the regulatory authorities, but the matter has not been conclusively determined.

- 12.54 The third condition that must be satisfied in a negligence action is that the defendant's breach of duty **caused** the damage complained of. This has often turned out to be the most difficult issue of all. In some of the major drug actions in recent years, defendant drug manufacturers have disputed any causal link between the drug and the injuries sustained, or, if a link is established, that it was the particular defendant's drug, as opposed to the same drug from other companies, that caused the plaintiff's injuries.
- 12.55 This brief outline of the law of negligence demonstrates that those injured in the course of medical or related activities involving the use of human tissue will often find it difficult, or impossible, to establish that the injuries have been caused by negligence. The unfairness of the negligence system was highlighted by the Thalidomide episode and the ensuing campaign for compensation in the 1960s. Many argued for a new system of compensation to replace negligence in which, if a person is injured by a defective product supplied directly or indirectly by the defendant, compensation should be paid.

### Strict liability<sup>26</sup>

- 12.56 These pressures eventually led to a European Community Directive on Product Liability in 1985 for compensation for injuries resulting from defective products; and this was implemented in the UK by Part I of the Consumer Protection Act 1987. The need to prove fault was abandoned. If a person can show that he or she was injured by a "*defective product*", then compensation is payable.
- 12.57 A product is "*defective*" when it does not provide the safety which a person is entitled to expect, taking all the circumstances into account. Thus, instructions for use, contraindications and warnings and supplied information in one form or another may in some cases assist in determining whether the product was "*defective*". Contaminated blood supplied to patients, or a defective organ used for transplantation, are likely to be regarded as "*defective products*" regardless of the information which is given to patients.

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<sup>26</sup> In certain cases, where a dangerous activity is being conducted on land and there is an escape from that land causing physical injury, an action for damages will lie without proof of negligence. This action, known as the Rule in *Rylands v Fletcher* is not commonly used today.

- 12.58 Liability is imposed upon producers, including manufacturers, importers and suppliers of such products. It is likely that human tissue would be regarded as “*products*” for these purposes. This was recommended by the Pearson Royal Commission in 1978.<sup>27</sup> Human tissue used for medical purposes, although not strictly manufactured, would possess the “*essential characteristics attributable to an industrial or other process*”.
- 12.59 Although these strict liability provisions are an improvement on the negligence action, there are still many difficult hurdles which an injured person has to face before liability can be established. The two most difficult are the so-called “*development-risk*” defence and, once again, causation.

### “Development risk” or “state of the art” defence

- 12.60 When the Product Liability Directive was being drafted, many large manufacturing industries, and in particular the pharmaceutical industry, urged that they should not be made responsible for the unforeseeable consequences of “*state of the art*” drugs. Such vast potential liability would act as a disincentive to industrial research and development.
- 12.61 The European Commission left it to Member states to decide whether or not it would introduce a “*development risk*” defence. The UK accepted the arguments of industry. Accordingly, s.4(1)(e) of the Consumer Protection Act provides that in any proceedings for liability for a defective product, it shall be a defence to show “*that the state of scientific and technical knowledge at the relevant time was not such that a producer of products of the same description as the product in question might be expected to have discovered the defect if it had existed in his products while they were under his control.*” What this means in the context of human tissue, is that if any product involving human tissue causes damage as the result of a risk which the defendant company can show could not have been generally foreseen at the time, there will be no liability: for “*state of the art*” products, negligence has been retained, although the burden of disproving it is for the defendant. In all other cases, however, fault is not a component of this action.

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<sup>27</sup> Royal Commission on Civil Liability and Compensation for Personal Injury (the Pearson Report) (1978. Cmnd. 7054-1):

“An operation may have unexpected consequences. Blood products may be used which contain viruses the presence of which could not be foreseen. There are now three thousand drugs in common use and ten thousand listed drug interactions, both detrimental and beneficial. More will doubtless be discovered.” (Para. 1350)

“We recommend that human blood and organs should be regarded as products and the authorities responsible for distributing them as their “producers” for the purpose of products liability.” (Para. 1276).

12.62 The need to prove causation remains, however. Not many cases have come before the courts, but those which have demonstrate what a formidable hurdle this can be. Thus, the issue in *Loveday v Renton*<sup>28</sup> was whether the whooping cough (pertussis) vaccine could cause permanent brain damage in young children. The court held that the plaintiffs had not been able to prove that there was a causal link. The Vaccine Damage Payments Act 1979 provides a scheme for limited payments of compensation for certain types of victim of vaccine damage. Here, too, there can be difficult problems of causation.

### Class or group actions

12.63 In recent years, where multiple actions are being contemplated for similar injuries against the same defendant, for example in a drug case, attempts have been made to use procedures which would allow a type of American style class action. This is now, to some extent permitted in English litigation:<sup>29</sup> for example, in connection with Opren (an anti-inflammatory drug prescribed for arthritis); and in respect of claims, which were ultimately settled out of court, by haemophiliacs who had been given HIV infected blood products in the early 1980s when the risks of infection were known, but it was alleged, were not dealt with satisfactorily so as to protect recipients.

### Compensation for research injury

12.64 Patients or volunteers who suffer any injury in the course of research in the UK are in no special position as far as compensation law is concerned. Their rights will be determined in accordance with the general law. There are European Guidelines which require the pharmaceutical industry to provide adequate insurance and compensation for subjects in the event of trial related injury or death. In the UK the pharmaceutical industry undertakes to compensate injured non-patient research subjects and also, in more limited circumstances, injured patients; whereas in other areas of research activity, for example, in NHS hospitals, the Medical Research Council and universities, compensation is paid only on an *ex gratia* basis. Fortunately, the number of cases where injuries of this kind occur is low. We would, however, add our voice to those who would prefer to see a fairer and binding obligation upon all researchers to provide adequate compensation.

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<sup>28</sup> *Loveday v Renton* [1990] 1 MLR 117

<sup>29</sup> RSC O.15 Rule 2, provides that where “numerous persons have the same interest in any proceedings [these] may be begun and, unless the court otherwise orders, continued, by or against any one or more of them, as representing all or as representing all but one or more of them.”

### Conclusions

- 12.65 Medical malpractice litigation in the UK has increased significantly in the last decade. Claims involving defective medicinal products have been brought, for example, in connection with hormone pregnancy tests, Debendox, Opren, pertussis vaccine, blood products, human insulin and human growth hormone. The deficiencies of the present law, even after the introduction of strict product liability, have been emphasised frequently. Even though procedural changes provide some assistance to those seeking compensation, there are many who feel that the law, as it is at present, is failing us. The cost of litigation is high; the procedures complicated and lengthy; the burdens placed on claimants unfairly weighted against them; and the adversarial nature of litigation procedures socially and professionally damaging. There is dissatisfaction in many quarters. Some would seek to change the present system, for example, to allow liberally applied 'no-fault' or insurance compensation schemes.
- 12.66 It is beyond the remit of this Working Party to contribute to that particular debate. However, we do agree with those who criticise the present state of the law, and support those who seek a further review of it.



