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.[1] 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.

[1] 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.

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.[2]

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

[2] 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;

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.[3]

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.

[3] 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

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[4], from the Medical Research Council[5], and from the British Paediatric Association.[6] 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).

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

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

[6] British Paediatric Association (1992) **Guidelines for the Ethical Conduct of Medical Research Involving Children**

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[4] and the Medical Research Council.[7] 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.[8]

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

[7] Medical Research Council, MRC Ethics Series (1991) **The ethical conduct of research on the mentally incapacitated** London

[8] 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'.[9] 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;

[9] 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;[10]

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;[11]

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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[10] 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.*

[11] 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.[12] 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.[13] 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

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

[13] 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.