

## Chapter 10. Human Tissue Act

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### 1. Background

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- 1.1 The Human Tissue Act 1961 came into force on 27 September 1961, two months after it received Royal Assent. It is central to the deliberations of this Inquiry and covers hospital post mortem examinations as against those under the jurisdiction of the Coroner.
- 1.2 The purpose of the Act was to provide for:
- the use of parts of bodies of deceased persons for therapeutic purposes and purposes of medical education and research;
  - the circumstances in which post mortem examinations may be carried out;
  - the permission for the cremation of bodies removed for anatomical examination.

## 2. The Relevant Provisions to Make Post Mortem Examination Lawful

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- 2.1 Our Inquiry is restricted to matters relating to babies and children. However, the following analysis covers those provisions within the Act that concern the questions parents must be asked before a hospital post mortem examination or the use of body parts of babies and children is lawful. In order to concentrate on what is essential, unnecessary phrases are removed and some uncontroversial aids to interpretation inserted to make the meaning clear.

## 3. Phrases Extracted from Section 1(2)

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- 3.1 There are a number of phrases to be extracted from **section 1(2)** to show the test to be applied. If, but only if, the test is satisfied the removal and retention of tissue is made lawful by virtue of **section 1(3)**.
- The person lawfully in possession of the body of a deceased person [for our purposes the doctor or other person designated on behalf of the hospital] ...
  - may authorise the removal of any part from the body for use for therapeutic purposes or for purposes of medical education or research **if** [indicating a *condition* or that what follows must be satisfied] ...
  - **having made** [indicating a *condition precedent* or that he must do it first] **such reasonable enquiry as may be practicable ...**
  - **he has no reason to believe** that ... any surviving relative of the deceased objects to the body being so dealt with.
- 3.2 The remaining subsections within **section 1** are not relevant to this analysis but can be seen in the Act itself.
- 3.3 **Section 2** deals with a ‘hospital’ post mortem examination where there is no intention to retain tissue for therapeutic purposes, medical education or research. In this situation the examination is for the purpose of establishing or confirming the causes of death, or of investigating the existence or nature of abnormal conditions. Then the person in lawful possession of the body has to satisfy the same conditions but with a hospital post mortem as the purpose, as against the purposes of therapy, medical education and research covered in **section 1(2)**.
- 3.4 The Act does not contain any criminal sanction for breach of its provisions. Neither does it support a civil claim in respect of breach.

## 4. Background to the Act – the Parliamentary Debate

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- 4.1 In the Second Reading of the Bill on 20 December 1960 the Parliamentary Secretary to the Minister of Health Miss Edith Pitt said,

‘It is important that the dissemination of knowledge and the progress of research should be encouraged. The study and, if need be, the retention of parts of the body are essential for this purpose. The Bill removes whatever doubt there may be as to the legality of this at the present time so long as the conditions in the Bill are complied with.’

- 4.2 Speaking of the Corneal Grafting Act 1952, which was repealed by the Human Tissue Act 1961, Miss Pitt went on to say,

‘The Minister advised them [medical practitioners] strongly not to rely on the power given in the Corneal Grafting Act to remove eyes in the absence of any known objection, but, wherever relatives were available, to seek their consent. *It is proposed to recommend hospital authorities to adopt the same procedure of obtaining the consent of relatives where they are available in relation to the removal of any part of the body as authorised by this [Human Tissue] Bill.*’  
[Emphasis added.]

- 4.3 Later Miss Pitt said,

‘The provisions in the Bill relating to the removal and use of parts of the body have the wholehearted support of leading members of the medical profession.’

- 4.4 During the debate Mr Kenneth Robinson MP reminisced about an approach he had received some time earlier from certain members of the medical profession concerning the difficulty of obtaining sufficient corneas for the purposes of corneal grafting. He spoke to the then Minister of Health about whether there was anything he could do by way of publicity and Parliamentary questioning. Following consultation the reply was,

‘For heaven’s sake do not raise this matter. Corneal grafting is going on but the moment we give it any publicity there will be religious objections and the whole matter may come to an end. So please leave it alone.’