## **Section V**

### **Conclusions and recommendations**

#### **Chapter 13      Conclusions and recommendations**



## Chapter 13

# Conclusions and recommendations

### Introduction

- 13.1 Advances in medical treatment, scientific research and biotechnology are using human tissue in an ever increasing variety of ways. These uses include the increasing success of, and consequent demand for, organ and tissue transplantation, the use of human tissue for research on new medicines and the use of human cell lines and genetic material for studying fundamental biological processes.
- 13.2 Society demands general respect for the human body and its parts: human tissue should not be used at will or abused. Increasing public concern has been expressed over a number of ethical issues raised by the uses of human tissue as they have developed in the 1980s and 1990s. Practices that have been questioned include the sale of organs, the patenting of life-forms and the commercial exploitation of products derived from the tissue of patients or research subjects. A particular set of questions was opened up by a case which has been the subject of much legal argument in the USA: the attempt by John Moore to claim an interest in products developed from his tissue. The circumstances of that case were exceptional, but it has prompted important questions about UK law and procedures bearing on the use of human tissue.
- 13.3 While expressing anxiety about certain issues, the public has also welcomed advances in medicine and biotechnology involving the use of human tissue in clinical therapy. Examples of this can be seen in the public's response to appeals for funds to send children abroad for advanced transplant surgery, and in the interest in genetic research into diseases such as cystic fibrosis and the associated potential for new treatments. In this report we have attempted to balance the potential benefits for diagnosis and treatment that may stem from medical and scientific advances with the need both to safeguard those from whom tissue is removed and to ensure that the use made of human tissue is acceptable.
- 13.4 There is an important and urgent need to consider, clarify and, where necessary, strengthen the ethical and legal framework within which the clinical and research uses of human tissue take place. The ethical issues relate directly to the core of respect for human beings, namely that they and their bodies should not be injured and that nothing should be done to them and their bodies without their consent. The legal status of human tissue is unclear. The limitations of the existing framework of legal and professional regulation point to the conclusion that a coherent approach is needed to any further regulation. That approach will not necessarily require

## Conclusions and recommendations

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legislation; given the pace of change in biomedical research, a more rapid and flexible approach to regulation may be preferable. But the need to clarify the law is important insofar as its uncertainty may impede legitimate treatment, teaching, study or research or even, at worst, may encourage illegitimate uses of human tissue.

### Ethical principles

13.5 Any clarification of the legal and regulatory framework for the use of human tissue must be based on appropriate ethical principles. The basis for the recommendations that follow is the ethical review presented in Chapter 6. The fundamental ethical considerations are as follows:

- 1 uses of human tissue which injure in that they destroy, damage or degrade are unacceptable because such uses show lack of respect for human beings and their bodies. However, when action that would otherwise count as injury is undertaken for therapy, it is legitimate;
- 2 it is ethically acceptable to make use of human tissue for medical treatment, and for medical training, for fundamental and applied research and for other purposes that may contribute indirectly to medical treatment;
- 3 these uses of human tissue are only ethically permissible when the tissue has been removed with the consent of those whose tissue is used or, where that is not possible, by procedures that give equivalent protection;
- 4 there are strong arguments against the commercial acquisition and supply of human tissue for medical and scientific purposes, however acceptable those purposes may be in themselves.

13.6 When it comes to putting those ethical considerations into practice, our principal conclusion has been that they can and should be reflected in the procedures used to organise and regulate the removal, storage and further use of human tissue. Our recommendations are designed to build on existing legal and professional regulation to produce a coherent framework for ensuring the appropriate use of human tissue. One example of how the basis of such a framework has been laid is the existing requirement that only appropriately qualified professionals, accountable as such, may remove human tissue. Existing professional requirements extend, beyond the removal of tissue, to its storage and many of its further uses. Our recommendations on the acceptable organisation of the acquisition, supply and further use of human tissue accordingly emphasise and build on widely recognised professional responsibilities. From these accepted professional responsibilities, and following the thinking of the Polkinghorne Committee in its guidance on the research use of fetuses and fetal material, we develop the role of what we term *medical intermediaries*.

- 13.7 We have argued that human tissue should be acquired and supplied through non-commercial procedures. Further uses of human tissue, however, include some which can lead to the development of products that may be used as commodities; some of these products may be patentable, although the extent to which inventions derived from human tissue are, or should be, patentable is still a matter of debate. There must, therefore, be intermediaries to control the relations between the non-commercial acquisition and supply of human tissue on the one hand, and the commercial organisations which may create and distribute products derived from human tissue on the other hand. The role of these medical intermediaries in the acceptable organisation of the acquisition, supply and further use of human tissue is discussed below in Sections II and III.

### Legal matters

- 13.8 Much legal argument has turned on the question of whether human tissue should be treated as property (Chapter 9 and Chapter 10). There is limited statute law relating to human tissue, and the common law leaves its status uncertain in many respects. Given the uncertainty as to whether human tissue is or should be regarded as property, it is important to determine the ways in which human tissue may be dealt with. We have examined the legal regulation of the removal of human tissue, from the living and from the dead (Chapter 7) and the law relating to the use of human tissue (Chapter 8). In particular, it is necessary to be clear about the purposes for which the use of human tissue is regarded as acceptable and the circumstances under which tissue or its derivatives can be the subject of commercial transactions (paragraphs 8.5, 10.8 - 10.9).
- 13.9 Despite the lack of clarity about the legal status of human tissue, there has been general agreement that human tissue legally cannot and ethically should not be treated as a commodity. Other important questions are whether, and in what circumstances, claims can be made to tissue, either by those from whom it is removed (Chapter 9) or by those who use it (Chapter 10), whether inventions derived from human tissue are, or should be, patentable (Chapter 11), and what regulations exist to ensure the safety and quality of human tissue for different uses (Chapter 12).
- 13.10 Our recommendations are grouped under the following five heads:

- I Removal of tissue**
- II Acquisition and supply of tissue**
- III Uses of tissue**
- IV Patents**
- V Safety and quality**

# I Removal of tissue

## Current situation

- 13.11 Human tissue is most commonly removed from living persons in the course of medical treatment. Removal of tissue may also result from donation by a living person, or after death. In all cases, tissue must be removed in accordance with existing law and professionally regulated standards of medical practice (Chapter 4 and Chapter 7).

## Removal of tissue in the course of medical treatment : patient consent

- 13.12 Medical treatment for which consent has been given may involve the removal of tissue for the purposes of diagnosis or treatment. There may be surplus tissue left over once diagnosis and treatment have been provided for. This surplus is ordinarily discarded and destroyed. Such left-over tissue, and also material archived during diagnosis and treatment, may, however, be made available for scientific research, medical training and scholarship, or for medical audit (paragraphs 4.2 - 4.4). **We recommend that when a patient consents to medical treatment involving the removal of tissue, the consent should be taken to include consent also to the subsequent disposal or storage of the tissue and to any further acceptable use provided that this is regulated by appropriate ethical, legal and professional standards** (paragraph 6.29.1).
- 13.13 The consent which patients give to their treatment is inevitably general. It must nevertheless be genuine and based on adequate understanding of that treatment and what it involves (paragraphs 6.19 - 6.21). Consent to treatment should be in general terms, but refer to the possibility that removed tissue may be discarded or stored; and, if stored, that it may at some time be used for diagnosis, further treatment, research, teaching or study. **As an aid to ensuring that consent to treatment is properly informed, we recommend that bodies such as NHS trusts and independent hospitals responsible for consent procedures should consider whether any additions to their explanations or forms are needed to make it clear that consent covers acceptable further uses of human tissue removed during treatment** (paragraph 6.29.1).

