

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

- 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.

Background to the study

- 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.