- 4.5 The Human Tissue Bill was drafted in order to address in part the mischief of the secretive way in which matters had been handled previously.

4.6 Lord Balniel MP said during the debate,

‘This is an important Bill because it touches on some of the most deeply felt instincts of man; instincts that say that the human body, once life has been extinguished from it, should be treated with the utmost dignity and respect, and that pending interment or cremation, it should be left in peace. These instincts are felt by most persons whatever religious – or indeed, irreligious – beliefs they may have.

I confess that I shared those instincts when I first read the Bill. Knowing some of the consequences that will flow from it I read it with a certain amount of emotional disquiet. On the other hand if one tries to throw away untenable prejudices and to look at the matter objectively there is something infinitely wonderful in the thought that the advance of medical science now allows men to use the tissues and organs from a dead body in order to bring health and happiness to the living and in particular to those who, because of misfortune or disease are deprived of the good health that most of us enjoy.

To my mind there is something infinitely wonderful in the thought that this advance that we are now legalising enables medical science to create something approaching the immortality of the living cell, because the living cell will now be transferred, and can be transferred from generation to generation, bringing with it new health.’

4.7 The controls introduced in the Human Tissue Act 1961 were to allay these deeply felt and instinctive fears expressed so cogently but with perfect balance by Lord Balniel.

4.8 In the second reading of the Bill the Minister of Health, Mr J Enoch Powell, dealt with the meaning of the phrase ‘any surviving relative’. He said,

‘If he [the Honourable Member] looks at the context he will see that the reference is to having ‘no reason’ after ‘reasonable enquiry’ ‘to believe’ that ‘any surviving relative’ objects. In that context I have deliberately left the term ‘any surviving relative’ undefined so that if a relative makes it known, or *if there is reason to believe, that there is objection, it shall not be necessary nicely to enquire into the degree of consanguinity*; because *I am convinced that far more harm can be done to the cause which the House has at heart tonight by a single case in which a strongly held scruple is overridden than perhaps a temporary loss of opportunity due to the width in which this clause has been drawn*. So I say it is quite deliberately left at large that anyone who can claim to be a relative may be able to express an objection under Clause 1(2)’.  
[Emphasis added.]

## 5. The Evidence before the Inquiry

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- 5.1 We have had the benefit of lengthy and detailed evidence from parents. We have also heard from numerous doctors, clinical academics including those currently in charge of undergraduate medical training and a Professor of Bio-Ethics.

## 6. The Attitude of the Parents who Gave Evidence

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- 6.1 It was the common experience of the parents that they had been given little or no information as to what would happen to their babies and children or their organs and tissue, during and following the post mortem examination. The most common experience was that they were *not* told that the heart would be taken for the Heart Collection in the Institute of Child Health at Alder Hey, or that the brain also would be removed and retained for fixation prior to examination so that they would bury the body without the brain. No parent had understood that every organ in the body would be taken during the van Velzen years and that they would only bury the 'shell' of their child.
- 6.2 Many parents from whom we heard expressed a desire at the time of the death of their baby or child to donate organs to save the life of another child. Many parents, had they been approached properly, with transparency and openness at the time, would have been prepared to discuss the use of organs and tissue from their deceased baby or child for therapeutic, medical education and research purposes. In retrospect fewer would have been willing for their child's heart or brain to be retained in a collection. However, had they been treated at the outset with transparency and openness they may have given it serious consideration. The parents' evidence is now highly coloured by their experiences surrounding the issue of organ retention, and the retention and handling of the heart and brain in particular provoke the most emotion. Those experiences remain an overriding impediment to their retrospective consideration of whether they would have agreed to the use of the heart or brain for medical education, research purposes and in particular as part of a collection.
- 6.3 Nevertheless several parents expressed the view that, properly approached at the time, they would have given serious consideration to the use of organs and tissue, including the heart and brain from their deceased baby or child. To illustrate this we refer to those parents who carried organ donor cards and several older children who had expressed the wish to carry organ donor cards. Sadly, the attitude of the medical profession, as it has affected parents of children involved in this Inquiry, has resulted in some of them destroying their cards. They cannot comprehend how the medical profession could conceal the retention of organs and tissue from them by omission.