13.14 Patients may be deemed legally incompetent and therefore not in a position to consent to treatment (paragraphs 6.22 and 7.8 - 7.9). In these circumstances, tissue may be removed **in the course of treatment** only if this is in their best interests. Children between the ages of 16 and 18 are deemed legally competent and must, like adults, consent to medical treatment. Children younger than this must be asked for their consent if they are judged competent. For children not deemed competent to consent, the consent of the person with parental responsibility must be obtained (paragraphs 6.24 and 7.8). No-one has legal authority to consent to treatment on behalf of incompetent adults; the attending doctor may remove tissue if this is in the patient's best interests (paragraph 6.24 and 7.9).

### **Removal of tissue in the course of medical treatment : disposal of tissue**

13.15 The most usual fate of tissue left over from diagnosis or treatment is that it is disposed of (paragraph 4.2). **We recommend that bodies such as NHS trusts and independent hospitals review their practices on all handling and disposal of human parts, excised tissue and abortuses to ensure that they meet the requirements both of law and of professional standards and also to ensure that major body parts (for example, limbs, hands), and tissue subject to special public concern or scrutiny (for example, fetal tissue), are handled and disposed of in ways which show respect** (paragraph 4.4).

### **Removal of tissue from living donors : consent**

13.16 Removal of tissue from living donors, where this is not part of their treatment, but is a donation for the treatment of others or for medical research, calls for special safeguards since it has no therapeutic benefit for the donor. A recent statute offers an example of the use of procedures for securing explicit consent as one of the principal means of protecting donors. The Human Organ Transplants Act 1989 requires that for unrelated donors *"the donor understands the nature of the medical procedure and the risks . . . and consents to the removal of the organ in question."* (paragraph 7.3). We believe that it is ethically important to meet comparable standards whenever tissue is donated. **We recommend that those involved in the removal of tissue from donors should ensure that the explanation given to the donor is explicit about the range of intended uses of the tissue and about any risks the donor may incur either in having the tissue removed or as a consequence of its removal. Only on these conditions can the consent of the donor, and hence the procedure itself, be valid** (paragraph 7.7).

## Conclusions and recommendations

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- 13.17 Removal of tissue from living persons who are deemed **legally incompetent**, where this is not part of their treatment, but is for the treatment of others or for medical research, raises complex issues. This is because the safeguard normally provided by the requirement for consent is not available. Procedures which provide equivalent protection have to be devised and followed (paragraphs 6.23 - 6.28 and 7.8 - 7.10). The removal of tissue from the dead, who when living were legally incompetent, is permissible provided that the next-of-kin do not object (paragraph 7.11.1).
- 13.18 For the removal of tissue from **children**, where this is not part of their treatment, the law is complicated and unclear. In the past, the important legal principles would probably have been that any child under 18 would have been deemed incompetent to consent, as a matter of public policy, to anything other than a trivial intervention, perhaps the taking of a blood sample; the consent of the person with parental responsibility would therefore be required; removal of tissue would be lawful, if such consent were given, only if it was not against the child's interests, that is, of negligible risk and minimal burden, and if the tissue could not equally well be taken from an adult (paragraph 7.8). The law concerning the removal of tissue from **legally incompetent adults** other than in the course of their treatment is also complex and unclear. Unlike children, where there is a safeguard provided by the requirement for consent of the person with parental responsibility, no-one has legal authority to consent on behalf of legally incompetent adults (paragraphs 7.9 - 7.10). A recent European Directive appears to provide that research involving clinical trials of new medicines may be conducted only on those competent to consent, and would therefore exclude incompetent children and adults from any such research that might involve the removal of tissue (paragraphs 7.8 - 7.9).
- 13.19 We note with concern the legal uncertainty concerning the removal of tissue from children and from legally incompetent adults. We note also that there is general agreement among the UK bodies that have examined the issue, that research involving children and legally incompetent adults, although of no therapeutic benefit to them, may be ethical, subject to strict safeguards.<sup>1,2,3,4</sup> We have reviewed the specific case of the non-therapeutic removal of tissue from such persons and consider that this too may be ethical, in limited circumstances (paragraphs 6.25 - 6.28).

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<sup>1</sup> Royal College of Physicians (1990) **Guidelines on the practice of ethics committees in medical research involving human subjects** (2nd Edition) London

<sup>2</sup> Medical Research Council, MRC Ethics Series (1991) **The ethical conduct of research on children** London

<sup>3</sup> British Paediatric Association (1992) **Guidelines for the ethical conduct of medical research involving children**

<sup>4</sup> Medical Research Council, MRC Ethics Series (1991) **The ethical conduct of research on the mentally incapacitated** London



Where **children** are concerned, we consider that such removal would be ethically acceptable only on the following conditions (paragraph 6.25):

- 1 the procedures should be of negligible risk and minimal burden;
- 2 the consent of the person with parental responsibility should be obtained;
- 3 the children themselves, where appropriate, should be consulted and their agreement obtained. They should not object, or appear to object, to the procedures.

13.20 We consider that **incompetent adults** should be afforded protection equivalent to, but not exceeding, that afforded children. We consider that non-therapeutic removal of tissue from living incompetent adults would be ethically acceptable only if the procedures were of negligible risk and minimal burden. The person should not object, or appear to object, to the procedures (paragraph 6.27).

13.21 We have already drawn attention to guidance on the wider issues raised by research involving children and legally incompetent adults.<sup>1,2,3,4</sup> Additional safeguards include recommendations that such persons should be included in research only if the relevant knowledge could not be obtained otherwise and if the research is approved by a research ethics committee (paragraphs 6.26 - 6.28).

13.22 The issue of medical treatment and research involving mentally incapacitated adults has been considered by the Law Commission in its report on mental incapacity.<sup>5</sup> The report reached the conclusion that research of no therapeutic benefit to the participants would currently be unlawful. The new legislative scheme proposed by the Law Commission recommends that “*research which is unlikely to benefit a participant, or whose benefit is likely to be long delayed, should be lawful in relation to a person without capacity to consent . . .*” subject to strict safeguards. A new statutory Mental Incapacity Research Committee is proposed that would be required to approve non-therapeutic research procedures. In addition, procedures for approving the participation of each individual in the research project are recommended. We endorse the view of the Law Commission, noting that it would not contemplate the removal of tissue save in circumstances where the procedure is of negligible risk and is not unduly invasive; where the research would add to the knowledge of the incapacitating condition with which any participant is affected; and where the knowledge could not be obtained without involving such persons. **We recommend that the Law Commission’s proposed legislation should be enacted** (paragraph 7.9).

