

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.¹ 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.

¹ 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.² 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.³ 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.

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

³ 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**.⁴ (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.

⁴ *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.⁵ 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.⁶ 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.⁷

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

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

⁶ Gedye, R (1993) **British Medical Journal**, 307:1229

⁷ 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.⁸ Further work, on which this report draws, was done by the Law Reform Commission of Canada.⁹

French legislation

- 2.24 In France the Inspection Générale des Affaires Sociales (IGAS) has enquired into and reported on **Human Tissue Banks**¹⁰ and on **Growth Hormone and Creutzfeldt-Jakob disease (CJD)**.¹¹ 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 body¹² 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.¹³

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

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

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

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

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

¹³ 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)¹⁴ 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.¹⁵ 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.¹⁶ 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*

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

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

¹⁶ Recommendation N° R(94)1 adopted on 14 March 1994

principles and additional protocols on specific aspects".¹⁷ 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 1994.¹⁸ 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.¹⁹ 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).

¹⁷ In its Recommendation 1160 (Rapporteur: Mr Marcelo Palacios)

¹⁸ 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**

¹⁹ See, for example, Butler, D (1995) **Nature** 373:466