## 7. The Evidence of the Medical Profession

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- 7.1 There was no real factual dispute between the medical profession and the parents. There was no evidence from the doctors that they made enquiries beyond the next of kin as a matter of routine. We heard evidence from one younger consultant who explained to parents about the removal of the brain for the purpose of fixation and what would happen in general terms at the post mortem examination. None of the others went anywhere near as far. We heard no evidence from any doctor that parents were ever told that they would be burying the body without the brain or heart. It was conceded that no mention had been made of retaining hearts for the Heart Collection. The doctors themselves were ignorant of Professor van Velzen's practice of removing all the organs for fixation, so they could not have explained this to the parents. In reality, none would have begun to attempt an explanation of such an unjustifiable practice.
- 7.2 We were surprised at the general ignorance of the medical profession concerning the provisions of the Human Tissue Act 1961. No doctor could remember having read it before preparing to give evidence to the Inquiry. This included the University-based clinical doctors in charge of, and active in, the Institute of Child Health at Alder Hey. It also included the very people who ran, and often collected for, the Heart Collection. None had any training in the legal requirements at undergraduate level and nor did they receive training in their various clinical training posts. Most had seen a senior consultant deal with parents on the issue of post mortem examination in the course of their careers. Some, however, had not even had that experience and had devised their own approach. All had as their starting point an overwhelming desire not to upset the parents further than they thought necessary at their time of grief. This should be contrasted with the parents' overwhelming view that the worst had already happened, the death of their child, and that they could not have been more upset. They might have objected in their grief but they correctly considered that was their right. From doctors' evidence the implication was they did not want to tell the parents the details precisely because they did not want to face the parents' likely objections. Understanding the medical benefits, the medical profession was naturally keen that post mortem examinations were carried out.

## 8. The Real Issues

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- 8.1 The medical profession has recently and publicly admitted what has been called a 'paternalistic' approach in the past to the issue of the enquiry into the parents' objection to post mortem examination. It claims this was done with the best motives of the profession and asserts that times have changed, so that there is now a new climate

requiring openness, frankness and transparency of approach. Whereas in the past the attitude has been to spare the feelings of parents by not giving them full information, it is now proposed that fully informed consent should be the standard to be applied in future.

- 8.2 The issues before us, having set out our findings of fact, are to see whether the Human Tissue Act 1961 has been complied with in the past and to see whether there should be recommendations for changes in the Act, notwithstanding the present position of the medical profession.

## 9. The Analysis

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- 9.1 The Human Tissue Act 1961 was drawn up against a backdrop of advice from the Minister for medical practitioners to obtain the 'consent' of relatives, where available, in relation to the removal of eyes for corneal grafting. There is no indication in the debate of any intention to relax that advice after the Act came into force, there is rather an indication of the intention to enforce it.
- 9.2 The Minister clearly believed that he was recommending a test with the safeguard that it was a high threshold for the doctor or designated person to climb in order to say that he had *no reason to believe* in objection. He expressly stated this in the debate at the Second Reading of the Bill in relation to the degree of consanguinity to be required. *No reason to believe* in the objection of *any surviving relative* meant precisely that. If there was to be a dispute as to the closeness of the relationship the doctor was not to attempt to resolve it. He could no longer say that he had *no reason to believe* in an objection. There was no suggestion, however that a doctor had to enquire as a matter of routine beyond the next of kin if they did not object.
- 9.3 The Minister clearly recognized the harm that would be done if even one strongly held objection were overridden by the medical profession.
- 9.4 The concept of the high threshold before a doctor can have *no reason to believe* is just as relevant to the existence of an objection at all as it is to the closeness of the surviving relative. While the section introduces the condition precedent of making *such reasonable enquiry as may be practicable* that condition can conveniently be put on one side for a moment to consider the main thrust of the section. We can have a reason to believe that someone might object to something without ever asking that person or even knowing that person. The context will often suffice. For instance, we can be overwhelmingly confident that there would be objection to a burglary without ever asking or identifying the householder. The context of the matters under consideration in this Inquiry makes it clear that the starting point of the medical practitioner can only