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<sup>5</sup> Law Commission Report No 231 (1995) **Mental Incapacity** HMSO. See, in particular, pp 96-102 and Clause 11 of the draft Bill (p 228)

### Removal of tissue from the dead

13.23 Removal of tissue from the dead is regulated by at least four statutes (paragraph 7.11). The Human Tissue Act 1961 regulates the removal of parts of the body “*for therapeutic purposes or for the purposes of medical education or research.*” The Human Organ Transplants Act 1989 regulates the removal of organs for transplantation. The Anatomy Act 1984 regulates the conduct of anatomical examinations. The Coroners Act 1988 regulates the conduct of post-mortem examinations. Removal of tissue for other purposes, which may include archiving and banking, may lie outside these statutes (paragraphs 7.12 - 7.14). **We recommend that removal of tissue from the dead for purposes which are acceptable in that they contribute directly or indirectly to medical treatment, but may not be expressly provided for by statute, should, if appropriate consent has been obtained, be regarded as lawful** (paragraph 7.14).

### Removal of tissue : commercial transactions

13.24 The Human Organ Transplants Act 1989 prohibits commercial dealings in organs (paragraph 7.3). The Human Fertilisation and Embryology Act 1990 restricts commercial dealings in gametes and embryos (paragraph 10.8). There is a growing body of international regulation and guidance prohibiting commercial dealings in organs and other human tissue (paragraph 2.21). We discuss the arguments for and against the commercial organisation of the procurement of human tissue in Chapter 6 (paragraphs 6.32 - 6.36). Our conclusion is that there are strong reasons against organising the procurement of human tissue along commercial lines.<sup>6</sup> The reasons are strongest where difficult medical decisions are being made at vulnerable times in donors’ and patients’ lives. The altruistic motivation of those who donate tissue should be respected and encouraged. **We recommend that bodies such as NHS trusts and independent hospitals responsible for removing donated human tissue should operate on a non-commercial basis. Payment to donors may cover only their reasonable expenses and inconvenience incurred and should not act as an inducement** (paragraph 6.35).

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<sup>6</sup> Certain body products, such as hair, may be bought and sold. These, however, are commonly waste products that are customarily discarded (paragraphs 3.7 and 6.16).

13.25 *Rewarded gifting* is a term that has come into use to describe the offer of incentives for donation where the rewards are in kind, not money. Examples have been the offer of lifetime medical treatment in exchange for kidney donation or of free IVF treatment in return for the donation of ova. **We recommend that *rewarded gifting* arrangements should be viewed as commercial transactions in that they offer inducements for permitting removal of human tissue and, in line with paragraph 13.24, that removal of human tissue should be neither encouraged nor recompensed by *rewarded gifting* (paragraph 6.36).**

### Claims of people from whom tissue is removed

13.26 We have discussed in Chapter 9 whether a person has or retains any claim over tissue removed from his or her body. This issue has been highlighted by the attempt by John Moore in the US courts to claim an interest in products developed using tissue from his body (paragraphs 9.12 - 9.13 and Appendix 1). The implication of the Human Tissue Act 1961, the Human Organ Transplants Act 1989 and the Anatomy Act 1984, is that tissue removed from donors is given free of all claims. The Human Fertilisation and Embryology Act 1990 makes use of a scheme of consents to avoid questions of ownership arising. The Act does, however, allow donors a say in the further use of gametes which they have donated for their own use (paragraph 9.3). **We recommend that the law should proceed on any claim over removed tissue by examining the basis of the consent given to the procedure that resulted in the removal of tissue. In particular, it should be regarded as entailed in consent to medical treatment that tissue removed in the course of treatment will be regarded as having been abandoned by the person from whom it was removed (paragraph 9.14).**

13.27 We recognise that legally incompetent adults cannot give consent. Thus, it is difficult to see how a consent scheme such as that proposed above could deal with possible claims over tissue removed from legally incompetent adults. **We recommend, therefore, that where tissue has been removed from legally incompetent adults in accordance with our recommendation in paragraph 13.22, the incompetent adults or their representatives should not have any claim over the tissue and that, if necessary, suitable legislation to this effect should be enacted (paragraphs 9.15 - 9.17).**

## II Acquisition and supply of tissue

- 13.28 New developments in the use of human tissue, especially in transplantation, have led to high levels of demand for human tissue. The development of tissue banks and of coordinating services, such as the United Kingdom Transplant Support Service Authority, is a reflection of the need to meet this demand (paragraphs 4.7 and 4.12–4.16). The increasing use of human tissue, and the concomitant increase in activities concerned with its acquisition and supply, highlight the need to ensure that tissue is acquired and supplied in ethically acceptable ways.
- 13.29 We have argued that organising the removal of tissue along commercial lines is unethical: donors should not be offered payment or other inducements for tissue (paragraphs 13.24 and 13.25). Organisations which do not collect tissue directly from patients or from those who donate tissue, but which develop products derived from human tissue, are in a different position and may have substantial reasons for adopting standard market practices (paragraph 6.37). If human tissue is procured by non-market procedures, while the products derived from human tissue may be manufactured and distributed by commercial organisations, there must be some intermediate institution, guided by professional codes and practices, which connects the market and the non-market structures. At present in the UK, doctors, hospitals, archives and tissue banks act as *medical intermediaries* that separate the non-commercial acquisition and supply of tissue from the users of human tissue, some of whom may operate using market structures (paragraphs 6.38 – 6.40). We use the term *medical intermediaries*, not to invent new personnel or new functions, but to clarify the responsibilities of professionals already concerned with the acquisition and supply of tissue. *Medical intermediaries* should follow the recommendations concerning the **non-commercial removal** of tissue in paragraphs 13.24 –13.25. **We recommend that medical intermediaries should supply users of human tissue on a non-profit making basis. Reasonable handling charges only should be levied, and human tissue as such should not be bought or sold or otherwise treated as an object of commerce** (paragraphs 6.40 and 10.8). **We further recommend that the appropriate professional bodies, such as the medical Royal Colleges, should ensure their professional guidelines clearly establish the responsibilities of the increasing number of their members who will find themselves acting as medical intermediaries involved in the acquisition and supply of human tissue.**
- 13.30 Recent concern has focused on possible commercial transactions involving blood and blood components (paragraphs 4.9 – 4.10). One view is that sales of fractionated blood components surplus to therapeutic requirements in the UK could subsidise the domestic supply of therapeutic blood and blood components. Nevertheless, we consider that the ethical principle of non-commercial dealings in human tissue should apply equally to human blood. What is freely given by donors should not be used to make a profit. This is especially important given the considerable sensitivity of donors to issues surrounding the use made of donated blood. **We recommend that**

**blood and fractionated blood components, like other human tissue, should be supplied on a cost recovery basis. Payment should only cover the cost of collection, processing, testing, storage and distribution.**

