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

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).

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.[1,2,3,4] 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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1 Royal College of Physicians (1990) **Guidelines on the practice of ethics committees in medical research involving human subjects** (2nd Edition) London

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

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

4 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.[1,2,3,4] 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.[5] 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).

[5] 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.[6] 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).

[6] 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).