be he *has* reason to believe that there might be objection. We can remember the instinctive response of Lord Balneil quoted from the Parliamentary debate. In fairness, no doctor contended otherwise during the Inquiry.

- 9.5 Whether or not the Statute puts the express burden on the doctor to make reasonable enquiry, as it does in fact, the *only* way a doctor can overcome the obvious starting point that there *might* be objection is to ask. Indeed many doctors who gave evidence to the Inquiry conceded in questioning the lack of detail given by them to parents when making enquiry on the basis that if they were told they would be upset and object! That thought process in itself would suffice to render a breach of the section, subject to whatever protection is afforded to the doctor who claims to have made reasonable enquiry, which is considered below. The doctor simply could not state that he had *no reason to believe* in objection. Again in fairness, when it was put to the doctors in these terms in evidence at the Inquiry they did not contend otherwise but recognized the force of the position.
- 9.6 It is now convenient to return to the *condition precedent* in the section *having made such reasonable enquiry as may be practicable*. Many doctors in evidence stated that it was a difficult exercise to tell the parents the detail of a post mortem examination and that organs would be retained. The paternalistic approach of the medical profession to spare the parents further grief has already been stated. The question is whether this approach to the enquiry of parents can lead to the medical profession reacting along the following lines,
- ‘We do not want to upset the parents unnecessarily. A *reasonable enquiry* is not an *upsetting enquiry*. We will tell what we can without upsetting them unduly and if at this point they do not object we can then say we have complied with the Act. After all we have made a reasonable enquiry and that suffices to comply with the condition precedent and thereby to negate the starting point of having reason to believe that the parents might object.’
- 9.7 This reaction is based upon the evidence of the medical profession to the Inquiry. Is such a formulation a proper one under the Human Tissue Act 1961?
- 9.8 Just as the concept of *no belief in objection* depended on the context, what is or is not a *reasonable enquiry* must also depend on the context. Nobody could contend that it is *not practicable* to make a detailed enquiry in the setting of the issues before this Inquiry, unless in the context that the next of kin were incapable of being traced or contacted. Conversely it would not usually be practicable to enquire of all surviving relatives even if they could be traced or contacted. The issue of relevance for the next of kin is the *reasonableness* of the enquiry. The context in which to judge the reasonableness or otherwise of the enquiry can only be whether or not the doctor can truly say, after the enquiry, he has no reason to believe in objection.

- 9.9 It stands to reason that if the very issues, known to the doctor but not known to the parents, that may provoke them to object are not raised in the enquiry, the enquiry is fundamentally flawed and therefore *unreasonable*. The question 'Do you object?' cannot be answered in a vacuum. The context of the question is vital to the obtaining of a meaningful answer. The question is incapable of meaningful answer by parents ignorant of the procedures involved. If the answer lacks meaning, how can the doctor dismiss the starting point that he has reason to believe in objection?
- 9.10 It is a sad fact of life that many important decisions have to be made when we are upset, under pressure or otherwise, when we would wish to turn away. Parliament, in the Human Tissue Act 1961, expressly cast the fundamental decision regarding objection to post mortem examination and tissue retention on to the surviving relatives. As Professor Harris, Professor of Bio-Ethics at the University of Manchester, said in evidence, the parents were wronged if their consent was not obtained or they were not given enough information to provide competent consent.
- 9.11 It was not the intention of the Act to leave the essential decision to the doctors, with an exercise in window-dressing under the guise of reasonable enquiry of relatives. Such a construction would offend the clear language and intent of the Act. In any event we are impressed by the reasoning within the Polkinghorne Report at paragraph 6.2 on the issue of informed consent as long ago as 1989. We have slightly adapted the following quotation from that report to substitute 'child/organs' for 'fetus' but otherwise leaving the meaning unaltered.