- 13.31 The development of tissue banks is one response to the need to improve the supply of human tissue. Hitherto, in the UK, tissue banks have been maintained in NHS establishments, in specialised Medical Research Council units and by some medical research charities (paragraphs 4.12 - 4.16). This has made it possible for these institutions to adhere to the non profit-making principles we recommend for medical intermediaries (paragraph 13.29). **We recommend that tissue banks should continue to operate as professional organisations on a non profit-making basis and not as commercial organisations** (paragraphs 6.40 and 10.8).
- 13.32 Tissue banks vary in the purpose for which they store human tissue, the nature of the tissue stored, their organisational structure, and their method of operation (paragraphs 4.12 - 4.16). This, and the need for rapid use of much tissue, make it impractical and undesirable to centralise tissue banking. There is, however, a need for the coordination and regulation of tissue banks. This would help maximise the efficiency of tissue supply. It would also facilitate the standardisation and harmonisation of procedures for ensuring the safety and quality of human tissue so that best standards of practice are maintained throughout different centres in the UK. This need for the coordination and regulation of tissue banks has been recognised by the Department of Health, which has set up a review of tissue banks in the UK. **We recommend that the Department of Health establish a central register of tissue banks approved for supplying tissue for medical treatment and for research** (paragraphs 12.32 - 12.33). The maintenance of such a register would serve to coordinate the activities of different tissue banks and would help maximise the efficiency of tissue supply, ensure that tissue is supplied to users on a cost-recovery rather than a profit-making basis, and regulate standards of safety and quality.
- 13.33 There is a need to safeguard confidentiality for those from whom tissue is removed when tissue is supplied to the user. Confidentiality in the handling of human tissue and its records is governed both by law and by professional guidelines. We recognise that the case law on confidentiality is complex, and that application of the professional guidelines may be difficult in borderline cases. **We recommend that the Department of Health, in its current review of confidentiality in the NHS, should take account of the requirements for confidentiality and traceability in the storage and use of human tissue, including biological samples** (paragraph 12.37).

### III Uses of tissue

- 13.34 In Chapter 6 we argue that certain uses of human tissue are injurious and hence unacceptable because they destroy, damage or degrade human beings or their bodies and thus fail to afford them due respect. Where action that would otherwise count as injurious is undertaken for therapeutic purposes, however, it is acceptable (paragraphs 6.10 - 6.11). The therapeutic uses of human tissue can be broadly divided. Some uses, such as the transfusion of blood or the transplantation of organs contribute directly to therapy. Other uses of tissue, for medical training, medical and biological research and the development of diagnostic and therapeutic products derived from human tissue, contribute indirectly to therapy (paragraph 6.13).
- 13.35 The statute law relating to the use of tissue removed from the dead is relatively complete. With regard to the use of tissue removed from the living, statutes regulate the use of organs for transplantation and the use of gametes and embryos for infertility treatment or research. In other areas statute law is lacking (paragraphs 8.2 -8.4). We have argued that the ethical acceptability, and thus the legality, of any use of human tissue must depend on the direct or indirect therapeutic purpose of that use (paragraphs 6.13 - 6.16). The initial control over the uses of human tissue will be effected by the medical intermediaries who supply those who use tissue.
- 13.36 An important use of human tissue is in the development or manufacture of therapeutic products that are derived from, or which contain, human tissue. The development of such products often requires long-term investment. We have argued that such products may be sold commercially (paragraph 6.37). **We recommend that human tissue used for the development of, or used in products for, direct or indirect therapeutic use, should be obtained only from sources that are subject to, and governed by, recognised codes of professional practice and in accordance with our recommendations in paragraph 13.29.**
- 13.37 The use of human tissue for medical and scientific research is a sensitive issue. Researchers should assure themselves that any proposal involving human tissue is ethically acceptable. We draw attention to the requirement, in certain circumstances, to seek specific approval from local research ethics committees or other research ethics committees for research proposals (paragraph 6.14). Appendix 6 sets out our preliminary guidance on the circumstances in which proposals involving human tissue should be submitted to research ethics committees. **We recommend that the Department of Health, in conjunction with the appropriate medical Royal Colleges, gives further consideration to the preliminary guidance that we have formulated.**

- 13.38 When tissue is removed during the course of treatment there may be tissue left over once diagnosis and treatment have been provided for. This left-over tissue may occasionally be used for medical treatment or research (paragraphs 4.2 - 4.4). In general, such use of left-over tissue does not require research ethics committee approval (Appendix 6, paragraph 4.1). In rare cases, like that of John Moore, tissue removed during the course of treatment may be identified as especially valuable for research or development. **In cases where left-over tissue might prove to be of special interest for research or for commercial development, we recommend that the proposal is referred to a research ethics committee** (Appendix 6, paragraph 3.3).
- 13.39 We have argued that using human tissue for no direct or indirect therapeutic purpose is unacceptable. We give some examples of unacceptable uses in paragraph 6.15. The display of human body parts is acceptable only for purposes connected with education or ritual. **We recommend that body parts, anatomical specimens or preserved bodies should not be displayed in connection with public entertainment or art** (paragraphs 6.15 - 6.16). Medical practitioners should not participate in mutilating procedures at the request of persons who wish to photograph or video the results in furtherance of commercial or 'artistic' aims.

## IV Patents

- 13.40 There has been considerable discussion about the patenting of a wide range of inventions derived from human tissue, the vast majority of which are potentially useful in treating illness in humans. We recognise that inventions derived from human tissue are open to patenting. Over two hundred patent applications have been published where the criteria for patentability have been met (paragraph 11.8). We accept this position as a matter of fact.
- 13.41 There is at present a major controversy about patenting in the area of human genes. The law, as it stands, discriminates between discoveries and inventions (paragraph 11.15). Fundamental to the application of the notion of invention in this area is that some technical intervention should have taken place that justifies the granting of an intellectual property right. We note that questions of fact arise in each case on whether patent applications meet the existing legal criteria.
- 13.42 The European Patent Office has had great difficulty in applying the immorality exclusion of the European Patent Convention to advances in biotechnology. The immorality exclusion, which has a long-standing existence, has now a greater influence than was originally intended (paragraphs 11.16 - 11.26). We recognise that there is a need to take account of ethical factors and sensitivities in the patenting of inventions derived from human tissue (paragraphs 11.37 - 11.43).

13.43 We attach great importance to the fuller consideration and review of the process by which ethical issues are taken account of in relation to the question of patenting inventions derived from human tissue. **We recommend that the Government joins with other member states of the European Patent Convention (EPC) in adopting a protocol to the EPC which would set out in some detail the criteria to be used by national courts when applying the immorality exclusion to patents in the area of human and animal tissue** (paragraph 11.43).

## V Safety and quality

13.44 The regulation of the safety and quality of human tissue for different uses, and of medicinal products or devices incorporating human tissue, is discussed in Chapter 12. There is, rightly, much concern stimulated by these issues. The regulatory regime is voluminous and complicated, originating as it does from different sources: local, national, European and international (paragraphs 12.2 - 12.5). Recently, attempts have been made to harmonise and standardise regulatory provisions (paragraphs 12.38 - 12.40). In the UK, if the protection offered by regulation fails, or is thought to have failed, and harm ensues, there are limited opportunities to pursue claims through the courts (paragraph 12.41 - 12.66).

13.45 One area of uncertainty is in the regulation of medical devices incorporating human tissue. The extent to which medical devices incorporating human tissue will be covered in proposed European legislation is not clear. It is undesirable that such devices should fall through a gap in the regulatory network and we believe that there should be comprehensive guidelines covering their manufacture and use. **We recommend that the Department of Health should seek to ensure that the proposed European Directive on In Vitro Diagnostic Medical Devices, and other relevant guidelines covering medical devices, include medical devices incorporating human tissue** (paragraphs 12.17 - 12.20).

13.46 We have highlighted the need for the coordination and regulation of tissue banks in order to maximise the efficiency of tissue supply, ensure that tissue is supplied to users on a cost-recovery rather than a profit-making basis and regulate the safety and quality of human tissue so that best standards of practice are maintained throughout different centres in the UK (paragraph 12.33). The increased use of donated tissue, and awareness of the need for strict safety precautions, is leading to increasingly stringent screening and selection of donors. Ethical issues arise in connection with the role of consent to questioning, the obligation to disclose information, record-keeping, confidentiality, counselling and the ability to trace donors. These issues will also have arisen in the review of tissue banking that is currently being carried out by the Department of Health. **We recommend that, when the tissue banking review**



**is completed, the Department of Health, in consultation with the appropriate professional bodies, should seek to take account of these concerns** (paragraph 12.36).

- 13.47 There are currently inconsistencies in the arrangements for compensation of patients or healthy volunteers who suffer any injury in the course of research in the UK. Fortunately, such cases are rare. **We recommend that the major bodies responsible for research funding, such as the Department of Health, the Medical Research Council, medical research charities, and pharmaceutical and biotechnology companies, should consider how arrangements could be standardised to provide fair and adequate compensation in such cases** (paragraph 12.64).
- 13.48 Apart from injuries sustained during research activity, those seeking compensation for harm suffered as a direct or indirect consequence of the use of human tissue have to rely upon civil laws relating to medical malpractice and drug litigation. These procedures are complicated, lengthy, costly and widely regarded as unsatisfactory. We support those who seek a further review of this area of the law (paragraphs 12.65 - 12.66).

## Conclusions and recommendations

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# Appendices and Acknowledgements

- Appendix 1** *Moore v Regents of the University of California*
- Appendix 2** **The report of the Health Council of the Netherlands : *Proper use of human tissue***
- Appendix 3** **Human tissue used in transfusion, transplanstation or reconstructive surgery**
- Appendix 4** **Therapeutic and research products derived from human tissue**
- Appendix 5** **Strategies for tissue replacement**
- Appendix 6** **Guidance for the referral of proposals for research on human tissue to research ethics committees**

## **Acknowledgements**



**Appendix 1**

***Moore v Regents of the University of California***

- 1 The judgment of the Supreme Court of California on the preliminary legal issues was given in 1990.<sup>1</sup> Panelli J in his judgment summarised the facts as follows:

*“Moore first visited UCLA Medical Center on October 5, 1976, shortly after he learned that he had hairy-cell leukaemia. After hospitalizing Moore and “withdr[awing] extensive amounts of blood, bone marrow aspirate, and other bodily substances”, Golde confirmed that diagnosis. At this time all defendants, including Golde, were aware that “certain blood products and blood components were of great value in a number of commercial and scientific efforts” and that access to a patient whose blood contained these substances would provide “competitive, commercial, and scientific advantages.”*

*On October 8, 1976, Golde recommended that Moore’s spleen be removed. Golde informed Moore “that he had reason to fear for his life, and that the proposed splenectomy operation . . . was necessary to slow down the progress of his disease.” Based upon Golde’s representations, Moore signed a written consent form authorizing the splenectomy.*

*Before the operation, Golde and Quan “formed the intent and made arrangements to obtain portions of [Moore’s] spleen following its removal” and to take them to a separate research unit. Golde gave written instructions to this effect on October 18 and 19, 1976. These research activities “were not intended to have . . . any relation to [Moore’s] medical . . . care.” However, neither Golde nor Quan informed Moore of their plans to conduct this research or requested his permission. Surgeons at UCLA Medical Center, whom the complaint does not name as defendants, removed Moore’s spleen on October 20, 1976.*

*Moore returned to the UCLA Medical Center several times between November 1976 and September 1983. He did so at Golde’s direction and based upon representations “that such visits were necessary and required for his health and well-being, and based upon the trust inherent in and by virtue of the physician-patient relationship. . . .” On each of these visits Golde withdrew additional samples of “blood, blood serum, skin, bone marrow aspirate, and sperm.” On each occasion Moore travelled to the UCLA Medical Center from his home in Seattle because he had been told that the procedures were to be performed only there and only under Golde’s direction.*

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<sup>1</sup> *Moore v Regents of the University of California* (1990) 793 P 2d 479

*“In fact, [however], throughout the period of time that [Moore] was under [Golde’s] care and treatment, . . . the defendants were actively involved in a number of activities which they concealed from [Moore]. . . . Specifically, defendants were conducting research on Moore’s cells and planned to “benefit financially and competitively . . . [by exploiting the cells] and [their] exclusive access to [the cells] by virtue of [Golde’s] on-going physician-patient relationship. . . .”*

*Sometime before August 1979, Golde established a cell line from Moore’s T-lymphocytes. On January 30, 1981, the Regents applied for a patent on the cell line, listing Golde and Quan as inventors. “[B]y virtue of an established policy . . . [the] Regents, Golde and Quan would share in any royalties or profits . . . arising out of [the] patent.” The patent issued on March 20, 1984, naming Golde and Quan as the inventors of the cell line and the Regents as the assignee of the patent (US Patent No 4,438,032 (Mar 20, 1984).)*

*The Regent’s patent also covers various methods for using the cell line to produce lymphokines. Moore admits in his complaint that “the true clinical potential of each of the lymphokines . . . [is] difficult to predict, [but] . . . competing commercial firms in these relevant fields have published reports on biotechnology industry periodicals predicting a potential market of approximately \$3.01 Billion Dollars by the year 1990 for a whole range of [such lymphokines]. . . .”*

*With the Regents’ assistance, Golde negotiated agreements for commercial development of the cell line and products to be derived from it. Under an agreement with Genetics Institute, Golde “became a paid consultant” and “acquired the rights to 75,000 shares of common stock.” Genetics Institute also agreed to pay Golde and the Regents “at least \$330,000 over three years, including a pro-rata share of [Golde’s] salary and fringe benefits, in exchange for . . . exclusive access to the materials and research performed” on the cell line and products derived from it. On June 4, 1982, Sandoz “was added to the agreement,” and compensation payable to Golde and the Regents was increased by \$110,000. “[T]hroughout this period, . . . Quan spent as much as 70 [percent] of her time working for [the] Regents on research” related to the cell line.*

- 2 Moore initially filed suit in 1984 in the California Superior Court against Golde, Quan, the Regents of the University of California, Sandoz, and Genetics Institute. Moore alleged that he had a cause of action in conversion (wrongful interference with another’s property) and for lack of informed consent. The case passed from the Superior Court to the California Court of Appeal and then to the Supreme Court of California. The majority of the Supreme Court decided that Moore had no property rights in cells taken from his body, but remitted for trial the issue of whether the doctors had been in breach of the duty to obtain Moore’s informed consent and of the duty of loyalty to the Moore as their patient.<sup>1</sup> The case was subsequently settled out of court.