'Discussion of consent has been affected by the consideration that a 'mother' may be distressed if she has to consider too closely the possibility of her child/organs being used for 'medical education or research purposes'. The Peel Committee had this in mind when reaching the form of words in their Code at Paragraph 3(ii) that there should be no known objection on the part of parents. We regard this as insufficient. We are conscious of the need to avoid distress but are even more strongly opposed to formulations which disguise the reality of what is to take place. Distress will be caused to the mother if she later feels that she did not know what was going to happen to her 'child/organs'.

We recommend that positive explicit consent should be obtained from mothers to the use of the child/organs. We see the process of consent as requiring the mother to be counselled and given all the information in a form that is 'comprehensible to enable her to make a proper judgement of whether or not to allow the child/organs to be used for 'medical or research purposes ....'

While we also would wish to avoid needless upset, the immediate upset at the time of the enquiry has to be balanced by that to be caused in later years if parents eventually discover what has happened, as this Inquiry all too poignantly demonstrates.'

- 9.12 We are fortified in our view because even the rationale of the ‘paternalistic’ attitude is put forward in hindsight. There is no evidence that the medical profession ever attempted to construe the Act and came to the decision that the construction now put forward on their behalf is correct. Even now, we are told, these matters are not dealt with at any stage of the process of medical education and training, despite the experience of Mr Kenneth Robinson MP expressed in the debate. However it did not appear that the doctors individually were unable to grasp the wording and requirements of the Act under questioning. When taken through the Statute most acknowledged the difficulties in reconciling the ‘paternalistic’ attitude with the wording of the Act.
- 9.13 The concessions of the doctors went even further. It was acknowledged as a mistake that parents had not been told their child’s heart would be removed and placed in the Heart Collection at the Institute of Child Health, Alder Hey. It would no doubt have been upsetting to explain this to a grieving parent. However once the concession is made, and rightly so, that parents should have been asked about the retention of hearts, the ‘paternalistic’ attitude cannot be sustained as a explanation for what has occurred. The fact is that the medical profession did not properly consider the Human Tissue Act 1961 in the first place.
- 9.14 Leaving aside the Heart Collection and the strict terms of the Act, what occurred in the van Velzen years cannot go unmentioned at this point. The comment does not relate to the actual processes in which individual doctors made their enquiries of parents under the Act, because they did not know what would happen. However the enormity of what has happened in the eyes of parents can be summed up in the following question put to a number of witnesses,

‘Would any parent not have objected if told that every organ of their child would be taken and in most cases left untouched for years, without even an attempt at clinical histological examination?’

## 10. Conclusions

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- While the wording of the Human Tissue Act 1961 differs from the concept of *informed consent*, in practical terms there had to be informed consent for the next of kin at least for there to have been compliance with the Act in the overwhelming majority of cases.
- There has been a general failure to comply with the terms of the Human Tissue Act 1961 with regard to the enquiries that should made of parents to see if they objected to post mortem examination and retention of organs.