Appendix 2

The report of the Health Council of the  
Netherlands : *Proper use of human tissue*<sup>1</sup>

1 The report of the Health Council of the Netherlands on the **Proper use of human tissue** “*formulated a number of principles to be observed in the further use of human tissue:*

- 1 *The intended use must be morally acceptable in so far as its purpose is to promote human health.*
- 2 *Human tissue should always be used with the greatest of care.*
- 3 *The relationship between patient and doctor must not be undermined by the use of bodily material. The patient must rest safe in the knowledge that his or her own needs will continue to come first. The doctor should exercise openness regarding the storage and use of human tissue and must duly inform the patient thereof.*
- 4 *People cannot be forced to co-operate with the use of material obtained from them, even if it is in a good cause.*
- 5 *The privacy of those whose material is put to further use must be respected and protected.*
- 6 *The Committee endorses the principle of non-commercialism which applies to donation and extends this principle to the collection of human tissue in general. Such material should not be handed over or transferred to a third party by anyone whomsoever (whether patient, donor, doctor or institution) with a view to making profit.”*

2 These principles are broadly consistent with our arguments and conclusions. We would have some marginal reservations. The fourth principle we have found difficult to interpret: if it applies to tissue removed during treatment, then in some circumstances we disagree (paragraphs 13.12, 13.26). The fifth principle invokes the concept of ‘privacy’, which is difficult to define in UK law and practice: nevertheless our report makes the same points, we think, in terms of confidentiality (paragraph 13.33).

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<sup>1</sup> Health Council of the Netherlands (1994) **Proper Use of Human Tissue** Publication N° 1994/01E The Hague

3 The policy recommendations of the Health Council's report are as follows. The partial contrast with the conclusions and recommendations of this report illuminates our arguments and offers the readers an opportunity to judge their force. The Health Council's "*recommendations concerning the acquisition, storage and use of human tissue are designed to ensure that:*

- 1 *institutions provide patients with general information concerning the storage and use of human tissue;*
- 2 *human tissue is donated or transferred to a third party without gain;*
- 3 *no more material is obtained than is necessary for the purpose originally intended;*
- 4 *material is not stored without a good reason;*
- 5 *such material is managed carefully and safely;*
- 6 *identifiable material, if stored, is given a number or code (ie coded);*
- 7 *institutions regulate the management of human tissue;*
- 8 *there is an administrator responsible for ensuring compliance with the rules;*
- 9 *non-identifiable material is used wherever possible in preference to identifiable or indirectly identifiable material;*
- 10 *the person concerned is given the opportunity to object to the further use of non-identifiable material;*
- 11 *the consent of the person concerned is sought for the storage (and subsequent use) of identifiable material for reasons other than that originally intended;*
- 12 *one is reserved in storage (and subsequent use) of material from persons who are not competent to give consent, for reasons other than that originally intended;*
- 13 *material supplied to third parties is either non-identifiable or only indirectly identifiable;*
- 14 *the advice of medical ethics committees is sought, where necessary."*

### **Mechanisms for controlling the further use of human tissue**

4 The Health Council's report identifies the role of patients' consent as a mechanism for the control of the further use of tissue. We have not placed the same emphasis on patients' consent as a possible control on the further use of human tissue removed during treatment. Consider the problems that would arise if a patient demanded the return of removed tissues. In fact good medical practice requires the archiving of



tissue for continuing therapy and medical audit. It seems to us inadvisable to hold out a possibility, however theoretical, that ought to be denied as a matter of proper medical practice. Second, there is a practical problem with patient consent as a control: patients are often difficult to trace even only one year after treatment and over a lengthy period of time the proportion that cannot be traced increases greatly.

- 5 Nevertheless, we are at one with the Health Council's report in thinking that there should be a clear mechanism or set of mechanisms controlling the further use of human tissue. This, as we see it, is the role of the medical intermediary. The medical intermediary, whether it be the pathologist archiving tissue or the medical professional in charge of a tissue bank, works within the framework of law and of professional codes of conduct. In English common law the professional code of conduct has traditionally been accorded the backing of the courts. We see such intermediaries as the proper custodians both of patient's rightful expectations of tissue being treated with appropriate dignity and respect and of the patients' rights to confidentiality. We have indicated also the role of medical intermediaries in providing a barrier to profit-making in the procurement and supply of human tissue (paragraphs 6.38 - 6.40).
- 6 In the UK, medical intermediaries are already well established in the role that we attribute to them in controlling the further use of human tissue. They operate under professional codes of conduct that can be fairly rapidly adapted to new developments. Our recommendations, if they are accepted, should lead to a greater consistency and tightness in the control mechanism.

### **Balance between the public good and individual patient wishes**

- 7 The Health Council's report emphasises individual patient wishes. We have attempted to pay attention to what seem to us the balancing considerations of the potential for public benefit. The availability of archived tissue, not only for medical audit but also for epidemiological research, works both for the benefit of individual patients and for the public good. Indeed in our view, to insist on the availability of tissue removed during treatment for medical audit and for further medical and scientific uses does more for the real rights of patients than providing for the wishes of a patient who might wish for tissue not to be archived. In practice, however, we would hope that there would not be such a great difference between the two sets of recommendations. For our own proposals are designed to protect patients' rights while ensuring the necessary availability of tissue for therapeutic ends. We would emphasise that only a small proportion of tissue is used for anything but the therapy of the original source.

**Appendix 3**

**Human tissue used in transfusion,  
transplantation or reconstructive surgery**

Amnion

Blood and blood components

Blood vessels

Bone chips and bone segments

Bone marrow

Cornea

Dura mater

Fallopian tube

Fascia lata

Fetal serum

Fetal tissues or cultures, for example

thymus, liver, pituitary, brain

Fibroblast cultures

Heart valves

Intestines

Islets of Langerhans

Organs, for example kidneys, heart, lungs,

liver, spleen, pancreas

Ossicles

Ova, embryos

Semen

Skin

Tendons

Trachea

## Appendix 4

# Therapeutic and research products derived from human tissue

This list offers examples and is not intended to be exhaustive. Some of these products may be derived both from human tissue and by alternative methods involving recombinant DNA technology, cell culture or the use of animals.

### Blood and blood products

Whole blood  
Serum albumin  
Fibrinolytic drugs: urokinase, tissue-type plasminogen activator, antistreptase  
Anti-fibrinolytic drugs: aprotinin, Factor VIII, Factor IX, Factor XI.

### Immunological products

Normal human immunoglobulin  
Specific immunoglobulins: tetanus, hepatitis B, rabies, varicella-zoster, anti-D(Rh<sub>0</sub>).