- The medical need for information and samples from post mortem examination is clear. There is no present justification for shifting the burden of the decision away from surviving relatives to the medical profession.
- The medical profession has recently introduced new consent forms and thereby, whether intentionally or otherwise, an additional test before post mortem examination can be carried out. There are consent forms at Alder Hey which specifically provide for the consent of the 'next of kin', in line with previous practice of making enquiries of the closest relatives. However, the legal test remains that of 'lack of objection in any surviving relative'. There is now effectively a two-tier test without foundation in law.
- The concept of 'informed consent' is only workable with an ascertained class narrower than that of all surviving relatives. The *Concise Oxford English Dictionary* defines 'next of kin' as 'a person's closest living relative or relatives'. There may be more than one person who qualifies as 'next of kin'. Such a class is workable in the context of informed consent. The actual definition of next of kin to be used in this context is a matter for the legislative draftsman.
- It is possible to continue to apply a test of 'informed consent of next of kin' on top of an underlying test of 'no known objection' in the wider class of surviving relatives. However, we regard the importance of post mortem examination to the next of kin and medical science to be such that if all those who qualify as next of kin provide fully informed consent, any objections of wider surviving relatives should no longer prevail. In terms of previous practice all surviving relatives were not asked as a matter of course. If the next of kin did not object the doctor no doubt concluded that he could satisfy the test of no belief in objection *after such reasonable enquiry was practicable*. It is unworkable to enquire of all surviving relatives to see if they object and still more to get their fully informed consent. In practice the next of kin are in the best position to be in contact with the wider group and to take their wishes into account in forming their own fully informed consent or refusal. We strongly recommend drawing a certain line between the next of kin and all remaining relatives.
- All reasonably practicable steps should be taken to trace the next of kin. Where there is more than one next of kin it may not be reasonably practicable to trace each of them. We regard it as sufficient for post mortem examination to be carried out if all traced next of kin give fully informed consent and there is no known objection on the part of the remaining next of kin.
- The evidence before this Inquiry strongly suggests that the sensitive painting of a full and balanced picture can overcome an instinctive reaction on the part of the next of kin to refuse consent. There will be sufficient numbers of post mortem examinations and samples available for the purposes of medical advancement. The full picture includes the benefits to them in knowing the cause of death and any complicating or hereditary conditions and the potential benefits to medical science flowing from the

examination. It also includes necessary detail of the post mortem process and the organs and/or samples to be retained. Where relatives nevertheless refuse their consent, they must be respected in that decision.

- We recognise that our conclusions and the recommendations that follow differ from those expressed in the Interim Report of the Bristol Royal Infirmary Inquiry. We have striven to form our own conclusions on this and on all matters before us. Our Inquiry was set up specifically to consider the issues covered in this chapter. We have had the considerable benefit of far more evidence, tailored to the issue and subjected to detailed questioning, than has previously been possible.

## 11. Recommendations

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### 11.1 We respectfully recommend that:

- The Department of Health, the Royal Colleges and medical schools shall instruct members of the medical profession in the precise terms and provisions of the Human Tissue Act 1961, on the basis of our analysis, and the need for strict compliance.
- The Human Tissue Act 1961 shall be amended to provide a test of fully informed consent for the lawful post mortem examination and retention of parts of the bodies of deceased persons. While we have concluded that there has been little difference between ‘lack of objection’ and ‘informed consent’ in practical terms for the next of kin, it is important that the law and future practice are brought into line and updated.
- The class of persons relevant to the obtaining of fully informed consent shall be defined as the ‘next of kin’.
- The class of ‘any surviving relative’ shall no longer be relevant to post mortem examination.
- There shall be a programme of health education for the public relevant to the medical need for continued post mortem examination and access to organs and samples for therapeutic, educational and research purposes.
- The Department of Health, the Royal Colleges and medical schools shall provide training for all those involved in obtaining fully informed consent.
- The Human Tissue Act 1961 shall be amended to impose a criminal penalty by way of fine for breach of its provisions in order to encourage future compliance.

- Guidelines relating to the requirements of the Human Tissue Act 1961 and the obtaining of fully informed consent shall be drawn up and provision made for breach to result in disciplinary proceedings which could lead to suspension, dismissal or financial penalty.
- The Human Rights Act 1998 makes provision for an effective remedy other than in criminal proceedings. If breaches of the Human Tissue Act 1961 amount to breaches of the Human Rights Act 1998 consideration shall be given to incorporating a financial remedy with the Human Tissue Act 1961 itself. If necessary, reference should be made to the Law Commission.