### Monoclonal antibodies

Examples of monoclonal antibodies are IgM antibody to E.coli endotoxin and radiodiagnostic antibodies to tumour antigen and myosin

### Endocrine Agents

Insulin  
Thyroid hormone  
Parathyroid hormone: calcitonin  
Cortisone  
Male and female sex hormones  
Hypothalamic hormones: gonadorelin, protirelin, sermorelin  
Anterior Pituitary hormones:  
    corticotrophin replaced by tetracosactrin,  
    growth hormone replaced by somatotropin,  
    chorionic gonadotrophin, menotrophin, urofollitrophin.  
Posterior pituitary hormones: vasopressin (analogues lypressin, desmopressin), oxytocin.

### **Exocrine Agents**

Prostaglandins

Cytokines: interferon, erythropoetin, interleukins, colony stimulating factors, tumour necrosis factors, transforming growth factors

### **Structural Products**

Collagen

Hyaluronic acid

Dura preparations

### **Products for Somatic Cell Therapy**

Hepatocytes, myoblasts or pancreatic islet cells for implantation

Cells for implantation as an in-vivo source of a therapeutic product such as an enzyme, cytokine or coagulation factor

Activated lymphoid cells such as lymphokine activated killer cells and tumour-infiltrating lymphocytes for infusion

### **Products for Somatic Cell Gene Therapy**

Cells modified ex-vivo by addition of genetic material to correct a genetic disorder such as adenosine deaminase deficiency (ADA), or cystic fibrosis.

Future techniques may include direct administration to patients of retroviral or other vectors to alter genetic content of cell.

### **Research Products derived from Human Tissue**

Human cell lines

Genomic DNA libraries, cDNA libraries, purified RNA, Southern blots of genomic DNA and Northern blots of poly A+ RNA. These products may be derived from a variety of human adult, infant and fetal tissues (for example, placenta, adrenal gland, aorta, bone marrow, intestine, fibroblast, breast, eye, ovary, prostate, thymus, stomach, trachea, testis, heart, brain, pancreas, lung, kidney, skin, liver).

## Appendix 5

### Strategies for tissue replacement

Many of these examples are still in the process of development and are not yet used therapeutically.

#### 1 **Nervous system**

- ▶ Fetal dopamine producing cells used to treat Parkinson's disease
- ▶ Dopamine releasing immortalised cell lines encapsulated in polymer membranes
- ▶ Enkephalin and catecholamine releasing cell implants used in relief of pain
- ▶ Autologous bridging nerve grafts with synthetic guiding conduits; acceleration by Schwann cells seeded to polymer membranes

#### 2 **Cornea**

- ▶ Corneal epithelial cells pre-seeded on polyvinyl alcohol hydrogels

#### 3 **Skin and other wounded tissues**

- ▶ Composites of silicon, and chondroitin sulphate and collagen to induce new blood vessel formation and connective tissue growth in dermis
- ▶ Culture of keratinocytes in irradiated fibroblasts to produce large grafts  
Human neonatal dermal fibroblasts grown on degradable polyglycolic acid mesh
- ▶ Fibroblasts placed on hydrated collagen gel

#### 4 **Liver**

- ▶ Suspensions of hepatocytes encapsulated in microcapsules or hollow fibres attached to polymer networks

#### 5 **Pancreas**

- ▶ Pancreatic islets encapsulated in membrane

#### 6 **Cartilage, bone and muscle**

- ▶ Collagen-glycosaminoglycan templates, isolated chondrocytes, chondrocytes attached to natural or synthetic polymers
- ▶ Bone morphogenic proteins, transforming growth factor
- ▶ Cells grown on synthetic polymers or ceramics
- ▶ Myoblast transfer

#### 7 **Blood vessels and cells**

- ▶ Polymers with cell adhesion ligands lined with endothelial cells
- ▶ Cell free haemoglobin
- ▶ Platelet proteins encapsulated in lipid vesicles
- ▶ Bone marrow stem cells and specific inducers

Appendix 6

**Guidance for the referral of proposals for research on human tissue to research ethics committees**

- 1 Research proposals involving human subjects, material or records and taking place broadly within the NHS are submitted for approval to a Local Research Ethics Committee (LREC) administered by the District Health Authority.<sup>1</sup> The Medical Research Council, medical research charities and private-sector companies may also refer proposals to LRECs or to a variety of other research ethics committees including, for example, the Royal College of General Practitioners' Clinical Research Ethics Committee.
- 2 Where there is any doubt whatsoever in the mind of the research investigator or collaborators on the ethics or propriety of the research to be undertaken, recourse to a research ethics committee is advised. This will be particularly important in instances where the relationship between research investigator and subject, whether patient or healthy volunteer, is close and trusting.
- 3 The guidance offered by the Working Party for referral to research ethics committees of research proposals involving the removal of human tissue from patients or volunteers is to refer those programmes:
  - 1 that require the identity of patients and healthy volunteers to be made known to the research investigator even if the research is retrospective and the tissue has been stored or archived;
  - 2 that require prospective collection of tissue over and above that strictly necessitated by diagnosis or treatment of disease. Here, the specific consent of the subject to the research procedure must be secured. This applies to all studies on healthy volunteers;
  - 3 where research is of an unusual or essentially innovative nature, particularly where this may lead or is intended to lead to commercial or therapeutic developments, or may have implications that could arouse public concern;
  - 4 where handling charges or fees in respect of tissue are to be paid to the person supplying the tissue or that person's institution or employer;

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<sup>1</sup> Department of Health (1991) **Local research ethics committees** London

## Guidance for the referral of proposals for research on human tissue to research ethics committees

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- 5 where any research will, may, or is intended to lead to therapy involving the use of autologous or heterologous transplantation, transfusion or other transfer between human beings, living or dead;
  - 6 where research may lead to or presage alteration of germ cells or lines;
  - 7 that involve any research on the human fetus or embryo, except that on left-over tissue (see 4.2 below).
- 4 Thus, the advice of research ethics committees should be sought in connection with almost all research involving human tissue, **subject to the following exceptions:**
- 1 research use of anonymised left-over tissue. Such tissue is ordinarily removed by surgeons or pathologists who are not closely involved with the proposed research. Even where this is not the case, provided that no more tissue has been taken than is required in the necessary course of diagnosis or treatment, recourse to a research ethics committee is not required;
  - 2 research use of anonymised tissue left over from investigations or treatment of the fetus *in utero*, subject to the provisos outlined in paragraph 3.2 above;
  - 3 use of anonymised left-over tissue in the course of developing technology, or implementation of quality control or assurance programmes;
  - 4 review of anonymised archived material from any source;
  - 5 DNA extraction from left-over or archived tissue where anonymity is assured, or the procedure is in furtherance of diagnosis or preventive medicine of the patient.

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The Working Party has drawn on a large body of legal, medical and scientific literature. References have been given only in specific support of particular points in the text. Those professionally engaged in these subjects will have access to detailed bibliographical tools.

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## **Submissions received**

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Imperial Cancer Research Fund, Division of Pathology  
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Medical Defence Union  
Medical Research Council



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